

Evidence Search Service

Covid vaccines: Information prepared for

the

Let's Talk Vaccines event

17th November 2021

This information was sourced by several of the Librarians within the HHLS team. We have looked at topics such as side effects of the vaccines and the reporting of side effects through the Yellow Card scheme, the independence of the vaccine trials and vaccine hesitancy.

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A. Institutional Publications

CDC

Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021 (2021)

[Available online at this link](#)

What is already known about this topic? Previous infection with SARS-CoV-2 or COVID-19 vaccination can provide immunity and protection against subsequent SARS-CoV-2 infection and illness. What is added by this report? Among COVID-19–like illness hospitalizations among adults aged ≥ 18 years whose previous infection or vaccination occurred 90–179 days earlier, the adjusted odds of laboratory-confirmed COVID-19 among unvaccinated adults with previous SARS-CoV-2 infection were 5.49-fold higher than the odds among fully vaccinated recipients of an mRNA COVID-19 vaccine who had no previous documented infection (95% confidence interval = 2.75–10.99). What are the implications for public health practice? All eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2.

Centers for Disease Control and Prevention (CDC)

Myths and Facts about COVID-19 Vaccines (2021)

[Available online at this link](#)

Information from the US which includes comment about the events reported to the Vaccine Adverse Event Reporting System (VAERS) caused Covid vaccination? "VAERS data alone cannot determine if the reported adverse event was caused by a COVID-19 vaccination. Anyone can report events to VAERS, even if it is not clear whether a vaccine caused the problem. Some VAERS reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. These adverse events are studied by vaccine safety experts who look for unusually high numbers of health problems, or a pattern of problems, after people receive a particular vaccine. Recently, the number of deaths reported to VAERS following COVID-19 vaccination has been misinterpreted and misreported as if this number means deaths that were proven to be caused by vaccination. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem."

Full Fact

Get the facts on Covid-19 (2021)

[Available online at this link](#)

A range of information from the registered charity Full Fact about Covid-19 that looks at claims such as RNA Covid-19 vaccines changing your DNA.

Medicines & Healthcare products Regulatory Agency

Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance (2021)

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In May 2020, the Commission on Human Medicines established an Expert Working Group (EWG) to advise the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s). The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities. Based on this advice, the MHRA has developed, and now has in place, a four-stranded approach to vigilance, which is summarised in this report

Medicines and Healthcare Products Regulatory Agency (MHRA)

Coronavirus vaccine - weekly summary of Yellow Card reporting (2021)

[Available online at this link](#)

Updated 11th November 2021 At the time of this report, over 141,639 people across the UK have died within 28 days of a positive test for coronavirus (COVID-19). Vaccination is the single most effective way to reduce deaths and severe illness from COVID-19. A national immunisation

campaign has been underway since early December 2020. Any member of the public or health professional can submit suspected side effects through the Yellow Card scheme. The nature of Yellow Card reporting means that reported events are not always proven side effects. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated, and especially when vaccines are being given to the most elderly people and people who have underlying illness. This safety update report is based on detailed analysis of data up to 3 November 2021. As of 27 October 2021, an estimated 23.5 million* first doses of the COVID-19 Pfizer/BioNTech Vaccine and 24.9* million first doses of the COVID-19 Vaccine AstraZeneca had been administered, and around 20.3 million* and 24.1 million* second doses of COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine AstraZeneca respectively. An approximate 1.5 million first doses and approximately 1.3 million* second doses of the COVID-19 Vaccine Moderna have also now been administered. As of 3 November 2021, for the UK, 128,734 Yellow Cards have been reported for the COVID-19 Pfizer/BioNTech Vaccine, 236,386 have been reported for the COVID-19 Vaccine AstraZeneca, 17,321 for the COVID-19 Vaccine Moderna and 1,203 have been reported where the brand of the vaccine was not specified. For the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 3 to 6* Yellow Cards per 1,000 doses administered. In the week since the previous summary for 27 October 2021 we have received a further 2,131 Yellow Cards for the COVID-19 Pfizer/BioNTech Vaccine, 511 for the COVID-19 Vaccine AstraZeneca, 134 for the COVID-19 Vaccine Moderna and 18 where the brand was not specified. It is important to note that Yellow Card data cannot be used to derive side effect rates or compare the safety profile of COVID-19 vaccines as many factors can influence ADR reporting. For all COVID-19 vaccines, the overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness. These types of reactions reflect the normal immune response triggered by the body to the vaccines. They are typically seen with most types of vaccine and tend to resolve within a day or two. The nature of reported suspected side effects is broadly similar across age groups, although, as was seen in clinical trials and as is usually seen with other vaccines, they may be reported more frequently in younger adults. Overall, our advice remains that the benefits of the vaccines outweigh the risks in the majority of people.

Freedom of Information request on a covid 19 vaccine (FOI 20-569) (2021)

[Available online at this link](#)

Response to a FOI request "Under the freedom of information act please can you provide me with all the details and information you hold that was used to determine how the Pfizer covid 19 vaccine was safe and effective to be used and granted a licence to be used in an emergency.if this was decided by a vote please provide the names who voted and how they voted"

Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 (2020)

[Available online at this link](#)

Information for healthcare professionals and the public about the Pfizer/BioNTech vaccine. Last updated 15 November 2021

Nature

The tangled history of mRNA vaccines (2021)

[Available online at this link](#)

An article which explains the history of vaccine development - Hundreds of scientists had worked on mRNA vaccines for decades before the coronavirus pandemic brought a breakthrough.

Public Health Scotland

Vaccines protect against death from COVID-19 though some clinical characteristics can increase vulnerability (2021)

[Available online at this link](#)

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Findings from a Scottish study, published in the Lancet Medical Journal, show that people who have received two doses of COVID-19 vaccine are far better protected against death from the virus than those who are unvaccinated, however, there are certain characteristics which can make people more vulnerable.

Reuters

The ex-Pfizer scientist who became an anti-vax hero (2021)

[Available online at this link](#)

An article about Michael Yeadon was a scientific researcher and vice president at drugs giant Pfizer Inc. He co-founded a successful biotech but in 2020 he co-authored a petition to Europe's medicines regulator to halt COVID-19 vaccine clinical trials as they speculated, without providing evidence, that the vaccines could cause infertility in women.

University of Oxford

Vaccine Knowledge Project (2021)

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The Vaccine Knowledge Project aims to be a source of independent information about vaccines and infectious diseases, providing clear information on complex topics supported by references to high-quality, reliable research. All content is aimed at the general public and designed to help people make informed decisions about vaccine issues. The content is also suitable for healthcare professionals.

ZOE COVID Symptom Study

Are COVID booster jabs safe? (2021)

[Available online at this link](#)

A research summary about the booster from the Zoe Study run through King's College. Contributors to the study have recorded a quarter of a million COVID boosters and third primary doses through the ZOE COVID Study and this has helped researchers better understand their safety and effectiveness. The summary looks at What's the difference between a booster and a third COVID jab? What's the dosage of the booster? How can you book your booster jab? Should you get a booster if you've already had COVID? What's the risk of reinfection after a booster jab? Worse after effects from vaccine indicates higher protection How important are boosters?

B. Original Research

1. **A comprehensive analysis of the efficacy and safety of COVID-19 vaccines.**

Cai Changjing Molecular therapy : the journal of the American Society of Gene Therapy 2021;29(9):2794-2805.

The numbers of cases and deaths from coronavirus disease 2019 (COVID-19) are continuously increasing. Many people are concerned about the efficacy and safety of the COVID-19 vaccines. We performed a comprehensive analysis of the published trials of COVID-19 vaccines and the real-world data from the Vaccine Adverse Event Reporting System. Globally, our research found that the efficacy of all vaccines exceeded 70%, and RNA-based vaccines had the highest efficacy of 94.29%; moreover, Black or African American people, young people, and males may experience greater vaccine efficacy. The spectrum of vaccine-related adverse drug reactions (ADRs) is extremely broad, and the most frequent ADRs are pain, fatigue, and headache. Most ADRs are tolerable and are mainly grade 1 or 2 in severity. Some severe ADRs have been identified (thromboembolic events, 21-75 cases per million doses; myocarditis/pericarditis, 2-3 cases per million doses). In summary, vaccines are a powerful tool that can be used to control the COVID-19 pandemic, with high efficacy and tolerable ADRs. In addition, the spectrum of ADRs associated with the vaccines is broad, and most of the reactions appear within a week, although some may be delayed. Therefore, ADRs after vaccination need to be identified and addressed in a timely manner.

2. **Accelerated COVID-19 vaccine development: milestones, lessons, and prospects.**

Bok Karin Immunity 2021;54(8):1636-1651.

The development of effective vaccines to combat infectious diseases is a complex multi-year and multi-stakeholder process. To accelerate the development of vaccines for coronavirus disease 2019 (COVID-19), a novel pathogen emerging in late 2019 and spreading globally by early 2020, the United States government (USG) mounted an operation bridging public and private sector expertise and infrastructure. The success of the endeavor can be seen in the rapid advanced development of multiple vaccine candidates, with several demonstrating efficacy and now being administered around the globe. Here, we review the milestones enabling the USG-led effort, the methods utilized, and ensuing outcomes. We discuss the current status of COVID-19 vaccine development and provide a perspective for how partnership and preparedness can be better utilized in response to future public-health pandemic emergencies.

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3. **Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review.**

Kaur Rimple Jeet Indian journal of clinical biochemistry : IJCB 2021;;1-13.

COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time. The public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic. The emergency use approval has been granted to COVID-19 vaccines before the completion of conventional phases of clinical trials. However, there is no comprehensive review of safety data reported from the vaccine trials, which is critical information to inform the policies in order to improve uptake of COVID-19 vaccines and mitigate the risk aversion perceived due to the COVID-vaccine side effects. This study aims to systematically review and synthesize the evidence on the safety data from the published COVID-19 vaccine trials. This study followed PRISMA guidelines. We searched three major electronic databases (PubMed, Embase, and Google Scholar) for published studies between Dec 2019 and 2020. Eligible study designs were randomized trials and pre-and post-intervention evaluations. Descriptive findings of included studies were reported stratified by target population, setting, outcomes, and overall results. From PubMed, Embase, WHO database, and Google Scholar screened titles and abstracts, 11 studies were identified in this review. Most of the reactions reported were mild to moderate whereas a few with severe intensity. All reactions resolved within 3-4 days. The commonly reported local adverse events were pain at the site of injection, swelling, and redness. The systemic reactions included fever, fatigue, myalgia, and headache. Some trials also reported laboratory derangements like decreased hemoglobin, increased bilirubin, altered SGOT and SGPT. None of these alterations were clinically manifested and were self-limiting. Few clinical trials reported serious adverse events, but they were unrelated to vaccination. This systematic review indicates that COVID-19 vaccines can be safe with no serious adverse events. However, long-term post-marketing surveillance data, particularly in high-risk vulnerable populations (elderly and those with co-morbidities, pregnant women, and children) is warranted to ensure the safety of COVID-19 vaccines.

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4. **Allergenic components of the mRNA-1273 vaccine for COVID-19: Possible involvement of polyethylene glycol and IgG-mediated complement activation.**
Klimek Ludger Allergy 2021;76(11):3307-3313.

Following the emergency use authorization of the mRNA-1273 vaccine on the 18th of December 2020, two mRNA vaccines are in current use for the prevention of coronavirus disease 2019 (COVID-19). For both mRNA vaccines, the phase III pivotal trials excluded individuals with a history of allergy to vaccine components. Immediately after the initiation of vaccination in the United Kingdom, Canada, and the United States, anaphylactic reactions were reported. While the culprit trigger requires investigation, initial reports suggested the excipient polyethylene glycol 2000 (PEG-2000)-contained in both vaccines as the PEG-micellar carrier system-as the potential culprit. Surface PEG chains form a hydrate shell to increase stability and prevent opsonization. Allergic reactions to such PEGylated lipids can be IgE-mediated, but may also result from complement activation-related pseudoallergy (CARPA) that has been described in similar liposomes. In addition, mRNA-1273 also contains tromethamine (trometamol), which has been reported to cause anaphylaxis to substances such as gadolinium-based contrast media. Skin prick, intradermal and epicutaneous tests, in vitro sIgE assessment, evaluation of sIgG/IgM, and basophil activation tests are being used to demonstrate allergic reactions to various components of the vaccines.

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5. **Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020.**

CDC COVID-19 Response Team MMWR. Morbidity and mortality weekly report 2021;70(2):46-51.

As of January 3, 2021, a total of 20,346,372 cases of coronavirus disease 2019 (COVID-19) and 349,246 associated deaths have been reported in the United States. Long-term sequelae of COVID-19 over the course of a lifetime currently are unknown; however, persistent symptoms and serious complications are being reported among COVID-19 survivors, including persons who initially experience a mild acute illness.* On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19, administered as 2 doses separated by 21 days. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine (1); initial doses were recommended for health care personnel and long-term care facility residents (2). As of December 23, 2020, a reported 1,893,360 first doses of Pfizer-BioNTech COVID-19 vaccine had been administered in the United States, and reports of 4,393 (0.2%) adverse events after receipt of Pfizer BioNTech COVID-19 vaccine had been submitted to the Vaccine Adverse Event Reporting System (VAERS). Among these, 175 case reports were identified for further review as possible cases of severe allergic reaction, including anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that does occur rarely after vaccination, with onset typically within minutes to hours (3). Twenty-one cases were determined to be anaphylaxis (a rate of 11.1 per million doses administered), including 17 in persons with a documented history of allergies or allergic reactions, seven of whom had a history of anaphylaxis. The median interval from vaccine receipt to symptom onset was 13 minutes (range = 2-150 minutes). Among 20 persons with follow-up information available, all had recovered or been discharged home. Of the remaining case reports that were determined not to be anaphylaxis, 86 were judged to be nonanaphylaxis allergic reactions, and 61 were considered nonallergic adverse events. Seven case reports were still under investigation. This report summarizes the clinical and epidemiologic characteristics of case reports of allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine during December 14-23, 2020, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States (4) and interim considerations for preparing for the potential management of anaphylaxis (5). In addition to screening for contraindications and precautions before administering COVID-19 vaccines, vaccine locations should have the necessary supplies available to manage anaphylaxis, should implement postvaccination observation periods, and should immediately treat persons experiencing anaphylaxis signs and symptoms with intramuscular injection of epinephrine (4,5).

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6. **Allergic Reactions to Current Available COVID-19 Vaccinations: Pathophysiology, Causality, and Therapeutic Considerations.**

Kounis Nicholas G. Vaccines 2021;9(3):No page numbers.

Vaccines constitute the most effective medications in public health as they control and prevent the spread of infectious diseases and reduce mortality. Similar to other medications, allergic reactions can occur during vaccination. While most reactions are neither frequent nor serious, anaphylactic reactions are potentially life-threatening allergic reactions that are encountered rarely, but can cause serious complications. The allergic responses caused by vaccines can stem from activation of mast cells via Fcε receptor-1

type I reaction, mediated by the interaction between immunoglobulin E (IgE) antibodies against a particular vaccine, and occur within minutes or up to four hours. The type IV allergic reactions initiate 48 h after vaccination and demonstrate their peak between 72 and 96 h. Non-IgE-mediated mast cell degranulation via activation of the complement system and via activation of the Mas-related G protein-coupled receptor X2 can also induce allergic reactions. Reactions are more often caused by inert substances, called excipients, which are added to vaccines to improve stability and absorption, increase solubility, influence palatability, or create a distinctive appearance, and not by the active vaccine itself. Polyethylene glycol, also known as macrogol, in the currently available Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines, and polysorbate 80, also known as Tween 80, in AstraZeneca and Johnson & Johnson COVID-19 vaccines, are excipients mostly incriminated for allergic reactions. This review will summarize the current state of knowledge of immediate and delayed allergic reactions in the currently available vaccines against COVID-19, together with the general and specific therapeutic considerations. These considerations include: The incidence of allergic reactions and deaths under investigation with the available vaccines, application of vaccination in patients with mast cell disease, patients who developed an allergy during the first dose, vasovagal symptoms masquerading as allergic reactions, the COVID-19 vaccination in pregnancy, deaths associated with COVID-19 vaccination, and questions arising in managing of this current ordeal. Careful vaccine-safety surveillance over time, in conjunction with the elucidation of mechanisms of adverse events across different COVID-19 vaccine platforms, will contribute to the development of a safe vaccine strategy. Allergists' expertise in proper diagnosis and treatment of allergic reactions is vital for the screening of high-risk individuals.

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7. **Anaphylaxis is a rare reaction in COVID-19 vaccination.**

Bellomo R. G Journal of biological regulators and homeostatic agents 2021;35(3):839-842.

