Centers for Disease Control and Prevention

COVID-19

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Sept. 12, 2023

COVID-19 vaccine recommendations have been updated as of September 12. The content on this page is no longer current and will be updated to align with the new recommendations. Learn more.

At the April 19, 2023 meeting of the Advisory Committee on Immunization Practices, CDC presented data related to further analyses of a preliminary safety signal for persons ages 65 years and older who received the updated (bivalent) Pfizer-BioNTech COVID-19 vaccine in one safety monitoring system, the Vaccine Safety Datalink (VSD). Other safety monitoring systems have not observed similar findings. As time has passed and more safety data have accumulated, the initial finding has decreased, and scientists believe factors other than vaccination might have contributed to the initial finding. The current evidence does not support the existence of a safety issue. FDA and CDC will continue to evaluate data as they are available and update the public as needed.

Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects—such as headache, fatigue, and soreness at the injection site—that are generally mild to moderate and go away within a few days.

What You Need to Know

- The benefits of COVID-19 vaccination continue to outweigh any potential risks.
- Severe reactions after COVID-19 vaccination are rare.
- CDC recommends everyone ages 6 months and older get vaccinated to protect against COVID-19 and its potentially severe complications.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of COVID-19 vaccines.

Anaphylaxis after COVID-19 Vaccination

Anaphylaxis after COVID-19 vaccination is rare. It has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.

CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public.

Scientific Publications about Anaphylaxis following COVID-19 Vaccination

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine
Synopsis: CDC and FDA safety monitoring of the Pfizer-BioNTech COVID-19 vaccine in the Vaccine Adverse Event Reporting System (VAERS) identified 21 reports of anaphylaxis from the 1.89 million first doses of the vaccine administered from December 14 through 23, 2020, corresponding to an estimated rate of 11.1 cases per million doses administered; 17 of those cases (81%) had a history of allergies or allergic reactions. No deaths from anaphylaxis were reported.

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021
Synopsis: From December 14, 2020, through January 18, 2021, CDC safety monitoring of mRNA COVID-19 vaccines in VAERS identified 66 reports of anaphylaxis: 47 cases following receipt of the Pfizer-BioNTech vaccine and 19 cases following receipt of the Moderna vaccine. No deaths from anaphylaxis were reported. Continued safety monitoring of mRNA COVID-19 vaccines has confirmed that anaphylaxis following vaccination is rare.

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021
Synopsis: From December 21, 2020, through January 10, 2021, CDC safety monitoring of the Moderna COVID-19 vaccine in VAERS identified 10 cases of anaphylaxis from a reported 4,041,396 first doses of the vaccine, corresponding to an estimated 2.5 cases per million doses administered. In nine of those cases, anaphylaxis symptoms began within 15 minutes of vaccination. No deaths from anaphylaxis were reported.

Reports of Deaths after COVID-19 Vaccination

Multiple factors contribute to reports of death after COVID-19 vaccination, including heightened public awareness of COVID-19 vaccines, requirements under FDA authorization for COVID-19 vaccines that healthcare providers report any death after COVID-19 vaccination to VAERS (even if it is unclear whether the vaccine was the cause), and reporting requirements in CDC vaccine provider agreements. People receiving COVID-19 vaccines are less likely to die from COVID-19 and its complications **and are at no greater risk of death** from non-COVID causes, than unvaccinated people.

CDC scientists and partners have performed detailed assessments of deaths after COVID-19 vaccination and made the information available to healthcare providers and the public.

Scientific Publications about Death following COVID-19 Vaccination

A Safety Study Evaluating Non-COVID-19 Mortality Risk Following COVID-19 Vaccination
Synopsis: This study found that rates of death among people who received COVID-19 vaccines were lower than those of people who did not receive COVID-19 vaccines. In the largest study of its kind to date, the authors found no increased risk of death among people who received the Pfizer-BioNTech, Moderna, or Johnson and Johnson's Janssen (J&J/Janssen) COVID-19 vaccines.

