# Get answers about the COVID-19 vaccine



11/8/2021

The FDA has authorized the Pfizer/BioNTech (Comirnaty) COVID-19 vaccine for anyone 5 and older. This is an exciting and important step in the fight to end the pandemic. **The Pfizer vaccine is the only COVID-19 vaccine authorized for children.** The Moderna and Johnson & Johnson/Janssen vaccines are authorized for people ages 18 and older.

COVID-19 vaccines are not only incredibly effective at preventing sickness, hospitalization, and death¹ but will help us return to our normal activities. The vaccines work against the new variants of the virus identified so far.² People who choose to get vaccinated not only protect themselves from the virus, but also help protect those in our community who may be more vulnerable or who are unable to get vaccinated right now.





## Should I get vaccinated if I've already had COVID-19?

Right now, we recommend that you get vaccinated even if you've been diagnosed with COVID-19 before. We can't predict who will get severely ill from infection or suffer long-term health effects from it. Vaccination is a much safer and effective way to develop immunity than being infected by the virus and having COVID-19 as a disease.

We know people can get immunity from both infection and vaccination. The vaccines provide additional protection from the disease and possible reinfections.<sup>3</sup> Right now, we don't have good tests that can tell us how immune someone is from COVID-19 and for how long. Immunity from vaccination provides a much more consistent and predictable level of immunity across people and communities.

Studies<sup>4</sup> show varying levels of immunity after infection with COVID-19. Preliminary evidence from the United Kingdom indicates the Delta variant may cause more reinfections than other strains of the virus we've seen. According to the CDC, people get better protection by being fully vaccinated compared with having had COVID-19. One study<sup>5</sup> showed that unvaccinated people who already had COVID-19 are more than 2 times as likely than fully vaccinated people to get COVID-19 again.

- $1\ https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/04-COVID-Oliver-508.pdf$
- 2 https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
- $3\ \underline{https://yourlocalepidemiologist.substack.com/p/vaccine-for-5-11-year-olds-acip-cliff}$
- 4 https://yourlocalepidemiologist.substack.com/p/natural-immunity-protection-and-variants
- 5 https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm





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## What side effects could I have after getting the vaccine?<sup>6</sup>

The COVID-19 vaccine are safe and effective. But, like all medicines, some people may have side effects, so it's important to be aware of what those are and things to watch for.

#### **Common side effects**

You may feel sick after getting vaccinated or have other side effects, for a few days. These are normal signs the body is building protection and the immune system is doing what it is supposed to do. These side effects usually go away in 12-48 hours and don't require you to go to a doctor. Some people have no side effects or may have different side effects after their 2nd dose than they did after their 1st shot. You should still get your 2nd dose of mRNA COVID-19 vaccine if you had mild or moderate side effects after your first dose. You need both doses to be fully protected.

#### On the arm where you got the shot:

- Pair
- Redness
- Swelling

### Throughout the rest of your body:

- Chills
- Diarrhea
- Fever or feeling sweaty
- Headache
- Muscle pain
- · Nausea, or feeling sick to your stomach
- Tiredness

#### Less common side effects

Some children may experience swollen and tender lymph nodes (called lymphadenopathy), usually in the armpit or neck area.

Some people may have a red, itchy, swollen, or painful rash where they got the shot, often called "COVID arm." These rashes can start a few days to more than a week after the 1st shot. If your child has "COVID arm" after getting the 1st dose, they should still get the 2nd dose. Ask your child's doctor about treating this with an antihistamine to help with itchiness, or acetaminophen or a non-steroidal anti-inflammatory drug (NSAID) for pain.



## Helpful tips to manage side effects

It's best to wait as long as you can to take any pain medicine after you get a vaccine. Talk to your doctor about taking an over-the-counter medicine, like ibuprofen, acetaminophen (often called Tylenol), or naprosyn, to help with pain or discomfort from any side effects.

It's important to keep taking any long-term daily medications after vaccination, unless your doctor has told you not to.

#### To reduce pain and discomfort where you got the shot:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

#### To reduce discomfort from fever:

- Drink plenty of water.
- Dress lightly, in clothes that won't make you hot.











#### When to call a doctor

In most cases, you will only experience normal side effects that don't require you to go to a doctor. Call a doctor or healthcare provider:

- If the redness or tenderness where you got the shot starts to get worse after 24 hours (or 1 day).
- If you are worried about any unusual symptoms you may have, or have questions about a combination of side effects from getting more than one vaccine at the same time.
- If you are worried about your side effects or the side effects don't seem to be going away after a few days.

