

References | COVID-19 Vaccines and Boosters

Research about SARS-CoV-2 and COVID-19 is emerging and evolving rapidly. Marin County Public Health recommends residents gather and review information from high quality, validated, peer-reviewed research sources.

April 12, 2022 – **Newly Added**

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Reliable and Credible Resources

Centers for Disease Control and Prevention (CDC).

<https://www.coronavirus.gov/>

<https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research.html>

CDC Morbidity and Mortality Weekly Report.

https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

California Department of Public Health - COVID-19 Literature Review Digest Team

<https://www.notion.so/Collaborative-COVID-19-Literature-Review-Synopses-CoCOLRS-Database-63a4bf37bc8b4b9ca206fa7b3905628d>

CDPH. Evidence Summary: TK-6 Schools and COVID-19 Transmission

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Safe-Schools-for-All-Plan-Science.aspx>

Johns Hopkins Center for Health Security <https://www.centerforhealthsecurity.org/>

LitCovid: Comprehensive curated literature collection regarding the 2019 novel Coronavirus

<https://www.ncbi.nlm.nih.gov/research/coronavirus/>

Massachusetts Institute of Technology (MIT) Press. Rapid Review | COVID-19

<https://rapidreviewscovid19.mitpress.mit.edu/>

National Institutes of Health <https://www.nih.gov/coronavirus>

PubMed <https://pubmed.ncbi.nlm.nih.gov/?term=covid-19>

PubMed Central (PMC) <https://www.ncbi.nlm.nih.gov/pmc/about/covid-19>

University of Minnesota. Center for Infectious Disease Research and Policy (CIDRAP)
<https://www.cidrap.umn.edu/infectious-disease-topics/covid-19>

World Health Organization. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

Open Access

Public Health and Medical Professionals for Transparency

Pfizer's documents. Public Health and Medical Professionals for Transparency. (2022, March 2). Retrieved March 5, 2022, from <https://phmpt.org/pfizers-documents/>

What is a vaccine?

Vaccines are our most powerful tool against infectious diseases. A [vaccine](#) is a preparation that is injected into your body to stimulate your immune response against a specific infectious disease (e.g., COVID-19). Most vaccines consist of weakened virus or bacteria (or specific parts of a virus or bacteria). When the immune system sees the weakened virus or bacteria or the specific parts, it begins to produce antibodies against them.

When the vaccinated person later encounters the virus or bacteria, the immune system is already primed and defeats the infection rapidly. In other words, *vaccines don't always prevent the infection. They work because the rapid immune response in the vaccinated individual defeats the infection before it can cause damage and usually with no symptoms.*

How does the mRNA vaccine work?

The Pfizer-BioNTech and Moderna vaccines consist of genetic instructions encoded in messenger RNA (m-RNA) that direct our own body cells to make the "spike protein" portion of the coronavirus. The spike protein primes the immune system, so that if we are exposed to the coronavirus, our immune system is ready to defeat the infection quickly, often without symptoms and before we are able to infect others. The body naturally breaks down the m-RNA, so it disappears after it has primed the immune system.

mRNA vaccine technology is not new

Messenger-RNA technology is not new--it is based on research that began in the 1970s. It has some major advantages over other vaccines:

- New vaccines can be rapidly developed and inexpensively produced in large quantities.
- It is extremely effective in building the desired immune response.
- The m-RNA is broken down and disintegrates after doing its job. (Messenger RNA is very fragile--that is why it has to be stored at super-cold temperatures.)

What is in the m-RNA vaccines?

The m-RNA vaccines have the following ingredients.

- mRNA carrying instructions telling our cells to make viral spike protein to prime the immune system

- Fat droplets (lipid nanoparticles, LNP) to protect the m-RNA from premature degradation. These fat droplets have positively charged portions that help it to cling to the negatively charged backbone of the mRNA molecule.
- To improve stability, the fats have been PEGylated, i.e., combined with polyethylene glycol (PEG), a nontoxic material used in everyday products like toothpaste, shampoo, and laxatives.
- The fat droplets are further stabilized with phosphate molecules and cholesterol.

Although allergic reactions to some of these components have been reported, they are extremely rare.

Why should children and adolescents be vaccinated?

- Children and adolescents are highly social, so they can easily spread the virus among themselves, and from there to their families, neighbors and community.
- Although children and adolescents themselves tend to recover without incident, the same may not be true for friends, family, and community members.
- Adolescents tend not to observe masking and social distancing. Vaccination is highly effective in protecting them and those around them.

mRNA vaccines have an acceptable safety profile.

COVID-19 vaccines are continuously monitored for adverse effects / events.

- [Center for Biologics Evaluation and Research \(CBER\)](#) is the Center within [Food and Drug Administration \(FDA\)](#) that regulates biological products for human use under applicable federal laws, including vaccine products.
- [Advisory Committee on Immunization Practices \(ACIP\)](#) develop expert recommendations on the use of vaccines for Centers for Disease Control and Prevention (CDC). CDC sets the U.S. adult and childhood immunization schedules based on ACIP recommendations. CDC and FDA co-administer the Vaccine Adverse Event Reporting System (VAERS), which is a national early warning system to detect possible safety problems in U.S. licensed vaccines.
- Pfizer is now conducting [Phase IV Clinical Trials](#) on the COVID-19 vaccine. On May 7th, Pfizer initiated a Biologics License Application (BLA) with the FDA for regular authorization of the COVID-19 vaccine for individuals 16 years of age and older. Their BLA submission includes [the most recent analyses](#) from the Phase 3 clinical trial, where the vaccine's efficacy and favorable safety profile were observed up to six months after the second dose. Vaccine safety has now been evaluated in more than 44,000 study participants aged 16 years and older with more than 12,000 vaccinated participants having at least six months of follow-up after their second dose.

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9. Structural and functional properties of SARS-CoV-2 spike protein: potential antiviral drug development for COVID-19 (2020). Access at <https://www.nature.com/articles/s41401-020-0485-4>
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11. Ensuring COVID-19 Vaccine Safety in the US. Access at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>
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14. Cell-Mediated Immune Response: <https://www.ncbi.nlm.nih.gov/books/NBK10762/>
15. COVID-19 Trends Among Persons Aged 0–24 Years — United States, March 1–December 12, 2020. Access at <https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e1.htm>
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Annotated Bibliography

Vaccine and Booster Safety and Efficacy

Adverse Events and Safety Monitoring

Frequency and severity of adverse vaccine reactions

Frequency	Occurrence among persons vaccinated in percent	Severity of reactions
Very common	≥ 10%	Common and usually minor reactions: Are part of the immune response to vaccine, Reactions settle on their own, Examples include: Fever, Malaise.
Common (frequent)	≥ 1% and < 10%	
Uncommon (infrequent)	≥ 0.1% and < 1%	Rare, usually more severe reactions: Usually require clinical management, Examples include: Severe allergic reaction (e.g., anaphylaxis) including an exaggerated response to the vaccine antigen or component, Vaccine specific reactions, such as BCG osteitis.
Rare	≥ 0.01% and < 0.1%	
Very Rare	< 0.01%	

Source: World Health Organization. Adverse Events: Frequency and Severity. Access at <https://vaccine-safety-training.org/frequency-and-severity.html>

[Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe – 3/7/22](#)

During the first 6 months of the US COVID-19 vaccination program, more than 50% of the eligible population received at least one vaccine dose. VAERS and v-safe data show a safety profile for mRNA COVID-19 vaccines that is generally consistent with clinical trials and early surveillance reports. Serious adverse events, including myocarditis, have been identified following mRNA vaccinations; however, these events are rare.

[COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021 – 10/22/21](#)

Since COVID-19 vaccinations became available in December 2020, an estimated 182 million people in the United States were fully vaccinated against COVID-19 by September 21, 2021. Researchers conducted a study using the Vaccine Safety Datalink, comparing those who received COVID-19 vaccines and those who did not between December 2020 through July 2021. This study included data from 11 million people; 6.4 million received either Pfizer-BioNTech, Moderna or Janssen COVID-19 vaccine and 4.6 were unvaccinated. The analysis showed that those who received COVID-19 vaccinations had lower rates of mortality for non-COVID-19 causes than those unvaccinated. These findings provide evidence that COVID-19 vaccines are safe and support current vaccination recommendations.