Anaphylaxis is a severe multisystem reaction that occurs rapidly after the introduction of an antigen that would otherwise be a harmless substance. It is characterized by airway and respiratory problems, cardiovascular collapse, mucosal inflammation, and other complications, all severe symptoms that can cause death. IgE-dependent anaphylaxis involves mast cells (MCs) which are the main sources of biologically active mediators that contribute to the pathological and lethal phenomena that can occur in anaphylaxis. Antibody-mediated anaphylaxis can follow multiple pathways such as that mediated by MCs carrying the FcεRI receptor, which can be activated by very small amounts of antigen including a vaccine antigen and trigger an anaphylactic reaction. In addition, anaphylaxis can also be provoked by high concentrations of IgG antibodies that bind to the FcγR receptor present on basophils, neutrophils, macrophages and MCs. For this reason, the IgG concentration should be kept under control in vaccinations. Activation of MCs is a major cause of anaphylaxis, which requires immediate treatment with epinephrine to arrest severe lethal symptoms. MCs are activated through the antigen binding and cross-linking of IgE with release of mediators such as histamine, proteases, prostaglandins, leukotrienes and inflammatory cytokines. The release of these compounds causes nausea, vomiting, hives, wheezing, flushing, tachycardia, hypotension, laryngeal edema, and cardiovascular collapse. mRNA and viral vector vaccines have been cleared by the United States, Food and Drug Administration (FDA), generating hope of prevention and cure for COVID-19 around the world. Scientists advise against giving the vaccine to individuals who have had a previous history of anaphylaxis. The US Centers for Disease Control and Prevention (CDC) advises people with a previous history of any immediate allergic reaction to remain under observation for approximately 30 minutes after COVID-19 vaccination. To date, vaccines that prevent SARS-CoV-2 infection have not raised major concerns of severe allergic reactions, although, in some cases, pain and redness at the injection site and fever have occurred after administration of the vaccine. These reactions occur in the first 24-48

hours after vaccination. It has been reported that probable forms of anaphylaxis could also occur, especially in women approximately 40 years of age. But after tens of millions of vaccinations, only a few patients had this severe reaction with a low incidence. Anaphylactic and severe allergic reactions can also occur to any component of the vaccine including polysorbates and polyethylene glycol. To date, there is no precise information on allergic reactions to COVID-19 vaccines. Individuals with MCs and complement with higher activation than others may be at greater allergic risk. Moreover, the reactions called anaphylactoids, are those not mediated by IgE because they do not involve this antibody and can also occur in COVID-19 vaccination. These not-IgE-mediated reactions occur through direct activation of MCs and complement with tryptase production, but to a lesser extent than IgE-mediated anaphylaxis. However, at the moment it is not known exactly which component of the vaccine causes the allergic reaction and which vaccine causes the most side effects, including anaphylaxis. Thus, individuals who have a known allergy to any component of the vaccine should not be vaccinated. However, should an anaphylactic reaction occur, this requires immediate treatment with epinephrine to arrest severe lethal symptoms. In conclusion, the purpose of this editorial is to encourage the population to be vaccinated in order to extinguish this global pandemic that is afflicting the world population, and to reassure individuals that anaphylactic reactions do not occur with a higher incidence than other vaccinations.

8. **Are the Allergic Reactions of COVID-19 Vaccines Caused by mRNA Constructs or Nanocarriers? Immunological Insights.**

Selvaraj Gurudeeban Interdisciplinary sciences, computational life sciences
2021;13(2):344-347.

The Food and Drug Administration (FDA) has recently authorized the two messenger RNA (mRNA) vaccines BNT162b2 and mRNA-1273 for emergency use against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing the COVID-19 coronavirus disease. BNT162b2 and mRNA-1273 vaccines were developed by Pfizer-BioNTech and Moderna, respectively, in 2020. The United Kingdom, Bahrain, Canada, Mexico, United States, Singapore, Oman, Saudi Arabia, Kuwait, and European Union began their vaccination programs with the BNT162b2 vaccine, while the United States and Canada also started the mRNA-1273 vaccination program in mid December 2020. On 28th December 2020, studies reported severe allergic reactions in people who received the BNT162b2, and few people who received the mRNA-1273 vaccine. Authors of the letter thus attempt to explore possible causes of anaphylaxis following COVID-19 vaccination.

[Available online at this link](#)

9. **Assessing COVID-19 Vaccine Uptake and Effectiveness Through the North West London Vaccination Program: Retrospective Cohort Study.**

Glampson Ben JMIR public health and surveillance 2021;7(9):e30010.

BACKGROUND On March 11, 2020, the World Health Organization declared SARS-CoV-2, causing COVID-19, as a pandemic. The UK mass vaccination program commenced on December 8, 2020, vaccinating groups of the population deemed to be most vulnerable to severe COVID-19 infection. **OBJECTIVE** This study aims to assess the early vaccine administration coverage and outcome data across an integrated care system in North West London, leveraging a unique population-level care data set. Vaccine effectiveness of a single dose of the Oxford/AstraZeneca and Pfizer/BioNTech vaccines were compared. **METHODS** A retrospective cohort study identified 2,183,939 individuals eligible for COVID-19 vaccination between December 8, 2020, and February 24, 2021, within a primary, secondary, and community care integrated care data set. These data were used to assess vaccination hesitancy across ethnicity, gender, and socioeconomic deprivation measures (Pearson product-moment correlations); investigate COVID-19 transmission

related to vaccination hubs; and assess the early effectiveness of COVID-19 vaccination (after a single dose) using time-to-event analyses with multivariable Cox regression analysis to investigate if vaccination independently predicted positive SARS-CoV-2 in those vaccinated compared to those unvaccinated. RESULTS In this study, 5.88% (24,332/413,919) of individuals declined and did not receive a vaccination. Black or Black British individuals had the highest rate of declining a vaccine at 16.14% (4337/26,870). There was a strong negative association between socioeconomic deprivation and rate of declining vaccination ($r=-0.94$; $P=.002$) with 13.5% (1980/14,571) of individuals declining vaccination in the most deprived areas compared to 0.98% (869/9609) in the least. In the first 6 days after vaccination, 344 of 389,587 (0.09%) individuals tested positive for SARS-CoV-2. The rate increased to 0.13% (525/389,243) between days 7 and 13, before then gradually falling week on week. At 28 days post vaccination, there was a 74% (hazard ratio 0.26, 95% CI 0.19-0.35) and 78% (hazard ratio 0.22, 95% CI 0.18-0.27) reduction in risk of testing positive for SARS-CoV-2 for individuals that received the Oxford/AstraZeneca and Pfizer/BioNTech vaccines, respectively, when compared with unvaccinated individuals. A very low proportion of hospital admissions were seen in vaccinated individuals who tested positive for SARS-CoV-2 (288/389,587, 0.07% of all patients vaccinated) providing evidence for vaccination effectiveness after a single dose. CONCLUSION There was no definitive evidence to suggest COVID-19 was transmitted as a result of vaccination hubs during the vaccine administration rollout in North West London, and the risk of contracting COVID-19 or becoming hospitalized after vaccination has been demonstrated to be low in the vaccinated population. This study provides further evidence that a single dose of either the Pfizer/BioNTech vaccine or the Oxford/AstraZeneca vaccine is effective at reducing the risk of testing positive for COVID-19 up to 60 days across all age groups, ethnic groups, and risk categories in an urban UK population.

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10. **Association of COVID-19 Vaccination and Facial Nerve Palsy: A Case-Control Study.** Shemer Asaf JAMA otolaryngology-- head & neck surgery 2021;147(8):739-743.

Importance Peripheral facial nerve (Bell) palsy has been reported and widely suggested as a possible adverse effect of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine. Israel is currently the leading country in vaccination rates per capita, exclusively using the BNT162b2 vaccine, and all residents of Israel are obligatory members of a national digital health registry system. These factors enable early analysis of adverse events. Objective To examine whether the BNT162b2 vaccine is associated with an increased risk of acute-onset peripheral facial nerve palsy. Design, Setting, and Participants This case-control study was performed from January 1 to February 28, 2021, at the emergency department of a tertiary referral center in central Israel. Patients admitted for facial nerve palsy were matched by age, sex, and date of admission with control patients admitted for other reasons. Exposures Recent vaccination with the BNT162b2 vaccine. Main Outcomes and Measures Adjusted odds ratio for recent exposure to the BNT162b2 vaccine among patients with acute-onset peripheral facial nerve palsy. The proportion of patients with Bell palsy exposed to the BNT162b2 vaccine was compared between groups, and raw and adjusted odds ratios for exposure to the vaccine were calculated. A secondary comparison with the overall number of patients with facial nerve palsy in preceding years was performed. Results Thirty-seven patients were admitted for facial nerve palsy during the study period, 22 (59.5%) of whom were male, and their mean (SD) age was 50.9 (20.2) years. Among recently vaccinated patients (21 [56.7%]), the mean (SD) time from vaccination to occurrence of palsy was 9.3 (4.2 [range, 3-14]) days from the first dose and 14.0 (12.6 [range, 1-23]) days from the second dose. Among 74 matched controls (2:1 ratio) with identical age, sex, and admittance date, a similar proportion were vaccinated

recently (44 [59.5%]). The adjusted odds ratio for exposure was 0.84 (95% CI, 0.37-1.90; P = .67). Furthermore, analysis of the number of admissions for facial nerve palsy during the same period in preceding years (2015-2020) revealed a relatively stable trend (mean [SD], 26.8 [5.8]; median, 27.5 [range, 17-35]). Conclusions and Relevance In this case-control analysis, no association was found between recent vaccination with the BNT162b2 vaccine and risk of facial nerve palsy.

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11. **Attitudes of Spanish hospital staff towards COVID-19 vaccination and vaccination rates.**

Mena Guillermo PLoS one 2021;16(9):e0257002.

BACKGROUND COVID-19 vaccine hesitancy seems to be universal across countries and subgroups, and so are its determinants. We studied the willingness and factors associated with the decision to be vaccinated against COVID-19 in healthcare workers (HCW) in a Spanish tertiary hospital. Furthermore, we compared the percentage of willingness to vaccinate against COVID with actual vaccination rates among HCW in our hospital. **METHODS** From December 21, 2020 to January 4, 2021, before initiation of the COVID-19 HCW vaccination campaign at Germans Trias i Pujol University Hospital (HUGTiP), an anonymous self-administered questionnaire was administered to HCW. Univariate and multivariate logistic regression of the association of variables with the outcome "intention to receive the COVID-19 vaccine as soon as possible" was conducted. Vaccination rates were extracted from the hospital information systems. **RESULTS** Forty-four percent of HCW included in the study declared a willingness to be vaccinated against COVID-19 as soon as possible. This was associated with male sex [1.66 (95%CI 1.13-2.43); p = 0.009], older age [1.02 (95%CI 1.00-1.03); p = 0.014], belonging to the occupational groups "physician" or "other" [5.76 (95%CI 3.44-9.63) and 2.15 (95%CI 1.25-3.70); p<0.001], respectively, and reporting influenza vaccination during the last three seasons or at least one of the last three seasons [3.84 (95%CI 2.56-5.75) and 2.49 (95%CI 1.71-3.63); p<0.001]. One in ten hospital workers reported they were unwilling to receive COVID-19 vaccination. Actual COVID-19 vaccination uptake among HCW was higher (80.4%) than the percentage of willingness to vaccinate estimated from the questionnaire. Physicians not only had the highest vaccination rate, but also the highest correlation between the reported intention to vaccinate and the final decision to receive COVID-19 vaccination. **CONCLUSIONS** COVID-19 vaccination uptake was higher than previously estimated according to the stated intentions of HCW. Doubts and fears must be addressed, particularly in persons less inclined to be vaccinated: females, younger people and those not vaccinated against influenza in recent seasons. The study of barriers and strategies aimed at promoting COVID-19 vaccination must be adapted in relation to occupational groups' attitudes, understanding their idiosyncrasies with respect to this and other vaccines.

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12. **Biphasic anaphylaxis after exposure to the first dose of Pfizer-BioNTech COVID-19 mRNA vaccine.**

Abi Zeid Daou Christophe Journal of medical virology 2021;93(10):6027-6029.

In the setting of a coronavirus disease 2019 (COVID-19) global pandemic and increased disease burden, vaccination has become one of the major solutions. With the increase in

vaccination numbers worldwide, it is important to stay vigilant to the potential side effects and life-threatening complications of such vaccines. We report the case of a 30-year-old male with a biphasic allergic reaction post messenger (mRNA) Pfizer-BioNTech COVID-19 vaccination. Several reports of allergic reactions have been cited in the literature after the administration of the mRNA Pfizer-BioNTech COVID-19 vaccine. It is important to keep a high index of suspicion in severe anaphylactic cases as some patients may have a recurrence of symptoms after discharge. It is crucial to acknowledge the potential risk of anaphylaxis in select individuals and have the appropriate measures in place to deal with adverse events. In case of severe symptoms, the administration of epinephrine is advised to prevent the development of a delayed biphasic anaphylactic reaction.

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13. Blood clots and bleeding events following BNT162b2 and ChAdOx1 nCoV-19 vaccine: An analysis of European data.

Cari Luigi Journal of autoimmunity 2021;122:102685.

The involvement of viruses and SARS-CoV-2 in autoimmune diseases is well known. The recent demonstration that ChAdOx1 nCoV-19 Covid-19 (AstraZeneca) vaccine (ChA) favors the production of anti-platelet factor 4 (anti-PF4) antibodies, blood clots, and thrombocytopenia raises the question of whether other anti-CoVID-19 vaccines favor the same patterns of events. We assessed the frequency of severe adverse events (SAEs) documented in the EudraVigilance European database up to April 16, 2021 related to thrombocytopenia, bleeding, and blood clots in recipients of ChA compared to that of recipients of the BNT162b2 Covid-19 (Pfizer/BioNTech) vaccine (BNT). ChA administration was associated with a much higher frequency of SAEs in each AE Reaction Group as compared with that elicited by BNT. When considering AEs caused by thrombocytopenia, bleeding and blood clots, we observed 33 and 151 SAEs/1 million doses in BNT and ChA recipients, respectively. When considering patients with AEs related to cerebral/splanchnic venous thrombosis, and/or thrombocytopenia, we documented 4 and 30 SAEs and 0.4 and 4.8 deaths/1 million doses for BNT and ChA recipients, respectively. The highest risk following ChA vaccination is in young people and, likely, women of reproductive age, as suggested by hypothesized scenarios. In conclusion, the immune reaction promoted by ChA vaccine may lead to not only thrombocytopenia and cerebral/splanchnic venous thrombosis but also other thrombotic and thromboembolic SAEs. These events are not favored by BNT vaccine. Our study may help in the evaluation of the benefit/risk profile of the ChA vaccine considering the epidemic curve present in a country.

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14. BNT162b2 vaccine uptake and effectiveness in UK healthcare workers - a single centre cohort study.

Azamgarhi Tariq Nature communications 2021;12(1):3698.

In this single centre cohort study we assessed BNT162B2 vaccine uptake and effectiveness among UK healthcare workers (HCWs) during a time of high community COVID-19 prevalence. Early uptake among HCWs was 62.3% (1409/2260), however there were significant differences in uptake between age groups, ethnic origins, and job roles. Uptake increased to 72.9% after a vaccine hesitancy working group implemented specific measures. In the 42 days after vaccination, 49 new cases of COVID-19 were identified, of which 7 (14.3%) occurred in HCWs who were beyond 10 days of vaccination. Kaplan-Meier curves for partially vaccinated and unvaccinated groups were congruent until day 14 and

continued to diverge up to 42 days. Cox regression analysis showed a 70.0% (95%CI 6.0-91.0; p=0.04) risk reduction for COVID-19 infection in partially vaccinated HCWs. Here we report early vaccination rates among HCWs are generally high although uptake is lower in certain groups. It is possible to improve vaccine uptake and efforts should focus on this, however, significant resource is required. The BNT162B2 vaccine is effective from 14 days post-vaccination in a frontline clinical setting and protection continues beyond 21 days post 1st dose without a 2nd dose, being given.

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15. Cerebral Venous Sinus Thrombosis is not Significantly Linked to COVID-19 Vaccines or Non-COVID Vaccines in a Large Multi-State Health System.

Pawlowski Colin Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association 2021;30(10):105923.

OBJECTIVETo assess the association of COVID-19 vaccines and non-COVID-19 vaccines with cerebral venous sinus thrombosis (CVST).**MATERIALS AND METHOD**We retrospectively analyzed a cohort of 771,805 vaccination events across 266,094 patients in the Mayo Clinic Health System between 01/01/2017 and 03/15/2021. The primary outcome was a positive diagnosis of CVST, identified either by the presence of a corresponding ICD code or by an NLP algorithm which detected positive diagnosis of CVST within free-text clinical notes. For each vaccine we calculated the relative risk by dividing the incidence of CVST in the 30 days following vaccination to that in the 30 days preceding vaccination.**RESULTS**We identified vaccination events for all FDA-approved COVID-19 vaccines including Pfizer-BioNTech (n = 94,818 doses), Moderna (n = 36,350 doses) and Johnson & Johnson - J&J (n = 1,745 doses). We also identified vaccinations events for 10 common FDA-approved non-COVID-19 vaccines (n = 771,805 doses). There was no statistically significant difference in the incidence rate of CVST in 30-days before and after vaccination for any vaccine in this population. We further found the baseline CVST incidence in the study population between 2017 and 2021 to be 45 to 98 per million patient years.**CONCLUSION**This real-world evidence-based study finds that CVST is rare and is not significantly associated with COVID-19 vaccination in our patient cohort. Limitations include the rarity of CVST in our dataset, a relatively small number of J&J COVID-19 vaccination events, and the use of a population drawn from recipients of a SARS-CoV-2 PCR test in a single health system.

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16. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

2021;:1-32.

This Israeli study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant. (This article is a preprint

and has not been peer-reviewed It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice)

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17. Comparison of medium-term adverse reactions induced by the first and second dose of mRNA BNT162b2 (Comirnaty, Pfizer-BioNTech) vaccine: a post-marketing Italian study conducted between 1 January and 28 February 2021.

Ossato Andrea European journal of hospital pharmacy : science and practice 2021;;No page numbers.

