Vaccine Safety

Coronavirus Disease 2019 (COVID-19) Vaccine Safety

JAN. 31, 2025

COVID-19 VACCINE RECOMMENDATIONS

COVID-19 vaccine recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule. Learn more.

KEY POINTS

- Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by the SARS-CoV-2 virus.
- You can protect against severe COVID-19 disease with vaccination.
- CDC continuously monitors the safety of COVID-19 vaccines using several different safety systems.

Overview

COVID-19 (coronavirus disease 2019) is a disease caused by the SARS-CoV-2 virus. COVID-19 most often causes respiratory symptoms that can feel much like a cold, the flu, or pneumonia. Most people with COVID-19 have mild symptoms, but some people become severely ill. You can protect against severe COVID-19 disease with vaccination. CDC, working with FDA and other federal agencies, continuously monitors COVID-19 vaccines through several safety systems.

Available vaccines

Everyone ages 6 months and older should get an updated COVID-19 vaccine. Currently, there are two types of COVID-19 vaccines for use in the United States: mRNA and protein subunit.

Did you know?

These vaccines have been updated for 2024-2025 to protect against circulating variants of the virus that causes COVID-19.

Fully licensed FDA vaccines

Below are fully licensed COVID-19 vaccines.

- Comirnaty is an mRNA COVID-19 vaccine manufactured by Pfizer, Inc. It is approved for use in people ages 12 years and older. It is a single dose injection.
- Spikevax is an mRNA COVID-19 vaccine manufactured by Moderna, Inc. It is approved for use in people ages 12 years and older. It is a single dose injection.

Emergency Use Authorized vaccines

Below are COVID-19 vaccines authorized for emergency use by FDA.

- Pfizer-BioNTech COVID-19 vaccine is authorized for emergency use in children ages 6 months to 11 years.
- Moderna COVID-19 vaccine is authorized for emergency use children ages 6 months to 11 years.
- Novavax is a protein subunit COVID-19 vaccine. It is authorized for emergency use in people ages 12 years and older.

KEEP READING

Vaccine Information Statements

Who should & should not get the vaccine

CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination. Specific COVID-19 vaccine recommendations vary by group.

- People ages 6 months and older
- Moderately to severely immunocompromised people
- Women who would like to have a baby
- Women who are pregnant or breastfeeding
- Long-term care residents

Common side effects

Vaccines, like any medical product, can have side effects. Side effects reported after COVID-19 vaccination vary from person to person. Most common side effects are usually mild, such as soreness in the area where the shot was given. Everyone who gets a COVID-19 vaccine may be monitored onsite for at least 15 minutes after vaccination (people who experience or have experienced non-severe allergic reactions to COVID-19 vaccines may be monitored for 30 minutes).

mRNA vaccines (Pfizer-BioNTech and Moderna)

- Pain, soreness, redness at injection site
- Fatigue
- Headache
- Muscle pain
- Joint pain
- Chills
- Fever
- Nausea/vomiting (Moderna)
- In infants and toddlers, common symptoms include irritability or crying, decreased appetite, and sleepiness.

Protein subunit vaccine (Novavax)

- Pain, soreness, redness, swelling at injection site
- Fatigue
- Headache
- Muscle pain
- Joint pain
- Chills
- Fever
- Nausea/vomiting

Keep in mind

If you had side effects (e.g., vomiting; shortness of breath; a red, itchy, swollen, or painful rash where you got the shot) within 4 hours of getting a COVID-19 vaccine, you can likely still receive the same type of vaccine at your next recommended dose (or your next annual dose). Your provider might recommend giving the vaccine in the opposite arm or observing you for 30 minutes after vaccination. If your doctor or healthcare provider thinks your reaction might be because of an allergy, they may refer you to an allergy and immunology specialist for additional care or advice.

