

# Is the COVID-19 Vaccine Safe?

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The arrival and distribution of safe, effective COVID-19 vaccines is a major development in the coronavirus pandemic. As more people are vaccinated, families and communities will be able to gradually return to a more normal routine.

[Lisa Maragakis, M.D., M.P.H.](#), senior director of infection prevention, and [Gabor Kelen, M.D.](#), director of the Johns Hopkins Office of Critical Event Preparedness and Response, answer questions about the safety of the COVID-19 vaccines.

## Vaccine for Coronavirus: Is it safe?

All three vaccines authorized for emergency use by the Food and Drug Administration (FDA) have been thoroughly tested and found to be safe and effective in preventing severe COVID-19. They continue to undergo continuous and intense safety monitoring.

Please see below for more information and safety guidance for the Johnson & Johnson COVID-19 vaccine and information about rare cases of myocarditis associated with the Pfizer and Moderna COVID-19 vaccines.

Johns Hopkins Medicine is administering all three COVID-19 vaccines: [Pfizer-BioNTech](#), [Moderna](#) and [Johnson & Johnson](#). We view all three vaccines as highly

effective in preventing serious disease, hospitalization and death from COVID-19 and that their benefits outweigh their risks.

## Myocarditis and the COVID-19 Vaccines

Since April 2021, there have been more than a thousand reports of cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) happening after receiving the Pfizer-BioNTech or Moderna coronavirus vaccines in the United States, according to the U.S. Centers for Disease Control and Prevention (CDC).

Considering the hundreds of millions of COVID-19 vaccine doses that have been administered, these reports are very rare. The problem occurs more often in adolescents (teens) and young adults, and in males. The myocarditis or pericarditis in most cases is mild and resolves quickly.

Seek medical attention right away if, within a few days of receiving the second injection of an mRNA COVID-19 vaccination (Pfizer-BioNTech, Moderna), you or your child experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heartbeat.

## Johnson & Johnson Vaccine

In April 2021, the Johnson & Johnson vaccine was paused while the FDA and the Centers for Disease Control and Prevention (CDC) investigated a small number of cases of rare blood clots in people who had received that vaccine. Nearly all reports of this problem have been in adult women younger than age 50. After careful review, the FDA and CDC recommended that administration of the J&J COVID-19 vaccine could safely resume. Johns Hopkins Medicine followed these recommendations, temporarily pausing and then resuming use of the J&J vaccine.

[Learn more about how Johns Hopkins Medicine responded to the pause.](#)

## Johnson & Johnson Vaccine and TTS, A Possible, Rare Side Effect

A small number of people have developed a serious blood clot condition after they received the J&J vaccine. Nearly all reports of this problem have been in adult women younger than age 50. A review of all available data at this time shows that the J&J vaccine's known and potential benefits outweigh its known and potential risks.

However, women younger than age 50 should be aware of this rare adverse event and should know that other COVID-19 vaccines are available.

For three weeks after receiving the J&J vaccine, you should watch for possible symptoms of a blood clot with low platelets called thrombosis with thrombocytopenia syndrome, or TTS. Although very rare and treatable when diagnosed in time, TTS is serious.

Get medical help immediately if you have any of these symptoms within 3 weeks of receiving the J&J coronavirus vaccine:

- Severe or persistent headaches or blurred vision
- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Easy bruising or tiny blood spots under the skin near the injection site

## Should I be worried about vaccine safety?

Over the past months, millions of people in the U.S. have been safely vaccinated. The FDA and CDC continue to carefully monitor each of the authorized COVID-19 vaccines for safety concerns.

These organizations are being thorough and transparent. One example is that in April 2021 the CDC and FDA paused administration of the J&J vaccine so they could review data on a few reported cases of serious blood clots following vaccination with that vaccine. After this review, the FDA and CDC determined that the benefits of the J&J vaccine outweigh the risk of this very rare side effect, and authorized vaccination with the J&J shot to resume.

Similarly, after observing rare occurrences of myocarditis following the second injection of the Pfizer and Moderna COVID-19 vaccines, the CDC released [information for the public](#).

They will continue to communicate with the public about their findings and any possible safety issues with this or any other COVID-19 vaccine. Any potential safety risks of COVID-19 vaccines must be weighed against the known serious risk of harm due to the COVID-19 infection and the benefits of protection that the vaccines offer.

## What steps are taken to make sure the COVID-19 vaccines are safe?

Safety is always a top priority as federal agencies work with vaccine manufacturers to develop and authorize new vaccines. Here are some of the steps:

- **Careful testing.** All vaccines go through clinical trials to test safety and effectiveness. For the COVID-19 vaccine, the FDA set [high safety standards](#) for vaccine developers to meet. This [infographic from the National Institutes of Health shows the four phases a vaccine goes through](#) before it is released to the public.
- **Authorization for emergency use.** If a vaccine or medicine is needed to address an emergency situation such as the coronavirus pandemic, once it is shown to be safe and effective, the FDA can grant it an emergency use authorization, or EUA. An EUA allows a vaccine, treatment or medication to be used before the formal FDA approval.
- **Continuous monitoring for problems and side effects.** Once a vaccine gets an EUA and is being given to people, the FDA and the U.S. Centers for Disease Control and Prevention (CDC) continue to watch carefully to make sure no problems arise. Data on the vaccine's safety record accumulates over time when more and more people who receive it report on their experience and any side effects they experience. One important way to report any adverse events after vaccination is through the [Vaccine Adverse Events Reporting System \(VAERS\)](#).