OBJECTIVESOn 21 December 2020 the European Commission granted conditional marketing authorisation in the European Union for the anti-COVID-19 mRNA vaccine Bnt162b2 (Comirnaty, Pfizer/BioNTech). The main endpoint of this epidemiological, observational, prospective and monocentric study was to identify the number, types, and severity of adverse events following immunisation that occurred in subjects who had been previously infected with COVID-19, and in those who had not, after vaccination with Comirnaty, and to compare the two groups of subjects looking at events that occurred within a month after the first and the second dose.**METHODS**Data were gathered by a questionnaire. The results included the responses of all healthcare workers (2030) of the IRCCS Sacro Cuore Don Calabria Hospital (Italy) vaccinated between 1st January and 28th February 2021. Adverse effects of the vaccine were reported after the first and the second doses.**RESULTS**There was a statistically significant increase ($p < 0.001$, $\chi^2 = 35.60$) in participants who experienced some side-effects after receiving the first dose of the vaccine and who had previously been infected with the coronavirus, compared with participants who had not previously been infected. 46.76% (136) of the participants who had previously been infected experienced some side-effects after the first dose of vaccine, and 63.23% (184) experienced some side-effects after the second dose, compared with 29.15% (507) after the first dose and 70.79% (1231) after the second dose in those who had not been previously infected. The number of participants who experienced side-effects after the second dose and had previously been infected was significantly lower compared with participants who had not previously been infected ($p = 0.0094$, $\chi^2 = 6.743$).**CONCLUSIONS**Most of the side-effects identified in this trial were also reported by the manufacturer and the US Food and Drug Administration. Active surveillance should always continue to constantly check the vaccine's risk/benefit ratio over time.

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18. Coronavirus disease 2019 (COVID-19) vaccination uptake among healthcare workers.
Gilboa Mayan Infection control and hospital epidemiology 2021;;1-6.

OBJECTIVETo assess reasons for noncompliance with COVID-19 vaccination among healthcare workers (HCWs).**DESIGN**Cohort observational and surveillance study.**SETTING**Sheba Medical Center, a 1,600-bed tertiary-care medical center in Israel.**PARTICIPANTS**The study included 10,888 HCWs including all employees, students, and volunteers.**INTERVENTION**The BNT162b2 mRNA COVID-19 vaccine was offered to all HCWs of the hospital. Noncompliance was assessed, and pre-rollout and post-rollout surveys were conducted. Data regarding uptake of the vaccine as well as demographic data and compliance with prior influenza vaccination were collected, and 2 surveys were distributed. The survey before the rollout pertained to the intention to receive the vaccine, and the survey after the rollout pertained to all unvaccinated HCWs regarding causes of hesitancy.**RESULTS**In the pre-rollout survey, 1,673 (47%) of 3,563 HCWs declared their intent to receive the vaccine. Overall, 8,108 (79%) HCWs received the COVID-19 vaccine within 40 days of rollout. In a multivariate logistic regression model, the factors that were

significant predictors of vaccine uptake were male sex, age 40-59 years, occupation (paramedical professionals and doctors), high socioeconomic level, and compliance with flu vaccine. Among 425 unvaccinated HCWs who answered the second survey, the most common cause for hesitancy was the risk during pregnancy (31%).

CONCLUSIONS Although vaccine uptake among HCWs was higher than expected, relatively low uptake was observed among young women and those from lower socioeconomic levels and educational backgrounds. Concerns regarding vaccine safety during pregnancy were common and more data about vaccine safety, especially during pregnancy, might improve compliance.

19. Correlates of COVID-19 vaccine hesitancy in Austria: trust and the government.

Schernhammer Eva Journal of public health (Oxford, England) 2021;:No page numbers.

BACKGROUND With the coronavirus disease 2019 (COVID-19) pandemic surging and new mutations evolving, trust in vaccines is essential.

METHODS We explored correlates of vaccine hesitancy, considering political beliefs and psychosocial concepts, conducting a non-probability quota-sampled online survey with 1007 Austrians.

RESULTS We identified several important correlates of vaccine hesitancy, ranging from demographics to complex factors such as voting behavior or trust in the government. Among those with hesitancy towards a COVID-19 vaccine, having voted for opposition parties (opp) or not voted (novote) were (95% Confidence Intervall (CI) opp, 1.44-2.95) to 2.25-times (95% CI novote, 1.53-3.30) that of having voted for governing parties. Only 46.2% trusted the Austrian government to provide safe vaccines, and 80.7% requested independent scientific evaluations regarding vaccine safety to increase willingness to vaccine.

CONCLUSIONS Contrary to expected, psychosocial dimensions were only weakly correlated with vaccine hesitancy. However, the strong correlation between distrust in the vaccine and distrust in authorities suggests a common cause of disengagement from public discourse.

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20. COVID-19 vaccination in pregnancy and postpartum.

Brillo Eleonora The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 2021;:1-21.

Pregnant women were excluded from the initial phase 3 clinical trials of COVID-19 vaccines resulting in limited data on their efficacy and safety during pregnancy and postpartum. As a result, since December 2020, there has been conflicting advice from public health, governmental, and professional authorities on this matter. From the end of 2020 up to now, some consensus guidance has been published with a prevalent precautionary approach on the administration of vaccines in pregnant women, in breastfeeding ones, or for those who are planning a pregnancy (either spontaneously or with assisted technologies). After the first few months of vaccine administration in some countries, more permissiveness seems to prevail, although with inconsistencies. Some little indicative advice, their inconsistency around the world and their changes in a short time have probably disoriented both women and their health care providers and placed the burden of decision making upon women and their health care providers without information to assist in making an informed choice. We reviewed the COVID-19 vaccination guidance for pregnant and breastfeeding women published to date and evidence from cases of unplanned pregnancy during the course of vaccine trials, preclinical experimental and observational clinical studies, and discuss their implications. In this way, we have tried to identify the safety of COVID-19 vaccines for pregnant or breastfeeding women, and their offspring.

21. Covid-19 vaccine acceptance, hesitancy, and refusal among Canadian healthcare workers: A multicenter survey.

Dzieciolowska Stefania American journal of infection control 2021;49(9):1152-1157.

BACKGROUNDDeterminants of COVID-19 vaccine acceptance among healthcare workers (HCW) remains poorly understood. We assessed HCWs' willingness to be vaccinated and reasons underlying hesitancy.**METHODS**Cross-sectional survey across 17 healthcare institutions. HCWs eligible for vaccination (Pfizer-BioNTech mRNA) in December 2020 were invited to receive immunization. Multivariate logistic regression was performed to identify predictors of acceptance. Reasons for refusal among those who never intended to be vaccinated (ie, firm refusers) and those who preferred delaying vaccination (ie, vaccine hesitants) were assessed.**RESULTS**Among 2,761 respondents (72% female, average age, 44), 2,233 (80.9%) accepted the vaccine. Physicians, environmental services workers and healthcare managers were more likely to accept vaccination compared to nurses. Male sex, age over 50, rehabilitation center workers, and occupational COVID-19 exposure were independently associated with vaccine acceptance by multivariate analysis. Factors for refusal included vaccine novelty, wanting others to receive it first, and insufficient time for decision-making. Among those who declined, 74% reported they may accept future vaccination. Vaccine firm refusers were more likely than vaccine hesitants to distrust pharmaceutical companies and to prefer developing a natural immunity by getting COVID-19.**CONCLUSIONS**Vaccine hesitancy exists among HCWs. Our findings provide useful information to plan future interventions and improve acceptance.

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22. COVID-19 vaccine efficacy and effectiveness-the elephant (not) in the room.

Olliaro P. The Lancet. Microbe 2021;2(7):e279-e280.

[Available online at this link](#)

23. COVID-19 vaccine hesitancy among healthcare workers

Paris C. Infectious Diseases Now 2021;51(5):484-487.

Objective: To characterize healthcare workers' (HCWs) intention to receive the COVID-19 vaccine by the beginning of the vaccine campaign in France. **Method(s):** Data were collected on a self-administered questionnaire through the website of a tertiary care center (February 9-18, 2021). **Result(s):** Among 1,965 respondents, 1,436 (73.1%), 453 (23.1%), and 76 (3.9%) declared themselves in favor, hesitant, or against the COVID-19 vaccine: < 60% of auxiliary nurses and technicians intended to be vaccinated, as compared to 60-79% of nurses and support staff, and > 80% of medical staff. On multivariate analysis, age, occupation, flu vaccine history, and controversy over the AstraZeneca vaccine tolerability were independently associated with COVID-19 vaccine intention. **Conclusion(s):** Patterns of vaccine hesitancy related to the COVID-19 and influenza vaccines are similar among HCWs. Media communication on vaccine side effects have a dramatic effect on vaccine hesitancy. Efforts are requested to inform HCWs about the risk/benefit balance of COVID-19 vaccines.
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24. **COVID-19 vaccine trials: The potential for "hybrid" analyses.**

Fleming Thomas R. *Clinical trials (London, England)* 2021;18(4):391-397.

BACKGROUND Although several COVID-19 vaccines have been found to be effective in rigorous evaluation and have emerging availability in parts of the world, their supply will be inadequate to meet international needs for a considerable period of time. There also will be continued interest in vaccines that are more effective or have improved scalability to facilitate mass vaccination campaigns. Ongoing clinical testing of new vaccines also will be needed as variant strains continue to emerge that may elude some aspects of immunity induced by current vaccines. Randomized clinical trials meaningfully enhance the efficiency and reliability of such clinical testing. In clinical settings with limited or no access to known effective vaccines, placebo-controlled randomized trials of new vaccines remain a preferred approach to maximize the reliability, efficiency and interpretability of results. When emerging availability of licensed vaccines makes it no longer possible to use a placebo control, randomized active comparator non-inferiority trials may enable reliable insights. **METHODS** In this article, "hybrid" methods are proposed to address settings where, during the conduct of a placebo-controlled trial, a judgment is made to replace the placebo arm by a licensed COVID-19 vaccine due to emerging availability of effective vaccines in regions participating in that trial. These hybrid methods are based on proposed statistics that aggregate evidence to formally test as well as to estimate the efficacy of the experimental vaccine, by combining placebo-controlled data during the first period of trial conduct with active-controlled data during the second period. **RESULTS** Application of the proposed methods is illustrated in two important scenarios where the active control vaccine would become available in regions engaging in the experimental vaccine's placebo-controlled trial: in the first, the active comparator's vaccine efficacy would have been established to be 50%-70% for the 4- to 6-month duration of follow-up of its placebo-controlled trial; in the second, the active comparator's vaccine efficacy would have been established to be 90%-95% during that duration. These two scenarios approximate what has been seen with adenovirus vaccines or mRNA vaccines, respectively, assuming the early estimates of vaccine efficacy for those vaccines would hold over longer-term follow-up. **CONCLUSION** The proposed hybrid methods could readily play an important role in the near future in the design, conduct and analysis of randomized clinical trials performed to address the need for multiple additional vaccines reliably established to be safe and have worthwhile efficacy in reducing the risk of symptomatic disease from SARS-CoV-2 infections.

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25. **COVID-19 Vaccine Uptake and Intent Among Emergency Healthcare Workers: A Cross-Sectional Survey**

Pacella-LaBarbara M.L. *Journal of occupational and environmental medicine* 2021;63(10):852-856.

OBJECTIVE: Vaccine hesitancy limits population protection from SARS-CoV (coronavirus disease [COVID-19]). Vaccine hesitancy among healthcare workers (HCW) could put patients and coworkers at risk. **METHOD(S):** We surveyed 475 emergency department and emergency medical service workers from January to February 2021 to determine vaccine intent/uptake, perceived COVID-19 vulnerability, and factors associated with vaccine intent/uptake. **RESULT(S):** Although 79% of HCWs received or had plans to receive the COVID-19 vaccine, 21% had no intent/were unvaccinated; intent/uptake was lower among females (odds ratio [OR] = 0.34) and those with a history of COVID-19 infection (OR = 0.55), and higher among those with advanced degrees (OR = 3.53) and high perceived COVID-19 vulnerability (OR = 1.99). **CONCLUSION(S):** This study provides a timely assessment of vaccination status among frontline HCWs and highlights subgroups who may be at high risk of exposure and transmission. **Copyright** © 2021 American College of Occupational and Environmental Medicine.

26. **COVID-19 vaccines and thrombosis with thrombocytopenia syndrome.**

Lai Chih-Cheng Expert review of vaccines 2021;20(8):1027-1035.

INTRODUCTIONTo combat COVID-19, scientists all over the world have expedited the process of vaccine development. Although interim analyses of clinical trials have demonstrated the efficacy and safety of COVID-19 vaccines, a serious but rare adverse event, thrombosis with thrombocytopenia syndrome (TTS), has been reported following COVID-19 vaccination.**AREAS COVERED**This review, using data from both peer-reviewed and non-peer-reviewed studies, aimed to provide updated information about the critical issue of COVID-19 vaccine-related TTS.**EXPERT OPINION:** The exact epidemiological characteristics and possible pathogenesis of this adverse event remain unclear. Most cases of TTS developed in women within 2 weeks of the first dose of vaccine on the receipt of the ChAdOx1 nCoV-19 and Ad26.COV2.S vaccines. In countries with mass vaccination against COVID-19, clinicians should be aware of the relevant clinical features of this rare adverse event and perform related laboratory and imaging studies for early diagnosis. Non-heparin anticoagulants, such as fondaparinux, argatroban, or a direct oral anticoagulant (e.g. apixaban or rivaroxaban) and intravenous immunoglobulins are recommended for the treatment of TTS. However, further studies are required to explore the underlying mechanisms of this rare clinical entity.**PLAIN LANGUAGE SUMMARY**What is the context?Thrombosis with thrombocytopenia syndrome (TTS) usually develops within 2 weeks of the first doses of the ChAdOx1 nCoV-19 and Ad26.COV2.S COVID-19 vaccines.TTS mainly occurs in patients aged < 55 years and is associated with high morbidity and mortality.What is new?TTS mimics autoimmune heparin-induced thrombocytopenia and can be mediated by platelet-activating antibodies against platelet factor 4. Non-heparin anticoagulants, such as fondaparinux, argatroban, or a direct oral anticoagulant (e.g. apixaban or rivaroxaban) should be considered as the treatment of choice if the platelet count is > 50 × 10⁹/L and there is no serious bleeding. Intravenous immunoglobulins and glucocorticoids may help increase the platelet count within days and reduce the risk of hemorrhagic transformation when anticoagulation is initiated.What is the impact?TTS should be a serious concern during the implementation of mass COVID-19 vaccination, and patients should be educated about this complication along with its symptoms such as severe headache, blurred vision, seizure, severe and persistent abdominal pain, painful swelling of the lower leg, and chest pain or dyspnea. The incidence of TTS is low; therefore, maintenance of high vaccination coverage against COVID-19 should be continued.

27. **COVID-19 Vaccines in Cancer Patients. Seropositivity and Safety. Systematic Review and Meta-Analysis.**

Cavanna Luigi Vaccines 2021;9(9):No page numbers.

Patients with cancer are among the most vulnerable groups of the COVID-19 pandemic, whereas vaccinations can represent a cornerstone in overcoming the pandemic itself. However, cancer patients were excluded from clinical trials for COVID-19 vaccinations, and thus the data on the immunogenicity and safety of COVID-19 vaccines in cancer patients are limited. In this systematic review, we assessed the seroconversion rate and the safety of COVID-19 vaccinations in cancer patients. We searched a bibliographic database up until 31 July 2021. Utilizing inclusion criteria, six studies were selected and analyzed for this meta-analysis. This included 621 cancer patients and 256 controls. Results show that patients with solid tumors show adequate antibody responses (>90%), though the antibody titers were significantly lower than those of healthy controls. Similarly, a significantly lower rate of seroconversion was registered in patients with hematologic malignances. The vaccines showed a good safety profile; no grade 3-4 adverse events were registered. This review demonstrates generally high immunogenicity from COVID-19 vaccines in patients with cancer, with better results for solid tumors than hematological malignances, and with a good safety profile.

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28. **COVID-19 vaccines: concerns beyond protective efficacy and safety.**

Lai Chih-Cheng Expert review of vaccines 2021;20(8):1013-1025.

INTRODUCTIONSeveral vaccine candidates have been developed using different platforms, including nucleic acids (DNA and RNA), viral vectors (replicating and non-replicating), virus-like particles, peptide-based, recombinant proteins, live attenuated, and inactivated virus modalities. Although many of these vaccines are undergoing pre-clinical trials, several large clinical trials investigating the clinical efficacy and safety of coronavirus disease 2019 (COVID-19) vaccines have produced promising findings.**AREAS COVERED**In this review, we provide a status update on COVID-19 vaccines currently undergoing clinical trials and discuss issues of concern beyond vaccine efficacy and safety, including dosing regimens, the mixed vaccine strategy, prior severe acute respiratory syndrome coronavirus-2 infection, antibody levels, cellular immunity and protection, variants of concern, COVID-19 vaccine distribution, vaccination willingness, herd immunity, immunity passports, and vaccine indications.**EXPERT OPINION**Four vaccines have obtained emergency use authorization, 87 are at the clinical development stage, and 186 are in pre-clinical development. While the knowledge and development of COVID-19 vaccines is rapidly expanding, the benefits of COVID-19 vaccines must outweigh the potential risks of adverse events. To combat the COVID-19 pandemic, clinicians should consistently update COVID-19-associated information, and healthcare authorities and manufacturers should work together to provide adequate and appropriate vaccinations for the prevention of COVID-19.**PLAIN LANGUAGE SUMMARY**What is the context?Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) caused a global pandemic: the coronavirus disease 2019 (COVID-19) outbreak. The development and implementation of the COVID-19 vaccine could be an important measure to control the COVID-19 pandemic.What is new?Several phase 3 clinical trials have demonstrated the effectiveness and safety of COVID-19 vaccines for the prevention of SARS-CoV-2 infections. Several COVID-19 vaccines have obtained emergency use authorization and been implemented in many countries. Although concerns regarding unusual blood clots and low platelet counts have been raised, the benefits of COVID-19 vaccines outweigh the potential risks of adverse events.What is the impact?Except for children, the COVID-19 vaccine is recommended for all people, including those pregnant or immunocompromised. Healthcare authorities should advise people receiving the vaccine that they must seek medical attention if they have associated thromboembolism and thrombocytopenia symptoms. More studies are necessary to determine the appropriate vaccine dose and regimen strategy, as well as the effectiveness of COVID-19 vaccines against variants of concerns. A global effort must be made to achieve widespread vaccination and herd immunity.