Call a doctor right away if you have any of these symptoms up to 3 weeks after getting a COVID-19 vaccine:

- Abnormal heartbeat (feelings of having a fast-beating, fluttering, or pounding heart)
- Blurred vision
- · Chest pain
- Confusion or trouble speaking
- Fainting or loss of consciousness
- Leg swelling
- New or easy bruising
- Petechiae (tiny red spots on the skin)
- Severe abdominal pain that won't go away
- Severe headaches or headaches that won't go away
- Seizures
- Shortness of breath
- Weakness or sensory changes



## Severe or serious side effects after getting a vaccine are rare<sup>7</sup>

Allergic reactions are considered severe if someone needs to be treated with epinephrine or an EpiPen© or go to the hospital. These types of reactions are called anaphylaxis, and almost always happen within 30 minutes after getting the vaccine. These types of reactions are rare (about 2 to 5 people per million who are vaccinated). People may have trouble breathing, have swelling of the face and throat, a fast heartbeat, a bad rash all over the body, or dizziness and weakness. This is why it's important to stay for 15-30 minutes after getting vaccinated, so your doctor can watch you and make sure everything is okay. Medicines are available to treat anaphylaxis. Anyone who has an anaphylactic reaction after their 1st dose of the vaccine should not get the 2nd dose.

#### Non-severe, immediate allergic reactions are also rare.

Allergic reactions that do not require emergency care or hospitalization are called a nonsevere, immediate allergic reaction. These types of reactions happen within 4 hours after getting vaccinated. People may get hives, swelling, or wheezing. If your child has a nonsevere, immediate allergic reaction after getting a dose of the COVID-19 vaccine he or she should not get a 2nd dose, even if the reaction was not severe enough to require emergency care or hospitalization.



7 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html





#### The chance of long-term side effects is extremely low.

While it's true we don't have decades of information on potential side effects of COVID-19 vaccines, we do have many years of knowledge of the human body and mRNA. Based on this information, we don't expect to see long-term side effects from the vaccines.

If you look at the history of all vaccinations, almost every long-term side effect from vaccination shows up within 6 weeks after the vaccine is given. That's why the FDA requires a wait time of at least 60 days after the end of a clinical trial before an emergency use authorization (EUA) can be given. We have more than a year of follow up data from the first people who got the vaccines in clinical trials and there is no evidence of any long-term side effects.

Vaccine ingredients are cleared from our bodies very quickly after vaccination. mRNA is fragile and breaks down in the body in a few days. The ingredients in the vaccines don't stay in your body.

#### The FDA and CDC will keep monitoring any possible rare side effects.

The vaccines were developed with decades of research and by cutting red tape and bureaucracy, not by cutting corners or skipping any safety precautions. Scientists have been working for more than a decade with the technology used to develop the vaccines. The millions of cases of COVID-19 across the world allowed scientists to quickly study the virus to develop a vaccine that was safe and effective. Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in history. The FDA, CDC, Vaccines and Related Biological Products Advisory Committee (VRBPAC),<sup>8</sup> and Advisory Committee on Immunization Practices (ACIP)<sup>9</sup> have carefully reviewed all available data and are confident the vaccines are safe and effective to prevent COVID-19. **The chance you'll have of a life-threatening case of COVID-19 is much higher than your potential risk of ever getting a serious side effect from the vaccine.** 





The United States has one of the best systems in the world<sup>10</sup> to look for rare side effects that can only be found when vaccines are administered widely to many people. The CDC reports to the public whenever someone has reported an illness after getting a vaccine, whether or not the illness is caused by the vaccine. Anyone can report an illness or side effect after getting a vaccine, not just doctors. This information is reported through the Vaccine Adverse Event Reporting System (VAERS). VAERS data shows the number of things reported to VAERS—by anyone. It's important to remember that if a health problem is reported to VAERS, it doesn't mean that the vaccine caused the problem. It simply warns scientists, vaccine safety experts, and doctors of any potential problems that may need to be looked at more carefully. VAERS is our early warning system.

To make sure that COVID-19 vaccines are safe, the CDC expanded and strengthened the country's ability to monitor vaccine safety. The CDC created new ways to gather more information about the safety of COVID-19 vaccines. These web-based platforms give CDC scientists information about the safety of COVID-19 vaccines in real time. As a result, vaccine safety experts can monitor and find issues that may not have been seen during the COVID-19 vaccine clinical trials. If any vaccine safety issues—also called adverse events—are reported, CDC scientists can quickly study them and determine if there is a safety concern with a particular vaccine.