[Safety Monitoring of mRNA Vaccines Administered During the Initial 6 months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System \(VAERS\) and v-safe](#) - 10/26/21

In December 2020, two mRNA COVID-19 vaccines were authorized for emergency use in the United States. Clinical trials showed these vaccines to be safe, and post-authorization monitoring is necessary to evaluate their safety in larger and diverse populations. During the first six months of the COVID-19 vaccination program (December 14, 2020 through June 14, 2021) over 298 million doses of mRNA vaccines were administered in the U.S. In that period, over 7.9 million people enrolled in v-safe. Local (pain, redness, swelling at injection site) and systemic (fever, fatigue, and headache) reactions were reported more frequently following dose 2 compared to dose 1. The majority of symptoms were reported as mild, peaked on day 1 following vaccination, and were short-lived. Of the 340,000 adverse event reports to VAERS, the majority (92%) were classified as non-serious (similar to the local and systemic reactions reported to v-safe); 6.6% serious, non-death; 1.3% deaths. An in-depth review of reports of death found rates of death reported to VAERS were lower than expected background rates by age group. This analysis reinforces the safety of COVID-19 vaccines.

[Expected Rates of Select Adverse Events Following Immunization for COVID-19 Vaccine Safety Monitoring](#) – 9/5/21

Researchers estimated expected rates of select medical conditions considered potential AESI that may occur among vaccinated persons in the general population within 1 day, 7 days, and 42 days of COVID-19 vaccination. Knowledge of expected rates of these medical conditions occurring in the general population is useful for evaluating COVID-19 vaccine safety. The observed rates of these medical conditions following vaccination can be compared to the rates that would be expected to occur coincidentally among vaccinated persons in the general population regardless of COVID-19 vaccination.

[Surveillance for Adverse Events After COVID-19 mRNA Vaccination](#) – 9/3/21

Between December 14, 2020 through June 25, 2021, over 11.8 million doses of mRNA were administered to 6.2 million people in the VSD network; 57% received Pfizer-BioNTech and 43% received Moderna. During that time period, VSD monitored 23 pre-specified health outcomes, including myocarditis/pericarditis and anaphylaxis. Researchers identified 34 cases of myocarditis/pericarditis in people ages 12 to 39 years; a majority (85%) were males. Among this age group, there is an increased risk of 6.3 additional myocarditis cases per million mRNA vaccinations administered in the first week following vaccination. The rate of anaphylaxis following vaccination was 4.8 cases per million doses of Pfizer-BioNTech and 5.1 per million doses of Moderna vaccination. VSD monitoring did not detect safety signals for any other pre-specified outcomes.

[Evaluation of the safety profile of COVID-19 vaccines: a rapid review](#) – 7/28/21

A total of 87 publications with safety data from clinical trials and post-authorization studies of 19 COVID-19 vaccines on 6 different platforms were included. The pooled rates of local and systemic reactions were significantly lower among inactivated vaccines (23.7%, 21.0%), protein subunit vaccines (33.0%, 22.3%), and DNA vaccines (39.5%, 29.3%), compared to RNA vaccines (89.4%, 83.3%), non-replicating vector vaccines (55.9%, 66.3%), and virus-like particle vaccines (100.0%, 78.9%). Solicited injection-site pain was the most common local reactions, and fatigue and headache were the most common systemic reactions. The frequency of vaccine-related serious adverse events was low (< 0.1%) and balanced between treatment groups.

[U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines – 5/14/21](#)

This is the first large-scale compilation of U.S. incidence rates for medical conditions that are historically or generally monitored as AESI for vaccine safety. These rates may be useful for epidemiological analyses that assess adverse events temporally associated with COVID-19 vaccination and for surveillance of new vaccines in the future.

[Anxiety-Related Adverse Event Cluster After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021 - 4/20/21](#)

From April 7-9, 2021, 5 weeks after the J&J/Janssen COVID-19 vaccine was authorized by FDA for emergency use, clusters of anxiety-related events after Janssen vaccination were reported to CDC. The reports came from 5 mass vaccination sites in different states; 4 closed temporarily to investigate the cases. Of the 8,624 Janssen vaccine recipients, there were 64 reports of anxiety-related events, including 17 reports of fainting. Commonly reported symptoms were light-headedness/dizziness (56%), excessive sweating (31%), fainting (27%), nausea or vomiting (25%) and low blood pressure (16%). Additionally, CDC reviewed all reports to VAERS of fainting after Janssen vaccine between March 2 through April 11, 2021 and identified 653 reports out of 8 million doses administered. Review of reports found that fainting occurs in 8 per 100,000 doses administered. Vaccine providers should observe individuals for 15 minutes after COVID-19 vaccination for signs of immediate anxiety-related reactions or fainting.

[First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020-January 13, 2021 – 2/26/21](#)

From December 14, 2020 through January 13, 2021, almost 14 million vaccine doses were distributed. During that time, over 1.6 million vaccine recipients enrolled in v-safe, and VAERS received 6,994 reports of adverse events following vaccination. About 91% of VAERS reports were non-serious; commonly reported symptoms included headache (22.4%), fatigue (16.5%) and dizziness (16.5%). V-safe enrollees reported similar local and systemic reactions. While deaths were reported to VAERS, available documentation did not suggest a causal link between the vaccine and death. Overall, no unusual or unexpected reporting patterns were detected.

[Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021 – 2/12/21](#)

In December 2020, FDA issued Emergency Use Authorizations for two mRNA-based vaccines for prevention of COVID-19 disease: Pfizer-BioNTech COVID-19 vaccine (December 11) and Moderna COVID-19 vaccine (December 18). After implementation of the vaccines, cases of anaphylaxis following both vaccines were reported. During December 14, 2020 through January 18, 2021, over 9.9 million doses of Pfizer-BioNTech vaccine and over 7.5 million doses of Moderna vaccine were administered. In this same time, CDC identified 66 anaphylaxis cases reported to VAERS: 47 following Pfizer-BioNTech vaccine (rate of 4.7 cases per million doses) and 19 following Moderna vaccine (rate of 2.5 cases per million doses). There were no deaths from anaphylaxis reported after either vaccine.

Boosters

[Effectiveness of a third dose of BNT162b2 mRNA COVID-19 vaccine in a large US health system: a retrospective cohort study. 2/14/22](#)

After only two doses, vaccine effectiveness (VE) against infection declined from 85% (95% CI 83–86) during the first month to 49% (46–51) \geq 7 months following vaccination. Three-dose VE (median follow-up 1.3 months [SD 0.6]) was 88% (95% CI 86–89) against infection and 97% (95–98) against hospitalization. Effectiveness after three doses was higher than that seen one month after receiving only two doses for both outcomes. Relative VE of three doses compared to two (with at least six months after the second dose) was 75% (95% CI 71–78) against infections and 70% (48–83) against hospital admissions.

[Association of homologous and heterologous vaccine boosters with COVID-19 incidence and severity in Singapore](#) - 2/11/22

The study included 22 643 521 and 9 339 981 person-days among the nonbooster and booster groups, respectively. Heterologous boosting was associated with lower SARS-CoV-2 incidence rates than homologous boosting. Severe infections were lower among those receiving a booster after BNT162b2 as the primary series compared with the nonboosted individuals, regardless of the type of booster.

[Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021–February 6, 2022](#) – 2/11/22

CDC reviewed adverse events and health impact surveys following a booster dose reported to the v-safe after vaccination health checker and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). From September 22, 2021–February 6, 2022, about 82.6 million U.S. residents ages 18 years and older received a COVID-19 vaccine booster dose. People who received the same mRNA COVID-19 vaccine booster as they did for the primary series reported local and systemic reactions (such as pain, fatigue, and headache) less frequently than after dose 2. Myocarditis was rarely reported following mRNA COVID-19 vaccine boosters. No unexpected patterns of adverse events were identified, and COVID-19 vaccine boosters are recommended for everyone ages 12 years and older.

[Waning 2-dose and 3-dose effectiveness of mRNA vaccines against COVID-19–associated emergency department and urgent care encounters and hospitalizations among adults during periods of Delta and Omicron variant predominance—VISION Network, 10 states, August 2021–January 2022](#) - 2/18/22

Vaccine effectiveness (VE) against COVID-19–associated emergency department/urgent care (ED/UC) visits and hospitalizations was higher after the third dose than after the second dose but waned with time since vaccination. During the Omicron-predominant period, VE against COVID-19–associated ED/UC visits and hospitalizations was 87% and 91%, respectively, during the 2 months after a third dose and decreased to 66% and 78% by the fourth month after a third dose. Protection against hospitalizations exceeded that against ED/UC visits.

[Homologous and heterologous COVID-19 booster vaccinations](#) – 1/26/22

Homologous and heterologous booster vaccines had an acceptable safety profile and were immunogenic in adults who had completed a primary Covid-19 vaccine regimen at least 12 weeks earlier.

[Effectiveness of BNT162b2 COVID-19 booster vaccine against COVID-19 related symptoms and hospitalization in England](#) – 1/14/22

The relative effectiveness against symptomatic disease 14–34 days after a BNT162b2 or mRNA-1273 (Moderna) booster ranged from around 85 to 95%. Absolute VE ranged from 94–97% and was similar in all age groups. Limited waning was seen 10+ weeks after the booster. Absolute effectiveness of a BNT162b2 booster against hospitalization and death ranged from around 97% to 99% in all age groups

irrespective of the primary course with no evidence of waning up to 10 weeks. This study provides real world evidence of significant increased protection from the booster vaccine dose against mild and severe disease irrespective of the primary course.