29. **Covid-19: First UK vaccine safety data are "reassuring," says regulator.**

Torjesen Ingrid BMJ (Clinical research ed.) 2021;372:n363.

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30. **Covid-19: How independent were the US and British vaccine advisory committees?**

Thacker Paul D. BMJ (Clinical research ed.) 2021;373:n1283.

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31. **Cumulative Adverse Event Reporting of Anaphylaxis After mRNA COVID-19 Vaccine (Pfizer-BioNTech) Injections in Japan: The First-Month Report.**

Iguchi Toyotaka Drug safety 2021;44(11):1209-1214.

INTRODUCTIONIn mid-February, the nationwide immunization plan for the prevention of coronavirus disease 2019 (COVID-19) started in Japan (at first primarily focused on health professionals) using an mRNA-based vaccine (Pfizer/BioNTech). During the phase-in period from February to March, attention was focused on post-vaccination anaphylaxis and anaphylactoid symptoms from the viewpoint of ensuring the safety of the vaccination program.**OBJECTIVE**The aim of this report was to provide an update on the status of anaphylaxis and anaphylactoid symptoms occurring after vaccination for COVID-19, as reported under the Adverse Event Following Immunization (AEFI) reporting system in Japan.**METHODS**The Pharmaceutical and Medical Devices Agency (PMDA) received AEFI reports from health professionals and manufacturers under the reporting system for AEFI after vaccination for COVID-19, which has been in operation since mid-February 2021. Reported AEFIs of anaphylaxis and anaphylactoid symptoms were assessed using the Brighton Collaboration Criteria to assess diagnostic certainty.**RESULTS**1-month since Japan started the vaccination program for COVID-19 in February 2021, 578,835 doses have been administered to health professionals, with the PMDA receiving 181 suspected event reports of anaphylaxis and anaphylactoid symptoms. In 171 of these 181 cases, women developed these symptoms. Among 181 cases evaluated according to the Brighton Collaboration Criteria, 47 cases (26%) were classified as level 1-3 (reporting rate: 8.1/100,000 doses).**CONCLUSION**The results appear similar to reported AEFIs in foreign studies of coronavirus vaccine administration to health professionals, although the reporting rate was higher. Further work is needed to examine the causal relationship of anaphylaxis reactions to coronavirus vaccine administration. Issues of multiple reporting and possible sex/age bias also remain to be analyzed.

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32. **Efficacy and effectiveness of COVID-19 vaccines against SARS-CoV-2 infection: interim results of a living systematic review, 1 January to 14 May 2021.**

Harder Thomas Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin 2021;26(28):No page numbers.

Evidence on COVID-19 vaccine efficacy/effectiveness (VE) in preventing asymptomatic SARS-CoV-2 infections is needed to guide public health recommendations for vaccinated people. We report interim results of a living systematic review. We identified a total of 30 studies that investigated VE against symptomatic and/or asymptomatic infection. In fully vaccinated individuals, VE against symptomatic and asymptomatic infections was 80-90% in nearly all studies. Fully vaccinated persons are less likely to become infected and contribute to transmission.

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33. **Efficacy and safety of COVID-19 vaccines in older people.**

Soiza Roy L. Age and ageing 2021;50(2):279-283.

Several vaccines against coronavirus disease 2019 (COVID-19) are on the cusp of regulatory approval. Their safety and efficacy in older people is critical to their success. Even though care home residents and older people are likely to be amongst the first to be vaccinated, these patient groups are usually excluded from clinical trials. Data from several Phase II trials have given cause for optimism, with strong antibody responses and reassuring safety profiles but, with the exception of AstraZeneca's vaccine, recruited few older people. Overall, the sparse data from Phase II trials suggest a reduction in both antibody responses and mild to moderate adverse events in well older people compared to younger participants. Many of the Phase III trials have made a conscious effort to recruit older people, and interim analyses of the Pfizer and Moderna vaccine have led to press releases announcing high degrees of efficacy. However, older people with co-morbidities and frailty have once again been largely excluded and there are no published data on safety and efficacy in this group. Although the speed and impact of the pandemic on older people with frailty justify an approach where they are offered vaccination first, patients and their carers and supervising health care professionals alike will need to make a decision on accepting vaccination based on limited evidence. Here we review the main candidate vaccines that may become available, with a focus on the evidence of safety and efficacy in older people.

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34. **Efficacy and Safety of COVID-19 Vaccines in Phase III Trials: A Meta-Analysis.**

Cheng Haoyue Vaccines 2021;9(6):No page numbers.

Nowadays, the vaccination with COVID-19 vaccines is being promoted worldwide, professionals and common people are very concerned about the efficacy and safety of COVID-19 vaccines. No published systematic review and meta-analysis has assessed the efficacy and safety of the COVID-19 vaccines based on data from phase III clinical trials. Therefore, this study has estimated the efficacy and safety of COVID-19 vaccines and the differences between vaccine types. PubMed, Embase, the Cochrane Library, CNKI, Wanfang, medRxiv databases and two websites were used to retrieve the studies. Random-effects models were used to estimate the pooled efficacy and safety with risk ratio (RR). A total of eight studies, seven COVID-19 vaccines and 158,204 subjects were included in the meta-analysis. All the vaccines had a good preventive effect on COVID-19 (RR = 0.17, 95% CI: 0.09-0.32), and the mRNA vaccine (RR = 0.05, 95% CI: 0.03-0.09) was the most effective against COVID-19, while the inactivated vaccine (RR = 0.32, 95% CI: 0.19-0.54) was the least. In terms of safety, the risk of overall adverse events showed an increase in the vaccine group after the first (RR = 1.46, 95% CI: 1.03-2.05) or second (RR = 1.52, 95% CI: 1.04-2.20) injection. However, compared with the first injection, the risk of local (RR = 2.64, 95% CI: 1.02-6.83 vs. RR = 2.25, 95% CI: 0.52-9.75) and systemic (RR = 1.33, 95% CI: 1.21-1.46 vs. RR = 1.59, 95% CI: 0.84-3.01) adverse events decreased after the second injection. As for the mRNA vaccine, the risk of overall adverse events increased significantly, compared with the placebo, no matter whether it was the first (RR = 1.83, 95% CI = 1.80-1.86) or the second (RR = 2.16, 95% CI = 2.11-2.20) injection. All the COVID-19 vaccines that have published the data of phase III clinical trials have excellent efficacy, and the risk of adverse events is acceptable. The mRNA vaccines were the most effective against COVID-19, meanwhile the risk and grade of adverse events was minimal, compared to that of severe symptoms induced by COVID-19.

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35. Efficacy, Immunogenicity and Safety of COVID-19 Vaccines: A Systematic Review and Meta-Analysis.

Sharif Nadim *Frontiers in immunology* 2021;12:714170.

There is a significant research gap in meta-analysis on the efficacy and safety of coronavirus disease 2019 (COVID-19) vaccines. This study analyzed the efficacy of COVID-19 vaccines. Published phase I, phase II, and phase III trials analyzing safety and immunogenicity and phase III randomized clinical trials evaluating the efficacy of COVID-19 vaccines were included. We searched MEDLINE, Scopus, and The Lancet for published articles evaluating the relative reduction in COVID-19 risk after vaccination. Selected literatures were published between December 15, 2019 and May 15, 2021 on the safety, efficacy, and immunogenicity of COVID-19 vaccines. This meta-analysis included studies that confirmed cases of COVID-19 using reverse transcriptase polymerase chain reaction. This study detected 8,926 eligible research articles published on COVID-19 vaccines. Of these, 25 studies fulfilled the inclusion criteria. Among the selected articles, 19 randomized clinical trials, 2 non-randomized clinical trials, and 3 observational studies were analyzed. Seven (28%) studies were included in the meta-analysis. The efficacy of the adenovirus vector vaccine was 73% (95% CI = 69-77) and that of the messenger RNA (mRNA) vaccine was 85% (95% CI = 82-88) in participants aged ≥ 18 years. There are no reports of clinical trials in participants aged under 16 years. The production of neutralizing antibodies against receptor-binding domains (RBDs) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in $>90\%$ of the vaccinated samples was reported within 0-30 days of the first or the second dose of the vaccine. Pain at the injection site was the most common local symptom in people receiving mRNA vaccines (29%-85% of participants). Fever (0.2%-95%) was the most prevalent in people receiving adenovirus vector vaccines, and fatigue (8.4%-55%) was the most common side effect in people receiving the mRNA vaccines. Studies suggest that mRNA vaccines and adenovirus vector vaccines can provide moderate to high protection against COVID-19 infection in people over 18 years. Evidence of the long-term protection of the vaccines in people aged under 16 years against the multiple variants of COVID-19 are limited. This study will provide an integrated evaluation on the efficacy, safety, and immunogenicity of the COVID-19 vaccines.

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36. Evidence-informed vaccination decision-making in countries: Progress, challenges and opportunities.

Steffen Christoph A. *Vaccine* 2021;39(15):2146-2152.

Countries face an increasingly complex vaccination landscape. As well as ever-changing infectious disease epidemiology, the number and diversity of vaccine-preventable diseases, vaccine products, and vaccine technologies continue to increase. To ensure that vaccination decision-making is transparent, country-owned and informed by sound scientific evidence, many countries have established national immunization technical advisory groups (NITAGs) to provide independent expert advice. The past decade has seen substantial growth in NITAG numbers and functionality, and there is now a need to consolidate this progress, by further capacity building, to ensure that NITAGs are responsive to the changing face of immunization over the next decade.

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37. **General determination of causation between Covid-19 vaccines and possible adverse events.**

Hampton Lee M. Vaccine 2021;39(10):1478-1480.

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38. **Healthcare workers' (HCWs) attitudes and related factors towards COVID-19 vaccination: a rapid systematic review.**

Li Mei Postgraduate medical journal 2021;:No page numbers.

Herd immunity through vaccination is a key measure to control COVID-19 pandemic. However, vaccine hesitancy remains a public health threat, which is still common among healthcare workers (HCWs). This systematic review aimed to synthesise evidence on HCWs' attitudes towards COVID-19 vaccination and analyse associated factors to provide information for vaccine policy development and practice. We searched PubMed, Embase, ScienceDirect, Web of Science and three Chinese databases for literature published on 12 February 2021. Two researchers screened the literature independently, and 13 studies were included in the systematic review. Vaccine acceptance varied widely and ranged from 27.7% to 77.3%. HCWs had positive attitudes towards future COVID-19 vaccines, while vaccine hesitancy was still common. Demographic variables such as men, older age and physicians were positive predictive factors. Women and nurses had more vaccine hesitancy. Previous influenza vaccination and self-perceived risk were facilitators. Concerns for safety, efficacy and effectiveness and distrust of the government were barriers. Influences of direct (COVID-19) patient care towards vaccination intention were less conclusive. Tailored communication strategies were needed to increase the uptake rate of COVID-19 vaccines among HCWs. More importantly, more data and information on the safety and efficacy of vaccines should be provided with transparency.

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39. **High anaphylaxis rates following vaccination with the Pfizer BNT162b2 mRNA vaccine against COVID-19 in Japanese healthcare workers: a secondary analysis of initial post-approval safety data.**

Hashimoto Takanao Journal of travel medicine 2021;28(7):No page numbers.

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40. **Immune Response to Vaccination against COVID-19 in Breastfeeding Health Workers.**

Jakuszkó Katarzyna Vaccines 2021;9(6):No page numbers.

BACKGROUNDInitially, there were no data on the safety of COVID-19 vaccines in lactating women. The aim of our study was to evaluate the immune response to COVID-19 vaccinations in breastfeeding women.**METHODS**The study included 32 breastfeeding women who, regardless of the study, had decided to be vaccinated. Maternal serum and breast milk samples were simultaneously collected on days 8 ± 1 , 22 ± 2 , 29 ± 3 , and 43 ± 4 after the first dose of the vaccine. The immune response was assessed by determining the presence of anti-SARS-CoV-2 IgG and IgA.**RESULTS**The breast milk IgG level was

detectable (6.50 ± 6.74 , median 4.7, and maximum 34.2 BAU/mL) and highly correlated to serum IgG level ($r_S 0.89$; $p < 0.001$). The breast milk ratio of IgA to the cut-off value was higher in serum IgA-positive (4.18 ± 3.26 , median 2.8, and maximum >10) than in serum IgA-negative women (0.56 ± 0.37 , median 0.5, and maximum 1.6; $p < 0.001$). The highest concentrations of serum and breast milk antibodies were observed on day 29 ± 3 with a decrease on day 43 ± 4 . **CONCLUSION** The immune response to the vaccination against SARS-CoV-2 is strongest 7 ± 3 days after the second dose of the vaccine. Lactating mothers breastfeeding their children after vaccination against SARS-CoV-2 may transfer antibodies to their infant.

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41. **Influence of a COVID-19 vaccine's effectiveness and safety profile on vaccination acceptance**

Kaplan R.M. Proceedings of the National Academy of Sciences of the United States of America 2021;118(10):No page numbers.

Although a safe and effective vaccine holds the greatest promise for resolving the COVID-19 pandemic, hesitancy to accept vaccines remains common. To explore vaccine acceptance decisions, we conducted a national survey of 1,000 people from all US states in August of 2020 and a replication in December of 2020. Using a $3 \times 3 \times 3$ factorial experimental design, we estimated the impact of three factors: probability of 1) protection against COVID-19, 2) minor side effects, and 3) a serious adverse reactions. The outcome was respondents' reported likelihood of receiving a vaccine for the coronavirus. Probability of vaccine efficacy (50%, 70%, or 90%) had the largest effect among the three factors. The probability of minor side effects (50%, 75%, 90%) including fever and sore arm, did not significantly influence likelihood of receiving the vaccine. The chances of a serious adverse reaction, such as temporary or permanent paralysis, had a small but significant effect. A serious adverse reaction rate of 1/100,000 was more likely to discourage vaccine use in comparison to rates of 1/million or 1/100 million. All interactions between the factors were nonsignificant. A replication following the announcement that vaccines were 95% effective showed small, but significant increases in the likelihood of taking a vaccine. The main effects and interactions in the model remained unchanged. Expected benefit was more influential in respondents' decision making than expected side effects. The absence of interaction effects suggests that respondents consider the side effects and benefits independently. Copyright © 2021 National Academy of Sciences. All rights reserved.

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42. **Influenza vaccine uptake, COVID-19 vaccination intention and vaccine hesitancy among nurses: A survey**

Kwok Kin On International Journal of Nursing Studies 2021;114:1.

Background A healthy healthcare system requires healthy healthcare workers. Protecting healthcare workers including nurses against COVID-19 is crucial, and vaccination could be a viable future option. However, vaccine hesitancy remains a global challenge. Nurses, as a trustworthy and creditable source of vaccine-related information, may build public

confidence in vaccination. Hence, research on vaccine hesitancy among nurses is warranted. Objectives This study estimated nurses' influenza vaccination behaviors and intention to receive COVID-19 vaccine when available, and examined their corresponding 5C psychological antecedents (confidence, complacency, constraints, calculation, and collective responsibility). To investigate the impact of COVID-19-related work demands, the mediation effects of work stress on the association between work demands and COVID-19 vaccination intention were also examined. Design Cross-sectional online survey Settings Nurses were invited to participate via the promotion of a professional nursing organization and by personal referrals during the COVID-19 outbreak in Hong Kong between mid-March and late April 2020. Participants 1,205 eligible nurses (mean age = 40.79, SD = 10.47; 90% being female) were included in the analyses. Methods Demographics, influenza vaccination, intention to have COVID-19 vaccine, the 5C vaccine hesitancy components, work stress and COVID-19-related work demands (insufficient supply of personal protective equipment, involvement in isolation rooms, and unfavorable attitudes towards workplace infection control policies) were reported in the survey. Results The influenza vaccine uptake rate and the proportion intending to take COVID-19 vaccine were 49% and 63%, respectively. Influenza vaccination was associated with working in public hospitals and all 5C constructs (more confidence, more collective responsibility and less complacency, constraints, and calculation), whereas stronger COVID-19 vaccination intention was associated with younger age, more confidence, less complacency and more collective responsibility. COVID-19-related demands were associated with greater work stress, and hence stronger COVID-19 vaccination intention. Conclusion The potential uptake rate of COVID-19 vaccine among nurses was suboptimal to achieve herd immunity. The 5C constructs were useful in predicting influenza vaccination and, to a lesser extent, the intention to take COVID-19 vaccine. The uncertain attributes such as effectiveness, side effects, and effective duration of the COVID-19 vaccine may contribute to this discrepancy. With less work stress among nurses in the post-pandemic period, the intention to take COVID-19 vaccine will likely drop. The 5C constructs should be infused in vaccination campaigns. While a COVID-19 vaccine could be ready soon, the nursing profession may not be ready to accept it. More research work is needed to boost the uptake rate.

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43. **Lessons learned from frontline skilled nursing facility staff regarding COVID-19 vaccine hesitancy.**

Berry Sarah D. Journal of the American Geriatrics Society 2021;69(5):1140-1146.

BACKGROUNDPresently a median of 37.5% of the U.S. skilled nursing facility (SNF) workforce has been vaccinated for COVID-19. It is essential to understand vaccine hesitancy among SNF workers to inform vaccine campaigns going forward.**OBJECTIVE**To describe the concerns raised among healthcare workers and staff from SNFs during town hall meetings.**DESIGN**Sixty-three SNFs from four corporations were invited to send Opinion Leaders, outspoken staff from nursing, nurse aid, dietary, housekeeping or recreational therapy, to attend a 1-h virtual town hall meeting. Meetings used a similar format where the moderator solicited concerns that the attendees themselves had or had heard from others in the facility about the COVID-19 vaccine. Physicians and moderators used personal stories to address concerns and reaffirmed positive emotions.**SETTING**Twenty-six video town hall meetings with SNF staff.**PARTICIPANTS**Healthcare workers and staff, with physicians serving as content experts.**MEASUREMENT**Questions and comments about the COVID-19 vaccines noted by physicians.**RESULTS**One hundred and ninety three staff from 50 facilities participated in 26 meetings between December 30, 2020 and January 15, 2021. Most staff reported getting information about the vaccine from friends or social media. Concerns about how rapidly the vaccines were developed and side effects, including infertility or pregnancy related concerns, were frequently raised. There were no differences in concerns raised by discipline. Questions about returning to prior activities after being vaccinated were common and offered the opportunity to build on positive emotions to reduce vaccine hesitancy.**CONCLUSIONS**Misinformation about the COVID-19 vaccine was

widespread among SNF staff. Sharing positive emotions and stories may be more effective than sharing data when attempting to reduce vaccine hesitancy in SNF staff.

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44. Longitudinal assessment of COVID-19 vaccine acceptance and uptake among frontline medical workers in Los Angeles, California.

Halbrook Megan Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 2021;:No page numbers.

BACKGROUNDSentiments of vaccine hesitancy and distrust in public health institutions have complicated the government-led COVID-19 vaccine control strategy in the United States. As the first to receive the vaccine, COVID-19 vaccine attitudes among front line workers are consequential for COVID-19 control and public opinion of the vaccine.**METHODS**This study employed a repeated cross-sectional survey administered at three time points between September 24 - February 6, 2021 to a cohort of employees of University of California, Los Angeles (UCLA) Health and the Los Angeles County Fire Department (LACoFD). The primary outcome of interest was COVID-19 vaccination intent and vaccine uptake.**RESULTS**Confidence in COVID-19 vaccines and vaccine uptake rose significantly over time. At Survey 1, confidence in vaccine protection was 46.4% among healthcare workers (HCW) and 34.6% among first responders (FR); by Survey 3, this had risen to 90.0% and 75.7%, respectively. At Survey 1, about one-third of participants intended to receive a vaccine as soon as possible. By Survey 3, 96.0% of HCW and 87.5% of FR had received a COVID-19 vaccine.**CONCLUSIONS**Attitudes towards vaccine uptake increased over the study period, likely a result of increased public confidence in COVID-19 vaccines, targeted communications, a COVID-19 winter surge in LA County, and ease of access from employer-sponsored vaccine distribution.

45. Low Rates of Urologic Side Effects Following Coronavirus Disease Vaccination: An Analysis of the Food and Drug Administration Vaccine Adverse Event Reporting System.

Zhao Hanson Urology 2021;153:11-13.

OBJECTIVETo quantify and describe urologic adverse events and symptoms after vaccination with the Pfizer-BioNTech and Moderna COVID-19 vaccines.**METHODS AND MATERIALS**We queried the FDA Vaccine Adverse Event Reporting System (VAERS) for all reported symptoms following the Pfizer-BioNTech and Moderna vaccines as of February 12th, 2021. All urologic symptoms were isolated and the reported adverse events associated with each symptom were reviewed.**RESULTS**Out of 15,785 adverse event reports, only 0.7% (113) described urologic symptoms. A total of 156 urologic symptoms were described amongst the 113 adverse event reports. The Pfizer-BioNTech vaccine was responsible for 61% of these reports and the Moderna vaccine was responsible for 39%. These symptoms were grouped into five different categories: Lower Urinary Tract Symptoms (n = 34, 22%), Hematuria (n = 22, 14%), Urinary Infection (n = 41, 26%), Skin and/or Soft Tissue (n = 16, 10%), and Other (n = 43, 28%). The median age of the patients reporting urologic symptoms was 63 years (IQR 44-79, Range: 19-96) and 54% of the patients were female.**CONCLUSION**Urologic symptoms reported after COVID-19 vaccination are extremely rare. Given the common prevalence of many of these reported symptoms in the general population, there does not appear to be a correlation between vaccination and urologic symptoms, but as the vaccination criteria expands, further monitoring of the Vaccine Adverse Event Reporting System is needed.

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46. Monitoring the safety of COVID-19 vaccines in pregnancy in the US.

Moro Pedro L. Human vaccines & immunotherapeutics 2021;:1-9.

Pregnant persons are at increased risk of severe illness from COVID-19. The first COVID-19 vaccines in the U.S. were authorized for emergency use in December 2020 and pregnant persons were eligible and could get vaccinated despite scarce safety data in this population. To monitor the safety of COVID-19 vaccination during pregnancy, four surveillance systems are used by the Centers for Disease Control and Prevention (CDC). The Vaccine Adverse Event Reporting System is a national, passive system that captures reports of potential adverse events. V-safe is a novel, active system that uses text messaging and web-based surveys to provide health check-ins after vaccination; and enrolls eligible v-safe participants in the v-safe pregnancy registry. The Vaccine Safety Datalink is a collaboration between the CDC and nine integrated health care organizations which performs near-real time surveillance and traditional epidemiologic studies on pregnant vaccine recipients. The CDC is committed to timely and comprehensive monitoring of COVID-19 vaccine safety in pregnancy.

47. Motivation to COVID-19 Vaccination and Reasons for Hesitancy in Employees of a Czech Tertiary Care Hospital: A Cross-Sectional Survey.

Štěpánek Ladislav Vaccines 2021;9(8):No page numbers.

High vaccination coverage among healthcare workers (HCWs) is crucial for managing the COVID-19 pandemic. The aim was to determine the demand for vaccination among all employees (n = 4553) of a tertiary care hospital after several weeks of the vaccine's availability, and to analyze motives for acceptance and reasons for hesitancy through an anonymous online questionnaire. Upon the completion of data collection, the hospital's vaccination coverage was at 69.8%. A total of 3550 completed questionnaires were obtained (2657 from vaccinated, 893 from unvaccinated employees). Significant predictors of vaccine acceptance were: age (odds ratio (OR) 1.01, 95% confidence interval (CI) 1.01-1.02), sex (OR (females) 0.58, 95% CI 0.45-0.75), job type (OR (non-physician HCWs) 0.54, 95% CI 0.41-0.72; OR (non-HCWs) 0.51, 95% CI 0.37-0.71), fear of COVID-19 (OR 1.4, 95% CI 1.34-1.46), history of COVID-19 (OR 0.41, 95% CI 0.34-0.49) and of influenza vaccination (OR 2.74, 95% CI 2.12-3.57). The most frequent motive for acceptance was the effort to protect family members (84%), while concerns about vaccine safety and side effects (49.4%), followed by distrust in the vaccine's efficacy (41.1%) were the top reasons for hesitancy. To increase vaccination coverage among HCWs, it is necessary to raise awareness of vaccine safety and efficacy.

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48. mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach.

Banerji Aleena The journal of allergy and clinical immunology. In practice 2021;9(4):1423-1437.

The U.S. Food and Drug Administration (FDA) has recently issued an Emergency Use Authorization (EUA) for 2 highly effective coronavirus disease 2019 (COVID-19) vaccines from Pfizer-BioNTech and Moderna. This has brought hope to millions of Americans in the midst of an ongoing global pandemic. The FDA EUA guidance for both vaccines is to not administer the vaccine to individuals with a known history of a severe allergic reaction (eg,

anaphylaxis) to any component of the COVID-19 vaccine. The Centers for Disease Control and Prevention (CDC) additionally advises individuals with a history of an immediate allergic reaction to a vaccine or injectable or any history of anaphylaxis be observed for 30 minutes after COVID-19 vaccination. All other individuals should be observed for 15 minutes after COVID-19 vaccination. Staff at vaccine clinics must be able to identify and manage anaphylaxis. Post-FDA EUA, despite very strong safety signals in both phase 3 trials, reports of possible allergic reactions have raised public concern. To provide reassurance and support during widespread global vaccination, allergists must offer clear guidance to individuals based on the best information available, but also in accordance with the broader recommendations of regulatory agencies. This review summarizes vaccine allergy epidemiology and proposes drug and vaccine allergy expert opinion informed risk stratification for Allergy specialist use in conjunction with guidance of public health and regulatory authorities. The risk stratification schema guide care for (1) individuals with different allergy histories to safely receive their first mRNA COVID-19 vaccine and (2) individuals who develop a reaction to their first dose of mRNA COVID-19 vaccine.

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49. National control laboratory independent lot testing of COVID-19 vaccines: the UK experience.

Rose Nicola J. NPJ vaccines 2021;6(1):100.

The past 18 months have seen an unprecedented approach to vaccine development in the global effort against the COVID-19 pandemic. The process from discovery research, through clinical trials and regulatory approval often takes more than 10 years. However, the critical need to expedite vaccine availability in the pandemic has meant that new approaches to development, manufacturing, and regulation have been required: this has necessitated many stages of product development, clinical trials, and manufacturing to be undertaken in parallel at a global level. Through the development of these innovative products, the world has the best chance of finding individual, or combinations of, vaccines that will provide adequate protection for the world's population. Despite the huge scientific and regulatory achievements and significant investment to accelerate vaccine availability, it is essential that safety measures are not compromised. Here we focus on the post regulatory approval testing by independent laboratories that provides an additional assurance of the safety and quality of a product, with an emphasis on the UK experience through the National Institute for Biological Standards and Control (NIBSC), an expert centre of the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

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50. Neurological symptoms and neuroimaging alterations related with COVID-19 vaccine: Cause or coincidence?

Corrêa Diogo Goulart Clinical imaging 2021;80:348-352.

Although vaccination against Coronavirus disease-2019 (COVID-19) is still occurring, several adverse effects temporally related to these vaccines are already being reported, even if through isolated case reports. In the present study, we describe the lesions seen on magnetic resonance imaging (MRI) of three patients who developed neurological symptoms after receiving the ChAdOX1 nCoV-19 vaccine (Oxford/AstraZeneca). The first patient presented with an ischemic stroke in the posterior limb of the left internal capsule, two days after vaccination. The second patient presented with a left facial nerve palsy, seven days after vaccination. The third patient presented with myelitis, eight days after receiving the

vaccine. All patients presented the symptoms after the first dose of the vaccine and did not have a history of previous COVID-19. The real incidence of these types of complications is not known yet, but it is important to consider the possibility of COVID-19 vaccine complications, in patients with a recent history of vaccination and recent development of neurological symptoms, even though this association is only casual. Longitudinal studies are necessary to further analyze the incidence of the adverse effects of each vaccine against SARS-CoV-2.

51. **Ocular Adverse Events After COVID-19 Vaccination.**

Ng Xin Le Ocular immunology and inflammation 2021;:1-9.

PURPOSEThe COVID-19 pandemic has galvanized the development of new vaccines at an unprecedented pace. Since the widespread implementation of vaccination campaigns, reports of ocular adverse effects after COVID-19 vaccinations have emerged. This review summarizes ocular adverse effects possibly associated with COVID-19 vaccination, and discusses their clinical characteristics and management.**METHODS**Narrative Literature Review.**RESULTS**Ocular adverse effects of COVID-19 vaccinations include facial nerve palsy, abducens nerve palsy, acute macular neuroretinopathy, central serous retinopathy, thrombosis, uveitis, multiple evanescent white dot syndrome, Vogt-Koyanagi-Harada disease reactivation, and new-onset Graves' Disease. Studies in current literature are primarily retrospective case series or isolated case reports - these are inherently weak in establishing association or causality. Nevertheless, the described presentations resemble the reported ocular manifestations of the COVID-19 disease itself. Hence, we hypothesize that the human body's immune response to COVID-19 vaccinations may be involved in the pathogenesis of the ocular adverse effects post-COVID-19 vaccination.**CONCLUSION**Ophthalmologists and generalists should be aware of the possible, albeit rare, ocular adverse effects after COVID-19 vaccination.

52. **People's Willingness to Vaccinate Against COVID-19 Despite Their Safety Concerns: Twitter Poll Analysis.**

Eibensteiner Fabian Journal of medical Internet research 2021;23(4):e28973.

BACKGROUNDOn January 30, 2020, the World Health Organization's Emergency Committee declared the rapid, worldwide spread of COVID-19 a global health emergency. Since then, tireless efforts have been made to mitigate the spread of the disease and its impact, and these efforts have mostly relied on nonpharmaceutical interventions. By December 2020, the safety and efficacy of the first COVID-19 vaccines were demonstrated. The large social media platform Twitter has been used by medical researchers for the analysis of important public health topics, such as the public's perception on antibiotic use and misuse and human papillomavirus vaccination. The analysis of Twitter-generated data can be further facilitated by using Twitter's built-in, anonymous polling tool to gain insight into public health issues and obtain rapid feedback on an international scale. During the fast-paced course of the COVID-19 pandemic, the Twitter polling system has provided a viable method for gaining rapid, large-scale, international public health insights on highly relevant and timely SARS-CoV-2-related topics.**OBJECTIVE**The purpose of this study was to understand the public's perception on the safety and acceptance of COVID-19 vaccines in real time by using Twitter polls.**METHODS**We developed 2 Twitter polls to explore the public's views on available COVID-19 vaccines. The surveys were pinned to the Digital Health and Patient Safety Platform Twitter timeline for 1 week in mid-February 2021, and Twitter users and influencers were asked to participate in and retweet the polls to reach the largest possible audience.**RESULTS**The adequacy of COVID-19 vaccine safety (ie, the safety of currently available vaccines; poll 1) was agreed upon by 1579 out of 3439 (45.9%) Twitter users. In contrast, almost as many Twitter users (1434/3439, 41.7%) were unsure about the safety of COVID-19 vaccines. Only 5.2% (179/3439) of Twitter users rated the available COVID-19 vaccines as generally unsafe. Poll 2, which addressed the question of

whether users would undergo vaccination, was answered affirmatively by 82.8% (2862/3457) of Twitter users, and only 8% (277/3457) categorically rejected vaccination at the time of polling. CONCLUSIONS In contrast to the perceived high level of uncertainty about the safety of the available COVID-19 vaccines, we observed an elevated willingness to undergo vaccination among our study sample. Since people's perceptions and views are strongly influenced by social media, the snapshots provided by these media platforms represent a static image of a moving target. Thus, the results of this study need to be followed up by long-term surveys to maintain their validity. This is especially relevant due to the circumstances of the fast-paced pandemic and the need to not miss sudden rises in the incidence of vaccine hesitancy, which may have detrimental effects on the pandemic's course.

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53. **Predicting COVID-19 vaccination intention using protection motivation theory and conspiracy beliefs.**

Eberhardt Judith Vaccine 2021;39(42):6269-6275.

BACKGROUND While COVID-19 vaccine uptake has been encouraging overall, some individuals are either hesitant towards, or refuse, the vaccine. Protection Motivation Theory (PMT) has been applied to influenza vaccine acceptance, but there is a lack of research applying PMT to COVID-19 vaccine acceptance. Additionally, prior research has suggested that coronavirus conspiracy beliefs and demographic factors may play a role in attitudes towards the vaccine. This study aimed to predict COVID-19 vaccination intention using PMT, coronavirus conspiracy beliefs, and demographic factors. Furthermore, vaccinated and unvaccinated individuals were compared in relation to their coronavirus conspiracy beliefs. METHODS An online survey was administered to 382 (278 vaccinated, and 104 unvaccinated) individuals in the United Kingdom (77 males, 301 females, one non-binary/third gender, and three unstated). Respondents' mean age was 43.78 (SD = 12.58). RESULTS A hierarchical multiple linear regression was performed in three stages. Initially, four PMT constructs - severity, susceptibility, maladaptive response costs, and self-efficacy - emerged as significant predictors of COVID-19 vaccination intention. The final model accounted for 75% of the variance and retained two significant predictors from PMT - maladaptive response rewards and self-efficacy - alongside coronavirus conspiracy beliefs and age. An independent t-test established that unvaccinated individuals held greater coronavirus conspiracy beliefs than vaccinated ones. CONCLUSIONS Interventions and campaigns addressing COVID-19 vaccine acceptance should employ strategies increasing individuals' perceived severity of COVID-19, perceived susceptibility, and perceived ability to get vaccinated, while decreasing perceived rewards of not getting vaccinated. Additionally, coronavirus conspiracy beliefs should be addressed, as these appear to play a role for some vaccine-hesitant individuals.

54. **Prevalence of Allergic Reactions After Pfizer-BioNTech COVID-19 Vaccination Among Adults With High Allergy Risk.**

Shavit Ronen JAMA network open 2021;4(8):e2122255.

