WVUMedicine

COVID-19 Vaccine Frequently Asked Questions

Disclaimer: This FAQ is based on the current available literature and is subject to change.

What is an Emergency Use Authorization (EUA)?

Emergency Use Authorization occurs when the FDA allows a drug or vaccine to be used during a public health emergency. The FDA may choose to grant EUA once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted, or the FDA has completed its formal review of the license application. EUAs provide timely access to critical medical products during a medical emergency when there are no sufficient treatments or vaccines available.

Which vaccines have been granted EUA?

Vaccine	Ages included	Dosing	Date EUA granted
Pfizer	12 and older	2 doses given intramuscularly 21 days apart	12/11/20
Moderna	18 and older	2 doses given intramuscularly 28 days apart	12/18/20
Janssen	18 and older	1 dose given intramuscularly	2/27/21

*The FDA expanded use of the Pfizer vaccine to ages 12 and older on 5/10/21

Are the COVID-19 vaccines be safe?

Yes. In phase 3 clinical trials, COVID-19 vaccines are tested in tens of thousands of participants for safety and efficacy. No serious safety concerns were reported by an independent Data and Safety monitoring Board overseeing the phase 3 clinical trials of the Pfizer, Moderna, and Janssen vaccines. All 3 vaccines met the safety and efficacy requirements outlined by the FDA to obtain EUA. After the EUA was granted for the Janssen vaccine, reports of adverse events suggest an increased risk of a rare event called TTS. Please see Janssen vaccine updates below for more information.

What side effects will the vaccine have?

In the vaccine clinical trials, the majority of side effects were mild to moderate, short lived, and happened within the first few days of receiving the vaccine. Examples of common mild to moderate side effects include pain at the injection site, headache, fatigue, fever, or chills. Side effect occurrence is typically higher after the second dose of the Pfizer and Moderna vaccines. In Phase 3 clinical trials, the most common severe side effects reported were as follows:

COVID-19 Vaccine Severe* Side Effects					
Pfizer		Moderna		Janssen	
Side effect	Percent reported	Side effect	Percent reported	Side effect	Percent reported
Fatigue	3.8%	Fatigue	9.7%	Fatigue	2%
Headache	2%	Headache	4.5%	Headache	1.3%
		Joint pain	5.2%	Muscle Pain	1.6%
		Muscle pain	8.9%	Nausea	0.3%
		Pain	4.1%	Fever	0.4%

* ≥ Grade 3

What are the updates on the use of the Janssen Vaccine?

On April 23rd the CDC and FDA recommended to resume the use of the Janssen vaccine after a temporary pause was lifted.

- The vaccine has been associated with an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS). TTS is a rare blood clot with low platelets.
- These events are rare
- After reviewing all the data, the CDC and FDA have concluded the potential benefits of receiving the Janssen vaccine outweigh the potential risks
- At this time the available data suggest the risk of TTS is very low. The FDA and CDC will continue to monitor this risk
- Nearly all reports have been in adult women between 18-49 years old. It is important that women under 50 be aware of this rare risk
- Symptoms developed between 6-15 days after Janssen vaccination
- These events have not been seen with the Moderna and Pfizer vaccines at this time

Individuals that receive the Janssen vaccine, should monitor for the following symptoms for **3 weeks** after they receive the vaccine

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

If any of these symptoms develop within 3 weeks of receiving the Janssen vaccine, seek medical care right away.

Experts believe that people with risk factors for blood clots or prior history of blood clots that were not associated with low platelets, are not at an increased risk of TTS. Additionally they state pregnancy and oral contraceptives do not make people more likely to develop TTS. People who take aspirin or anticoagulants as part of their routine medications do not need to stop taking these medications prior to receiving the Janssen vaccine. If people do not take aspirin or anticoagulants as part of their routine medications, they do not need to start taking them prior to the Janssen vaccine.

TTS shares similarities with autoimmune heparin induced thrombocytopenia (HIT). HIT is when low platelets develop after a person receives heparin. If a person has had HIT, they should be offered an mRNA vaccine until 90 days have passed since HIT resolves.

Are there going to be long term side effects from the vaccines?

Historically, long term side effects from vaccines has been rare. A vaccine advisory committee member to the FDA stated that historically, most side effects have been seen within the first 60 days of receiving vaccines.

How will side effects from the vaccines be treated?
Side effects from vaccines are typically short lived. You may take medications for pain or fever after you have been vaccinated. If you are concerned about your health after getting vaccinated, talk with your doctor. They will determine the appropriate treatment. You or your doctor can choose to report the side effect to the Vaccine Adverse Event Reporting System (VAERS). Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967.

Should premedications be given prior to vaccination?
Taking medications as acetaminophen, ibuprofen, or antihistamines before receiving the vaccine to try to prevent side effects is not recommended at this time. This is because there is not enough information on how this will impact antibody responses, though, you can take these medications after receiving the vaccine if you develop side effects.

