

6/7/2021

## Pfizer/BioNTech COVID-19 vaccine for children ages 12 and older

The FDA has authorized the Pfizer/BioNTech COVID-19 vaccine for anyone 12 and older. Pfizer is the only vaccine authorized for children younger than 18 years old. This is an exciting and important step in the fight to end the pandemic.

COVID-19 vaccines are not only incredibly effective at preventing sickness, hospitalization, and death<sup>1</sup> but will help our adolescent patients return to their normal activities at school and with their peers. Recent studies show the vaccines work against new variants of the virus identified so far<sup>2</sup> and prevent transmission of the virus to other people. Young 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.

### How many children in Utah have been diagnosed with COVID-19?

Since the beginning of the pandemic, 77,827 Utah children ages 0-18 have been diagnosed with COVID-19, with 683 needing to be hospitalized. Of those requiring hospitalization in that age group, 74 developed multisystem inflammatory syndrome in children (MIS-C). To date in the United States, MIS-C has contributed to 35 deaths (<https://www.cdc.gov/mis-c/cases/index.html>).

There is a common misunderstanding in the public that children do not get COVID-19 or are not at risk for severe illness from the virus. In addition to acute illness, there is much we still don't know about how COVID-19 will continue to impact children long-term. Children suffer from serious, potentially long-lasting side effects, such as fatigue, headaches, abdominal pain, muscle and joint pain, and difficulty with memory and processing information, at rates similar to adults, even when they never had symptoms or had only mild symptoms at the time of their infection. COVID-19 is far more dangerous than the potential risks from getting a vaccine.

### How effective is the Pfizer vaccine for children ages 12-15?

The FDA authorized use of the vaccine for children ages 12-15 after reviewing data from Pfizer-BioNTech's clinical trial of 2,260 participants between the ages of 12-15<sup>3</sup>. In this clinical trial, 1,131 adolescent participants received the COVID-19 vaccine and 1,129 received a saline placebo. No cases of COVID-19 occurred after participants got the vaccine and 16 cases of

<sup>1</sup> <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/04-COVID-Oliver-508.pdf>

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

<sup>3</sup> <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-05-12.html>



COVID-19 occurred after participants got a placebo. The vaccine was 100% effective in preventing COVID-19 in the clinical trial.

The FDA updated the [Fact Sheets for Healthcare Providers Administering the Vaccine \(Vaccination Providers\)](#) and for [Recipients and Caregivers](#) with information to reflect the use of the vaccine in adolescents.

### Should my patients get vaccinated if they have already had COVID-19?

Yes, even if your patients already had COVID-19 they should still get vaccinated. The vaccines provide additional protection from the disease and possible reinfections. Studies show the vaccine better protects against variants of the virus and provides longer lasting immunity compared to natural immunity. Vaccination is a much safer and effective way to develop immunity than being infected by the virus and having COVID-19 as a disease.

### What side effects could my patients have<sup>4</sup>?

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

#### Common side effects

Your patients may have mild to moderate 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. Some people have no side effects or may have different side effects after their 2nd dose than they did after their 1st shot. A side effect is not a contraindication or reason not to get a 2nd dose of mRNA COVID-19 vaccine.

	Dose 1 12-15 Years		Dose 2 12-15 Years	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
<b>Redness*, n (%)</b>				
Any	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0

<sup>4</sup> <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html>



<b>Swelling*, n (%)</b>				
Any	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0	0	0	0
Grade 4	0	0	0	0
<b>Pain at the injection site†, n (%)</b>				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0	7 (0.6)	0
Grade 4	0	0	0	0
<b>Fever, n (%)</b>				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0	0	0
<b>Fatigue‡, n (%)</b>				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Grade 4	0	0	0	0
<b>Headache‡, n (%)</b>				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)



Grade 4	0	0	0	0
<b>Chills‡, n (%)</b>				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0
Grade 4	0	0	0	0
<b>Vomiting§, n (%)</b>				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
<b>Diarrhea¶, n (%)</b>				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0	0	0	0
Grade 4	0	0	0	0
<b>New or worsening muscle pain‡, n (%)</b>				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0	6 (0.5)	2 (0.2)
Grade 4	0	0	0	0
<b>New or worsening joint pain‡, n (%)</b>				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0	4 (0.4)	0



Grade 4	0	0	0	0
<b>Any systemic event</b>	877 (77.8)	636 (56.4)	904 (82.4)	439 (40.7)
<b>Use of antipyretic or pain medication, n (%)</b>	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)
*Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).				
†Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.				
‡Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.				
§Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.				
¶Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.				