Importance Allergic reactions among some individuals who received the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine discourage patients with allergic conditions from receiving this vaccine and physicians from recommending the vaccine. Objective To describe the assessment and immunization of highly allergic individuals with the BNT162b2

vaccine. Design, Setting, and Participants In a prospective cohort study from December 27, 2020, to February 22, 2021, 8102 patients with allergies who applied to the COVID-19 vaccine referral center at the Sheba Medical Center underwent risk assessment using an algorithm that included a detailed questionnaire. High-risk patients (n = 429) were considered "highly allergic" and were immunized under medical supervision. Exposures Pfizer-BioNTech (BNT162b2) COVID-19 vaccine. Main Outcomes and Measures Allergic and anaphylactic reactions after the first and second doses of BNT162b2 vaccine among highly allergic patients. Results Of the 429 individuals who applied to the COVID-19 referral center and were defined as highly allergic, 304 (70.9%) were women and the mean (SD) age was 52 (16) years. This highly allergic group was referred to receive immunization under medical supervision. After the first dose of the BNT162b2 vaccine, 420 patients (97.9%) had no immediate allergic event, 6 (1.4%) developed minor allergic responses, and 3 (0.7%) had anaphylactic reactions. During the study period, 218 highly allergic patients (50.8%) received the second BNT162b2 vaccine dose, of which 214 (98.2%) had no allergic reactions and 4 patients (1.8%) had minor allergic reactions. Other immediate and late reactions were comparable with those seen in the general population, except for delayed itch and skin eruption, which were more common among allergic patients. Conclusions and Relevance The rate of allergic reactions to BNT162b2 vaccine, is higher among patients with allergies, particularly among a subgroup with a history of high-risk allergies. This study suggests that most patients with a history of allergic diseases and, particularly, highly allergic patients can be safely immunized by using an algorithm that can be implemented in different medical facilities and includes a referral center, a risk assessment questionnaire, and a setting for immunization under medical supervision of highly allergic patients. Further studies are required to define more specific risk factors for allergic reactions to the BNT162b2 vaccine.

55. Pseudo-Anaphylactic Reactions to Pfizer BNT162b2 Vaccine: Report of 3 Cases of Anaphylaxis Post Pfizer BNT162b2 Vaccination.

Lim Xin Rong *Vaccines* 2021;9(9):No page numbers.

Anaphylactic reactions were observed after Singapore's national coronavirus disease 2019 (COVID-19) vaccination programme started in December 2020. We report the clinical and laboratory features of three patients in our institution who developed anaphylactic reactions after receiving the Pfizer BNT162b2 vaccine. IgM and IgG antibodies, but not IgE antibodies to the Pfizer BNT162b2 vaccine, were detected in all subjects. Similarly, mild to high elevated levels of anti-polyethylene glycol (PEG) IgG (1035-19709 U/mL, vs. vaccine-naive < 265 U/mL, vaccine-tolerant < 785 U/mL) and IgM (1682-5310 U/mL, vs. vaccine-naive < 1011 U/mL, vaccine-tolerant < 1007 U/mL) were detected in two out of three patients via commercial ELISA. High levels of serum anaphylatoxin C3a (79.0 ± 6.3 $\mu\text{g/mL}$, mean \pm SD, vs. normal < 10 $\mu\text{g/mL}$) were observed in all three patients during the acute phase of the reaction, while tryptase levels, a marker of mast cell activation, were not elevated. Finally, one patient with the highest levels of anti-PEG IgG, IgM, and anti-Pfizer BNT162b2 IgG and IgM exhibited an enhanced Th2 cytokine serum profile during an acute reaction, with high levels of IL-4 (45.7 pg/mL, vs. vaccine-naive/tolerant < 2.30 pg/mL), IL-33 (86.4 pg/mL, vs. vaccine-naive/tolerant < 5.51 pg/mL) and IL-10 (22.9 pg/mL, vs. vaccine-naive/tolerant < 12.49 pg/mL) diminishing over time following corticosteroid treatment. Taken together, we propose these cases of anaphylaxis described are driven by a complement activation-related pseudoallergy (CAPRA), rather than classical IgE-mediated mechanisms.

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56. Reporting at Least One Adverse Effect Post-COVID-19 Vaccination From Primary Health Care in Muscat.

Al Ghafri Thamra S. *Cureus* 2021;13(8):e17055.

Introduction Vaccinations against COVID-19 were licensed with limited testing assurances to the public triggering a widespread hesitancy around expected adverse reactions. Limited data was reported from Arabian Gulf countries on vaccine adverse effects. Objectives This study looked at the rate of reporting at least one side effect post-COVID-19 vaccination and its associated factors (sociodemographic characteristics, clinical condition, and type of vaccines). Additionally, questions about safety and willingness to recommend them were included. Study design Phone interviews on post-COVID-19 vaccination adverse effects were utilized to record responses related to reporting at least one side effect post vaccinations across the studied variables. Data collection continued for two months (from 1st March to 30th April 2021). Methodology Participants were adults (Omani citizens and non-citizens) who received AstraZeneca (AZ) or Pfizer (PF) vaccines from primary care facilities in Muscat and were randomly selected from the health information system. Responses were saved in a bespoke Google form/questionnaire. Chi-squared tests were utilized to determine potential factors associated with the dependent variable. Results A total of 753 participants completed the phone interviews. The mean age was 52 (3.5), males (54.1%), and 65.1% were Omanis. Hypertension (39.7%), diabetes (34.1%), and asthma (16.7%) were the commonest comorbidities. AZ and PF were administered to 78% and 22% of the participants. Of them, 49.8% reported at least one adverse effect post-COVID-19 vaccination. The proportion of participants with at least one adverse effect was significantly more in individuals who were younger, females, with more than secondary education, and employed (p value < 0.001, 0.01, <0.001, and <0.001, respectively). There was no severe reaction (anaphylactic shock) to the vaccines, and most adverse effects were mild-moderate. The proportion of individuals who reported adverse effects were higher with AZ vs PF (53% vs 38.6, $p = 0.001$). The most common reported localized adverse effects were pain and tenderness (28.3% and 12.1%). Fever and body aches were the commonly reported systemic adverse effects (33.5% and 29.2%). The safety of COVID-19 vaccines was well perceived, and most participants were willing to recommend them to others. Conclusions The current study confirms findings from existing literature on the mild to moderate adverse effects of AZ and PF vaccines. Despite the subjective nature of this study, it is reassuring that the studied COVID-19 vaccines can be administered safely. However, more longitudinal studies are needed to test their efficacy in disease prevention.

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57. **Safeguarding evidence-based decision making in the FDA for COVID-19 vaccines.** Angelis Aris Vaccine 2021;39(17):2328-2330.

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58. **Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia** Logunov Denis Y. The Lancet 2021;397(10275):671.

Summary Background A heterologous recombinant adenovirus (rAd)-based vaccine, Gam-COVID-Vac (Sputnik V), showed a good safety profile and induced strong humoral and cellular immune responses in participants in phase 1/2 clinical trials. Here, we report preliminary results on the efficacy and safety of Gam-COVID-Vac from the interim analysis of this phase 3 trial. Methods We did a randomised, double-blind, placebo-controlled, phase 3 trial at 25 hospitals and polyclinics in Moscow, Russia. We included participants aged at

least 18 years, with negative SARS-CoV-2 PCR and IgG and IgM tests, no infectious diseases in the 14 days before enrolment, and no other vaccinations in the 30 days before enrolment. Participants were randomly assigned (3:1) to receive vaccine or placebo, with stratification by age group. Investigators, participants, and all study staff were masked to group assignment. The vaccine was administered (0.5 mL/dose) intramuscularly in a prime-boost regimen: a 21-day interval between the first dose (rAd26) and the second dose (rAd5), both vectors carrying the gene for the full-length SARS-CoV-2 glycoprotein S. The primary outcome was the proportion of participants with PCR-confirmed COVID-19 from day 21 after receiving the first dose. All analyses excluded participants with protocol violations: the primary outcome was assessed in participants who had received two doses of vaccine or placebo, serious adverse events were assessed in all participants who had received at least one dose at the time of database lock, and rare adverse events were assessed in all participants who had received two doses and for whom all available data were verified in the case report form at the time of database lock. The trial is registered at <ce:inter-ref id="interrefs10"

xlink:href="http://ClinicalTrials.gov">ClinicalTrials.gov</ce:inter-ref> (<ce:inter-ref id="interrefs20" xlink:href="ctgov:NCT04530396">NCT04530396</ce:inter-ref>). Findings Between Sept 7 and Nov 24, 2020, 21 977 adults were randomly assigned to the vaccine group (n=16 501) or the placebo group (n=5476). 19 866 received two doses of vaccine or placebo and were included in the primary outcome analysis. From 21 days after the first dose of vaccine (the day of dose 2), 16 (0.1%) of 14 964 participants in the vaccine group and 62 (1.3%) of 4902 in the placebo group were confirmed to have COVID-19; vaccine efficacy was 91.6% (95% CI 85.6–95.2). Most reported adverse events were grade 1 (7485 [94.0%] of 7966 total events). 45 (0.3%) of 16 427 participants in the vaccine group and 23 (0.4%) of 5435 participants in the placebo group had serious adverse events; none were considered associated with vaccination, with confirmation from the independent data monitoring committee. Four deaths were reported during the study (three [<0.1%] of 16 427 participants in the vaccine group and one [<0.1%] of 5435 participants in the placebo group), none of which were considered related to the vaccine. Interpretation This interim analysis of the phase 3 trial of Gam-COVID-Vac showed 91.6% efficacy against COVID-19 and was well tolerated in a large cohort. Funding Moscow City Health Department, Russian Direct Investment Fund, and Sberbank.

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59. Safety of ChAdOx1 nCoV-19 Vaccine: Independent Evidence from Two EU States.
Riad Abanoub Vaccines 2021;9(6):No page numbers.

Recent reports of thrombosis following AstraZeneca COVID-19 vaccine in young females (<55 years-old) led to temporary suspension and urgent investigation by the European Medicines Agency (EMA) that concluded that vaccine benefits still outweigh its side effects (SEs). Therefore, this study aims to provide early independent evidence on the vaccine SEs' prevalence and their potential risk factors; a cross-sectional survey-based study was carried out between February and March 2021 in Germany and Czech Republic among healthcare workers who recently received the AstraZeneca COVID-19 vaccine. The study used a validated self-administered questionnaire composed of twenty-eight multiple-choice items covering demographic variables, medical anamneses, and local, systemic, oral, and skin related SEs of the vaccine. Out of the ninety-two included participants, 77.2% were females and 79.3% were from Germany. Their mean age was 35.37 ± 12.62 (19-64) years-old, 15.2% had chronic illnesses and 22.8% were receiving medical treatments. Overall, 94.6% of the participants reported at least one SE. The most common local SE was injection site pain (72.8%), and the most common systemic SEs were fatigue (73.9%), muscle pain (55.4%), chills (48.9%), feeling unwell (46.7%), nausea (45.7%), and headache (29.3%). The vast majority (91.9%) resolved within 1-3 days, and the below 35 years-old group was the least affected age group. The SEs' frequency was insignificantly

higher in females and previously infected participants; the vaccine safety for the elderly was supported by the early findings of this study. Chronic illnesses and medical treatments were not associated with an increased risk of SE incidence and frequency. No blood disorder SEs were reported in our sample. Further independent studies are highly required to evaluate the safety of the AstraZeneca vaccine and to explore whether gender or previous infection could be associated with the vaccine SEs.

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60. Safety of components and platforms of COVID-19 vaccines considered for use in pregnancy: A rapid review.

Ciapponi Agustín Vaccine 2021;39(40):5891-5908.

BACKGROUNDRapid assessment of COVID-19 vaccine safety during pregnancy is urgently needed.**METHODS**We conducted a rapid systematic review, to evaluate the safety of COVID-19 vaccines selected by the COVID-19 Vaccines Global Access-Maternal Immunization Working Group in August 2020, including their components and their technological platforms used in other vaccines for pregnant persons. We searched literature databases, COVID-19 vaccine pregnancy registries, and explored reference lists from the inception date to February 2021 without language restriction. Pairs of reviewers independently selected studies through COVIDENCE, and performed the data extraction and the risk of bias assessment. Discrepancies were resolved by consensus. Registered on PROSPERO (CRD42021234185).**RESULTS**We retrieved 6757 records and 12 COVID-19 pregnancy registries from the search strategy; 38 clinical and non-clinical studies (involving 2,398,855 pregnant persons and 56 pregnant animals) were included. Most studies (89%) were conducted in high-income countries and were cohort studies (57%). Most studies (76%) compared vaccine exposures with no exposure during the three trimesters of pregnancy. The most frequent exposure was to AS03 adjuvant, in the context of A/H1N1 pandemic influenza vaccines, (n = 24) and aluminum-based adjuvants (n = 11). Only one study reported exposure to messenger RNA in lipid nanoparticles COVID-19 vaccines. Except for one preliminary report about A/H1N1 influenza vaccination (adjuvant AS03), corrected by the authors in a more thorough analysis, all studies concluded that there were no safety concerns.**CONCLUSION**This rapid review found no evidence of pregnancy-associated safety concerns of COVID-19 vaccines or of their components or platforms when used in other vaccines. However, the need for further data on several vaccine platforms and components is warranted, given their novelty. Our findings support current WHO guidelines recommending that pregnant persons may consider receiving COVID-19 vaccines, particularly if they are at high risk of exposure or have comorbidities that enhance the risk of severe disease.

61. Safety of COVID-19 vaccines administered in the EU: Should we be concerned?

Hernández Antonio F. Toxicology reports 2021;8:871-879.

The COVID-19 pandemic has had an unprecedented and devastating impact on public health, society and economics around the world. As a result, the development of vaccines to protect individuals from symptomatic COVID-19 infections has represented the only feasible health tool to combat the spread of the disease. However, at the same time the development and regulatory assessment of different vaccines has challenged pharmaceutical industries and regulatory agencies as this process has occurred in the shorter time ever though. So far, two mRNA and two adenovirus-vectored vaccines have received a conditional marketing authorisation in the EU and other countries. This review summarized and discusses the assessment reports of the European Medicine Agency

(EMA) concerning the safety of the 3 vaccines currently used in the EU (Pfizer, Moderna and Astra-Zeneca). A particular focus has been paid to safety information from pre-clinical (animal) and clinical (phase 3 trials) studies. Overall, the most frequent adverse effects reported after the administration of these vaccines consisted of local reactions at the injection site (sore arm and erythema) followed by non-specific systemic effects (myalgia, chills, fatigue, headache, and fever), which occurred soon after vaccination and resolved shortly. Rare cases of vaccine-induced immune thrombotic thrombocytopenia have been reported for Vaxzevria. Data on long-term studies, interaction with other vaccines, use in pregnancy/breast-feeding, use in immunocompromised subjects, and in subjects with comorbidities, autoimmune or inflammatory disorders are still missing for these vaccines. Therefore, careful follow-up and surveillance studies for continued vaccine safety monitoring will be needed to ascertain the potential risks of such adverse events or diseases. In conclusion, the benefits and risks of current COVID-19 vaccines must be weighed against the real possibility of contract the disease and develop complications and long-term sequels; all this on the basis of the available scientific evidence and in the absence of unmotivated biases.

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62. **Safety of COVID-19 vaccines, their components or their platforms for pregnant women: A rapid review.**

Ciapponi Agustín medRxiv : the preprint server for health sciences 2021;:No page numbers.

Background Pregnant women with COVID-19 are at an increased risk of severe COVID-19 illness as well as adverse pregnancy and birth outcomes. Many countries are vaccinating or considering vaccinating pregnant women with limited available data about the safety of this strategy. Early identification of safety concerns of COVID-19 vaccines, including their components, or their technological platforms is therefore urgently needed. **Methods** We conducted a rapid systematic review, as the first phase of an ongoing full systematic review, to evaluate the safety of COVID-19 vaccines in pregnant women, including their components, and their technological platforms (whole virus, protein, viral vector or nucleic acid) used in other vaccines, following the Cochrane methods and the PRISMA statement for reporting (PROSPERO-CRD42021234185). We searched literature databases, COVID-19 and pregnancy registries from inception February 2021 without time or language restriction and explored the reference lists of relevant systematic reviews retrieved. We selected studies of any methodological design that included at least 50 pregnant women or pregnant animals exposed to the vaccines that were selected for review by the COVAX MIWG in August 2020 or their components or platforms included in the COVID-19 vaccines, and evaluated adverse events during pregnancy and the neonatal period. Pairs of reviewers independently selected studies through the COVIDENCE web software and performed the data extraction through a previously piloted online extraction form. Discrepancies were resolved by consensus. **Results** We identified 6768 records, 256 potentially eligible studies were assessed by full-text, and 37 clinical and non-clinical studies (38 reports, involving 2,397,715 pregnant women and 56 pregnant animals) and 12 pregnancy registries were included. Most studies (89%) were conducted in high-income countries. The most frequent study design was cohort studies (n=21), followed by surveillance studies, randomized controlled trials, and registry analyses. Most studies (76%) allowed comparisons between vaccinated and unvaccinated pregnant women (n=25) or animals (n=3) and reported exposures during the three trimesters of pregnancy. The most frequent exposure was to AS03 adjuvant in the context of A/H1N1 pandemic influenza vaccines (n=24), followed by aluminum-based adjuvants (n=11). Aluminum phosphate was used in Respiratory Syncytial Virus Fusion candidate vaccines (n=3) and Tdap vaccines (n=3). Different aluminum-based adjuvants were used in hepatitis vaccines. The replication-deficient simian adenovirus ChAdOx1 was used for a Rift Valley fever vaccine. Only one study reported exposure to messenger RNA (mRNA) COVID-19 vaccines that also used lipid nanoparticles. Except for one preliminary report about A/H1N1 influenza vaccination (adjuvant AS03) - corrected by

the authors in a more thorough analysis, all studies concluded that there were no safety concerns. Conclusion This rapid review found no evidence of pregnancy-associated safety concerns of COVID-19 vaccines that were selected for review by the COVAX MIWG or of their components or platforms when used in other vaccines. However, the need for further data on several vaccine platforms and components is warranted given their novelty. Our findings support current WHO guidelines recommending that pregnant women may consider receiving COVID-19 vaccines, particularly if they are at high risk of exposure or have comorbidities that enhance the risk of severe disease.

