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Pfizer/BioNTech COVID-19 vaccine for children ages 5 and older

On October 29, 2021, the FDA issued emergency use authorization of the Pfizer/BioNTech COVID-19 vaccine for anyone 5 and older. This is an exciting and important step in the fight to end the pandemic. COVID-19 vaccines are FREE to anyone who lives in the U.S, even if you don't have health insurance or are not a U.S. citizen.

COVID-19 vaccines are not only incredibly effective at preventing sickness, hospitalization, and death[1] but will help our adolescent patients return to their normal activities at school and with their peers. The vaccines work against new variants of the virus identified so far[2]. Young people who choose to get vaccinated not only protect themselves from the virus, but also help protect those they care about such as grandparents, teachers, or siblings who are immunocompromised.

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[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

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What are the differences between the pediatric and adult doses?

Pfizer is the only vaccine authorized for children younger than 18 years old at this time. Prior, on August 23, 2021, the FDA gave full approval of the Pfizer/BioNTech vaccine (marketed under the brand name, Comirnaty) for those ages 16 and older.

Authorized For	Pfizer-BioNTech	Moderna	J&J / Janssen
4 years and under	No	No	No
5–11 years old	**Yes**	No	No
12–17 years old	**Yes**	No	No
18 years and older	**Yes**	**Yes**	**Yes**

Providers cannot use existing Pfizer stock for 5-11 year-old patients. The Pfizer pediatric vaccine for children ages 5 through 11 years has the same active ingredients as the vaccine given to adults and adolescents, but the doses are one-third that of an adult dose (pediatric doses are 10 micrograms each, adult doses are 30 micrograms each). Pediatric vaccine comes in a multiple dose vial with an orange cap and a label with an orange border. Smaller needles, designed specifically for children, are also used for children ages 5 through 11 years. The vaccine for children ages 5-11 is given as a 2-dose series, 3 weeks apart.

Pediatric doses are based on the patient's age the day they receive their vaccine, not weight. If a patient turns 12 in between doses, they should receive the pediatric dosage for their first dose and then the adult dosage for the second dose. Parents should be encouraged to get their child vaccinated as soon as possible, and not wait for their child to turn 12 years of age to get the adult dosage.

The FDA also authorized a manufacturing change for the vaccine to include a formulation that uses a different buffer. Buffers help maintain a vaccine's pH (a measure of how acidic or alkaline a solution is) and stability. This new formulation is more stable at refrigerated temperatures for

longer periods of time, which will make it easier for you to offer COVID-19 vaccines to your patients.

The new formulation of the vaccine contains a Tris buffer. This is a commonly used buffer in a variety of other FDA-approved vaccines and other biologics, including products for use in children. The FDA didn't find safety or effectiveness concerns when evaluating manufacturing data to support the use of Pfizer-BioNTech COVID-19 Vaccine containing Tris buffer.

Learn more about administering pediatric doses at:

- FDA Fact Sheet for Healthcare Providers Administering Vaccine https://www.fda.gov/media/153714/download
- CDC U.S. COVID-19 Vaccine Product Information https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

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

There is a **common misunderstanding** that children don't get COVID-19 or aren't at risk for severe illness from the virus. Parents may also believe not getting their child vaccinated is a safer choice than vaccination. It's important to make sure parents understand neither of these are true. COVID-19 is far more dangerous 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[3].

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% were school-aged (5-17 years old). More than 900 Utah children needed to be hospitalized from COVID-19. Of those requiring hospitalization, 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 U.S. 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 a top 10 cause of death for kids in the U.S.**

In addition to acute illness, we still don't know how 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. Children report "long COVID" symptoms which impact their daily life for many weeks after being infected with COVID[4], even

[3] https://yourlocalepidemiologist.substack.com/p/pediatric-vaccines-top-8-parental (Dr. Katelyn Jetelina, Your Local Epidemiologist)
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7927578/

when their initial infection was mild. Children suffer from serious, potentially long-lasting side effects at rates similar to adults, even when they never had symptoms or had only mild symptoms at the time of their infection, such as fatigue, headaches, abdominal pain, muscle and joint pain, and difficulty with memory and processing information.

How effective is the Pfizer vaccine for children?[5,6]

The FDA reviewed clinical trial data and found the 90-100% efficacy of the Pfizer/BioNTech COVID-19 vaccines, depending on the age group. Data showed the vaccines were effective against the Delta variant as well.

