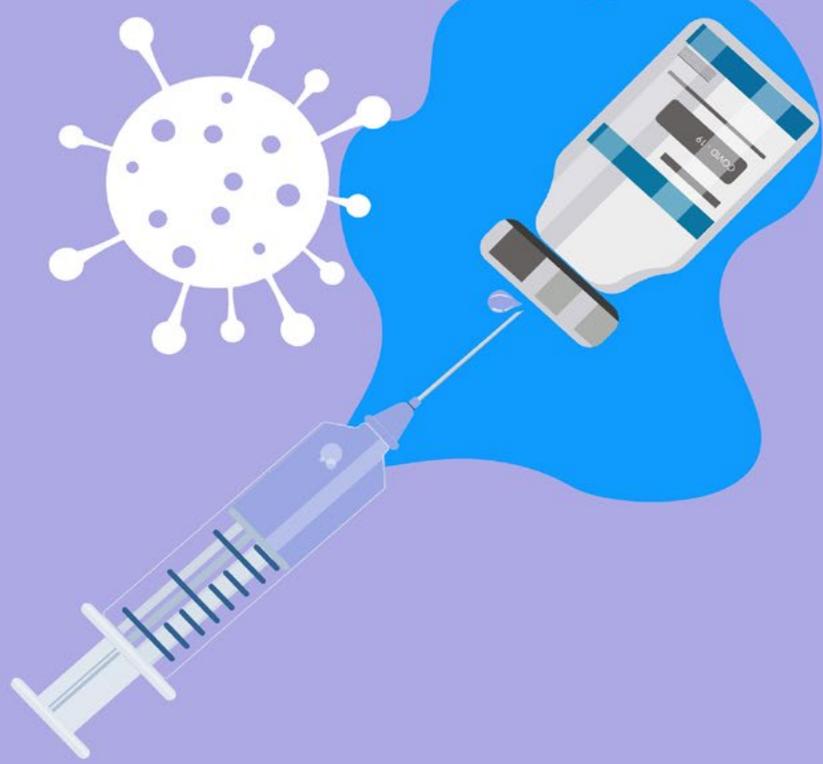


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# A primer on COVID-19 vaccines

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**COVID-19 has followed us into 2021.** The news of multiple successful vaccines has renewed hope and allowed us to look ahead and imagine of some semblance of a new normal in 2021 and beyond. As of this writing, both the Pfizer/BioNTech and the Moderna vaccines have been approved by the United States Food and Drug Administration (FDA) for emergency use authorization (EUA) to begin Phase 1 of inoculating our population against SARS-CoV-2, the virus which causes COVID-19 disease.

As updates are available, and as new vaccines come online and also seek approval for emergency use authorization by the FDA, updates will be made to this document. Specifically, with regard to the process for everyone in Phase 2 and beyond to receive the vaccine, clearer recommendations will be made and this document will be updated to reflect those changes.

## How our immune system works

To better understand how the new COVID-19 vaccines work, we first need to talk about our immune system. When the virus that causes COVID-19 gets into our bodies, usually by breathing in aerosol droplets created when someone else talks, coughs, blows their nose, or breathes, those virus particles attack our bodies and begin to multiply. Once enough virus particles have been created inside your body you may become sick and you can then easily spread the virus on to other people that you come into contact with on a daily basis. The immune system—our body’s defense system against infections—goes to work quickly against foreign germs like the virus that causes COVID-19 disease. When we are infected with a new virus that our body has not encountered before, our immune system can take a while to “catch up” to the virus and

create enough virus-killing cells to combat COVID-19. Once the body creates enough virus-killing cells, your immune system puts them to work against the virus, eventually making you feel better. One of the key types of cells doing the heavy lifting of fighting off the virus are T-lymphocytes—you may know them as T-cells. Remarkably, these T-cells can remember how they fought off a particular infection. In the case of COVID-19 disease, if someone who had COVID-19 encounters the virus again, those T-cells remember the virus and send viral antibodies to attack the virus much more quickly than the first time, providing partial immunity. Researchers are still discovering how long this natural immunity may last.