Severe allergic reactions

Severe allergic reactions following vaccination are rare but can be life threatening. Signs and symptoms of a severe allergic reaction can include:

- Anaphylaxis, a life-threatening reaction that needs to be treated with epinephrine (EpiPen) and that may require hospitalization. Symptoms include difficulty breathing, coughing, or wheezing.
- Low blood pressure or rapid heartbeat
- Swelling of the lips, tongue, or throat
- A widespread skin rash that can itch, be red, or cause raised bumps (hives). Can also include general swelling of parts of the body (like the face, arms, or legs).
- A rash in places like inside your mouth or nose. This requires hospitalization.

When to call 911

If someone has symptoms of a severe allergic reaction — which can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness — call 911 immediately.

If you had a severe allergic reaction after receiving a particular type of COVID-19 vaccine (either mRNA or Novavax), you should not get another dose of that type of vaccine. You will likely be able to receive the alternate vaccine type. Your doctor may refer you to an allergy and immunology specialist for additional care or advice.

In rare cases, people have experienced serious health events after COVID-19 vaccination. An adverse event (any side effect or health problem after vaccination that is concerning to you, even if you are not sure if the vaccine caused the event) can be caused by the vaccine or be a coincidental event that is not related to the vaccine, such as an unrelated fever, that happened following vaccination.

A closer look at the safety data

- During the COVID-19 pandemic, COVID-19 vaccines underwent the most intensive safety analysis in U.S. history.
- COVID-19 vaccines continue to be monitored for safety, even after FDA approval, to make sure they continue to meet FDA's standards for safety and effectiveness. [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] [11] [12] [13]

To date, the systems in place to monitor the safety of COVID-19 vaccines currently used in the United States have identified anaphylaxis and myocarditis or pericarditis as serious types of adverse events following COVID-19 vaccination. Other rare events, such as Guillain-Barré syndrome (GBS), are also monitored for and studied.

Anaphylaxis

- Anaphylaxis is a rare but serious type of allergic reaction that can occur after any vaccine. Anaphylaxis can require immediate treatment with epinephrine (EpiPen) and may require hospitalization. Healthcare providers can effectively and immediately treat the reaction. Symptoms of anaphylaxis can include wheezing, difficulty breathing, low blood pressure, or hives. Anaphylaxis after COVID-19 vaccination is rare. [1] [4] [5] [7] [11] [14] [15] [16]
- Anaphylaxis occurs at a rate of approximately 5 cases per one million vaccine doses administered.

Myocarditis and Pericarditis

Myocarditis and pericarditis after COVID-19 vaccination are rare. [1] [2] [3] [4] [5] [6] [7] [9] [11] [12] [17] [18] [19] [20] [21]

- Myocarditis is inflammation of the heart muscle. Most patients with myocarditis after COVID-19 vaccination respond well to medicine and rest and feel better quickly.
- Pericarditis is inflammation of the outer lining of the heart. Most patients with pericarditis after COVID-19 vaccination respond well to medicine and rest and feel better quickly.

The evidence suggests that, although rare, these events are linked to certain types of COVID-19 vaccinations. For example, myocarditis has been most frequently seen in adolescent and young adult males within 7 days of their second mRNA COVID-19 vaccine dose. (Cases have also been observed in females, in other age groups, and after other vaccine doses.) Healthcare providers should review additional recommendations and clinical guidance on myocarditis considerations.

Investigating long-term effects of myocarditis

- Surveys of patients diagnosed with myocarditis who developed symptoms at least three months prior to answering the survey showed most patients (80%) were considered by their cardiologist or other healthcare provider to have either fully or probably fully recovered. [22]
- Results of longer-term surveys (e.g., one year after a patient was diagnosed with myocarditis) are pending and should be available soon.