[Protection against COVID-19 by BNT162b2 booster across age groups](#) – 12/8/21

The rate of confirmed infection was lower in the booster group than in the nonbooster group by a factor of approximately 10. Across the age groups studied, rates of confirmed Covid-19 and severe illness were substantially lower among participants who received a booster dose of the BNT162b2 vaccine than among those who did not.

[Odds of testing positive for SARS-CoV-2 following receipt of 3 vs 2 doses of the BNT162b2 mRNA vaccine](#) – 11/30/21

In this case-control study that included 306,710 Israeli adults 40 years and older, there was an estimated significant reduction in the odds of SARS-CoV-2 infection within a few weeks of receiving the booster compared with receiving just the 2 primary doses. Those receiving the booster also had lower odds of hospitalization.

[Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12-September 19, 2021](#) – 9/28/21

From August 12 through September 19, over 22,000 v-safe enrollees reported an additional COVID-19 dose after completing the primary 2-dose mRNA vaccination series, most with the same vaccine. Among those who completed surveys for all 3 doses, local reactions (like pain or swelling where the shot was given) were reported slightly more after dose 3 compared with after dose 2 (79% vs. 78%), while reported systemic reactions (tiredness, headache) were slightly less common after dose 3 (74% vs. 77%). These side effects were mostly mild to moderate and short-lived. These findings did not show unexpected patterns of adverse events following an additional dose of COVID-19 vaccines.

2nd Booster / 4th Dose (Immunocompromised)

[Second Booster Vaccine and Covid-19 Mortality in Adults 60 to 100 Years Old](#) – 3/24/22

This retrospective cohort study included all members of Clalit Health Services, aged 60 to 100, eligible for the second booster. A total of 563,465 participants met the eligibility criteria. Of those, 328,597 (58%) received a second-booster dose during the 40-day study period. Death due to Covid-19 occurred in 92 second-booster recipients and in 232 participants who received one booster dose (adjusted hazard ratio 0.22; 95% confidence interval 0.17 to 0.28). This study demonstrates a substantial reduction in Covid-19 mortality by the second booster in eligible subjects

[SARS-CoV-2 Vaccination and the Bridge between First and Fourth Dose: Where Are We?](#) – 3/14/22

To achieve maximum public health benefit against the Omicron variant, many countries decided to give the third dose to as many individuals as possible. Despite the limitations of the studies conducted so far, results seem to confirm the efficacy of third dose administration, resulting in high efficacy and protection against COVID-19 symptoms, but new variants may require the administration of a fourth dose.

[Fourth dose of COVID-19 vaccines in Israel](#) – 1/10/22

On Jan 2, 2022, Israel's prime minister Naftali Bennett announced that the country would offer a fourth dose of the COVID-19 vaccine to health-care workers and people older than 60 years.

[Antibody Response to a Fourth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series – 12/21](#)

The antibody response after 2 doses of an mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine is excellent in the general population but less robust in transplant patients. This is the first series describing the antibody response among SOTRs after 4 doses of vaccine against COVID-19. Given neutralizing antibody level may be the best correlate of vaccine-associated immunoprotection to date, it is encouraging that 50% of participants with negative and all with low-positive titers pre-D4 showed boosting to high-positive titers post-D4.

[Assessment of 4 doses of SARS-CoV-2 messenger RNA–based vaccine in recipients of a solid organ transplant - 11/24/21](#)

In this case series study, researchers found that a 4th dose of SARS-CoV-2 vaccine was associated with slightly improved humoral response among patients with a weak response after 3 doses and with no improvement among those with no response after 3 doses.

[Suboptimal response to COVID-19 mRNA vaccines in hematologic malignancy patients: a need for vigilance in the post-masking era – 6/30/21](#)

This study showed that nearly half of patients with hematological malignancies do not generate antibodies after completing their COVID-19 vaccine series, which is in stark contrast with the results of phase 1/2 mRNA vaccine immunogenicity trials, in which antibody responses were seen in essentially all participants. This lack of response was particularly pronounced among patients with CLL.

Concomitant Administration – COVID and Seasonal Influenza Vaccines

[Safety and immunogenicity of concomitant administration of COVID-19 vaccines \(ChAdOx1 or BNT162b2\) with seasonal influenza vaccines in adults in the UK \(ComFluCOV\): a multicentre, randomised, controlled, phase 4 trial – 11/11/21](#)

Concomitant vaccination with ChAdOx1 or BNT162b2 plus an age-appropriate influenza vaccine raises no safety concerns and preserves antibody responses to both vaccines. Concomitant vaccination with both COVID-19 and influenza vaccines over the next immunisation season should reduce the burden on health-care services for vaccine delivery.

[Examining the potential benefits of the influenza vaccine against SARS-CoV-2: a retrospective cohort analysis of 74,754 patients – 8/3/21](#)

SARS-CoV-2-positive patients who received the influenza vaccine experienced decreased sepsis and stroke. ICU admissions were lower in SARS-CoV-2-positive patients receiving the influenza vaccine. Patients who received the influenza vaccine experienced fewer DVTs 60–120 days after positive SARS-CoV-2 diagnosis and experienced fewer emergency department (ED) visits 90–120 days post SARS-CoV-2-positive diagnosis.

Dosing

[Immunogenicity of extended mRNA SARS-CoV-2 vaccine dosing intervals – 12/3/21](#)

Longer mRNA vaccine dosing intervals demonstrated improved immunogenicity, which was consistent when responses were measured based on timing of the first or second dose. These data suggest that extending dosing intervals may be particularly advantageous against the Delta variant.

[A higher antibody response is generated with a 6- to 7-week \(vs standard\) severe acute respiratory syndrome coronavirus 2 \(SARS-CoV-2\) vaccine dosing interval](#) – 11/30/21

In this prospective study, we compared serology results of paramedics vaccinated with mRNA vaccines at the recommended short (17–28 days) vs long (42–49 days) interval. We found that a long dosing interval resulted in higher spike, receptor binding domain, and spike N terminal domain antibody concentrations.

[Epidemiological and evolutionary considerations of SARS-CoV-2 vaccine dosing regimens](#) – 4/23/21

The deployment of SARS-CoV-2 vaccines will strongly shape post-pandemic epidemiological trajectories and characteristics of accumulated population immunity. Our models show that the combination of different vaccine dosing regimens and variations in the robustness of natural and vaccinal immunity may result in a wide range of potential epidemiological and evolutionary outcomes in the medium term. There is an urgent need for global equity in vaccine distribution and deployment.

Effectiveness

Monitoring reports of the effectiveness of COVID-19 vaccination | Data on the real-world efficacy of the COVID-19 vaccines. Access at [UK Health Security Agency](#).

[COVID-19 vaccine waning and effectiveness and side-effects of boosters: a prospective community study from the ZOE COVID Study](#) – 4/8/22

A large-scale, community-based study of over 600 000 people found substantial waning of COVID-19 vaccine effectiveness against infection 5–8 months after the second vaccine dose. But, vaccine effectiveness against infection remained high overall (above 75%), especially among healthy individuals younger than 55 years old. The study also showed that receiving a booster dose of BNT162b2 or mRNA-1273 6 months after the second primary dose restored vaccine effectiveness to higher levels than those seen 1 month after the second dose.

[COVID-19 Vaccine Effectiveness against the Omicron BA.2 variant in England \(not peer reviewed\)](#) – 3/24/22

There was no evidence that vaccine effectiveness against symptomatic disease is reduced following infection with the BA.2 sub-lineage as compared to BA.1. Furthermore, similar rates of waning were observed after the second and booster dose for each sub-lineage. These data provide reassuring evidence of the effectiveness of the vaccines currently in use against symptomatic disease caused by BA.2.

[COVID-19 vaccination and SARS-CoV-2 Omicron \(B.1.1.529\) variant: a light at the end of the tunnel?](#) – 3/8/22

Italian research suggests that the efficacy of vaccination combined with an ostensibly lower severity of illness caused by the Omicron B.1.1.529 variant may substantially mitigate some of the pressure of COVID-19 on healthcare systems faced with a massive surge in cases involving also unvaccinated and immunodeficient populations.

[Current evidence on efficacy of COVID-19 booster dose vaccination against the Omicron variant: A systematic review](#) – 3/4/22

To address the present ongoing pandemic with new variants, currently both Delta and Omicron increasing a rapid surge in the number of new COVID-19 infections, hospitalization, and mortality, all the

findings reviewed from currently available studies support the evidence for booster-dose vaccine efficacy against SARS-CoV-2 variants, including Omicron.