## How COVID-19 vaccines work with our immune system

Vaccines are one tool in our collective toolbox to fight off COVID-19. Other tools used in preventing exposure to the COVID-19 virus include wearing a mask, washing your hands, and social distancing.

While different vaccines work in different ways (more on that later), all of the COVID-19 vaccines give the body a supply of those T-cells, like the ones mentioned above, that remember how to fight the virus in the future. The vaccines help your body build up a huge number of these T-cells, as well as another type of cell called B-lymphocytes, whose job it is to finish off any virus molecules not killed off by T-cells and other early responders. This process of building up defensive cells usually takes a few weeks, so it is important to continue practicing the wearing of a mask, the washing of your hands, and the social distancing from others, even after you are vaccinated.

## Types of Vaccines

You have probably heard about several different types of vaccines going through trials, being approved by the FDA for emergency use authorization and becoming available for use for healthcare workers and long-term care facilities.

The first vaccine to be approved by the FDA for emergency use authorization was the Pfizer-BioNTech COVID-19 Vaccine, which was approved on Dec. 11, 2020. This vaccine is what is known as an mRNA vaccine. This type of vaccine contains material from the virus that causes COVID-19, which gives our cells instructions for how to make a harmless protein unique to the virus. This triggers the creation of those cells we talked about before—T-cells and B-lymphocytes. These defensive cells go to work and remember how to fight the virus that causes COVID-19 if we are infected in the future.

The second vaccine approved by the FDA for emergency use authorization was the Moderna COVID-19 Vaccine, which was approved on Dec. 18, 2020. This vaccine is also an mRNA vaccine and works the same way as the Pfizer vaccine described above.

## Are the vaccines safe?

Currently, the safety of these vaccines for our families and loved ones is at the forefront of everyone's mind. As with all things COVID-19, we are still learning and our understanding of the virus evolves as new scientific data becomes available to the scientists, doctors, and public health officials doing their very best to keep us safe. Questioning the vaccines' safety is a perfectly natural response. By running through the questions below, we can't give anyone 100% confidence in the new vaccines, but what we can do is share with you what the science says about the safety of the vaccines today. Let's dive into some common questions about the new COVID-19 vaccines.

## Vaccine Q&A

### Question 1: Why is there more than one vaccine?

You may wonder why the vaccine manufacturing companies don't just create one vaccine and then mass produce it for everyone. Usually, when there is a race to create something new, the focus is on producing a single winner. This is not the case with the COVID-19 vaccines. Instead, the goal is to try to bring multiple vaccines into existence in a safe and responsible way. Since the virus that causes COVID-19 can infect anyone, anywhere in the world, we need to produce a lot of vaccine. This effort is a worldwide effort that requires multiple companies to produce viable vaccines so that everyone who wants a vaccine is able to get a vaccine. The more vaccines that are successful at inoculating us from the COVID-19 disease, the faster and more efficiently we can distribute those vaccines all across Arkansas, all across the United States, and ultimately the world.

### Question 2: Who should get the vaccine?

For the Pfizer/BioNTech vaccine, it is recommended that anyone over the age of 16 is vaccinated.

The recommendation for the Moderna vaccine is that anyone over the age of 18 is vaccinated.

### **Question 3: Is there anyone who should NOT get the COVID vaccine?**

You should not get the vaccine if:

- If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction—even if it was not severe—to any ingredient in an mRNA COVID-19 vaccine, you should not get an mRNA COVID-19 vaccine.\*
- If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction—even if it was not severe—after getting the first dose of the vaccine, you should not get another dose of an mRNA COVID-19 vaccine.\*
- An immediate allergic reaction means a reaction within 4 hours of getting vaccinated, including symptoms such as hives, swelling, or wheezing (respiratory distress).
- This includes allergic reactions to polyethylene glycol (PEG) and polysorbate. Polysorbate is not an ingredient in either mRNA COVID-19 vaccine but is closely related to PEG, which is in the vaccines. People who are allergic to PEG or polysorbate should not get an mRNA COVID-19 vaccine.

\* If you have had an immediate allergic reaction—even if the reaction was not severe—to a vaccine or injectable therapy for another disease, ask your doctor if you should get a COVID-19 vaccine. Your doctor will help you decide if it is safe for you to get vaccinated.