### Less common side effects

Some patients may experience lymphadenopathy, usually axillary or cervical lymphadenopathy, on the same side as vaccination but also in other areas. In the clinical trials, only 0.6% of participants aged 12-15 years in the vaccine group had lymphadenopathy compared to 0.1% of participants in the placebo group. Most participants with lymphadenopathy had symptoms within 2-10 days after vaccination.

Some people have experienced 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 patients have “COVID arm” after getting the 1st dose, they should still get the 2nd dose. You may want to recommend getting the 2nd shot in the opposite arm. Patients with “COVID arm” can be treated with an antihistamine and/or acetaminophen or a non-steroidal anti-inflammatory drug (NSAID) for pain.

### Helping patients manage side effects

It’s best for patients to wait as long as they can to take any pain medicine after getting vaccinated. However, you may recommend patients take an over-the-counter medicine, like ibuprofen, acetaminophen, or naprosyn, to help with pain or discomfort from any side effects. You may also recommend patients exercise their arm if it’s sore, apply a cold, wet washcloth to the area where the injection was given, and drink plenty of fluids. It’s important patients keep taking any long-term daily medications after vaccination, unless you have recommended otherwise.



Educate patients on when their side effects may need further evaluation. Symptoms that need further medical evaluation after vaccination may include:

- Abnormal heartbeat
- 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

Patients should also seek further medical evaluation if:

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

## Severe or serious side effects after getting a vaccine are rare<sup>5</sup>

### **Severe, allergic reactions are rare.**

Allergic reactions are considered severe if someone needs to be treated with epinephrine or EpiPen® or go to the hospital. Anaphylaxis almost always happens within 30 minutes after getting the vaccine. This is why it's important to monitor patients for 15-30 minutes after vaccination. Patients who have an anaphylactic reaction after their 1st dose of the vaccine should **not** get the 2nd dose.

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

Patients who have an allergic reaction that does not require emergency care or hospitalization are called non-severe, immediate allergic reactions. These types of reactions happen within 4 hours after getting vaccinated. Patients may get hives, swelling, or wheezing. Patients who have a non-severe, immediate allergic reaction after getting a dose of the COVID-19 vaccine should **not** get a 2nd dose, even if their reaction was not severe enough to require emergency care or hospitalization. You may want to refer patients who have this type of reaction to an allergy or immunology specialist to provide more care or advice.

---

<sup>5</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html>



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

If you look at the history of all vaccinations, the overwhelming majority of long-term side effects from vaccination occur between 30-45 days after the vaccine clinical trials end. 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.

**Ongoing investigation of any possible rare side effects**

The most common reasons for vaccine hesitancy are concerns about side effects and fears related to the vaccines being developed too quickly. It is important to let patients and families know the vaccines were developed quickly by cutting red tape and bureaucracy, not cutting corners or bypassing any safety precautions. The technology used to develop the vaccines had been under study for more than a decade and the millions of cases across the world allowed scientists to quickly study the vaccines' effectiveness and safety. Under the most intense safety monitoring in history, millions of people in the United States have received COVID-19 vaccines. The FDA, CDC, and Advisory Committee on Immunization Practices (ACIP)<sup>6</sup> have carefully reviewed all available data and are confident the vaccines are safe and effective in preventing COVID-19. The benefits of vaccination outweigh the risks.

CDC and FDA have extensive systems<sup>7</sup> to look for rare side effects that may only be detected as vaccines are administered widely to the public. The CDC collects reports through the Vaccine Adverse Event Reporting System (VAERS) on any illness that follows a vaccine, regardless if it is a known side effect. Medical and vaccination experts then look at these reports to determine if they are related to the vaccine. An example of how this works was the association of the Johnson & Johnson COVID-19 vaccine with thrombosis with thrombocytopenia syndrome (TTS). More than 200 million doses of the Pfizer and Moderna vaccines have been given and there has been no association with blood clots.

Since April 2021, there have been increased reports to VAERS of cases of myocarditis and pericarditis happening after mRNA vaccination in the United States. These reports are rare, given the number of vaccine doses administered, and CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination. Most cases occurred in male adolescents and young adults age 16 years or older, after getting the second dose, and typically within several days after COVID-19 vaccination. Most patients who received care responded well to medical treatment and rest and quickly felt better. CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older, given the greater risk of COVID-19 illness and related, possibly severe complications. Healthcare providers should consider myocarditis or pericarditis in an evaluation of chest pain or shortness of breath after vaccination and report all cases to VAERS.