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63. **Safety of COVID-19 vaccines.**

Al Khames Aga Qutaiba A. *Journal of medical virology* 2021;93(12):6588-6594.

This study is aimed to identify the adverse effects associated with three types of coronavirus disease 2019 vaccines. Approximately 1736 individuals agreed to participate in this study. The participants involved in the study were individuals who had received the first dose or full course (two doses) of the vaccine at least 30 days before the survey. A direct and interactive web-based system interview with a paper and electronic version of the questionnaire was used for all participants. A total of 1736 randomized individuals were identified. The reactogenicity of the vaccines including pain, redness, urticaria, and swelling at the site of the injection was reported in 34.56% of the participants. Local site reaction was reported in more individuals who had Pfizer and AstraZeneca vaccines than those who received the Sinopharm vaccine. The systemic events were more common with AstraZeneca and Pfizer vaccines, symptoms reported were fatigue, body pain, headache, muscle pain, fever, and gastrointestinal side effects. There were no correlations between age or gender, and the duration of the adverse effects for the three vaccines. Swelling and severe allergic reaction of the eyelids, severe hypotension, generalized body aches, shortness of breath, weakness and numbness on the injected arm, acute hyperglycemia, severe chest pain, and fever more than 39°C were among the unusual signs and symptoms reported by the participants. Pfizer, AstraZeneca, and Sinopharm vaccines were found to be safe and Sinopharm vaccine showed a lower prevalence of adverse effects compared with the other vaccines. The duration and severity of adverse effects were not affected by age or gender. Unusual side effects should be closely monitored to establish determine they are linked to the immunization.

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64. **Safety of SARS-CoV-2 vaccines: a systematic review and meta-analysis of randomized controlled trials.**

Chen Musha *Infectious diseases of poverty* 2021;10(1):94.

BACKGROUND Various modalities of vaccines against coronavirus disease 2019 (COVID-19), based on different platforms and immunization procedures, have been successively approved for marketing worldwide. A comprehensive review for clinical trials assessing the safety of COVID-19 vaccines is urgently needed to make an accurate judgment for mass vaccination. MAIN TEXT A systematic review and meta-analysis was conducted to determine the safety of COVID-19 vaccine candidates in randomized controlled trials (RCTs). Data search was performed in PubMed, Embase, Cochrane library, Scopus, Web of Science, and MedRxiv. Included articles were limited to RCTs on COVID-19 vaccines. A total of 73,633 subjects from 14 articles were included to compare the risks of adverse events following immunization (AEFI) after vaccinating different COVID-19 vaccines.

Pooled risk ratios (RR) of total AEFI for inactivated vaccine, viral-vectored vaccine, and mRNA vaccine were 1.34 [95% confidence interval (CI) 1.11-1.61, $P < 0.001$], 1.65 (95% CI 1.31-2.07, $P < 0.001$), and 2.01 (95% CI 1.78-2.26, $P < 0.001$), respectively. No significant differences on local and systemic AEFI were found between the first dose and second dose. In addition, people aged ≤ 55 years were at significantly higher risk of AEFI than people aged ≥ 56 years, with a pooled RR of 1.25 (95% CI 1.15-1.35, $P < 0.001$). CONCLUSION The safety and tolerance of current COVID-19 vaccine candidates are acceptable for mass vaccination, with inactivated COVID-19 vaccines candidates having the lowest reported AEFI. Long-term surveillance of vaccine safety is required, especially among elderly people with underlying medical conditions.

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65. Side effects after COVID-19 vaccinations among residents of Poland.

Andrzejczak-Grządka S. European review for medical and pharmacological sciences 2021;25(12):4418-4421.

OBJECTIVES Side effects of vaccines are common, but people react differently to different vaccines. Manufacturers provide lists of the side effects of their products. Adverse reactions are proof of the effectiveness of vaccines and that the immune system is responding. In this study, we compare the side effects of the AstraZeneca and Pfizer vaccines. Our survey results show that the side effects of the first dose of the AstraZeneca vaccine are more common than after the first and second doses of the Pfizer vaccine. Most respondents in our survey reported at least one side-effect after the AstraZeneca and Pfizer vaccine, but these reactions were less common after the Pfizer preparation. **PATIENTS AND METHODS** A survey was distributed via the internet. It was conducted among people vaccinated with Pfizer or AstraZeneca. The respondents were asked about the side effects after the first and second doses of the vaccines, such as injection site pain, arm pain, muscle pain, headache, fever, chills, and fatigue. **RESULTS** The questionnaire was completed by 705 people. 196 of them had been vaccinated with Pfizer and 509 with AstraZeneca. Among those vaccinated with the first dose of the AstraZeneca vaccine, 96.5% reported at least one post-vaccination reaction. 17.1% of respondents reported all the side effects listed in the survey. Among those vaccinated with the first Pfizer dose, vaccine reactions were reported by 93.9% of respondents; 2% of respondents experienced all the side effects mentioned in the survey. The second dose of the Pfizer vaccine caused post-vaccinal reactions in most of the subjects: 54.8% of respondents had more adverse reactions, and 15.8% had fewer adverse reactions than after the first dose of this vaccine; 29.4% experienced the same side effects after the first and second doses of the Pfizer vaccine. **CONCLUSIONS** Side effects as a result of vaccination are not rare and are proof that the immune system is responding. However, severe adverse reactions to vaccines can be dangerous, and they engender fear. Concerns about the side effects and complications of COVID-19 vaccines may eclipse opinions regarding their benefits. This study shows that the first dose of the AstraZeneca vaccine causes side effects more often than either dose of the Pfizer vaccine.

66. Side effects of BNT162b2 mRNA COVID-19 vaccine: A randomized, cross-sectional study with detailed self-reported symptoms from healthcare workers.

INTRODUCTIONConcerns are prevailing about the safety and side effects of the BNT162b2 mRNA vaccine for coronavirus disease 2019 (COVID-19).**METHODS**A randomized, cross-sectional study was performed to investigate the side effects of the BNT162b2 vaccine using an independent online questionnaire gathering responses from healthcare workers (HCWs) with detailed review of organ systems.**RESULTS**Of all HCWs, 87.98% (1245/1415) completed the survey. Of them, 64.5% (803/1245) received the BNT162b2 mRNA vaccine and reported at least one or more symptoms (classified based on organ systems and occurrence rate) post vaccination. Of these, 640/803 (79.7%) were able to continue activities of daily living (ADL), 103/803 (12.83%) had trouble temporarily to perform ADL, 99/803 (12.33%) took time off work temporarily, 20/803 (2.49%) required help from an outpatient provider, 5/803 (0.62%) required help from an emergency department and 2/803 (0.25%) required hospitalization. Despite this, 97.61% intended to have the second dose and 92.9% had already received it.**CONCLUSIONS**Commonly reported symptoms (occurrence in descending order) were soreness, fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasm, sweating, dizziness, flushing, feelings of relief, brain fogging, anorexia, localized swelling, decreased sleep quality, itching, tingling, diarrhoea, nasal stuffiness and palpitations. Despite this, remarkable acceptance for the second dose of the BNT162b2 vaccine was found among HCWs.

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67. Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials.

Voysey Merryn *Lancet* (London, England) 2021;397(10277):881-891.

BACKGROUNDThe ChAdOx1 nCoV-19 (AZD1222) vaccine has been approved for emergency use by the UK regulatory authority, Medicines and Healthcare products Regulatory Agency, with a regimen of two standard doses given with an interval of 4-12 weeks. The planned roll-out in the UK will involve vaccinating people in high-risk categories with their first dose immediately, and delivering the second dose 12 weeks later. Here, we provide both a further prespecified pooled analysis of trials of ChAdOx1 nCoV-19 and exploratory analyses of the impact on immunogenicity and efficacy of extending the interval between priming and booster doses. In addition, we show the immunogenicity and protection afforded by the first dose, before a booster dose has been offered.**METHODS**We present data from three single-blind randomised controlled trials-one phase 1/2 study in the UK (COV001), one phase 2/3 study in the UK (COV002), and a phase 3 study in Brazil (COV003)-and one double-blind phase 1/2 study in South Africa (COV005). As previously described, individuals 18 years and older were randomly assigned 1:1 to receive two standard doses of ChAdOx1 nCoV-19 (5×10^{10} viral particles) or a control vaccine or saline placebo. In the UK trial, a subset of participants received a lower dose (2.2×10^{10} viral particles) of the ChAdOx1 nCoV-19 for the first dose. The primary outcome was virologically confirmed symptomatic COVID-19 disease, defined as a nucleic acid amplification test (NAAT)-positive swab combined with at least one qualifying symptom (fever $\geq 37.8^{\circ}\text{C}$, cough, shortness of breath, or anosmia or ageusia) more than 14 days after the second dose. Secondary efficacy analyses included cases occurring at least 22 days after the first dose. Antibody responses measured by immunoassay and by pseudovirus neutralisation were exploratory outcomes. All cases of COVID-19 with a NAAT-positive swab were adjudicated for inclusion in the analysis by a masked independent endpoint review committee. The primary analysis included all participants who were SARS-CoV-2 N protein seronegative at baseline, had had at least 14 days of follow-up after the second dose, and had no evidence of previous SARS-CoV-2 infection from NAAT swabs. Safety was assessed in all participants who received at least one dose. The four trials are registered at ISRCTN89951424 (COV003) and ClinicalTrials.gov, NCT04324606

(COV001), NCT04400838 (COV002), and NCT04444674 (COV005). FINDINGS Between April 23 and Dec 6, 2020, 24 422 participants were recruited and vaccinated across the four studies, of whom 17 178 were included in the primary analysis (8597 receiving ChAdOx1 nCoV-19 and 8581 receiving control vaccine). The data cutoff for these analyses was Dec 7, 2020. 332 NAAT-positive infections met the primary endpoint of symptomatic infection more than 14 days after the second dose. Overall vaccine efficacy more than 14 days after the second dose was 66.7% (95% CI 57.4-74.0), with 84 (1.0%) cases in the 8597 participants in the ChAdOx1 nCoV-19 group and 248 (2.9%) in the 8581 participants in the control group. There were no hospital admissions for COVID-19 in the ChAdOx1 nCoV-19 group after the initial 21-day exclusion period, and 15 in the control group. 108 (0.9%) of 12 282 participants in the ChAdOx1 nCoV-19 group and 127 (1.1%) of 11 962 participants in the control group had serious adverse events. There were seven deaths considered unrelated to vaccination (two in the ChAdOx1 nCoV-19 group and five in the control group), including one COVID-19-related death in one participant in the control group. Exploratory analyses showed that vaccine efficacy after a single standard dose of vaccine from day 22 to day 90 after vaccination was 76.0% (59.3-85.9). Our modelling analysis indicated that protection did not wane during this initial 3-month period. Similarly, antibody levels were maintained during this period with minimal waning by day 90 (geometric mean ratio [GMR] 0.66 [95% CI 0.59-0.74]). In the participants who received two standard doses, after the second dose, efficacy was higher in those with a longer prime-boost interval (vaccine efficacy 81.3% [95% CI 60.3-91.2] at ≥ 12 weeks) than in those with a short interval (vaccine efficacy 55.1% [33.0-69.9] at < 6 weeks). These observations are supported by immunogenicity data that showed binding antibody responses more than two-fold higher after an interval of 12 or more weeks compared with an interval of less than 6 weeks in those who were aged 18-55 years (GMR 2.32 [2.01-2.68]). INTERPRETATION The results of this primary analysis of two doses of ChAdOx1 nCoV-19 were consistent with those seen in the interim analysis of the trials and confirm that the vaccine is efficacious, with results varying by dose interval in exploratory analyses. A 3-month dose interval might have advantages over a programme with a short dose interval for roll-out of a pandemic vaccine to protect the largest number of individuals in the population as early as possible when supplies are scarce, while also improving protection after receiving a second dose. FUNDING UK Research and Innovation, National Institutes of Health Research (NIHR), The Coalition for Epidemic Preparedness Innovations, the Bill & Melinda Gates Foundation, the Lemann Foundation, Rede D'Or, the Brava and Telles Foundation, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca.

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68. **Surveillance for Adverse Events After COVID-19 mRNA Vaccination.**

Klein Nicola P. JAMA 2021;326(14):1390-1399.

Importance Safety surveillance of vaccines against COVID-19 is critical to ensure safety, maintain trust, and inform policy. Objectives To monitor 23 serious outcomes weekly, using comprehensive health records on a diverse population. Design, Setting, and Participants This study represents an interim analysis of safety surveillance data from Vaccine Safety Datalink. The 10 162 227 vaccine-eligible members of 8 participating US health plans were monitored with administrative data updated weekly and supplemented with medical record review for selected outcomes from December 14, 2020, through June 26, 2021. Exposures Receipt of BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) COVID-19 vaccination, with a risk interval of 21 days for individuals after vaccine dose 1 or 2 compared with an interval of 22 to 42 days for similar individuals after vaccine dose 1 or 2. Main Outcomes and Measures Incidence of serious outcomes, including acute myocardial infarction, Bell palsy, cerebral venous sinus thrombosis, Guillain-Barré syndrome, myocarditis/pericarditis, pulmonary embolism, stroke, and thrombosis with

thrombocytopenia syndrome. Incidence of events that occurred among vaccine recipients 1 to 21 days after either dose 1 or 2 of a messenger RNA (mRNA) vaccine was compared with that of vaccinated concurrent comparators who, on the same calendar day, had received their most recent dose 22 to 42 days earlier. Rate ratios (RRs) were estimated by Poisson regression, adjusted for age, sex, race and ethnicity, health plan, and calendar day. For a signal, a 1-sided $P < .0048$ was required to keep type I error below .05 during 2 years of weekly analyses. For 4 additional outcomes, including anaphylaxis, only descriptive analyses were conducted. Results A total of 11 845 128 doses of mRNA vaccines (57% BNT162b2; 6 175 813 first doses and 5 669 315 second doses) were administered to 6.2 million individuals (mean age, 49 years; 54% female individuals). The incidence of events per 1 000 000 person-years during the risk vs comparison intervals for ischemic stroke was 1612 vs 1781 (RR, 0.97; 95% CI, 0.87-1.08); for appendicitis, 1179 vs 1345 (RR, 0.82; 95% CI, 0.73-0.93); and for acute myocardial infarction, 935 vs 1030 (RR, 1.02; 95% CI, 0.89-1.18). No vaccine-outcome association met the prespecified requirement for a signal. Incidence of confirmed anaphylaxis was 4.8 (95% CI, 3.2-6.9) per million doses of BNT162b2 and 5.1 (95% CI, 3.3-7.6) per million doses of mRNA-1273. Conclusions and Relevance In interim analyses of surveillance of mRNA COVID-19 vaccines, incidence of selected serious outcomes was not significantly higher 1 to 21 days postvaccination compared with 22 to 42 days postvaccination. While CIs were wide for many outcomes, surveillance is ongoing.

69. The Approach of Pregnant Women to Vaccination Based on a COVID-19 Systematic Review.

Januszek S. *Lawomir M. Medicina (Kaunas, Lithuania) 2021;57(9):No page numbers.*

Background and Objectives: Pregnant women are more likely to develop a more severe course of COVID-19 than their non-pregnant peers. There are many arguments for the safety and efficacy of COVID-19 vaccines in pregnant women. The aim of this study is to conduct a systematic review concerning the approach of pregnant women towards vaccination against COVID-19, with particular regard to determinants of vaccination acceptance. **Materials and Methods:** Articles were reviewed in which the aim was to evaluate-via a survey or questionnaire-the acceptance and decision to undergo vaccination against COVID-19. The articles were subjected to review according to recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (PRISMA). **Results:** In various studies, the percentage of pregnant women accepting the COVID-19 vaccine was between 29.7% and 77.4%. The strongest factors co-existing with the acceptance of the COVID-19 vaccination in pregnancy were trust in the importance and effectiveness of the vaccine, explicit communication about the safety of COVID-19 vaccines for pregnant women, acceptance of other vaccinations such as those for influenza, belief in the importance of vaccines/mass vaccination in one's own country, anxiety about COVID-19, trust in public health agencies/health science, as well as compliance to mask guidelines. The remaining factors were older age, higher education, and socioeconomic status. **Conclusions:** This review allowed us to show that geographic factors (Asian, South American countries) and pandemic factors (different threats and risks from infection) significantly influence the acceptance of vaccines. The most significant factors affecting acceptance are those related to public awareness of the risk of infection, vaccine safety, and the way in which reliable information about the need and safety of vaccines is provided. Professional and reliable patient information by obstetricians and qualified medical personnel would significantly increase the level of confidence in vaccination against COVID-19.

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70. The Nature and Extent of COVID-19 Vaccination Hesitancy in Healthcare Workers

Biswas N. *Journal of community health 2021;:No page numbers.*

COVID-19 vaccines were approved in late 2020 and early 2021 for public use in countries across the world. Several studies have now highlighted COVID-19 vaccination hesitancy in the general public. However, little is known about the nature and extent of COVID-19 vaccination hesitancy in healthcare workers worldwide. Thus, the purpose of this study was to conduct a comprehensive worldwide assessment of published evidence on COVID-19 vaccine hesitancy among healthcare workers. A scoping review method was adopted to include a final pool of 35 studies in this review with study sample size ranges from n=123 to 16,158 (average=2185 participants per study). The prevalence of COVID-19 vaccination hesitancy worldwide in healthcare workers ranged from 4.3 to 72% (average=22.51% across all studies with 76,471 participants). The majority of the studies found concerns about vaccine safety, efficacy, and potential side effects as top reasons for COVID-19 vaccination hesitancy in healthcare workers. The majority of the studies also found that individuals who were males, of older age, and doctoral degree holders (i.e., physicians) were more likely to accept COVID-19 vaccines. Factors such as the higher perceived risk of getting infected with COVID-19, direct care for patients, and history of influenza vaccination were also found to increase COVID-19 vaccination uptake probability. Given the high prevalence of COVID-19 vaccine hesitancy in healthcare workers, communication and education strategies along with mandates for clinical workers should be considered to increase COVID-19 vaccination uptake in these individuals. Healthcare workers have a key role in reducing the burden of the pandemic, role modeling for preventive behaviors, and also, helping vaccinate others.