Guillain-Barré Syndrome (GBS)

- Guillain-Barré syndrome (GBS) is a rare disorder in which the body's immune system damages nerves. The damage causes muscle weakness and sometimes paralysis.
- Based on data from the Vaccine Safety Datalink (VSD), the rate of GBS within the first 21 days after receiving the J&J/Janssen COVID-19 vaccine was found to be 21 times higher than after receiving the Pfizer-BioNTech or Moderna (mRNA) COVID-19 vaccines.
- After the first 42 days, the rate of GBS was 11 times higher after receiving the J&J/Janssen COVID-19 vaccine. Research found no increased risk of GBS after receiving the Pfizer-BioNTech or Moderna vaccines.
- Similar to the data findings, CDC found higher than expected rates of GBS reported to VAERS after receiving the J&J/Janssen COVID-19 vaccine but not after receiving the Pfizer-BioNTech or Moderna COVID-19 vaccines.
- Based on the findings from this data, the Advisory Committee on Immunization Practices (ACIP) recommended using mRNA COVID-19 vaccines instead of the J&J/Janssen COVID-19 vaccine, which is no longer available in the United States as of May 2023.

Thrombosis with Thrombocytopenia Syndrome (TTS)

- Thrombosis with thrombocytopenia syndrome (TTS) is a rare condition that has been seen in very few cases after getting the J&J/Janssen COVID-19 vaccine. It occurred in about 4 people per one million doses, with higher rates among women ages 30-49 years (9-10 cases per million). TTS causes blood clots and low platelets (blood cells that help with clotting).
- After reviewing data reports, a link between the J&J/Janssen vaccine and TTS was found. This finding led to the ACIP recommendation to use mRNA COVID-19 vaccines instead of the J&J/Janssen COVID-19 vaccine, which is no longer available in the United States. [23] [24] [25] [26]

Reports of deaths

Reports of death after COVID-19 vaccination can be concerning. CDC is committed to providing clear and accurate information so that you can make informed, confident decisions about your health.

- Several factors explain reports of death after COVID-19 vaccination. These include:
  - FDA rules that require healthcare providers to report any death after vaccination to VAERS (even if it is unclear that the vaccine was the cause).
  - CDC's reporting requirements for vaccine providers.
  - Increased public awareness of COVID-19 vaccines.
- Data shows that people who receive COVID-19 vaccines are less likely to die from COVID-19 or COVID-19-related complications than those who are unvaccinated.
- COVID-19 vaccines do not increase the risk of death from non-COVID causes when compared to those who have not been vaccinated. [27] [28] [29] [30]

How CDC monitors vaccine safety

CDC and FDA are committed to monitoring the safety of vaccines. Once vaccines are licensed or authorized by FDA for use in the United States, CDC, FDA, and other federal agencies work together to monitor them using several safety systems.

Report possible adverse events to VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system co-managed by CDC and FDA that monitors for potential vaccine safety problems. Healthcare providers and vaccine manufacturers are required to report specific adverse events (any side effect or health problem after vaccination that is concerning to you, even if you are not sure if the vaccine caused the event) following vaccination to VAERS, including those listed by the manufacturer as a contraindication (a reason not to get more doses of a vaccine). Patients and caregivers can also submit reports to VAERS.

Submitting a Vaccine Adverse Event Reporting System (VAERS) Report and Using VAERS Data

Share how you feel after COVID-19 vaccination with V-safe

V-safe is part of the U.S. vaccine safety system that monitors the safety of vaccines. V-safe lets you share with CDC how you or your dependent feel after getting a COVID-19 vaccine. After you sign up and select the vaccine you received, V-safe will send you questions by text message or email to ask how you feel after vaccination. It's important to know that sharing how you feel, even if you don't experience vaccine side effects, helps CDC monitor the safety of select vaccines.

KEEP READING
About CDC's Vaccine Safety Monitoring Program

Resources

Who Should NOT Get Vaccinated with these Vaccines?

Who should NOT Get Vaccinated?

ACIP Recommendations: COVID-19 Vaccine

Review current and archived ACIP vaccine recommendations for COVID-19.

CDC COVID-19 Vaccination Program Provider Requirements and Support

Requirements and support for COVID-19 vaccination providers participating in the CDC COVID-19 Vaccin...

Contraindications and Precautions

Contraindications and Precautions: General Best Practice Guidelines for Immunization. Advisory Commi...

Immunization Schedules

Stay up-to-date on getting recommended vaccines. Here are immunization schedules for people of all a...

SOURCES

CONTENT SOURCE:
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

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