[Effectiveness of mRNA-1273 against SARS-CoV-2 Omicron and Delta variants](#) – 2/21/22

SARS-CoV-2 Omicron (B.1.1.529) variant is highly transmissible with potential immune escape. The study included 26,683 SARS-CoV-2 test-positive cases with variants determined by S-gene target failure status (16% Delta, 84% Omicron). The 2-dose vaccine effectiveness (VE) against Omicron infection at 14–90 days was 44.0% but declined quickly. The 3-dose VE was 93.7% and 86.0% against Delta infection and 71.6% and 47.4% against Omicron infection at 14–60 days and >60 days, respectively. The 3-dose VE against hospitalization with Delta or Omicron was >99% across the entire study population. Our findings demonstrate high, durable 3-dose VE against Delta infection but lower effectiveness against Omicron infection, particularly among immunocompromised people. However, 3-dose VE of mRNA-1273 was high against hospitalization with Delta and Omicron variants.

[Vaccination against SARS-CoV-2 is associated with a lower viral load and likelihood of systemic symptoms](#) – 2/20/22

274 participants with known vaccination status contributed optional nasal swabs for viral load measurement. The mean viral load for those vaccinated <6 months was significantly lower than the unvaccinated group. Those vaccinated ≥ 6 months prior to enrollment did not differ from the unvaccinated with respect to viral load. The vaccinated group had fewer moderate/severe symptoms of subjective fever, chills, myalgias, nausea, and diarrhea. Vaccine- and booster-induced reduction in viral load may be an important component for achieving reduced coronavirus spread.

[Association of COVID-19 vaccination with symptomatic SARS-CoV-2 infection by time since vaccination and Delta variant predominance](#) – 2/14/22

In this test-negative, case-control study that included 1,634,271 tests from symptomatic adults, the odds ratio for prior mRNA vaccination and SARS-CoV-2 test positivity was lower before than during Delta variant predominance. The findings are consistent with a steady decline in estimated mRNA vaccine effectiveness over time, separate from variant-specific differences in protection.

[A tabulated summary of the evidence on humoral and cellular responses to the SARS-CoV-2 Omicron VOC, as well as vaccine efficacy against this variant](#) – 2/4/22

Omicron is strongly neutralized by antibodies induced by booster vaccination via messenger RNA vaccines (Pfizer or Moderna) or by heterologous vaccination. Omicron's humoral immune evasion explains the large number of breakthrough infections and reinfections. Omicron does not escape neutralization by CD4 and CD8 T cells, which provides protection against serious forms.

[Pfizer-BioNTech and Oxford AstraZeneca COVID-19 vaccine effectiveness and immune response among individuals in clinical risk groups](#) – 1/2/22

In most clinical risk groups, immune response to primary vaccination was maintained and high levels of vaccine effectiveness were seen. Reduced antibody response and vaccine effectiveness were seen after 1 dose of vaccine among a broad immunosuppressed group, and second dose vaccine effectiveness was moderate. These findings support maximizing coverage in immunosuppressed individuals and the policy of prioritization of this group for third doses.

[Effect of COVID-19 vaccination on transmission of alpha and delta variants](#) - 1/5/22

Vaccination was associated with a smaller reduction in transmission of the delta variant than of the alpha variant, and the effects of vaccination decreased over time.

[mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant](#) – 12/23/21

The SARS-CoV-2 Omicron variant harbors 34 mutations in the spike, more than other variants. Two doses of mRNA-based vaccines elicit poor neutralization of Omicron. Three mRNA vaccine doses elicit potent variant cross-neutralization, including Omicron.

[Effectiveness of COVID-19 vaccines against the Omicron \(B.1.1.529\) variant of concern \(not peer reviewed\)](#) – 12/14/21

Primary immunization with two BNT162b2 doses provided no or limited protection against symptomatic disease with the Omicron variant. Boosting with BNT162b2 following the primary course significantly increased protection.

[Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis](#) - 11/16/21

51 studies were included in this meta-analysis. In fully vaccinated populations, vaccine effectiveness against SARS-CoV-2 infection, COVID-19-related hospitalization, admission to the intensive care unit, and death was 89.1%, 97.2%, 97.4%, and 99.0%, respectively. The VE against infection in the general population aged ≥ 16 years, the elderly, and healthcare workers was 86.1%, 83.8%. and 95.3%, respectively.

[BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the SARS-CoV-2 Delta variant in Qatar](#) – 11/2/21

BNT162b2 effectiveness against any, symptomatic or asymptomatic, Delta infection was 45.3% ≥ 14 d after the first vaccine dose, but only 51.9% ≥ 14 d after the second dose, with 50% of fully vaccinated individuals receiving their second dose before 11 May 2021. Corresponding mRNA-1273 effectiveness ≥ 14 d after the first or second dose was 73.7% and 73.1%, respectively. Notably, effectiveness against Delta-induced severe, critical or fatal disease was 93.4% for BNT162b2 and 96.1% for mRNA-1273 ≥ 14 d after the second dose.

[Effectiveness of COVID-19 vaccine in preventing infection and disease severity: a case-control study from an Eastern State of India](#) – 10/11/21

This case-control study was conducted among people aged ≥ 45 years during April to June 2021. The adjusted VE for partial and full vaccination were estimated to be 52.0% and 83.0% respectively for preventing SARS CoV-2 infection. The sub-group analyses of the cases have shown that the length of hospital stays (LOS) and the severity of the disease (were significantly low among vaccinated compared to unvaccinated individuals. To conclude, four out of every five fully vaccinated individuals are estimated to be protected from contracting SARS CoV-2 infection. Vaccination lowered LOS and chances of development of severe disease.

[Effectiveness of SARS-CoV-2 mRNA vaccines for preventing COVID-19 hospitalizations in the United States](#) – 8/6/21

During March–May 2021, SARS-CoV-2 mRNA vaccines were highly effective for preventing COVID-19 hospitalizations among US adults. SARS-CoV-2 vaccination was beneficial for patients with immunosuppression, but effectiveness was lower in the immunosuppressed population.

Guillain Barre

[Guillain-Barré Syndrome after COVID-19 Vaccination in the Vaccine Safety Datalink – 12/5/21](#)

In this interim analysis of surveillance data of COVID-19 vaccines, findings were consistent with an elevated risk of GBS after primary Ad.26.COV2.S (Johnson & Johnson) vaccination. Surveillance is ongoing.

Janssen (Johnson & Johnson) COVID-19 Vaccine

[Use of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices – United States, December 2021 – 1/20/22](#)

Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination. The Janssen COVID-19 vaccine may be considered in some situations, including for persons with a contraindication to receipt of mRNA COVID-19 vaccines.

[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 – 8/10/21](#)

As of June 30, 2021, about 12.6 million doses of Janssen vaccine had been administered and 141 million 2nd mRNA vaccine doses had been administered. Overall, there were 7.8 cases of GBS per million J&J/Janssen doses; 3 cases of TTS per million J&J/Janssen doses and 3.5 cases of myocarditis per million 2nd mRNA vaccine doses. After assessing the data, ACIP concluded that the benefits of COVID-19 vaccination in preventing COVID-19 illness, associated hospitalizations, ICU admissions, and death outweigh serious but rare risks of GBS, TTS, and myocarditis.

[Safety Monitoring of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine – United States, March-April 2021 – 4/30/21](#)

By April 21, nearly 8 million doses of the Janssen COVID-19 vaccine had been administered. CDC researchers reviewed safety monitoring data from VAERS and the v-safe after-vaccination health checker, and found 97% of reported reactions after vaccination, such as headache, fever, chills, injection site pain, and fatigue, were nonserious and consistent with clinical trials data. CDC and FDA issued a pause of the Janssen vaccine April 12–23, 2021, after 6 cases of cerebral venous sinus thrombosis (CVST), a serious condition that involves blood clots in the brain, were identified in VAERS. By April 25, a total of 17 thrombotic (blood clots) events with thrombocytopenia (low platelet counts) were reported to VAERS, including 3 thrombotic events not occurring in the brain.

[Updated Recommendations from the Advisory Committee on Immunization Practices for Use of Janssen \(Johnson & Johnson\) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients – United States, April 2021 – 4/30/21](#)

The Advisory Committee on Immunization Practices (ACIP) held two emergency meetings to review reports of TTS following Janssen vaccine and conducted a risk-benefit assessment. The estimated reporting rate of TTS was 7 cases of TTS per million Janssen doses administered to women aged 18-49 years. After their review, on April 23, ACIP concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged 18 years and older outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization (EUA), which includes a new warning for rare clotting events, primarily in women aged 18-49 years.