Should my patients get vaccinated if they've already had COVID-19?

Yes. Right now, the CDC recommends that people get vaccinated even if he or she had COVID-19 before. We can't predict who will get severely ill from COVID-19 or suffer long-term health effects from it. Vaccination is a much safer and effective way to develop immunity than having COVID-19 as a disease.

We know people can get immunity from both infection and vaccination. The vaccines provide additional protection from COVID-19 and keep your child from being infected again[7]. 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[8] show varying levels of immunity after infection with COVID-19. For some people, protection may last up to 8 months (because we have 8 months of data). However, for others, natural immunity gets weaker within weeks. Natural immunity protection is random. This means some people's bodies will create strong protection against the virus and some people won't get enough natural immunity to protect them at all or for very long. A person's age and medical conditions can also have an impact on their level of immunity.

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5 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use

6 https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement#event-materials

7 https://yourlocalepidemiologist.substack.com/p/vaccine-for-5-11-year-olds-acip-cliff

8 https://yourlocalepidemiologist.substack.com/p/natural-immunity-protection-and-variants (Dr. Katelyn Jetelina, Your Local Epidemiologist)

As of October 21, 2021, more than 6.3 million COVID-19 children cases have tested positive for COVID-19 in the U.S. **This means that only 43% of children in the country younger than 12 years old have some level of natural immunity**[9].

Data shows 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. Studies[10,11] show that you are 2 to 5 times more likely to be reinfected, or get infected again after you've already had COVID-19, if you are unvaccinated compared to someone who is fully vaccinated. People who have had COVID-19 and been vaccinated have the strongest levels of immunity.

What side effects could my patients have[12]?

The COVID-19 vaccine is safe and effective. But, like all medicines, some people may have side effects. Severe side effects from vaccines are rare, but it's important for patients 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. Pain at the injection site, fatigue, headache, chills, and muscle pain were the most common side effects reported by clinical trial participants. 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.

[9] https://yourlocalepidemiologist.substack.com/p/pediatric-vaccines-top-8-parental (Dr. Katelyn Jetelina, Your Local Epidemiologist)
[10] https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm
[11] https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm?s_cid=mm7044e1_w
[12] https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html

Side effects reported in the Pfizer/BioNTech clinical trials for children ages 12-15[13]

	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
Redness*, n (%)				
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
Swelling*, n (%)				
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
Pain at the injection site†, n (%)				
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
Fever, n (%)				
≥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
Fatigue‡, n (%)				
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)

[13] https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html

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
Headache‡, n (%)				
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
Chills‡, n (%)				
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
Vomiting§, n (%)				
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
Diarrhea¶, n (%)				
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
New or worsening muscle pain‡, n (%)				
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
New or worsening joint pain‡, n (%)				
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
Any systemic event	877 (77.8)	636 (56.4)	904 (82.4)	439 (40.7)
Use of antipyretic or pain medication, n (%)	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.

Side effects reported in the Pfizer/BioNTech clinical trials for children ages 5-11[14]

	Dose 1 5-11 Years		Dose 2 5-11 Years	
	Pfizer-BioNTech Vaccine N=1511	Placebo N=749	Pfizer-BioNTech Vaccine N=1501	Placebo N=740
Redness*, n (%)				
Any	222 (14.7)	43 (5.71)	278 (18.5)	40 (5.4)
Mild	143 (9.5)	37 (4.9)	143 (9.5)	31 (4.2)
Moderate	79 (5.2)	6 (0.8)	132 (8.8)	9 (1.2)
Severe	0	0	3 (0.2)	0
Grade 4	0	0	0	0
Swelling*, n (%)				
Any	158 (10.5)	20 (2.7)	229 (15.3)	20 (2.7)

[14] https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html

Mild	85 (5.6)	13 (1.7)	117 (7.8)	15 (2.0)
Moderate	72 (4.8)	7 (0.9)	112 (7.5)	5 (0.7)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
Pain at the injection site†, n (%)				
Any	1119 (74.1)	234 (31.3)	1065 (71.0)	218 (29.5)
Mild	890 (58.9)	204 (27.3)	793 (52.8)	192 (25.9)
Moderate	225 (14.9)	30 (4.0)	267 (17.8)	26 (3.5)
Severe	4 (0.3)	0	5 (0.3)	0
Grade 4	0	0	0	0
Any local event	1150 (76.1)	254 (33.9)	1096 (73.0)	237 (32.0)
Fever, n (%)				
≥38.0°C	38 (2.5)	10 (1.3)	98 (6.5)	9 (1.2)
≥38.0°C to 38.4°C	23 (1.5)	4 (0.5)	51 (3.4)	5 (0.7)
>38.4°C to 38.9°C	12 (0.8)	5 (0.7)	38 (2.5)	3 (0.4)
>38.9°C to 40.0°C	3 (0.2)	1 (0.1)	8 (0.5)	1 (0.1)
>40.0°C	0	0	1 (0.1)	0
Fatigue‡, n (%)				
Any	508 (33.6)	234 (31.3)	592 (39.4)	180 (24.3)
Mild	333 (22.0)	150 (20.1)	321 (21.4)	96 (13.0)
Moderate	171 (11.3)	83 (11.1)	260 (17.3)	83 (11.2)
Severe	4 (0.3)	1 (0.1)	11 (0.7)	1 (0.1)
Grade 4	0	0	0	0
Headache‡, n (%)				
Any	339 (22.4)	180 (24.1)	420 (28.0)	138 (18.6)
Mild	249 (16.5)	131 (17.5)	281 (18.7)	93 (12.6)
Moderate	88 (5.8)	45 (6.0)	136 (9.1)	45 (6.1)
Severe	2 (0.1)	4 (0.5)	3 (0.2)	0
Grade 4	0	0	0	0
Chills‡, n (%)				
Any	70 (4.6)	35 (4.7)	147 (9.8)	32 (4.3)
Mild	54 (3.6)	30 (4.0)	105 (7.0)	24 (3.2)
Moderate	16 (1.1)	5 (0.7)	40 (2.7)	7 (0.9)
Severe	0	0	2 (0.1)	1 (0.1)
Grade 4	0	0	0	0

Vomiting§, n (%)				
Any	33 (2.2)	11 (1.5)	28 (1.9)	6 (0.8)
Mild	26 (1.7)	11 (1.5)	27 (1.8)	6 (0.8)
Moderate	7 (0.5)	0	1 (0.1)	0
Severe	0	0	0	0
Grade 4	0	0	0	0
Diarrhea¶, n (%)				
Any	89 (5.9)	31 (4.1)	79 (5.3)	35 (4.7)
Mild	79 (5.2)	31 (4.1)	72 (4.8)	32 (4.3)
Moderate	10 (0.7)	0	7 (0.5)	3 (0.4)
Severe	0	0	0	0
Grade 4	0	0	0	0
New or worsening muscle pain‡, n (%)				
Any	137 (9.1)	51 (6.8)	175 (11.7)	55 (7.4)
Mild	96 (6.4)	35 (4.7)	116 (7.7)	38 (5.1)
Moderate	40 (2.6)	16 (2.1)	58 (3.9)	17 (2.3)
Severe	1 (0.1)	0	1 (0.1)	0
Grade 4	0	0	0	0
New or worsening joint pain‡, n (%)				
Any	50 (3.3)	41 (5.5)	78 (5.2)	27 (3.6)
Mild	34 (2.3)	31 (4.1)	57 (3.8)	20 (2.7)
Moderate	16 (1.1)	10 (1.3)	21 (1.4)	7 (0.9)
Severe	0	0	0	0
Grade 4	0	0	0	0
Any systemic event	715 (47.3)	334 (44.6)	771 (51.4)	272 (36.7)
Use of antipyretic or pain medication, n (%)	217 (14.4)	62 (8.3)	269 (19.7)	60 (8.1)

*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. For clinical trial participants ages 5-11, 13 participants (0.9%) in the vaccine group and 1 participant (0.1%) had lymphadenopathy. The median time to onset was 2-3 days after either dose and all cases resolved within 2 weeks. Lymphadenopathy has been reported by adults too.

Among a safety expansion cohort (more than 2,250 children randomized 2:1 vaccine to placebo), 6 participants (0.4%) who received the vaccine and 3 participants (0.4%) who received the placebo had lymphadenopathy.

No Bell's palsy, anaphylaxis, or myocarditis was reported among vaccine recipients in either age group in the clinical trials.

Some people have experienced skin sensitivity or 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.[15]

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.

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 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.

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

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 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.

How are adverse side effects being monitored for?

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. Millions of people in the U.S. have received COVID-19 vaccines under the most intense safety monitoring in history.

The FDA, CDC, Vaccines and Related Biological Products Advisory Committee (VRBPAC)[16], and Advisory Committee on Immunization Practices (ACIP)[17] 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. The FDA added an **additional** independent review of the data by the VRBPAC which is a committee of pediatricians, immunologists, virologists, epidemiologists, and other scientists across the nation. This additional review is **not required** to get emergency use authorization. It was done to make sure independent medical experts from across the country felt confident the vaccine was safe and effective for young children.

The FDA and CDC will keep monitoring any possible rare side effects. The CDC and FDA have extensive systems[18] 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. Anyone can report an illness or side effect after getting a vaccine, not just healthcare providers. 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

16 https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee
17 https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w
18 https://www.cdc.gov/vaccinesafety/index.html

warning system. Medical and vaccination experts then look at these reports to determine if they are related to the vaccine.

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. The CDC and FDA identified 48 confirmed reports of people who got the Johnson & Johnson vaccine and later developed TTS out of 15.5 million doses of this vaccine given in the U.S. 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.

To make sure that COVID-19 vaccines are safe, the CDC expanded and strengthened the country's ability to monitor vaccine safety[19]. 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.

It's mandatory for Pfizer and other vaccination providers to report any serious adverse events, cases of Multisystem Inflammatory Syndrome, and cases of COVID-19 that result in hospitalization or death that happen in people who were vaccinated. It is also mandatory for vaccination providers to report to VAERS any errors that happened when the vaccines were being administered, and to include a summary and analysis of all identified vaccine administration errors in monthly safety reports to the FDA.

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[20]. This usually happens after the 2nd dose, and is most likely to happen in males 12-17 years of age[21]. These are serious health conditions, but are conditions that can be treated. Most patients with myocarditis or pericarditis responded well to treatment.

Myocarditis and pericarditis are very rare after a vaccination (only about 54 cases per 1 million doses[22]), but are not uncommon after being infected by a virus. About 10 to 20 people out of

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19 https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/323652-A_COVID-19_VaccineSafety_MonitoringSystems_v9.pdf

20 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

21 https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age

22 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html

every 100,000 people in the U.S. 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:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

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 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 U.S.**

The American Academy of Pediatrics[23] and the American Heart Association[24] have stated the benefits of COVID-19 vaccines outweigh any potential risk of myocarditis from vaccination.

Have the COVID-19 vaccines caused any fertility issues?

There is no data showing that any of the COVID-19 vaccines cause infertility or miscarriages. The CDC estimates only about 31% of pregnant people were fully vaccinated before or during their pregnancy[25]. Pregnant women have an increased risk for adverse pregnancy outcomes and being hospitalized from COVID-19. The American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine[26], CDC[27], MotherToBaby[28], and many other reputable medical organizations recommend pregnant women get vaccinated for COVID-19. It is safe to get vaccinated during pregnancy, while breastfeeding, or while receiving fertility treatments.

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[23] https://publications.aap.org/aapnews/news/16738?autologincheck=redirected

[24] https://newsroom.heart.org/news/covid-19-vaccine-benefits-still-outweigh-risks-despite-possible-rare-heart-complications

[25] https://emergency.cdc.gov/han/2021/han00453.asp

[26] https://www.acog.org/news/news-releases/2021/07/acog-smfm-recommend-covid-19-vaccination-for-pregnant-individuals

[27] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

[28] https://mothertobaby.org/fact-sheets/covid-19-vaccines/

MotherToBaby Utah is the state's local teratogen information center. Questions from healthcare providers, pregnant and breastfeeding people, and family members about COVID-19 or the COVID-19 vaccines during pregnancy or while breastfeeding are welcome.