- $8\ https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-other-biologic$
- 9 https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s\_cid=mm7020e1\_w
- 10 https://www.cdc.gov/vaccinesafety/index.html
- 11 https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/323652-A COVID-19 VaccineSafety MonitoringSystems v9.pdf





An example of how well the system works was finding out so quickly that the Johnson & Johnson COVID-19 vaccine was associated with a very rare type of blood clot (thrombosis with thrombocytopenia syndrome or TTS) that needed to be treated differently than other types of blood clots. Of the 15.5 million doses of the Johnson & Johnson vaccine given in the United States, the CDC and FDA identified 48 confirmed reports of people who got this vaccine and later developed TTS. The VAERS system was able to identify the rare side effect and the CDC was able to tell doctors the best way to treat these blood clots. Now, even if someone were to get this rare side effect, doctors can effectively treat it. It is important to point out that the Johnson & Johnson vaccine is a different type of vaccine than the mRNA vaccines by Pfizer and Moderna. There has been no association with blood clots in more than 200 million doses of the Pfizer and Moderna vaccines. The Pfizer vaccine is the only COVID-19 vaccine authorized for children.

## **Myocarditis**

The vaccine safety system has received some reports of myocarditis (swelling and inflammation of the heart muscle) or pericarditis (inflammation of the membrane surrounding the heart) after vaccination with mRNA vaccines. 12 This usually happens after the 2nd dose, and is most likely to happen in males 12-17 years of age. 13 These are serious health conditions, but are conditions that can be treated. Most patients with myocarditis or pericarditis responded well to medicine and rest and felt better quickly. You can usually return to your normal daily activities after your symptoms improve. If you've been diagnosed with myocarditis, talk to your cardiologist (heart doctor) before you start exercising or participate in sports.



Myocarditis and pericarditis are very rare after a vaccination (only about 54 cases per 1 million doses<sup>14</sup>), but are not uncommon after being infected by a virus. About 10 to 20 people out of every 100,000 people in the United States are diagnosed and successfully treated for myocarditis each year after getting sick from a virus, like Lyme disease, flu, or COVID-19.

Symptoms of myocarditis or pericarditis usually appear within 7 days of vaccination. No children have died after vaccination from these rare illnesses, but the majority of those cases needed to be hospitalized. All of the children fully recovered in about 34 days. The CDC presented data to the safety review committees about the investigations into myocarditis deaths among people younger than 30 years old who had been vaccinated. In the 86 million doses of COVID-19 vaccine administered, there have been 9 reports of vaccine-induced myocarditis deaths. Among these 9 cases, 6 have been fully investigated thus far. Three deaths were confirmed as myocarditis. **Most importantly, all 3 were due to classic myocarditis (caused from infection of a bacteria or virus) and not due to the vaccine.** No myocarditis deaths have been linked to the vaccine in the United States.

The American Academy of Pediatrics<sup>15</sup> and the American Heart Association<sup>16</sup> have stated the benefits of COVID-19 vaccines still far outweigh any potential risk of this side effect.

- 12 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- $13\ \ https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age$
- 14 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html
- $15\ \underline{https://publications.aap.org/aapnews/news/16738?autologincheck=redirected}$
- 16 https://newsroom.heart.org/news/covid-19-vaccine-benefits-still-outweigh-risks-despite-possible-rare-heart-complications





### Why do children need to get vaccinated for COVID-19?

There is a common misunderstanding that children don't get COVID-19 or are not at risk for severe illness from the virus. This is not true. **COVID-19 is far more dangerous to children than any potential risks from getting a vaccine.** Children are infected with the virus at rates similar to adults and some children do get sick enough to require treatment in the hospital. About 30% of children hospitalized for COVID-19 had no underlying medical condition<sup>17</sup>.

We still don't know how being infected with COVID-19 will continue to impact children long-term. Many people—including children— who have been infected with the virus continue to suffer severe symptoms long after they were first infected. The United Kingdom Office for National Statistics's estimates nearly 13% of children aged 2-11 and 15% of children aged 12-16 report "long COVID" symptoms 5 weeks after their infection, even when their initial infection was mild<sup>18</sup>.



Since the beginning of the pandemic, more than 104,000 Utah children ages 0-17 have been diagnosed with COVID-19. Of these children, almost 90% (n=93,592) were school-aged (5-17 years old). More than 900 Utah children needed to be hospitalized. Of those requiring hospitalization in that age group, 104 developed multisystem inflammatory syndrome in children (MIS-C). MIS-C is a serious condition that can lead to death.

More than 600 children in the United States have died from COVID-19. Although the number of deaths in children seems low compared to the number of adults who have died, **COVID-19 is now a top 10 cause of death for children in the United States.** 



## Have the COVID-19 vaccines caused any fertility issues?

There is absolutely no data showing that any of the COVID-19 vaccines cause infertility or miscarriages. The American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine<sup>19</sup>, CDC<sup>20</sup>, MotherToBaby<sup>21</sup>, and many other reputable medical organizations recommend pregnant women get vaccinated for COVID-19. It's also not biologically possible that the tiny spike on the coronavirus spike protein can puncture the uterine lining and cause bleeding. It is safe to get vaccinated during pregnancy or while breastfeeding.