[US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COVID.5 Vaccination, March 2 to April 21, 2021 – 4/3/21](#)

Around 7 million doses of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine were given between March 2–April 12, 2021. During this time, VAERS received reports following J&J/Janssen vaccination of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, which involves blood clots in the brain with low platelet counts. By April 21, there were 12 reports of CVST and thrombocytopenia. This serious condition was reported in women between 18 and under 60 years. All were hospitalized; 10 were admitted to intensive care units (ICU). As of April 21, 4 patients were sent home, 2 were moved to hospital units outside of ICU, 3 continued ICU care, and 3 died. The review shows that U.S. cases of CVST and thrombocytopenia after J&J/Janssen vaccination were clinically similar to CVST cases in Europe after Oxford/AstraZeneca COVID-19 vaccination. Investigation of the potential relationship between J&J/Janssen vaccine and CVST with thrombocytopenia is ongoing.

Moderna COVID-19 Vaccine

[Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine—United States, December 21, 2020-January 10, 2021 – 1/22/21](#)

From December 21, 2020 through January 10, 2021, VAERS received 108 reports following Moderna vaccine identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 10 cases were determined to be anaphylaxis (a rate of 2.5 cases of anaphylaxis per million doses). Of the 10 cases, 9 had a history of allergies or allergic reaction, including 5 who had a history of anaphylaxis. Anaphylaxis following Moderna vaccine appears to be a rare event.

[Real-world effectiveness of the mRNA-1273 vaccine against COVID-19: interim results from a prospective observational cohort study – 11/25/21](#)

These interim results provide reassuring evidence of the vaccine effectiveness of 2 doses of mRNA-1273 across age, sex, and racial/ethnic subgroups, and against asymptomatic and symptomatic COVID-19, and severe COVID-19 outcomes. Among individuals with history of COVID-19, mRNA-1273 vaccination may offer added protection beyond immunity acquired from prior infection.

Multisystem Inflammatory Syndrome in Adults (MIS-C)

[Multisystem Inflammatory Syndrome in Adults after SARS-CoV-2 infection and COVID-19 vaccination – 11/28/21](#)

From December 14, 2020 to April 30, 2021, 20 patients who met the case definition for MIS-A were reported to CDC. Their median age was 35 years (range, 21–66 years), and 13 (65%) were male. Overall, 16 (80%) patients had a preceding COVID-19-like illness a median of 26 days (range 11–78 days) before MIS-A onset. All 20 patients had laboratory evidence of SARS-CoV-2 infection.

Myocardial Infarction, Pulmonary Embolism and Stroke

[Myocardial infarction, stroke, and pulmonary embolism after BNT162b2 mRNA COVID-19 vaccine in people aged 75 years or older – 11/22/21](#)

In this nationwide study involving persons aged 75 years or older in France, no increase in the incidence of acute myocardial infarction, stroke, and pulmonary embolism was detected 14 days following each BNT162b2 mRNA vaccine dose.

Myocarditis

[Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021](#) – 1/18/22

Since mRNA-based COVID-19 vaccines were authorized for emergency use in December 2020, there have been reports of myocarditis, or inflammation of the heart muscle, following vaccination. From December 2020 through August 31, 2021, more than 192 million people ages 12 years and older have received at least one dose of mRNA COVID-19 vaccines. From this population, VAERS received 1,626 myocarditis reports that met case definition. The review found the rates myocarditis were highest following the second dose of mRNA vaccine among adolescent and young adult males. Myocarditis is a rare but serious adverse event that can occur following mRNA COVID-19 vaccination. The benefits of COVID-19 vaccination continue to outweigh any potential risks, including myocarditis.

[Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents following Comirnaty vaccination](#) – 11/28/21

Between 14 June 2021 and 4 September 2021, 33 Chinese adolescents who developed acute myocarditis/pericarditis following Comirnaty vaccination were identified. In total, 29 (87.88%) were male and 4 (12.12%) were female, with a median age of 15.25 years. And 27 (81.82%) and 6 (18.18%) cases developed acute myocarditis/pericarditis after receiving the second and first dose, respectively. All cases are mild and required only conservative management.

[Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021](#) – 7/9/21

Evidence presented showed that the highest rates of myocarditis were reported in males aged 12-17 and 18-24 (62.8 and 50.5 reported cases of myocarditis per million 2nd mRNA doses administered, respectively). On June 23, after reviewing all the available information, ACIP determined that the benefits of mRNA COVID-19 vaccination under EUA outweighed the risks of myocarditis in all populations.

[Myocarditis and pericarditis after vaccination for COVID-19](#) – 8/4/21

Among 2,000,287 individuals receiving at least 1 COVID-19 vaccination, twenty individuals had vaccine-related myocarditis (1.0 per 100 000) and 37 had pericarditis (1.8 per 100 000). Myocarditis occurred a median of 3.5 days. Fifteen individuals were male, and the median age was 36 years.

[Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines](#) – 6/29/21

CDC researchers reviewed several case reports of acute myocarditis occurring in people following mRNA-based COVID-19 vaccinations (Pfizer BioNTech or Moderna). The first report included 4 cases of myocarditis developed 1 to 5 days after getting dose 2 of mRNA-based COVID-19 vaccine. Second report included 23 cases of acute myocarditis within 4 days of vaccination, mostly after dose 2. The last report included 7 cases in adolescents, ages 14-19. All presented with myocarditis or myopericarditis (heart muscle and lining inflammation) within 4 days of dose 2. The review of these cases showed clinical

similarities and there were no other known causes for their acute myocarditis, suggesting a likely association with vaccination. Myocarditis following COVID-19 vaccination is rare.

[Myopericarditis after vaccination, Vaccine Adverse Event Reporting System \(VAERS\), 1990-2018](#) – 1/29/21

Myopericarditis, an inflammation of the heart muscle and tissue around the heart, has many causes including viral infections. During 1990–2018, VAERS received a total 620,195 reports: 708 (0.1%) met the case definition or were physician-diagnosed as myopericarditis. Most (79%) reports described males, 69% were serious, and 72% had symptom onset within 2 weeks of vaccination. Myopericarditis remains rarely reported after vaccines licensed for use in the United States.

Pfizer-BioNTech COVID-19 Vaccine

[Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine](#) – 2/23/21

From December 14–23, 2020, 1.89 million first doses of Pfizer-BioNTech COVID-19 vaccine were administered. The most commonly reported non-anaphylaxis allergic reactions included: rash, itchy skin, itchy and scratchy sensations in the throat, and mild respiratory symptoms. Safety monitoring identified 21 anaphylaxis reports, corresponding to an estimated rate of 11.1 cases per million doses administered; 17 (81%) had a history of allergies or allergic reactions. No deaths from anaphylaxis were reported.

[Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020](#) – 1/15/21

From December 14-23, 2020, VAERS received 175 reports identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 21 cases were determined to be anaphylaxis (a rate of 11.1 cases of anaphylaxis per million doses). Most anaphylaxis cases (81%) occurred in persons with a history of allergies or allergic reactions. Anaphylaxis following Pfizer-BioNTech vaccine appears to be a rare event.

[Effectiveness of BNT162b2 mRNA COVID-19 vaccine against SARS-CoV-2 variant Beta \(B.1.351\) among persons identified through contact tracing in Israel: a prospective cohort study](#) – 11/28/21

In a prospective observational study, two doses of BNT162b2 were effective against confirmed and probable Beta infections. Through the end of June 2021, introductions of Beta did not interrupt control of the pandemic in Israel.

Pregnancy

[Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020-July 22, 2021](#) – 1/4/22

In a retrospective cohort of >40,000 pregnant women, COVID-19 vaccination during pregnancy was not associated with preterm birth or small-for-gestational-age at birth overall, stratified by trimester of vaccination, or number of vaccine doses received during pregnancy, compared with unvaccinated pregnant women.

[Monitoring the safety of COVID-19 vaccines in pregnancy in the US](#) - 11/10/21

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).

[CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion](#) – 9/8/21

Researchers analyzed data on miscarriage, or a pregnancy loss that occurs before 20 weeks of pregnancy, collected from v-safe COVID-19 Vaccine Pregnancy Registry participants. Over 2,400 registry participants received at least one dose of an mRNA COVID-19 vaccine just before pregnancy or within the first 20 weeks of pregnancy. The cumulative risk of miscarriage among those who received an mRNA COVID-19 vaccine was similar (14.1%) to previously published background rates (11 to 16%). Therefore, this study demonstrated no increased risk of miscarriage following receipt of COVID-19 mRNA vaccine in early pregnancy.

[Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy](#) – 9/8/21

Researchers within the Vaccine Safety Datalink, a collaboration between CDC and 9 health systems, representing approximately 3% of the U.S. population, analyzed data from 8 health systems from December 15, 2020 through June 28, 2021 to evaluate whether there's an association between COVID-19 vaccine and miscarriage (pregnancy loss that occurs before 20 weeks of pregnancy). The analysis found that people who were currently pregnant at the time of COVID-19 vaccination and those who became pregnant after vaccination did not have an increased risk of miscarriage.

[Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons](#) – 4/21/21

Pregnant people were not included in the messenger RNA (mRNA) COVID-19 vaccine clinical trials. From December 14, 2020 through February 28, 2021, 35,691 v-safe participants ages 16 to 54 identified as pregnant. Injection site pain was commonly reported. Of those, 3,958 enrolled in the v-safe pregnancy registry: 827 completed pregnancy; 712 (86.1%) had live births, with most vaccinations completed in the 3rd trimester. In the VAERS reports following mRNA vaccinations, 155 (70.1%) were nonpregnancy specific; 66 (29.9%) were pregnancy and neonatal specific events. The analysis of v-safe and VAERS data did not show any safety concerns among pregnant persons who received mRNA COVID-19 vaccines.

Reactogenicity

[Reactogenicity within 2 weeks after mRNA COVID-19 vaccines: Findings from the CDC v-safe surveillance system](#) - 10/16/21

During post-authorization monitoring among >4 million vaccinees, local and systemic reactions were commonly reported following mRNA-based vaccines. Reactions were most common during the first week following dose 2 and among persons aged <45 years, females, and mRNA-1273 recipients.

[Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines](#) – 4/5/21

Over 3.6 million v-safe participants completed at least one health check-in after the first dose and over 1.9 million after the second dose. Injection site pain was commonly reported after first (70%) and second doses (75%) of either mRNA vaccine. Systemic reactions, such as fatigue, headache, muscle pain, chills, fever, and joint pain were the top symptoms reported by participants after the first mRNA vaccine dose. These reports increased substantially after the second dose among both mRNA vaccines. People aged 65 years and older reported fewer reactions than younger people. While v-safe is voluntary and

includes less than 10% of people vaccinated, reported reactions to the mRNA vaccines were consistent with results observed in clinical trials.

Thrombosis / Thrombocytopenia

[Case Series of Thrombosis with Thrombocytopenia Syndrome after COVID-19 vaccination—United States, December 2020 to August 2021](#) – 1/18/22

Thrombosis with thrombocytopenia syndrome (TTS) is a rare, potentially life-threatening condition that involves blood clots with low platelet counts and has been seen following COVID-19 vaccination. From December 14, 2020 through August 31, 2021, over 14.1 million doses of Johnson & Johnson's Janssen and 351 million doses of mRNA vaccines were given. CISA confirmed 57 reports of TTS: 54 following Janssen COVID-19 vaccine and 3 following mRNA COVID-19 vaccines. Most cases of TTS following Janssen vaccination occurred in females and in people younger than 50 years. Of the 54 cases, 37 were discharged home, 9 were discharged to post-acute care, and 8 died. This analysis of data concluded that TTS is a rare, but serious adverse event associated with Janssen COVID-19 vaccination.

Children and Adolescents

[BNT162b2 Protection against the Omicron Variant in Children and Adolescents](#) – 3/30/22

BNT162b2 vaccination reduced the risk of omicron-associated hospitalization by two thirds among children 5 to 11 years of age. Although two doses provided lower protection against omicron-associated hospitalization than against delta-associated hospitalization among adolescents 12 to 18 years of age, vaccination prevented critical illness caused by either variant.

[Effectiveness of BNT162b2 against COVID-19 in adolescents](#) – 3/21/22

The rapid waning of protection after the first and second BNT162b2 dose against symptomatic disease with the omicron variant indicates that the primary adolescent vaccine series as a stand-alone intervention is unlikely to sustain suppression of infections in the medium-to-long term. If the aim of the program is to reduce infections, then regular boosters will likely be needed.

[Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant \(not peer reviewed\)](#) - 2/28/22

In the Omicron era, the effectiveness against cases of BNT162b2 declined rapidly for children, particularly those 5-11 years. However, vaccination of children 5-11 years was protective against severe disease and is recommended. These results highlight the potential need to study alternative vaccine dosing for children and the continued importance layered protections, including mask wearing, to prevent infection and transmission.

[Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Children and Adolescents Aged 5–17 Years — VISION Network, 10 States, April 2021–January 2022](#) – 3/4/22

Two doses protect against COVID-19–associated emergency department and urgent care encounters among children and adolescents. However, vaccine effectiveness (VE) was lower during Omicron predominance and decreased with time since vaccination; a booster dose restored VE to 81% among adolescents aged 16–17 years. Overall, 2-dose VE against COVID-19–associated hospitalization was 73%–94%.

[Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12–17 Years — United States, December 9, 2021–February 20, 2022](#) – 3/4/22

This report provides findings from v-safe and VAERS data collected during the first 7–11 weeks of administration of homologous Pfizer-BioNTech booster doses to persons aged 12–17 years, during which time approximately 2.8 million booster doses were administered. Among adolescents, reports to v-safe and VAERS after receipt of a booster dose were generally similar to those previously described after a primary series dose, reinforcing that vaccination among this population is safe.

[Indirect protection of children from SARS-CoV-2 infection through parental vaccination](#) – 1/27/22

Researchers found that having a single vaccinated parent was associated with a 26.0% and 20.8% decreased risk and having two vaccinated parents was associated with a 71.7% and 58.1% decreased risk, in the early and late periods, respectively. Parental vaccination confers substantial protection for unvaccinated children in the household.

[Effectiveness of BNT162b2 vaccine against critical COVID-19 in adolescents](#) – 1/12/22

A total of 445 case patients and 777 controls were enrolled. Overall, 17 case patients (4%) and 282 controls (36%) had been fully vaccinated. Of the case patients, 180 (40%) were admitted to the ICU, and 127 (29%) required life support; only 2 patients in the ICU had been fully vaccinated. The overall effectiveness of the BNT162b2 vaccine against hospitalization for Covid-19 was 94%.

[COVID-19 Vaccine Safety in Children Ages 5-11 years — United States, November 3-December 19, 2021](#) – 12/31/21

Approximately 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine were administered to children aged 5–11 years during this period; VAERS received 4,249 reports of adverse events after vaccination with Pfizer-BioNTech COVID-19 vaccine in this age group, 4,149 (97.6%) of which were not serious. Approximately 42,504 children aged 5–11 years were enrolled in v-safe after vaccination with Pfizer-BioNTech COVID-19 vaccine; after dose 2, a total of 17,180 (57.5%) local and 12,223 systemic (40.9%) reactions (including injection-site pain, fatigue, or headache) were reported. The preliminary safety findings are similar to those from preauthorization clinical trials.

[Evaluation of the BNT162b2 COVID-19 vaccine in children 5 to 11 years of age](#) – 11/9/21

A Covid-19 vaccination regimen consisting of two 10-µg doses of BNT162b2 administered 21 days apart was found to be safe, immunogenic, and efficacious in children 5 to 11 years of age.

[Canadian parents' perceptions of COVID-19 vaccination and intention to vaccinate their children: results from a cross-sectional national survey](#) – 10/8/21

Parents' COVID-19 vaccination intentions for their children are better predicted by previous decisions regarding [influenza vaccination](#) than routine childhood vaccines, and other perceptions of COVID-19 vaccine-related factors.

[Effectiveness of BNT162b2 vaccine in adolescents during outbreak of SARS-CoV-2 Delta variant infection, Israel, 2021](#) – 9/27/21

Research findings are consistent with those of United Kingdom study, which demonstrated vaccine effectiveness of 88.0% against symptomatic disease caused by the SARS-CoV-2 Delta variant, compared with vaccine effectiveness of 93.7% against disease caused by the Alpha variant among persons >16 years of age who had received 2 doses of BNT162b2.

[COVID-19 Vaccine Safety in Adolescents—United States, December 14, 2020—July 16, 2021](#) – 7/30/21

Over 8.9 million Pfizer-BioNTech doses were administered to adolescents ages 12-17. VAERS received 9,246 reports of adverse events in adolescents; over 90% of reports were non-serious. Myocarditis was reported in 4.3% (397) of all VAERS reports. Of the 129,000 adolescents who enrolled in v-safe, the most frequently reported side effects included injection site pain, fatigue, headache, and weakness. With the exception of myocarditis, the safety findings were similar to what was observed during preauthorization trials. CDC and FDA are actively monitoring the safety of COVID-19 vaccines. Serious adverse events after COVID-19 vaccination are rare, and CDC continues to recommend everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19.

Infants

[Durability of anti-spike antibodies in infants after maternal COVID-19 vaccination or natural infection](#) – 2/7/22

This study found that the majority of infants born to COVID-vaccinated mothers had persistent anti-S antibodies at 6 months, compared with infants born to mothers with SARS-CoV-2 infection. Understanding the persistence of maternal antibody levels in infants is important because COVID-19 infections in this age group account for a disproportionate burden of pediatric SARS-CoV-2–associated morbidity and because COVID-19 vaccines are not currently planned for infants younger than 6 months.