Are there any contraindications (factors that would be a reason to withhold vaccination due to harm) to receiving the vaccine?

The CDC considers the following to be contraindications to vaccination with the **mRNA COVID-19** vaccines (Pfizer and Moderna):

- Severe allergic reaction (e.g., anaphylaxis) or immediate allergic reaction after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to polyethylene glycol (PEG)*

The CDC considers the following to be contraindications to vaccination with the **Janssen** vaccine:

- Severe allergic reaction (e.g., anaphylaxis) to any of its components
- Immediate allergic reaction to polysorbate*

(An immediate allergic reaction means any hypersensitivity-related signs of symptoms such as hives, angioedema (throat swelling), respiratory distress (wheezing), or anaphylaxis within 4 hours following administration).

*These individuals should not receive the COVID-19 vaccines unless they have been evaluated by an allergist/immunologist and have been cleared to receive the vaccine.

People with a contraindication to one of the mRNA vaccines may be able to receive the Janssen vaccine and vice versa provided certain precautionary measures are taken. However, because of potential cross-reactivity between ingredients in the mRNA vaccines and the Janssen vaccine, consultation with an allergist/immunologist should be considered to help determine whether the patient can safely receive vaccination.

For the Janssen vaccine, if a person had had autoimmune heparin induced thrombocytopenia (HIT), they should be offered an mRNA vaccine until 90 days have passed since resolution of HIT.

Should I take the COVID-19 vaccine if I have a significant history of allergic reactions (not related to the COVID-19 vaccine)?

The CDC states severe allergic reaction (i.e. anaphylaxis) to any other vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) is a precaution, but not a contraindication to receiving the COVID-19 vaccines. Vaccine providers should observe these patients for 30 minutes after vaccination to monitor for the development of immediate adverse reactions. Deferral of vaccination and consultation with an allergist/immunologist may be considered. People with a history of anaphylaxis due to any cause should be observed for 30 minutes. Those with allergies to food, pets, insects, latex, or oral medications do not fall under this precaution and are monitored similarly to all other vaccine recipients (15 minutes). If you have a history of severe allergic reactions you should discuss this with your healthcare provider and notify the healthcare workers administering your vaccine.

Can I take the vaccine if I am pregnant?

Observational data show that if a pregnant woman becomes infected with COVID-19, they may have an increased risk of severe illness or negative pregnancy outcomes, such as preterm birth.
The CDC has stated the COVID-19 vaccines are unlikely to pose any risk to the fetus and that there is minimal safety risk as all of the current authorized COVID-19 vaccines are not live vaccines.
If a pregnant woman is part of a group who is recommended to receive a COVID-19 vaccine, **she may choose to be vaccinated.** A discussion with her health care provider can help her make an informed decision. Pregnant women who develop a fever after vaccination should take acetaminophen as fever is associated with negative pregnancy outcomes.

Considerations for vaccination:

- Level of COVID-19 community transmission, (risk of acquisition)
- Her personal risk of contracting COVID-19, (by occupation or other activities)
- The risks of COVID-19 to her and potential risks to the fetus
- The efficacy of the vaccine
- The known side effects of the vaccine
- The lack of data about the vaccine during pregnancy

Can I take the vaccine if I am breastfeeding?

Currently, there is no data on the safety and efficacy of COVID-19 vaccines in breastfeeding women as they were excluded from clinical trials. The CDC has stated they do not think the COVID-19 vaccines will be a risk to breastfeeding infants since they are not live vaccines. If a breastfeeding woman is part of a group who is recommended to receive a COVID-19 vaccine, **she may choose to be vaccinated.** A discussion with her health care provider can help her make an informed decision.

Will the vaccines cause infertility?

There is no evidence that any of the COVID-19 vaccines cause infertility. Claims circulating on social media is that antibodies formed after vaccination which target the COVID-19 spike protein may also target a protein found in placenta called syncytin-1. This has not been proven. Expert virologists have stated the two proteins are not similar enough for this to happen. Additionally, if this were found to be true, then this would also suggest that people who become infected with COVID-19 and recover would carry a similar risk of infertility due to the formation of antibodies after natural infection. However, there is currently no definitive evidence that COVID-19 infection causes infertility.

Can children and adolescents take the vaccines?
Adolescents aged 12-15 may currently receive the Pfizer COVID-19 vaccine. The estimated efficacy of the Pfizer COVID-19 vaccine was 100% in preventing symptomatic, laboratory confirmed COVID-19 infection in this age group.

Can I take the vaccine if I am immunocompromised or am taking immunosuppressive therapies?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in immunocompromised people as they were excluded from clinical trials. However, people with immunocompromised conditions or those on immunosuppressant medications might be at increased risk for severe disease if they get COVID-19. The CDC recommends these individuals may still receive the COVID-19 vaccines. The currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a reduced immune response to the COVID-19 Vaccine. The CDC recommends that COVID-19 vaccination should be completed at least 2 weeks before initiation of immunosuppressive therapies. However, if this is not possible, these individuals may still receive the vaccination. Immunocompromised individuals should discuss this with their healthcare provider.

Can I take the vaccine if I have an autoimmune condition?
The CDC states people with autoimmune conditions may still receive the COVID-19 vaccines.

Can I take the vaccine if I currently am infected with COVID-19?
No. You should wait until you have recovered and no longer in isolation. See the question below for more information.

Can I take the vaccine if I have already had COVID-19 and recovered? How long after can I take it?
Yes. People who have already had COVID-19 and recovered should still receive the vaccine. This is because it is unknown exactly how long immunity lasts after recovering from COVID-19. Early studies show that it is not long lasting, and cases of reinfection have been reported. There is no recommended minimum interval between COVID-19 infection recovery and vaccination.

Can I take the vaccine if I am in quarantine?
Individuals in quarantine should wait until their quarantine period has ended to avoid exposing health care personnel during their vaccination visit.

Can I take the vaccine if I have had convalescent plasma or a monoclonal antibody for COVID-19?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in people who received convalescent plasma or a monoclonal antibody. Vaccination should be deferred until 90 days after receiving convalescent plasma or monoclonal antibodies. This is to avoid interference of these treatments with vaccine induced immune responses.

Can I take the vaccine if I am receiving antibody therapy for conditions other than COVID-19 (e.g., IVIG, RhoGAM etc.)?

Yes. There is no recommended interval between receiving these antibodies and the COVID-19 vaccines. The CDC states taking the COVID-19 vaccine with or at any interval before or after these antibody products is unlikely to negatively affect development of a protective antibody response.

Can I take the COVID-19 vaccine with other vaccines?
COVID-19 Vaccines may now be co-administered with other vaccines. This includes receiving other vaccines on the same day or within 14 days of receiving the COVID-19 vaccine. It is unknown whether there are likely to be more side effects with coadministration.

How effective are the vaccines?
The following is based on results from phase 3 clinical trials:

COVID-19 Vaccine Efficacy			
Vaccine	**Pfizer**	**Moderna**	**Janssen**
Efficacy	95% against symptomatic disease	94% against symptomatic disease	85% against severe disease

Comparing vaccine efficacy percentages should not be done as these vaccines were not studied in head to head trials against each other (they were all studied against placebo). They were also studied during different times during the pandemic, the emergence of variants may have had an impact on results.
All 3 vaccines are highly efficacious. It's important not to think that any of the vaccines are "better" than the others in terms of efficacy. They all have high efficacy in protecting against severe COVID-19 disease, and COVID-19 related hospitalizations and death. They all have been reviewed rigorously by the scientific experts and have met the FDA efficacy standards for emergency use authorization. The CDC states the any COVID-19 vaccine can be used when indicated. They do not have a product preference.

How long will immunity last after I get vaccinated? Will I need to be vaccinated every year? The full length of immunity following vaccination is not yet known for COVID-19. This is an area that is still being studied. New research conducted by Pfizer and Moderna indicates that the vaccine still has high efficacy even at 6 months after second dose.

How many people need to get the vaccine for "herd immunity"?
The number or percentage of population that need to be vaccinated in order to reach "herd immunity" is not yet known. This number is impacted by the pathogen itself (in this case a novel virus with still unknown aspects), how efficacious these vaccines are, and how long immunity lasts with these vaccines. This is an unknown at the moment as we do not know how long immunity lasts either from vaccination or from natural infection.

For 2 dose mRNA vaccines, what happens if I only receive one dose of the vaccine and not both?
It is recommended to receive both doses of the vaccine. Both doses of the vaccine are necessary for optimal protection.

For the 2-dose series vaccines, when do I take the second dose?
The Pfizer product is a 2-dose vaccination series given 21 days apart. The Moderna product is a 2-dose vaccination series given 28 days apart. If more than this interval of time has passed since the first dose, the second dose should be given at the earliest opportunity. You do not have to repeat any doses. The

second dose should be administered as close to the recommended interval as possible, however, if this is not feasible, the second dose may be scheduled up to 6 weeks (42 days) after the first dose. There is limited data on efficacy if the second dose is administered beyond this timeframe. If the second dose is administered beyond this interval, however, there is no need to restart the series.

For the 2-dose series vaccines, do I have to take the same product for both doses?
The mRNA COVID-19 vaccines are not interchangeable with each other. The safety and efficacy of a mixed-product series have not been evaluated. Both doses should be completed with the same product. In exceptional situations, where the product used for the first dose is no longer available, an alternate mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the vaccination series. If two doses of different mRNA COVID-19 vaccines are administered, no additional doses are needed.