---

<sup>6</sup> [https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s\\_cid=mm7020e1\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w)

<sup>7</sup> <https://www.cdc.gov/vaccinesafety/index.html>



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

More than 285 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through May 24, 2021. During this time, VAERS received 4,863 reports of death (0.0017%) among people who received a COVID-19 vaccine. CDC and FDA physicians review each case report of death, including medical records, death certificates, and autopsy reports. To date, these reviews have not established a causal link to COVID-19 vaccines; however, recent reports indicate a plausible causal relationship between the Johnson & Johnson COVID-19 Vaccine and TTS, which has been associated with 6 deaths<sup>8</sup>. TTS bears a strong resemblance to heparin-induced thrombocytopenia (HIT), with low platelets and development of antibodies to platelet factor 4. This “consumptive coagulopathy” has distinctive clinical features, is challenging to manage, and should not be treated with heparin — which can worsen the disease.

There has been no association with blood clots or TTS with the mRNA vaccines (Pfizer or Moderna).

## Who shouldn't get the Pfizer COVID-19 vaccine?

The Pfizer/BioNTech COVID-19 vaccine is authorized for people 12 years of age and older. Patients should not get this vaccine if they:

- Had a severe allergic reaction after the 1st dose of the vaccine.
- Had a severe allergic reaction to any ingredient in the vaccine. To see a list of ingredients in the Pfizer COVID-19 vaccines, visit <https://www.fda.gov/media/144414/download>.
- Patients should talk to you before getting a COVID-19 vaccine if they had an immediate allergic reaction to their 1st dose of COVID-19 vaccine, or an allergic reaction to another type of vaccine or injectable therapy for another disease, even if it was not severe.

Patients can get vaccinated even if they have a history of severe allergic reactions that are not related to vaccines or injectable medications, such as a food, pet, venom, environmental, or latex allergy. Patients with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated<sup>9</sup>.

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

Updated CDC guidelines now allow COVID-19 vaccines and other vaccines to be given at the same time<sup>10</sup>. **You no longer have to wait to vaccinate someone for COVID-19 if he or she**

---

<sup>8</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>

<sup>9</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html>

<sup>10</sup> <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration>





**has had a different type of vaccine in the last 14 days.** Substantial data have been collected regarding the safety of COVID-19 vaccines. We have extensive experience with other types of vaccines that shows immunogenicity and adverse event profiles are generally similar when vaccines are administered at the same time, compared to when they are given alone<sup>11</sup>.

Check to see if patients who are getting vaccinated for COVID-19 are up-to-date on their other vaccinations, including their annual flu shot. This is a good time to talk about the importance of vaccines and encourage patients to get any vaccinations they may be missing, right there at the same time. If you are giving more than one vaccine at the same time, administer each injection at a different injection site. You can give more than one intramuscular injection to adolescents and adults in the deltoid muscle. Although most side effects are mild, if you are giving more than one vaccine at the same time, it is very important to make sure patients understand they may experience side effects from BOTH vaccines at the same time. Most people had never even thought about the side effects of vaccines before the pandemic, so they may assume COVID-19 vaccines are the cause, especially if they experience side effects from two vaccines at once. This misunderstanding could be dangerous to not only COVID-19 vaccination efforts, but for future vaccination efforts as well. Many people are already hesitant to get vaccinated for COVID-19, sometimes based upon misinformation. It is critical to talk to your patients about the side effects of vaccines. You should make sure they understand what to expect and what is normal, and that for most people, the benefit of vaccination outweighs any risk.

## Where do I report if my patients have any side effects after getting a COVID-19 vaccine?

If you think your patient may have a side effect after getting vaccinated, you can report it to the CDC's Vaccine Adverse Event Reporting System (VAERS). Patients may also report their side effects to VAERS. Remind patients and families that VAERS helps scientists and medical experts quickly detect unusual or unexpected patterns of health problems that might indicate a possible safety problem with a vaccine, but that doesn't mean that the vaccine caused the problem. It simply warns vaccine safety experts of potential problems that may need to be looked at more carefully.

[Learn more](#) about VAERS and how to report side effects.

If you aren't sure if you should report a patient's side effect or have questions, you may call the Utah Poison Control Center at 1-800-222-1222. They have poison specialists available 24 hours a day 7 days a week to help answer questions.

---

<sup>11</sup> <https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html>



## Encourage your patients to sign up with V-safe

V-safe is an online tool that lets patients tell the CDC if they get any side effects after getting the COVID-19 vaccine. They can also get reminders if they need a 2nd dose. Learn more about v-safe at [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## Where can I find more information on the COVID-19 vaccines?

[Coronavirus.utah.gov](http://Coronavirus.utah.gov) offers a number of resources and educational materials in more than 30 languages on the latest vaccine information. The information has been gathered from a number of credible resources and compiled into materials to help you share important and relevant information with your patients.

[CDC](http://CDC) provides information for COVID-19 vaccination administration, storage and handling, reporting, and patient education for each type of vaccine.