




COVID-19

# Selected Adverse Events Reported after COVID-19 Vaccination

Updated May 31, 2023

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.

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## 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

- COVID-19 vaccines are **safe and effective and severe reactions after vaccination are rare**.
- CDC recommends everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) [↗](#).
- VAERS accepts reports of any adverse event following vaccination.

**The benefits of COVID-19 vaccination continue to outweigh any potential risks.**

CDC is providing timely updates on the following adverse events of interest:

- **Anaphylaxis after COVID-19 vaccination is rare** and 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:
  - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine [↗](#)
  - Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021 [↗](#)
  - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021
  - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020
- **Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare** 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. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

- US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 [🔗](#)
- [Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021](#) [🔗](#)
- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS) [📎](#)  
[1.3 MB, 39 Pages]

- **Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare.** GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.

Based on a recent analysis of data [🔗](#) from the Vaccine Safety Datalink, 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 vaccines). 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 (mRNA COVID-19 vaccines). Similarly, CDC found higher than expected rates of GBS reported [🔗](#) to the Vaccine Adverse Event Reporting System (VAERS) after J&J/Janssen COVID-19 vaccination but not after mRNA COVID-19 vaccination. 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 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. Most cases have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data [🔗](#) in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of March 2, 2023, there have been 1,059 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 244 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 715 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

- 5-11 years: 23 verified reports of myocarditis after 23,376,785 doses administered
- 12-15 years: 376 verified reports of myocarditis after 25,913,772 doses administered
- 16-17 years: 316 verified reports of myocarditis after 14,180,263 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

- **Reports of death after COVID-19 vaccination are rare.** FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.** More than 672 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 1, 2023. During this time, VAERS received 19,476 preliminary reports of death (0.0029%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

## 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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Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases