

COVID-19 VACCINE CLINICAL QUESTIONS

Q. Why is it important to get vaccinated for COVID-19?

1. If you get vaccinated it will help you keep your **residents** safe
2. If you get vaccinated it will help you keep your **family members** safe
3. If you get vaccinated it will help you keep your **co-workers** safe
4. This vaccine will help keep you from getting sick or seriously ill from COVID-19
5. This vaccine will help stop the pandemic

The CDC also provides information on the [benefits of COVID-19 vaccines](#).

Q. Why do we need to continue to follow infection control measures like wearing PPE, social distancing and testing after getting the vaccine?

A. There are a few reasons the CDC continues to recommend basic infection control measures after receiving the vaccine, which include:

- It will take up to four weeks after the second dose to achieve immunity.
- The clinical trial measured if this vaccine protects the recipient from getting sick or ill COVID-19 but did not yet measure if it stops a person from getting COVID and spreading it to others. So, a person could still be a carrier of the virus, but not show symptoms.
- No vaccine is 100% effective, and not everyone else in your community (residents and staff) will take the vaccine. Until there are high number of people vaccinated, the virus can still spread and cause infections in some people who were vaccinated.

Remember, the vaccine is still in very early stages of distribution and experts are still learning more. One of the key decision points on reducing these basic infection control measures will be the number of people who take the vaccine. So, it's important that you encourage others in your facility and community to take the vaccine.

Q. Has this vaccine been properly tested for adverse events?

A. In general, most adverse events to vaccines occur within a few weeks to months after receiving a vaccine. The Pfizer trial enrolled 40,000 people and followed them for an average of two months after the second dose, and the Moderna trial enrolled over 30,000 people and followed them for an average of 9 weeks after the second dose. The rate of "adverse events" (serious, life threatening events) in both trials was extremely low and essentially not different between the vaccine group and placebo (not vaccinated) groups. This means that the adverse event was likely not a result of the vaccine.

Q. What are the side effects of the Pfizer and Moderna vaccines?

A. The most side effects for both vaccines fall into two categories:

- local reactions at the site (such as pain, swelling or redness)
- systemic symptoms (such as fever, chills, fatigue, muscle or joint pains, or headaches)

Local reactions in the Moderna trial were common, with 87.4% reporting local reactions after dose 1 and 90.5% after dose 2. However, only 4% of participants reported grade 3 (severe) reactions after dose 1 and 7.4% after dose 2. [Local reactions reported after Pfizer](#) vaccine were also common, with 84.7% of participants reporting. Similar to the Moderna vaccine, severe local reactions were rare with only 1-2% of participants reporting severe reactions after either dose.

For both vaccines, the frequency and severity of systemic symptoms were slightly higher after Dose 2 than Dose 1. For both vaccines, fatigue, headache and new/worsened muscle pain were most common symptoms but most were either mild or moderate (see table below for frequency of symptoms following each dose).

Pfizer trial data is available [here](#) (pages 36-38) and summarized below for age group (15-55yrs):

% with symptoms	Dose 1			Dose 2		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	2.8%	0.7%	0.3%	9.2%	5.2%	1.2%
Fatigue	26.0%	19.9%	1.4%	21.1%	33.7%	4.6%
Headache	27.4%	13.4%	1.0%	25.6%	22.9%	3.2%
Chills	10.0%	3.6%	0.4%	17.1%	15.9%	2.1%
Muscle Aches	11.2%	9.5%	0.6%	15.5%	19.5%	2.2%
Joint Pain	6.4%	4.3%	0.2%	9.8%	11.2%	1.0%

Moderna trial data is available [here](#) (pages 36-38) and summarized below for the age 18 to 64:

% with symptoms	Dose 1		Dose 2	
	Mild or Moderate	Severe	Mild or Moderate	Severe
Fever	0.8%	0.1%	15.8%	1.6%
Fatigue	37.4%	1.1%	57.0%	10.6%
Headache	33.5%	1.9%	57.8%	5.0%
Chills	9.1%	0.1%	46.8%	1.5%
Muscle Aches	23.1%	0.6%	5.1%	1.0%
Joint Pain	0.0%	0.4%	0.0%	5.8%
Nausea/Vomitting	9.3%	0.1%	21.2%	0.1%

Q. What ages are the vaccines approved for?

A. The Pfizer vaccine has been [approved](#) for individuals 16 and older. The Moderna vaccine is approved for individuals 18 years and older.

Q. Are there any preexisting conditions that will exclude an individual from receiving the vaccination?

A. The FDA fact sheet for both [Pfizer](#) and [Moderna](#) indicates that individuals with a history of severe allergic reaction to any ingredient of this vaccine, or severe allergic reaction to a previous dose of this vaccine, should not receive the vaccine at this time.

The Pfizer has been approved for individuals older than 16 years of age. The Moderna has been approved for individuals over 18 years of age. There is no data indicating concerns in younger groups, the vaccine has simply not been properly tested among these age groups.

While the vaccine has been approved for use in pregnant women, CDC is recommending that individuals who are pregnant or breastfeeding discuss risks versus benefits of this vaccination with their healthcare provider.

While some immunocompromised individuals such as those with HIV were included in the trial, there were not enough participants to draw any conclusions about the vaccine's effectiveness in this group.

Q. Should individuals who have recovered from COVID-19 get the vaccine?

A. Yes, the vaccine is recommended individuals who have recovered from COVID-19. In the Pfizer trial, 10% of the participants already had COVID-19 and receiving the vaccine appeared beneficial. Also, some people who have recovered from the virus have low levels of antibodies and some have been shown to be re-infected.

Q. How long after does an individual who has recovered from COVID-19 need to wait to get the either vaccine?

A. They can get the vaccine right away after their recovery. Recovery is defined as 10 days after the diagnosis for mild to moderate infections and 20 days for severe infections.

Q. If an individual currently has COVID-19 can they get either vaccine?

A. Individuals who are sick with COVID-19 are not recommended to be vaccinated so they don't inadvertently spread the virus to others.

Q. Will someone who received the vaccine test positive on a PCR test due to the antibodies produced from the vaccine?

A. No, the first vaccines (Pfizer and Moderna) are RNA injections and PCR tests are not impacted by them.

Q. Will someone who receives the vaccine test positive for COVID-19 using the rapid antigen test?

A. No. The first vaccines (Pfizer and Moderna) are RNA injections so there's been some question on whether individuals who have received the vaccine would test positive on an antigen test. However, they do not cross react with the antigen tests, the antigen measured is completely distinct of the RNA injection. As such a person will not test positive just because they received the vaccine.

Q. Do these vaccines affect fertility in females?

A. No. Recently, this is a rumor that started on [social media](#) and falsely claims that this vaccine causes infertility. Research has found no link between this vaccine and fertility. The vaccine creates antibodies to the virus not to any human cells. Women who have been infected with the COVID-19 and developed these antibodies naturally have become pregnant. In addition, two large studies of pregnant women in Philadelphia and in England found no increase in preterm births or still births among women infected with COVID-19. Lastly, 12 women in the Pfizer vaccine trial became pregnant after getting the vaccine.

Q. I've been seeing some media posts about the vaccine causing allergic reactions, and that if you have severe allergies you shouldn't take it. Is this true?

A. Anaphylactic reactions have been reported in a small number of people in the UK and the US who have taken the Pfizer vaccine. Pfizer clinical trials showed no evidence of this reaction, so we are still learning more about what is causing these rare but serious reactions. The Pfizer FDA [fact sheet](#) indicates that individuals with a history of severe anaphylactic allergic reaction after receiving a vaccine or injectable medication or individual who have had a severe allergic reaction to any ingredient of this vaccine should not receive the vaccine at this time.

In all cases, the individuals who have had these reactions have responded to treatment and have recovered. The pharmacies administering these vaccines have experience in dealing with anaphylactic reactions and will have EpiPens available with them. If you have a history of anaphylactic allergic reactions, talk to the pharmacist about that before receiving the vaccination. The CDC also has information [here](#).

Each person needs to consider the risks of contracting COVID-19, as well as the risks of developing serious illness and dying from COVID-19 compared to the rare risk of anaphylaxis right after getting the vaccine.

As of now, there's been no similar reactions reported after administration from the Moderna vaccine.

ADDITIONAL RESOURCES

- [CDC Importance of Vaccines for LTC Residents and Staff](#)
- [CDC Post-Vaccine Considerations for Healthcare Personnel](#)
- [CDC COVID-19 Vaccination Communication Toolkit for Health Systems and Clinics](#)
- [AMDA FAQ on Vaccine Safety and Efficacy](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#)
 - [EUA Fact Sheet for Recipients](#)
 - [EUA Fact Sheet for Healthcare Providers](#)
- [Moderna COVID-19 Vaccine](#)
 - [EUA Fact Sheet for Recipients](#)
 - [EUA Fact Sheet for Healthcare Providers](#)