

## COVID-19 VACCINE CLINICAL QUESTIONS

### TOPIC HEADERS:

- [Top Five Questions](#)
- [Vaccine Development and Approval](#)
- [Vaccine Efficacy](#)
- [Vaccine Safety](#)
- [Contraindications](#)
- [Testing after Vaccination](#)
- [Additional Resources](#)

### TOP FIVE 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. 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. 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](#) and [Moderna](#) sheets both indicate that individuals who have had severe anaphylactic allergic reaction after receiving a previous dose of this vaccine or individuals 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.

**Q. How effective is this vaccine and how long does immunity last?**

**A.** Pfizer and Moderna vaccines are reported to be highly effective at 95.0% and 94.5% efficacy, respectively, based on data from the clinical trials. Duration of protection from these vaccines is not yet known and is something experts will be carefully evaluating in the months to come. However, it's expected that booster shots will be required such as with the seasonal flu vaccine.

**Q. Should individuals who have recovered from COVID-19 get the vaccine? How long do they need to wait?**

**A.** Yes, the vaccine is recommended for 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.

Individuals who have had COVID-19 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. 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:

- 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.
- 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 from COVID-19 but did not measure if it stops a person from getting COVID-19 and spreading it to others. So, a person could still be a carrier of the virus, but not show symptoms.

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.

## COVID-19 VACCINE DEVELOPMENT AND APPROVAL

### Q. How was this vaccine developed so quickly?

A. Prior to the COVID-19 vaccine, the fastest vaccine ever developed was for the mumps, and it took 4 years but used a different methodology that takes more time. So, the development of COVID-19 vaccines in under a year is a huge scientific accomplishment but relied on a technology that has been widely used and tested in cancer treatments and other vaccines. It did not happen by accident or by cutting corners. There are several factors that allowed the rapid development of the COVID-19 vaccines.

- COVID-19 is caused by the SARS-CoV-2 virus, which is a member of the coronavirus family. Researchers have been studying these viruses for years.
- Researchers across the world collaborated and shared data to successfully uncover the viral sequence of SARS-CoV-2 quickly
- COVID-19 vaccine received an influx of funding from the government and private sector. This allowed clinical trials and manufacturing to be completed in parallel, instead of sequentially as it normally done.
- Researchers used mRNA technology, which had been in development for years, to develop COVID-19 vaccines, which cuts the time to produce the vaccine way down.

For more information, check out this [article](#) in Nature.

### Q. How does an mRNA vaccine work? Are there any mRNA vaccines already in existence?

A. An mRNA vaccine causes the cells to make a harmless piece of the COVID-19 spike protein, which is found on the surface of the virus that causes COVID-19. Here's a summary of the CDC's [explanation](#) of how the mRNA vaccine works:

1. The COVID-19 mRNA vaccine is injected in your upper arm
2. Your immune system takes up the mRNA as it normally does for any new virus or infection, the immune cells use the mRNA to make the spike protein piece.
3. After the protein piece is made, the cell breaks down the mRNA instructions and gets rid of them.
4. Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.
5. At the end of the process, our bodies have learned how to protect against future infection.

The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

## **COVID-19 VACCINE EFFICACY**

### **Q. How long does it take for the vaccine to take effect?**

**A.** It can take up to four weeks after the second dose to gain full protection provided by the vaccine. The human body starts to make antibodies within 7 days of getting the vaccine and after 14 days most people have antibodies and by four weeks everyone should have their immune system and antibodies primed to work if you got exposed to the virus.

### **Q. Will this vaccine be effective against the new strains of COVID-19?**

**A.** Yes, experts all believe it will be effective because the antibodies made are to parts of the virus that is not changing in these new strains.

### **Q. What happens if you miss the second dose of the vaccination?**

**A.** The clinical trial data indicated that the second dose dramatically increases protection against COVID-19, which is why two doses are indicated for this vaccine. A person's immune system gets stronger after each time its exposed to an infection or antigen such as a virus. Individuals should make sure they know where they are getting the second dose of the vaccine and talk to their healthcare providers if there are any concerns about getting the second dose of the vaccine.

## **COVID-19 VACCINE SAFETY**

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

**A.** 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. In general, most adverse events to vaccines occur within a few weeks to months after receiving a vaccine.

### **Q. What symptoms might you expect to see after taking the vaccine?**

**A.** The most symptoms 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)

Mild 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. Mild [local reactions reported after Pfizer](#) vaccine were also common, with 84.7% of participants reporting. Like 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). People rated symptoms as mild or moderate when it did not affect their ability to do activities or was easily treatable with medication such as acetaminophen or ibuprofen.

Pfizer trial data is available [here](#) and summarized below for age group 15-55 years.

% 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](#) and summarized below for age group 18 to 64 years.

% 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. 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. In fact, 12 women in the Pfizer vaccine trial and six in the Moderna trial became pregnant after getting the vaccine. This is the same rate as those who received the placebo in the trials.

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.

## CONTRAINDICATIONS

### **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.

While the vaccine can be 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.

The CDC provides guidance on [COVID-19 vaccine considerations for persons with underlying medical conditions](#). Individuals that fall into the following categories are recommended to receive the vaccine but should discuss with their healthcare providers. More information is included below:

- People with weakened immune systems – recommended to receive vaccine
  - Limited safety data is available from the clinical trials.
  - People with HIV were included in clinical trials, but specific safety data is not yet available.
- People with autoimmune conditions – recommended to receive vaccine
  - Limited safety data is available from the clinical trials as these individuals were precluded from enrollment.
- People who previously had Guillain-Barre syndrome – recommended to receive vaccine
  - No cases of GBS were reported following vaccination in the clinical trials.
- People who previously had Bell's palsy – recommended to receive vaccine
  - A few cases of Bell's palsy were reported in trial participants; however, the scientists and FDA do not consider it to be above the rate expected in the general population if you were following tens of thousands of people for two to four months. Therefore, it has not been concluded that these cases were caused by vaccination.

**Q. How long must persons who previously received passive antibody therapy for COVID-19 wait to get vaccinated?**

**A.** Individuals who have received antibody therapy should wait at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

**Q. What ages are the vaccines approved for?**

**A.** 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.

**Q. If an individual currently has COVID-19 can they get the 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.

## **TESTING AFTER VACCINATION**

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

**A.** No, the PCR tests are not impacted by RNA injections.

## **ADDITIONAL RESOURCES**

- [CDC Importance of Vaccines for LTC Residents and Staff](#)
- [CDC Post-Vaccine Considerations for Healthcare Personnel](#)
- [CDC COVID-19 Long Term Care Facility Vaccination Toolkit](#)
- [AMDFA FAQ on Vaccine Safety and Efficacy](#)

- Pfizer-BioNTech COVID-19 Vaccine Resources
  - [CDC Pfizer-BioNTech COVID-19 Vaccine Website](#)
  - [FDA Pfizer-BioNTech COVID-19 Vaccine Website](#)
  - [EUA Fact Sheet for Recipients](#)
  
- Moderna COVID-19 Vaccine Resources
  - [CDC Moderna COVID-19 Vaccine Website](#)
  - [FDA Moderna COVID-19 Vaccine Website](#)
  - [EUA Fact Sheet for Recipients](#)