For the 2-dose series vaccines, how will the second dose of the vaccine be ensured if I do get the first dose?
The CDC, federal agencies and state public health departments are using a tool called the Vaccine Administration Management System (VAMS). This is an online tool that will allow clinicians to set up customized vaccine schedules, and allow recipients to make vaccination appointment, in addition to get a reminder about returning for a second dose if required.

How do the Pfizer and Moderna mRNA vaccines work?
The vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 spike protein. The spike protein is the part of the coronavirus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created it causes the immune system to make antibodies against the virus. These antibodies can the provide protection if a person comes into contact with the coronavirus. The mRNA vaccines are non-infectious and do not enter the human cell nucleus so it cannot be inserted into human DNA. Additionally, mRNA is rapidly broken down, and this theoretically reduces chances for long term side effects. The mRNA vaccines do not have the ability to cause cancer.

How does the Janssen viral vector vaccine work?
The Janssen vaccine contains a weakened “common cold” virus called an adenovirus. This virus cannot replicate in the human body, and will not cause an infection. The adenovirus carries a gene for the coronavirus spike protein which allows it to be created and recognized by the immune system. The spike protein is the part of the coronavirus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created it causes the immune system to make antibodies against the virus. These antibodies can the provide protection if a person comes into contact with the coronavirus.

Can I get COVID-19 from a vaccine?
No. None of the COVID-19 vaccines currently authorized for use or in development in the United States use the live virus that causes COVID-19. The vaccines will either contain mRNA (non-infectious genetic material), viral vectors, (modified versions of live viruses that cannot replicate), or protein subunits (parts of viral proteins) which cannot cause infection. Protection from the vaccine is not immediate, and it will take 1-2 weeks following the second dose of an mRNA vaccine, or 28 days following the Janssen

vaccine to be considered fully vaccinated. That means it is possible you could catch the virus from the community just before or after vaccination and get sick. The vaccine itself, does not cause infection.

Will taking the vaccine cause a false positive COVID test?
No. The COVID-19 vaccines will not cause a false positive result on COVID-19 viral tests that test for a current infection. There is a possibility that you will test positive on some antibody tests that detect antibodies to the spike protein. A positive antibody test means you may have previously been infected with COVID-19, or it may result from vaccination.

Why did vaccine development happen so fast?
The vaccine development process is happened faster because vaccine research and development, clinical trials, manufacturing, and plans for distribution occurred at the same time. This method removed delays that could have happened if these processes were carried out separately similarly to the past. Steps in the clinical trials to ensure safety and efficacy were not eliminated.

QR codes
Pfizer

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

Moderna

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

Janssen

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

References

Advisory Committee on Immunization Practices Meeting Webcast. December 12, 2020.
Centers for Disease Control and Prevention Clinical Partner Call: What Clinicians need to know about the Pfizer-BioNTech COVID-19 Vaccine. December 13, 2020.
Baden et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med 2020. DOI: 10.1056/NEJMoa2035389
Centers for Disease Control and Prevention. Clinical Care Considerations for COVID-19 Vaccination. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Centers for Disease Control and Prevention. Frequently asked questions about vaccination. Available from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
Centers for Disease Control and Prevention. Vaccines & Immunizations. Vaccination Communication Toolkit. Available from https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
Centers for Disease Control and Prevention. Ensuring the safety of COVID-19 vaccines in the United States. Available from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html COVID-19
Food and Drug Administration. Janssen COVID-19 Vaccine EUA Fact Sheet for Health Care providers. https://www.fda.gov/media/146304/download
Food and Drug Administration. Joint Media Call. https://www.youtube.com/watch?v=_ELXnGYgsJY
Pfizer. Pfizer-BioNTech announce positive topline results of pivotal COVID-19 vaccine study in adolecents. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-announce-positive-topline-results-pivotal
Polack F et al. Safety and efficacy of the BNT162b2 mRNA COVID-19 Vaccine. N Engl J Med 2020; 383: 2603-15
Rose DR et al. Antibody persistence through 6 months after the second dose of mRNA-1272 vaccine for COVID-19. April 2021. DOI: 10.1056/NEJMc2103916
Vaccine and Related Biological Products Advisory Committee Meeting. December 10 2020.
Vaccine side effects. US Department of Health and Human Services. Available from https://www.vaccines.gov/basics/safety/side_effects
Vaccine Management System. Deloitte. Available from https://www2.deloitte.com/us/en/pages/publicsector/solutions/vaccine-management-system.html
West Virginia Department of Health and Human Resources. West Virginia COVID-19 Vaccines Communication Toolkit.
West Virginia Department of Health and Human Resources. COVID-19 Vaccine. Vaccinate.wv.gov
Zhang et al. Advances in mRNA vaccine for infectious diseases. Front. Immunol. March 2019; 10:594