Multisystem Inflammatory Syndrome in Children (MIS-C)

[Reported Cases of Multisystem Inflammatory Syndrome in Children in Children \(MIS-C\) Aged 12-20 Years in the United States Who Received COVID-19 Vaccine, December 2020 through August 2021](#) - 1/6/22

Researcher identified six cases of MIS-C that occurred following COVID-19 vaccination without evidence of SARS-CoV-2 infection, a reporting rate of 6/21,335,331, or 0.3 cases per million persons aged 12–20 years who had received ≥1 dose of COVID-19 vaccine.

Community Immunity and Breakthrough Infections

[Analysis of vaccination rates and new COVID-19 infections by US county, July-August 2021](#) - 2/10/22

In this cross-sectional study, we found a negative ecological association between vaccination rates and the surge of COVID-19 infections. Areas with low vaccination experienced a more intense surge of new cases during the third wave of the pandemic in the US, primarily driven by the Delta variant. The results presented here illustrate the association of the spatial heterogeneity of vaccination coverage with the overall COVID-19 epidemic in the country. Most counties with low vaccination rates (ie, <30%) were rural (82.2%). Rural areas in the US face many challenges in responding to the pandemic, including lower health care resources, compared with urban communities. These areas have been characterized by vaccination hesitancy, limited vaccine availability, and hospital staff shortages that can be associated with the successful distribution of vaccines and hence the vaccination campaign's overall outcome.

[COVID-19 incidence and death rates among unvaccinated and fully vaccinated adults with and without booster doses during periods of Delta and Omicron variant emergence—25 U.S. jurisdictions, April 4–December 25, 2021](#) - 1/28/22

In 25 U.S. jurisdictions, decreases in case incidence rate ratios for unvaccinated versus fully vaccinated persons with and without booster vaccine doses were observed when the Omicron variant emerged in

December 2021. Protection against infection and death during the Delta-predominant period and against infection during Omicron emergence were higher among booster vaccine dose recipients, especially among persons aged 50–64 and ≥65 years.

[Rate and risk factors for severe/critical disease among fully vaccinated persons with breakthrough SARS-CoV-2 infection in a high-risk national population](#) – 12/10/21

The rate of severe/critical disease is higher among older persons and those with >4 comorbidities but lower among fully vaccinated persons with breakthrough infection compared with unvaccinated controls who develop infection.

[Nonpharmaceutical interventions remain essential to reducing COVID-19 burden even in a well-vaccinated society: a modeling study](#) – 8/9/21

Predictive modeling show that even with high vaccination coverage, concomitant NPIs are required to reduce cumulative deaths. NPI adherence figures prominently because NPIs drive total cases down faster than vaccinations alone. Even with no vaccination, a high level of NPI adherence averts 74% of COVID-19 cases and 61% of COVID-19 deaths over the simulation period between January and July 2021

[Outcomes among patients with breakthrough SARS-CoV-2 infection after vaccination](#) – 8/7/21

In persons with breakthrough SARS-CoV-2 infection, increasing age is associated with a higher risk of severe disease or death, while vaccination is associated with a lower risk. Presence of comorbidities was not associated with severe disease or death among persons with breakthrough infection.

[COVID-19 vaccination in Israel](#) – 8/9/21

The deployment of the COVID-19 vaccine in Israel was rapid and successful due to well organized national efforts of all health sectors in the country, the existing infrastructure, and the allocation of adequate resources. Remaining challenges include: (a) maintaining this success, especially with the removal of nearly all COVID-19 restrictions and alongside a current increase in disease incidence throughout July 2021, (b) increasing vaccine uptake among adolescents aged 12–15 years, (c) reducing the remaining gaps in COVID-19 vaccine uptake across specific population groups, and (d) understanding the duration of protection conferred by the BNT162b2 vaccine and protection against new SARS CoV-2 variants of concern.

[Vaccine effectiveness against SARS-CoV-2 transmission and infections among household and other close contacts of confirmed cases, the Netherlands, February to May 2021](#) – 8/2/21

This study showed that the COVID-19 vaccines not only protect the vaccinee against SARS-CoV-2 infection, but also offer protection against transmission to close contacts after completing the full schedule. This finding underscores the importance of full vaccination of close contacts of vulnerable persons.

[Vaccine breakthrough infection and onward transmission of SARS-CoV-2 Beta \(B.1.351\) variant, Bavaria, Germany, February to March 2021](#) – 7/29/21

This breakthrough infection of a fully vaccinated HCW with onward transmission to an unvaccinated partner highlights the risk of transmission by fully vaccinated individuals to their close contacts. This might be especially applicable for individuals with high occupational risk for an infection, in outbreak situations and if working in hospital wards with acute COVID-19 cases.

Disparities

[Disparities in national and state estimates of COVID-19 vaccination receipt and intent to vaccinate by race/ethnicity, income, and age group among adults ≥ 18 years, United States](#) – 11/18/21

Disparities in vaccination intent by racial/ethnic groups underscore the need for interventions and recommendations designed to improve vaccination coverage and confidence in underserved communities, such as younger and lower income racial/ethnic minority groups.

[Socioeconomic privilege and political ideology are associated with racial disparity in COVID-19 vaccination](#) – 7/2/21

We find that COVID vaccine disparities are associated with median income, education, and political ideology. In the face of an unprecedented pandemic, these racial disparities persist without signs of abating over a 3-wk (27 March to 19 April 2021) period of a massive national vaccination campaign with a doubling of the vaccination rate.

High Risk Settings and Healthcare Workers

[SARS-CoV-2 Delta outbreak among fully vaccinated nursing home residents likely initiated by a fully vaccinated staff member – Connecticut, July–August 2021](#) – 12/10/21

This SARS-CoV-2 Delta variant nursing home outbreak occurred in a setting of high vaccination coverage and was likely initiated by a fully vaccinated staff member. Prior COVID-19 was inversely associated with infection in residents. Regardless of vaccination status, consistent adherence to infection control measures and testing recommendations is important to reduce SARS-CoV-2 transmission, particularly in high-risk settings.

[COVID-19 vaccination coverage among hospital-based healthcare personnel reported through the Department of Health and Human Services Unified Hospital Data Surveillance System, United States, January 20, 2021-September 15, 2021](#) – 11/17/21

Mandates for healthcare partners (HCP) influenza vaccination have been associated with high influenza vaccination rates and a significant decrease in HCP absenteeism, healthcare-associated influenza among hospitalized patients, and patient mortality. The forthcoming CMS rule for vaccination in healthcare settings should substantially increase COVID-19 vaccine coverage among HCP.

[Uptake and impact of vaccination against COVID-19 among healthcare workers-evidence from a multicentre study](#) – 11/11/21

14837 healthcare workers across 20 different hospitals were prospectively surveyed. The overall uptake of the vaccine was 13335(90%). Infection rate in vaccinated HCW was 710(6.04%) and was significantly lower than unvaccinated HCW 148(9.9%). Uptake of vaccination among healthcare workers in our study was high and provided significant protection compared to unimmunized healthcare workers.

[Vaccination status and the detection of SARS-CoV-2 infection in health care personnel under surveillance in long-term residential facilities](#) – 11/10/21

This cohort study found that frequent, mandatory surveillance of HCP in a LTC setting was effective in detecting SARS-CoV-2 infection in HCP. The yield of positive test results was much higher in HCP who were unvaccinated than those who were vaccinated, consistent with an evolving literature that suggests full vaccination status reduces asymptomatic SARS-CoV-2 infection in HCP.

[In depth characterization of vaccine breakthrough infections with SARS-CoV-2 among healthcare workers of a Dutch academic medical center](#) – 11/6/21

This study characterizes 14 breakthrough infections among 5860 fully vaccinated Dutch health care workers ≥14 days after the final dose of vaccination. These breakthrough infections presented with regular B.1.1.7 (Alpha) and B.1.617.2 (Delta) variants and high viral loads, despite normal vaccine-induced B- and T-cell immune responses detected by live virus neutralization assays and ELISpot. High-risk exposure settings, such as in households, indicate a potential risk of viral transmission despite full vaccination.