You can learn more from the [CDC about the safety steps for the COVID-19 vaccine](#).

## Have there been any COVID-19 vaccine safety concerns?

Issues concerning the Johnson & Johnson COVID-19 vaccine and a rare incidence of myocarditis after the Pfizer and Moderna COVID-19 vaccines, as noted above have been reported.

Trials for the vaccines have had fully independent safety monitoring boards, and safety data are continuously reviewed by the FDA and expert panels. The number of serious problems in test participants was very low, and there was little difference between those who received the actual vaccine and those who received a placebo. Millions of people have received the vaccines since their authorization, and careful safety monitoring of all three COVID-19 vaccines continues.

## Is there risk of allergic reaction from COVID-19 vaccine?

According to the CDC, anyone who has a known severe allergy (e.g., anaphylaxis) to any of the vaccine ingredients **should not receive that vaccine**.

The CDC says people with allergies to certain foods, insects, latex and other common allergens can safely receive the COVID-19 vaccine. Those with a history of severe allergic reaction (anaphylaxis) to injectables or other vaccines should discuss the vaccination with their doctor, who can evaluate and assess their risk.

## How Do We Know a COVID-19 Vaccine Will Be Safe and Effective?

## What are the COVID vaccine side effects?

Some people notice side effects of the COVID-19 vaccine, such as pain or swelling where they got the vaccine. You may also get fever, muscle aches, chills, fatigue, headaches or a combination of these symptoms.

COVID-19 vaccine side effects may last about a day or two, and do not signify illness. These are signs that your immune system is responding and preparing to fight the coronavirus if you catch it. If symptoms persist, you should call your doctor.

## For the 2-dose vaccines, are side effects different from the first to second shot?

Both the Pfizer and the Moderna COVID-19 vaccinations involve two injections separated by several weeks. For these two-shot vaccinations:

- If you previously had COVID-19 before being vaccinated, the first injection may cause more noticeable side effects than for people who have not had the virus.
- If you have never had COVID-19, you may notice more side effects after the second dose than after the first dose.

## Demographics of the COVID-19 Vaccine Trials

### How was the COVID-19 vaccine developed so quickly?

In the past, vaccines have taken many years to develop. However, the relatively quick development of this vaccine does not mean safety measures were skipped. There are several reasons why the COVID-19 vaccines were developed faster than other vaccines:

- The technologies used to develop the COVID-19 vaccines have been years in development to prepare for outbreaks of infectious viruses. The manufacturing processes were ready very early in the pandemic.
- Countries shared genetic information about the SARS-CoV-2 coronavirus when it was available, which gave vaccine developers an early start at finding a vaccine.
- The testing processes for the vaccines didn't skip any steps, but the vaccine developers conducted some stages of the process simultaneously to gather as much data as quickly as possible.
- Governments gave money to vaccine developers in advance, so the companies had resources they needed.
- Some types of COVID-19 vaccines were created using [messenger RNA \(mRNA\)](#), a new technology that allows a faster approach than the traditional way vaccines are made.

- Social media enabled companies to reach out to and enroll study volunteers, and plenty of people wanted to help, so there were enough research participants to test the COVID-19 vaccines.
- Because the SARS-CoV-2 coronavirus is so contagious and widespread, many volunteers who got the vaccine were exposed to the virus, and with so many exposures, the trials took a shorter time to see if the vaccine worked.
- Companies began manufacturing vaccines ahead of their authorization or approval so some supplies would be ready if authorization occurred.

## How effective are COVID-19 vaccines?

All authorized vaccines are very good at preventing severe infection, hospitalization and death from COVID-19. The testing methods for the vaccines are not all alike, which makes it difficult to compare them. Johns Hopkins Medicine considers them to be equally effective.

### **Why is it Important that I Consider Getting the COVID-19 Vaccine?**

## Do I still have to wear a mask and continue COVID-19 safety precautions if I get the vaccine?

The CDC continues to monitor the spread of COVID-19 and makes recommendations for wearing face masks, both for those who are [fully vaccinated](#) as well as those who are not fully vaccinated.

The CDC also recommends that masks and physical distancing are required when going to the doctor's office, hospitals or long-term care facilities, including all Johns Hopkins hospitals, care centers and offices.

Johns Hopkins Medicine's current mask safety guidelines have not changed, and we still require all individuals to wear masks inside all of our facilities.

## Can I get COVID-19 from the vaccine?

You cannot and will not get COVID-19 from any of the vaccines. The COVID-19 vaccines do not have any virus or other infectious material in them.

## What about safety of the COVID-19 vaccination for diverse groups of people?

The FDA and other reviewers closely consider diverse populations included in the trials for safety purposes. The clinical trials for the first two COVID-19 vaccines included

underrepresented minorities, older age groups, and people with conditions such as obesity, diabetes and heart and respiratory conditions.

## Does Johns Hopkins Medicine recommend I get a COVID-19 vaccine?

Deciding whether or not to be vaccinated for COVID-19 is up to you. Johns Hopkins Medicine views all three available COVID-19 vaccines as highly effective in preventing serious disease, hospitalization and death from COVID-19. We believe the benefits of being vaccinated for COVID-19 significantly outweigh the risks. Along with the Centers for Disease Control and Prevention (CDC), we encourage those interested in getting vaccinated to take whichever vaccine is made available from any legitimate and authorized organization.