COVID-19 Vaccination and Non-COVID-19 Mortality Risk—Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021
Synopsis: Using data from the Vaccine Safety Datalink (VSD), this study found that rates of death among people who received COVID-19 vaccines were lower than those of people who did not receive COVID-19 vaccines. The authors determined that there is no increased risk of death among COVID-19 vaccine recipients, reinforcing the safety of COVID-19 vaccines currently authorized for use in the United States.

Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021
Synopsis: The authors of this study analyzed VAERS reports of death after COVID-19 vaccination and found that rates of death after vaccination were lower than background rates of death from any cause in the general population. The findings in this study do not suggest an association between COVID-19 vaccination and overall increased rates of death.

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
Synopsis: The authors of this study reviewed the initial six months of mRNA COVID-19 vaccine safety data from December 2020 through June 2021 in VAERS and v-safe and found that the most commonly reported side effects of mRNA vaccines were mild and short in duration and that the majority of reported adverse events were not serious. The authors also reviewed death reports submitted to VAERS and found no unusual patterns of death following mRNA vaccination.

Guillain-Barré Syndrome (GBS) after COVID-19 Vaccination

GBS is a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been observed among people ages 50 years and older.

Based on an analysis of data from the Vaccine Safety Datalink (VSD), the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA) COVID-19 vaccination. After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna vaccination.

Similarly, CDC found higher than expected rates of GBS reported to VAERS after J&J/Janssen COVID-19 vaccination but not after mRNA COVID-19 vaccination. These observations contributed to the preferential recommendation by the Advisory Committee on Immunization Practices (ACIP) to use mRNA COVID-19 vaccines over the J&J/Janssen COVID-19 vaccine, which is no longer available in the United States.

CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

Myocarditis and Pericarditis after COVID-19 Vaccination

Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly, and most cases have been reported after receiving mRNA COVID-19 vaccines.

To date, evidence indicates that the benefits of mRNA COVID-19 vaccination outweigh the risk of myocarditis. CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

Data from VSD and from VAERS indicate that rates of myocarditis after COVID-19 vaccination are highest among males in their late teens and early 20s, usually following the second dose of the vaccine.

CDC scientists have conducted detailed reviews of cases of myocarditis and pericarditis after COVID-19 vaccines and have made the information available to healthcare providers and the public.

Scientific Publications about Myocarditis and Pericarditis following COVID-19 Vaccination

Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States

Synopsis: Using VSD data, this study found that from December 14, 2020, through May 31, 2022 (for people ages 18-39 years) and from December 14, 2020, through August 20, 2022 (for people ages 5-17 years), 320 potential cases of myocarditis and pericarditis developed within 1-98 days after vaccination. Out of 320 potential cases, 224 were verified, with 137 occurring 0-7 days after vaccination: 18 after the first dose and 119 after the second dose. Adolescent males were shown to have higher incidence of myocarditis and pericarditis.

Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study

Synopsis: This study found that approximately 80% of patients diagnosed with myocarditis after receiving an mRNA COVID-19 vaccine were considered recovered by healthcare providers at least 90 days following onset of symptoms. CDC collected the data through follow-up surveys for people ages 12-29 years for whom a report of myocarditis after mRNA COVID-19 vaccination was made to VAERS from December 2020 through November 2021.

Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination

Synopsis: The authors of this study reviewed health records of a diverse population to assess any risk of myocarditis or pericarditis associated with receiving an mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) vaccine. From December 14, 2020, through January 15, 2022, 41 cases of myocarditis and pericarditis were reported after receipt of the Pfizer-BioNTech vaccine, and 38 were reported after receipt of the Moderna vaccine. In most cases, patients were hospitalized for one day or less, but no patients required intensive care. Both vaccines showed an increased risk of myocarditis and pericarditis among young males ages 18-39 years. Risk of myocarditis and pericarditis was higher after receipt of the Moderna vaccine than after receipt of the Pfizer-BioNTech vaccine within 0-7 days after administration.

Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination

Synopsis: This study revealed that a longer period between mRNA COVID-19 vaccine doses one and two may lower the risk of myocarditis and pericarditis. Data from VSD were evaluated for reported rates of myocarditis or pericarditis after receipt of an mRNA vaccine (Moderna or Pfizer-BioNTech). Results showed reported rates of myocarditis or pericarditis were higher after vaccination with Moderna than with Pfizer-BioNTech and were higher among adolescents and young adult males following the second dose.

Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021

Synopsis: This study found that there was a small but increased risk for myocarditis following receipt of mRNA-based COVID-19 vaccines. After a review of reports submitted to VAERS, this study found that the risk of myocarditis was highest following the second vaccine dose among adolescents and young adult males.

Thrombosis with Thrombocytopenia Syndrome (TTS) after COVID-19 Vaccination

Thrombosis with thrombocytopenia syndrome (TTS) has been rarely observed after J&J/Janssen COVID-19 vaccination and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. This observation contributed to the preferential recommendation by ACIP to use mRNA COVID-19 vaccines over the J&J/Janssen COVID-19 vaccine, which is no longer available in the United States.

CDC scientists have conducted detailed reviews of TTS cases and have made the information available to healthcare providers and the public.

Scientific Publications about Thrombosis with thrombocytopenia syndrome following COVID-19 Vaccination

US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021

Synopsis: This study revealed that, of the approximately 7 million doses of J&J/Janssen COVID-19 vaccine given from March 2 through April 12, 2021, VAERS received 12 reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia among women ages 18 to 59 years. All were hospitalized; 10 were admitted to intensive care units (ICUs). As of April 21, 2021, 4 patients had been sent home, 2 had been moved to hospital units outside of ICU, 3 were continuing ICU care, and 3 had 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, a similar vector vaccine as the J&J/Janssen COVID-19 vaccine.

Case Series of Thrombosis with Thrombocytopenia Syndrome After COVID-19 Vaccination—United States, December 2020 to August 2021

Synopsis: Clinicians from the Clinical Immunization Safety Assessment (CISA) Project reviewed VAERS reports of TTS following COVID-19 vaccination. Of over 14.1 million doses of J&J/Janssen vaccine and 351 million doses of mRNA vaccines administered from December 14, 2020, through August 31, 2021, CISA confirmed 57 reports of TTS: 54 following receipt of the J&J/Janssen vaccine and 3 following receipt of mRNA vaccines. Most cases of TTS following J&J/Janssen vaccination occurred in females and in people younger than 50 years, and all cases involved hospitalization. The reporting rate of TTS cases after J&J/Janssen vaccination was 3.83 per one million doses administered, whereas the rate following mRNA vaccination was consistent with the background rate of TTS (.0085 per million doses administered). This analysis concluded that TTS is a rare but serious adverse event associated with J&J/Janssen COVID-19 vaccination.

Updates on Thrombosis with Thrombocytopenia Syndrome (TTS) [1.3 MB, 39 Pages]

Synopsis: This December 16, 2021 CDC presentation to the Advisory Committee on Immunization Practices (ACIP) showed that the TTS case reporting rate (3.8 per one million doses) following J&J/Janssen COVID-19 vaccination in the U.S. was higher than that previously presented. Reporting rates for men ages 40-49 years and for women ages 50-64 years were similar to women ages 18-29 years (about 4-5 per one million doses). U.S. TTS deaths following J&J/Janssen vaccination had typical features of severe CVST and were more common than those known during previous presentations to ACIP. The TTS death reporting rate was approximately 2 per one million doses in women ages 30-49 years, and the proportion of TTS cases involving death did not decrease after the J&J/Janssen vaccination pause.

Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices – United States, December 2021

Synopsis: Cases of TTS and GBS have been reported after receiving the J&J/Janssen COVID-19 vaccine. On December 16, 2021, after reviewing updated vaccine effectiveness and safety data, ACIP made a preferential recommendation for mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccines over the J&J/Janssen COVID-19 vaccine for people ages 18 years and older in the United States.

Related Pages

- Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- COVID-19 Vaccine Safety Publications

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