[Determining the incidence of asymptomatic SARS-CoV-2 among early recipients of COVID-19 vaccines: a prospective cohort study of healthcare workers before, during and after vaccination \[DISCOVER-COVID-19\]](#) – 8/7/21

Researchers found that SARS-CoV-2 infection incidence decreased in a stepwise fashion following vaccination. They identified asymptomatic infections in the partial and fully vaccinated periods; however, all asymptomatic individuals who underwent serial retesting had negative repeat PCR tests within 2 days and none had culturable live virus. This suggests a shorter duration of viral shedding in these asymptomatic individuals than has been previously reported for prevaccination symptomatic infections

[Introduction of the BNT162b2 vaccine during a COVID-19 nursing home outbreak](#) – 8/4/21

This study describes a nursing home outbreak occurred from 12/2/20 to 1/7/21 with an attack rate of 30.8%; 46.7% of the cases were due to asymptomatic COVID-19. One unit accounted for 77.8% of the cases. Between the first and second dose, 15.5% (15/97) of vaccinated residents, and 21.2% (4/19) of unvaccinated residents developed COVID-19. One week after the second dose, no cases of COVID-19 occurred.

[Disparities in COVID-19 vaccination coverage among health care personnel working in long-term care facilities, by job category, National Healthcare Safety Network — United States, March 2021](#) – 7/30/21

During March 2021, 300 LTCFs reported COVID-19 vaccination coverage for their HCP. COVID-19 vaccination coverage was highest among physicians (75.1%) and lowest among aides (45.6%).

[Three-month analysis of total humoral response to Pfizer BNT 162b2 mRNA COVID-19 vaccination in healthcare workers](#) – 6/29/21

The results of our study extend evidence that shows total anti-SARS-CoV-2 S antibodies levels tend to decline at 3 months after the first vaccine dose, though we also showed that such decline occurs in both baseline seropositive and seronegative subjects, and with serum levels that tend to be significantly lower in older subjects. These findings ... provide further support to the conclusion that personalization of COVID-19 vaccine administration, with use of further vaccine boosters, may be advisable in selected categories of the population.

[Large scale screening for SARS-CoV-2 among healthcare workers: prevalence and risk factors for asymptomatic/pauci-symptomatic carriers, with emphasis on PPE use](#) – 2/24/21

The prevalence of SARS-CoV-2 among asymptomatic and pauci-symptomatic HCWs in a COVID-19 center in Mexico City was 5.5%. Nurses in critical areas represented the majority of PCR-positive tests. High adherence to PPE recommendations was observed, suggesting community transmission as the most likely source of infection.

Natural Infection

[Neutralizing response against SARS-CoV-2 variants 8 months after BNT162b2 vaccination in naive and COVID-19 convalescent individuals](#) – 12/28/21

Although breakthrough infection in vaccinated individuals is presumably a multifactorial event, low levels of neutralizing response against the delta variant in serum, and likely in mucosa, could be a relevant factor for infection of this variant that is highly adapted to human transmission. Most breakthrough SARS-CoV-2 infections appear not to result in clinically severe disease but can maintain chains of transmission among vaccinated and unvaccinated contacts. Surveillance of the evolution of the breadth of neutralizing response against variants of concern could inform decisions for boosting strategies.

[Durability of antibody levels after vaccination with mRNA SARS-CoV-2 vaccine in individuals with or without prior infection](#) – 11/1/21

Health care workers with prior SARS-CoV-2 infection followed by 2 doses of mRNA vaccine (3 independent exposures to spike antigen) developed higher spike antibody measurements than individuals with vaccination alone. Consistent with work comparing extended vaccine dosing intervals, the study showed that a longer interval between infection and first vaccine dose may enhance the antibody response.

[Two doses of the SARS-CoV-2 BNT162b2 vaccine enhances antibody responses to variants in individuals with prior SARS-CoV-2 infection](#) – 8/10/21

This study shows that multiple exposures to SARS-CoV-2 spike protein in the context of a delayed booster expand the neutralizing breadth of the antibody response to neutralization-resistant SARS-CoV-2 variants. This suggests that additional vaccine boosts may be beneficial in improving immune responses against future SARS-CoV-2 variants of concern.

Vaccine Hesitancy

[Associations between adverse childhood experiences, attitudes towards COVID-19 restrictions and vaccine hesitancy: a cross-sectional study](#) – 2/1/22

Increasing Adverse Childhood Experiences (ACE) counts were independently related to low trust in NHS COVID-19 information, feeling unfairly restricted by government and ending mandatory face coverings. High ACE counts were also associated with supporting removal of social distancing. Breaking COVID-19 restrictions increased with ACE count with likelihood doubling from no ACEs to 4+ ACEs. Vaccine hesitancy was threefold higher with 4+ ACEs (vs 0 ACEs) and higher in younger age groups. Thus, modelled estimates of vaccine hesitancy ranged from 3.42% with no ACEs to 38.06% with 4+ ACEs, aged 18–29 years.

[Changes in COVID-19 vaccine hesitancy among Black and white individuals in the US](#) – 1/21/22

This survey study of 1200 US adults found that COVID-19 vaccine hesitancy decreased more rapidly among Black individuals than among White individuals since December 2020. A key factor associated with this pattern seems to be the fact that Black individuals more rapidly came to believe that vaccines were necessary to protect themselves and their communities.

[Factors and reasons associated with low COVID-19 vaccine uptake among highly hesitant communities in the US – 1/4/22](#)

The 2 predictors associated with a low vaccination level within highly hesitant communities were: no high school education, and concern on vaccine availability and distribution. The most common reason driving vaccine hesitancy was lack of trust in COVID-19 vaccines (55%), followed by concerns around side effects of the vaccine (48%), and lack of trust in government (46%).

[Willingness to vaccinate against SARS-CoV-2: the role of reasoning biases and conspiracist ideation. – 12/4/21](#)

Results indicated that a bias toward reduced data gathering during reasoning may cause paranoia, increasing the perceived dangerousness of vaccines and thereby reducing willingness to vaccinate. Reduced willingness to vaccinate was identified as a likely cause of belief in conspiracy theories, subverting the common assumption that the opposite causal relation exists.

[Impact of COVID-19-related knowledge on protective behaviors: the moderating role of primary sources of information – 11/29/21](#)

Higher levels of knowledge were associated with increased self-reported engagement with protective behaviors against COVID-19. The primary information source significantly moderated the association between knowledge and behavior, and analyses of simple slopes revealed significant differences by primary information source. This study shows the important role of COVID-19 information sources in affecting people's engagement in recommended protective behaviors.

[COVID-19 vaccine hesitancy among physicians, physician assistants, nurse practitioners, and nurses in two academic hospitals in Philadelphia – 9/20/21](#)

Among 5,929 HCP (2,253 medical doctors [MDs] and doctors of osteopathy [DOs], 582 nurse practitioners [NPs], 158 physician assistants [PAs], and 2,936 nurses), a higher proportion of nurses (47.3%) were COVID-vaccine hesitant compared with 30.0% of PAs and NPs and 13.1% of MDs and DOs. The most common reasons for vaccine hesitancy included concerns about side effects, the newness of the vaccines, and lack of vaccine knowledge.

[University students' perspectives, planned uptake, and hesitancy regarding the COVID-19 vaccine: a multi-methods study – 8/3/21](#)

In June 77.8% of surveyed students (n = 483) were willing to get the COVID-19 vaccine; in September 79.6% were willing (n = 1269). Students who indicated they would be encouraged to get the COVID-19 vaccine if their doctor/pharmacist recommended it were 76 times more likely to be willing to get the vaccine than those who would not be encouraged by medical advice. Interviews revealed concerns about the speed of the vaccine roll out, safety, and efficacy.

[Behavioral nudges increase COVID-19 vaccinations - 8/2/21](#)

Our findings inform the design of behavioral nudges for promoting health decisions, and highlight the value of making vaccination easy and inducing feelings of ownership over vaccines.

[Prevalence and determinants of SARS-CoV-2 vaccine hesitancy in Hong Kong: A population-based survey – 6/16/21](#)

In a representative sample of Chinese adults in Hong Kong, only 45.3% of the participants intended to vaccinate against SARS-CoV-2 when available. Vaccine hesitancy was associated with inadequate

knowledge about SARS-CoV-2 transmission and lower perceived danger of COVID-19, which needed to be addressed to improve vaccination uptake.

Waning Immunity (Vaccine Effectiveness)

[Duration of effectiveness of vaccines against SARS-CoV-2 infection and COVID-19 disease: results of a systematic review and meta-regression](#) – 2/21/22

COVID-19 vaccine efficacy or effectiveness against severe disease remained high, although it did decrease somewhat by 6 months after full vaccination. By contrast, vaccine efficacy or effectiveness against infection and symptomatic disease decreased approximately 20-30 percentage points by 6 months.

[Waning 2-dose and 3-dose effectiveness of mRNA vaccines against COVID-19–associated emergency department and urgent care encounters and hospitalizations among adults during periods of Delta and Omicron variant predominance—VISION Network, 10 states, August 2021–January 2022.](#) - 2/18/22

Vaccine effectiveness (VE) against COVID-19–associated emergency department/urgent care (ED/UC) visits and hospitalizations was higher after the third dose than after the second dose but waned with time since vaccination.