- Call: 801-328-2229 or 800-822-2229
- Text: 855-999-3525
- Chat: www.mothertobaby.utah.gov
- Email: expertinfo@mothertobaby.org
- Website: https://mothertobaby.org/fact-sheets/covid-19-vaccines

Women who were pregnant and breastfeeding were excluded from the clinical trials but have been included in studies that started after the vaccines were authorized. COVID-19 mRNA vaccine particles are quickly broken down by the body. In one study[29,30] vaccine particles weren't found in the breast milk after those individuals had the mRNA vaccines. A second study [31] found that for most vaccinated individuals, the mRNA particles did not enter the breast milk. Even if vaccine particles were to get into the breast milk, mRNA vaccine particles would not likely be able to survive in a baby's stomach acid. So, no vaccine particles are likely to reach the breastfed baby.

Research on COVID-19 vaccines in pregnancy is also reassuring. The CDC V-safe and Vaccine Adverse Event Reporting System (VAERS) reported there were no increases in miscarriage rates or fertility problems. The thousands of pregnant women in the registries who've received COVID-19 vaccines had similar reactions to the vaccines as non-pregnant women. The studies are not showing any safety signals or problems. For example, miscarriage rates among vaccinated women were below the expected, or background, rate for pregnancies in general. Since mRNA vaccine particles are not likely to be found in the breastmilk of most vaccinated individuals, the vaccine particles are not likely to cross the placenta for most pregnant individuals. The Johnson & Johson vaccine works more like traditional vaccines that are commonly given in pregnancy, like the flu and Tdap vaccines.

No other vaccine has ever been found to increase any risks for unborn or breastfed babies, or for pregnancies. The CDC notes[32] that, "Although the absolute risk is low, compared with non-pregnant symptomatic people, symptomatic pregnant people have more than a two-fold increased risk of requiring ICU admission, invasive ventilation, and ECMO [extracorporeal membrane oxygenation], and a 70% increased risk of death."

Due to the risk of complications from the COVID-19 disease during pregnancy, pregnant individuals who test positive for COVID-19 and are within the first 10 days of their symptom onset automatically qualify for monoclonal antibody therapy. While the specific monoclonal antibodies that are currently being used for the treatment of COVID-19 have not been studied during pregnancy, those monoclonal antibodies have a high molecular weight and are unlikely to cross into the placenta early in pregnancy. Other monoclonal antibody treatments used in pregnancy for other conditions have not shown any increased risks during pregnancy. Learn more at https://coronavirus.utah.gov/noveltherapeutics/.

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[29] https://www.medrxiv.org/content/10.1101/2021.03.05.21252998v1
[30] https://pubmed.ncbi.nlm.nih.gov/34228115/
[31] https://pubmed.ncbi.nlm.nih.gov/34413319/
[32] https://emergency.cdc.gov/han/2021/han00453.asp

Individuals who are pregnant or who have given birth in the past 42 days qualify for the COVID-19 booster shot. Learn more at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html.

Have the COVID-19 vaccines caused any deaths?

Reports of death after COVID-19 vaccination are rare. There have been no deaths directly caused by the vaccines, out of more than 423 million doses of COVID-19 administered in the U.S. from December 14, 2020 to November 1, 2021[33]. 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, do not necessarily mean that a vaccine caused the health problem.** 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, reports indicate a plausible causal relationship between the Johnson & Johnson COVID-19 vaccine and TTS, which has been associated with 6 deaths[34]. 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). There have been no deaths from any side effects (even rare ones) for the mRNA vaccines (Pfizer and Moderna).

Which patients should not get a COVID-19 vaccine[35]?

Patients should **not** get a COVID-19 vaccine (any brand) if they:

- 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 ingredient in the vaccine.

To see a list of ingredients, visit:

- Pfizer/BioNTech (Comirnaty)
- Moderna

[33] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
[34] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
[35] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

- Johnson & Johnson/Janssen

Patients should talk to you before getting a COVID-19 vaccine if they had an allergic reaction to another type of vaccine or injectable therapy for another disease, even if it was not severe.

Patients who can't get one type of COVID-19 vaccine because they are allergic to an ingredient in that vaccine may be able to get a different type of COVID-19 vaccine.

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[36].

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[37]. **COVID-19 vaccines and other vaccines can be given on the same day.** 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[38].

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's 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.

[36] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html
[37] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration
[38] https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html

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 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.

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.

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

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 provides information for COVID-19 vaccination administration, storage and handling, reporting, and patient education for each type of vaccine.

FDA provides updates on COVID-19 vaccines, clinical trial data, patient and healthcare provider vaccine information sheets, and more.

MotherToBaby provides information on COVID-19 during pregnancy and breastfeeding.