Pregnant women have an increased risk for severe illness and being hospitalized from COVID-19. Talk to your doctor if you have questions.

- $17\ \underline{https://yourlocalepidemiologist.substack.com/p/pediatric-vaccines-top-8-parental}$
- 18 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7927578/
- 19 https://www.acog.org/news/news-releases/2021/07/acog-smfm-recommend-covid-19-vaccination-for-pregnant-individuals
- $20 \ \underline{https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html}$
- 21 https://mothertobaby.org/fact-sheets/covid-19-vaccines/





### Have the COVID-19 vaccines caused any deaths?

There have been no deaths directly caused by the vaccines, out of more than 423 million doses of COVID-19 administered in the United States from December 14, 2020 to November 1, 2021.<sup>22</sup> During this time, VAERS received 9,367 reports of death (0.0022%) among people who got a COVID-19 vaccine. The FDA requires healthcare providers to report all deaths after COVID-19 vaccination to VAERS, even if the vaccine wasn't the cause. Reports of adverse events to VAERS, including deaths, don't necessarily mean that a vaccine caused the health problem. Medical professionals, doctors, scientists, and vaccine experts review medical records, death certificates, and autopsy reports for each report of a death in VAERS. After careful review, there have been no deaths directly caused by the vaccines.





However, reports show that the Johnson & Johnson COVID-19 vaccine can cause a rare and serious adverse event —blood clots with low platelets—in a very small number of people. Many doctors were not aware that these rare blood clots needed to be treated differently than they would treat other blood clots. Unfortunately, treating these rare blood clots with the same medicine as other blood clots can have very serious side effects—and a few individuals died—because their blood clots were not treated with the correct medicine. There has been

no association with blood clots and the mRNA vaccines (Pfizer or Moderna).

Johnson Johnson

There have been no deaths from any side effects (even rare ones) for the mRNA vaccines (Pfizer and Moderna).

## Who shouldn't get the Pfizer COVID-19 vaccine?<sup>23</sup>

The Pfizer/BioNTech (Comirnaty) COVID-19 vaccine is authorized or approved for people 5 years of age and older. You should **not** get this vaccine if you:

- Had a severe allergic reaction (anaphylaxis) or immediate allergic reaction after the 1st dose of the vaccine.
- Had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction even if it was not severe to any <u>ingredient</u> in the vaccine.

An allergic reaction is severe when a person needs to be treated with epinephrine or an EpiPen© or if the person must go to the hospital. An immediate allergic reaction happens within 4 hours after getting vaccinated and could include symptoms such as hives, swelling, and wheezing (respiratory distress).

Talk to your child's doctor before getting a COVID-19 vaccine if they've had an allergic reaction to another type of vaccine or injectable therapy for another disease.

Your child can get vaccinated even if they have a history of allergic reactions that are not related to vaccines or injectable medications, such as a food, pet, venom, environmental, or latex allergy. Your child can also get vaccinated if he or she has a history of allergies to oral medications or a family history of severe allergic reactions<sup>24</sup>.





- 22 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
- $23 \ \underline{https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html}$
- ${\bf 23} \ \underline{https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html}$
- 24 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html





## Can I get other vaccines at the same time as the COVID-19 vaccine?

When you get your COVID-19 vaccine, it is a good time to make sure you and your child are up-to-date on other vaccinations. **COVID-19 vaccines and other vaccines may now be given on the same day, and you no longer have to wait to get vaccinated for COVID-19 if you've had a different type of vaccine in the last 14 days.**<sup>25</sup> Ask your doctor about the potential side effects of each vaccine, so you know what to watch out for. It's possible you may experience side effects from BOTH vaccines at the same time.



## Should I report any side effects my child has after getting a COVID-19 vaccine?

If you think your child has a side effect after getting vaccinated, you can report it to the CDC's <u>Vaccine Adverse Event Reporting System</u> (VAERS). You can also ask your doctor to report it to VAERS for you. VAERS helps scientists and medical experts quickly detect unusual or unexpected patterns of health problems (also called "adverse events") that might indicate a possible safety problem with a vaccine.



## Sign up with V-safe

V-safe is an online tool that lets you tell the CDC if you get any side effects after getting the COVID-19 vaccine. You can also get reminders if you need a 2nd dose. Learn more about v-safe at <a href="https://www.cdc.gov/vsafe">www.cdc.gov/vsafe</a>.



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