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71. The race to make a COVID-19 vaccine

Anon. *The Lancet* 2021;398(10303):832.

Sarah Gilbert, Catherine Green, and their scientific colleagues at the University of Oxford who made a vaccine against the novel coronavirus, SARS-CoV-2, that has brought the world to a standstill, are heroes of our time, already decorated in the UK by the Queen and, in Gilbert's case, lauded by Mattel, which has made a Barbie doll in her image. In summary, the bumps in the road for the Oxford–AstraZeneca vaccine included the US Food and Drug Administration's pause of 7 weeks in the US trial because of a serious adverse event, while the UK regulator allowed a resumption after 4 days; a dosing discrepancy which ended in confusion over efficacy in the UK; some uncertainty about how well the vaccine worked in older people because too few people older than 55 years were recruited to the first phase 3 trials; and rare but serious blood clotting events in Europe. Additionally, in March, 2021, concerns were raised by the Data and Safety Monitoring Board (DSMB) in relation to information released by AstraZeneca on initial data from the US COVID-19 vaccine clinical trial and the US National Institutes of Health issued a statement: "The DSMB expressed concern that AstraZeneca may have included outdated information from that trial, which may have provided an incomplete view of the efficacy data. Green was in charge of the Clinical BioManufacturing Facility (CBF) set up by the University of Oxford to manufacture vaccines for trials, but on nothing like the scale that would be needed for a global pandemic, which is why an alliance with the pharmaceutical industry was always going to be necessary.

72. The role of trust in the likelihood of receiving a COVID-19 vaccine: Results from a national survey.

Szilagy Peter G. *Preventive medicine* 2021;153:106727.

High acceptance of coronavirus disease 2019 (COVID-19) vaccines is instrumental to ending the pandemic. Vaccine acceptance by subgroups of the population depends on their trust in COVID-19 vaccines. We surveyed a probability-based internet panel of 7832 adults from December 23, 2020-January 19, 2021 about their likelihood of getting a COVID-19

vaccine and the following domains of trust: an individual's generalized trust, trust in COVID-19 vaccine's efficacy and safety, trust in the governmental approval process and general vaccine development process for COVID-19 vaccines, trust in their physician about COVID-19, and trust in other sources about COVID-19. We included identified at-risk subgroups: healthcare workers, older adults (65-74-year-olds and \geq 75-year-olds), frontline essential workers, other essential workers, and individuals with high-risk chronic conditions. Of 5979 respondents, only 57.4% said they were very likely or somewhat likely to get a COVID-19 vaccine. More hesitant respondents ($p < 0.05$) included: women, young adults (18-49 years), Blacks, individuals with lower education, those with lower income, and individuals without high-risk chronic conditions. Lack of trust in the vaccine approval and development processes explained most of the demographic variation in stated vaccination likelihood, while other domains of trust explained less variation. We conclude that hesitancy for COVID-19 vaccines is high overall and among at-risk subgroups, and hesitancy is strongly tied to trust in the vaccine approval and development processes. Building trust is critical to ending the pandemic.

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73. Thromboembolic events in younger women exposed to Pfizer-BioNTech or Moderna COVID-19 vaccines.

Sessa Maurizio Expert opinion on drug safety 2021;20(11):1451-1453.

Introduction: Concerns about the increased risk of blood clots associated with the VAXZEVRIA (previously named Oxford-AstraZeneca COVID-19 vaccine) and Johnson & Johnson (Janssen) COVID-19 vaccines raises the question of the thrombotic safety of other COVID-19 vaccines such as Pfizer-BioNTech or Moderna, especially in younger women, who at the early stage of the pandemic was a priority group for vaccination. Methods: Using the US-based Vaccine Adverse Event Reporting System (VAERS) and the FDA Event Reporting System (FAERS), we retrieved cases of thrombosis following vaccinations or hormonal contraceptive use in women aged \leq 50 years. We used the reporting odds ratio (ROR) as a disproportionality measure. Results: On 19 March 2021, out of 13.6 million women aged \leq 50 exposed to at least one dose of Pfizer-BioNTech or Moderna COVID-19 vaccines in the US, only 61 cases were reported with a total of 68 thromboembolic events (1 case per 222,951 vaccinated). None of the thromboembolic events included in our analysis were disproportionately reported for the two COVID-19 vaccines. Conclusion: Our results do support that, when compared to hormonal contraceptive use, the mRNA vaccines do not show disproportional reporting of thromboembolic events in younger women.

74. Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices - United States, July 2021.

Rosenblum Hannah G. MMWR. Morbidity and mortality weekly report 2021;70(32):1094-1099.

In December 2020, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for Pfizer-BioNTech and Moderna COVID-19 vaccines, and in February 2021, FDA issued an EUA for the Janssen (Johnson & Johnson) COVID-19 vaccine. After each EUA, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for vaccine use; currently Pfizer-BioNTech is authorized and recommended for persons aged \geq 12 years and Moderna and Janssen for persons aged \geq 18 years (1-3). Both Pfizer-BioNTech and Moderna vaccines, administered as 2-dose series, are mRNA-based COVID-19 vaccines, whereas the Janssen COVID-19 vaccine, administered as a single dose, is a recombinant replication-incompetent adenovirus-vector

vaccine. As of July 22, 2021, 187 million persons in the United States had received at least 1 dose of COVID-19 vaccine (4); close monitoring of safety surveillance has demonstrated that serious adverse events after COVID-19 vaccination are rare (5,6). Three medical conditions have been reported in temporal association with receipt of COVID-19 vaccines. Two of these (thrombosis with thrombocytopenia syndrome [TTS], a rare syndrome characterized by venous or arterial thrombosis and thrombocytopenia, and Guillain-Barré syndrome [GBS], a rare autoimmune neurologic disorder characterized by ascending weakness and paralysis) have been reported after Janssen COVID-19 vaccination. One (myocarditis, cardiac inflammation) has been reported after Pfizer-BioNTech COVID-19 vaccination or Moderna COVID-19 vaccination, particularly after the second dose; these were reviewed together and will hereafter be referred to as mRNA COVID-19 vaccination. ACIP has met three times to review the data associated with these reports of serious adverse events and has comprehensively assessed the benefits and risks associated with receipt of these vaccines. During the most recent meeting in July 2021, ACIP determined that, overall, the benefits of COVID-19 vaccination in preventing COVID-19 morbidity and mortality outweigh the risks for these rare serious adverse events in adults aged ≥ 18 years; this balance of benefits and risks varied by age and sex. ACIP continues to recommend COVID-19 vaccination in all persons aged ≥ 12 years. CDC and FDA continue to closely monitor reports of serious adverse events and will present any additional data to ACIP for consideration. Information regarding risks and how they vary by age and sex and type of vaccine should be disseminated to providers, vaccine recipients, and the public.

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75. Vaccine induced thrombotic thrombocytopenia: The shady chapter of a success story.

Tsilingiris Dimitrios *Metabolism* open 2021;11:100101.

The recognition of the rare but serious and potentially lethal complication of vaccine induced thrombotic thrombocytopenia (VITT) raised concerns regarding the safety of COVID-19 vaccines and led to the reconsideration of vaccination strategies in many countries. Following the description of VITT among recipients of adenoviral vector ChAdOx1 vaccine, a review of similar cases after Ad26.COV2-S vaccination gave rise to the question whether this entity may constitute a potential class effect of all adenoviral vector vaccines. Most cases are females, typically younger than 60 years who present shortly (range: 5-30 days) following vaccination with thrombocytopenia and thrombotic manifestations, occasionally in multiple sites. Following initial uncertainty, concrete recommendations to guide the diagnosis (clinical suspicion, initial laboratory screening, PF4-polyanion-antibody ELISA) and management of VITT (non-heparin anticoagulants, corticosteroids, intravenous immunoglobulin) have been issued. The mechanisms behind this rare syndrome are currently a subject of active research and include the following: 1) production of PF4-polyanion autoantibodies; 2) adenoviral vector entry in megacaryocytes and subsequent expression of spike protein on platelet surface; 3) direct platelet and endothelial cell binding and activation by the adenoviral vector; 4) activation of endothelial and inflammatory cells by the PF4-polyanion autoantibodies; 5) the presence of an inflammatory co-signal; and 6) the abundance of circulating soluble spike protein variants following vaccination. Apart from the analysis of potential underlying mechanisms, this review aims to synopsise the clinical and epidemiologic features of VITT, to present the current evidence-based recommendations on diagnostic and therapeutic work-up of VITT and to discuss new dilemmas and perspectives that emerged after the description of this entity.

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76. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study.

Menni Cristina *The Lancet. Infectious diseases* 2021;21(7):939-949.

BACKGROUNDThe Pfizer-BioNTech (BNT162b2) and the Oxford-AstraZeneca (ChAdOx1 nCoV-19) COVID-19 vaccines have shown excellent safety and efficacy in phase 3 trials. We aimed to investigate the safety and effectiveness of these vaccines in a UK community setting.**METHODS**In this prospective observational study, we examined the proportion and probability of self-reported systemic and local side-effects within 8 days of vaccination in individuals using the COVID Symptom Study app who received one or two doses of the BNT162b2 vaccine or one dose of the ChAdOx1 nCoV-19 vaccine. We also compared infection rates in a subset of vaccinated individuals subsequently tested for SARS-CoV-2 with PCR or lateral flow tests with infection rates in unvaccinated controls. All analyses were adjusted by age (≤ 55 years vs > 55 years), sex, health-care worker status (binary variable), obesity (BMI < 30 kg/m² vs ≥ 30 kg/m²), and comorbidities (binary variable, with or without comorbidities).**FINDINGS**Between Dec 8, and March 10, 2021, 627 383 individuals reported being vaccinated with 655 590 doses: 282 103 received one dose of BNT162b2, of whom 28 207 received a second dose, and 345 280 received one dose of ChAdOx1 nCoV-19. Systemic side-effects were reported by 13.5% (38 155 of 282 103) of individuals after the first dose of BNT162b2, by 22.0% (6216 of 28 207) after the second dose of BNT162b2, and by 33.7% (116 473 of 345 280) after the first dose of ChAdOx1 nCoV-19. Local side-effects were reported by 71.9% (150 023 of 208 767) of individuals after the first dose of BNT162b2, by 68.5% (9025 of 13 179) after the second dose of BNT162b2, and by 58.7% (104 282 of 177 655) after the first dose of ChAdOx1 nCoV-19. Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 and 2.9 times after the first dose of BNT162b2) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2). 3106 of 103 622 vaccinated individuals and 50 340 of 464 356 unvaccinated controls tested positive for SARS-CoV-2 infection. Significant reductions in infection risk were seen starting at 12 days after the first dose, reaching 60% (95% CI 49-68) for ChAdOx1 nCoV-19 and 69% (66-72) for BNT162b2 at 21-44 days and 72% (63-79) for BNT162b2 after 45-59 days.**INTERPRETATIONS**Systemic and local side-effects after BNT162b2 and ChAdOx1 nCoV-19 vaccination occur at frequencies lower than reported in phase 3 trials. Both vaccines decrease the risk of SARS-CoV-2 infection after 12 days.**FUNDING**ZOE Global, National Institute for Health Research, Chronic Disease Research Foundation, National Institutes of Health, UK Medical Research Council, Wellcome Trust, UK Research and Innovation, American Gastroenterological Association.

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77. Assessing the Safety of COVID-19 Vaccines: A Primer.

Petousis-Harris Helen *Drug safety* 2020;43(12):1205-1210.

Vaccines against COVID-19 are being developed at speeds not previously achieved. With this unprecedented effort comes challenges for post-marketing safety monitoring and challenges for vaccine safety communication. To deploy these new vaccines fast across diverse populations, it is vital that robust pharmacovigilance and active surveillance systems are in place. Not all countries have the capability or resources to undertake adequate surveillance and will rely on data from those who can. The tools exist to assess COVID-19 vaccines as they are deployed such as surveillance systems, administrative data and case definitions for adverse events of special interest. However, stitching these all together and using them effectively requires investment and collaboration. This paper

provides a high-level overview of some of the facets of modern vaccine safety assessment and how they are, or can be, applied to COVID-19 vaccines.

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78. Covid-19: People with history of significant allergic reactions should not receive Pfizer vaccine, says regulator

Mahase Elisabeth BMJ : British Medical Journal (Online) 2020;371:No page numbers.

Both people—who have recovered—had a history of severe allergic reactions and carried adrenaline auto injectors.¹ The MHRA has told people running sites that administer the vaccine to report any suspected adverse reactions through the yellow card scheme website² and to ensure that they have appropriate resuscitation facilities available. Monitoring system Pfizer's information sheet on the vaccine states that it should not be given to people if they are allergic to the active substance or any of the other ingredients of this medicine.⁴ As such, people with a history of severe allergic reaction to any component of the study intervention were excluded from clinical trials.⁵ However, a briefing document from the US Food and Drug Administration on 10 December⁶ noted that the trial data showed a "slight numerical imbalance of adverse events potentially representing allergic reactions, with more participants reporting hypersensitivity related adverse events in the vaccine group (137 (0.63%)) compared with the placebo group (111 (0.51%))." Penny Ward, visiting professor in pharmaceutical medicine at King's College, London, said, "It is understood that the people concerned had a history of allergy severe enough to require them to carry an adrenaline autoinjector; such people would be at increased risk of an allergic reaction to novel challenge compared to the population without a history of severe allergy.

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79. Making medicines safer: analysis of patient reports to the UK's Yellow Card Scheme.

O' Donovan B. Expert opinion on drug safety 2019;18(12):1237-1243.

Objectives: No studies describing UK patient Yellow Card reports have been published since the evaluation of the first two years of direct patient reporting (2005-7), when 5,180 reports were analyzed. Methods: Patient Yellow Card reports submitted July-December 2015 for vaccines and other drugs were analyzed. Comparisons to the initial evaluation were made of: reporting method, number of suspect drugs, proportion classed as serious. Factors affecting seriousness of reports were examined. Results: There were 3,060 patient Yellow Card reports analyzed. Vaccine reports have increased from very few in 2005-7 to 25% of reports. The proportion of reports citing one drug (94.3%) and the proportion considered serious (70.3%) increased from the 84% and 58% respectively found in 2005-7. The main method of reporting had changed from paper (61%) to internet (88.5%). Serious reports were more common in females, for vaccines in young persons, but in adults for other drugs, and included more reaction terms than non-serious reports. Conclusion: Patient reporting, in particular to vaccines, has increased dramatically since 2005-7. Increases in the proportion of reports concerning one drug and the proportion considered serious could indicate that the usability of patient reports may have improved in comparison to early reporting.

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80. **Monitoring drug safety: is the Yellow Card Scheme struggling?**

Chaplin S. Prescriber 2019;30(9):32-34.

In 2018, the Yellow Card Scheme reported a decline in the number of reported suspected adverse drug reactions, particularly among doctors and pharmacists. This article discusses the possible reasons for this and the action the MHRA is taking to improve reporting rates.
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81. **Enhanced Safety Surveillance of Seasonal Quadrivalent Influenza Vaccines in English Primary Care: Interim Analysis.**

de Lusignan Simon Advances in therapy 2018;35(8):1199-1214.

INTRODUCTIONThe European Medicines Agency (EMA) requires vaccine manufacturers to conduct enhanced safety surveillance (ESS) of seasonal influenza vaccines including a near real-time evaluation of collected data. The objective was to identify whether the use of passive surveillance or active surveillance provides different results of reported adverse events of interest (AEIs) by specified age strata and AEI type. We report the weekly incidence rates of AEIs within 7 days following seasonal influenza vaccination using passive and active surveillance.**METHODS**AEIs were collected within 7 days of vaccination from ten general practices predominantly administering inactivated quadrivalent influenza vaccine (IIV4, Fluarix Tetra, GSK). Vaccinees completed an adverse drug reaction (ADR) card. ADR card and medically attended AEIs data were recorded in practice electronic health records. We report the outcome of the first 5 weeks of safety surveillance (September 12, 2016-October 16, 2016); in an exploratory analysis, rates of AEI for IIV4 are compared to those passively reported through a sentinel network.**RESULTS**Practices vaccinated 13.1% (12,864/98,091) of their registered population; 5.6% (95% CI 5.20-6.00) of them reported AEIs, none serious. The most frequent were respiratory 2.60% (95% CI 2.33-2.88), musculoskeletal 1.82% (95% CI 1.59-2.05) and neurological 1.05% (95% CI 0.88-1.23). AEIs were more frequently reported for adults than for children; 5.91% (95% CI 5.49-6.34) compared to 1.49% (95% CI 0.69-2.29); 47.18% of the adults reported AEI using the ADR card, none were returned for subjects < 18 years old. The frequency of AEIs reporting was higher, 6.88% (95% CI 6.35-7.42) vs. 3.30% (95% CI 2.68-3.96, 100/3028, p < 0.000), through ESS than passive surveillance.**CONCLUSION**The ESS did not reveal any safety signal and we demonstrated the feasibility of conducting ESS following EMA recommendations. The use of a customised ADR card led to a doubling of AEIs reports over passive surveillance in adults.**FUNDING**GlaxoSmithKline Biologicals SA, Wavre, Belgium.

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