### **Question 4: What about pregnant and/or lactating women?**

Currently, there is not enough evidence to make a recommendation for either pregnant and/or lactating women to receive or not receive the vaccine. Talk to your doctor about your risk factors for COVID-19, and continue to wear a mask, wash your hands, and social distance from others.

### **Question 5: How can we be sure the vaccines are safe?**

Both the Pfizer/BioNTech and the Moderna vaccines had to go through the rigorous safety procedures and processes required for approval from the FDA. First, how well the vaccine works had to be tested during multiple phases of trials. Once the vaccine passes these initial trials, an independent group of vaccine experts reviews the safety of the vaccines based on these trials, the FDA's experts review the same data, and

finally, a national group called the Advisory Committee on Immunization Practices\* (ACIP) reviews the data so that they can make a recommendation about which populations should be first to receive the vaccine. Usually this process takes months, and in some cases, years. The importance of finding a working vaccine for COVID-19 was, and continues to be, so great that this process was sped up. However, this does not mean that steps were skipped, nor does it mean that the safety of these vaccines was jeopardized in any way. In fact, more scrutiny was given to these vaccines because the process needed to be sped up. Both vaccines have been found by the FDA to be safe and effective, and no significant safety concerns were identified during the review.

The Advisory Committee on Immunization Practices is chaired by Dr. Jose Romero, the Arkansas Secretary of Health.

### **Question 6: Which vaccine should I get? What are the differences?**

Either vaccine is safe for you to receive. The only difference is that the Pfizer vaccine is approved for persons over the age of 16 and the Moderna vaccine is approved for persons over the age of 18 (see Question 2).

Both the Pfizer/BioNTech and the Moderna vaccines require two separate doses (two different shots). The time in between the first dose and the second dose differs for the Pfizer/BioNTech and the Moderna vaccines. The recommendation for the Pfizer/BioNTech vaccine is to wait three weeks (21 days) between the first and second doses. For the Moderna vaccine, the recommendation is to wait one month (28 days) between the first and second doses.

When you receive your first dose, your healthcare provider, pharmacist, or other healthcare worker will schedule your next appointment to receive your second dose based on the timelines above.

### **Don't mix doses**

The CDC's Advisory Committee on Immunization Practices highly recommends that you receive both doses of the vaccine from the same manufacturer. This means that if you receive your first dose of the vaccine from the supply of Pfizer/BioNTech, your second dose must also be from the supply of the Pfizer-

er/BioNTech vaccine. Similarly, if you receive your first dose of the vaccine from the supply of Moderna, your second dose must also be from the supply of the Moderna vaccine.

**Question 7: What are the side effects? Are the side effects dangerous?**

Both the Pfizer/BioNTech and the Moderna vaccines are given via an injection in the large muscle of your upper arm.

The CDC advises that the following side effects may occur because of the injection.

Pfizer/BioNTech	Moderna
In the arm where you get the shot, you may have: Pain Swelling Redness	In the arm where you get the shot, you may have: Pain Swelling Redness
Throughout the rest of your body, you may have: Chills Tiredness Headache	Throughout the rest of your body, you may have: Chills Tiredness Headache

These side effects usually start within a day or two of getting the vaccine. They might feel like flu symptoms and might even affect your ability to do daily activities, but they should go away in a few days. The CDC offers guidance on [what to expect after getting vaccinated](#).

Generally, there is no danger associated with receiving the COVID-19 vaccine. Unless you have a history of severe allergic reactions (see Question 3), everyone over the age of 16 is eligible to receive the vaccine. The FDA has found both the Pfizer/BioNTech and the Moderna vaccines to be safe and effective, and there are no reported significant safety concerns. In fact, mild side effects, like those listed above, are signs that your body is building up its defensive mechanisms and building protection against COVID-19 disease.

**Question 8: Can either of the COVID-19 vaccines give me the COVID-19 disease?**

No. Unlike some of the other vaccines available that use a weakened or inactivated piece of a virus, the COVID-19 vaccines, known as mRNA vaccines, teach our cells how to create a specialized protein that activates the immune system to be ready.

**Question 9: When will the vaccine be available to me?**

**Phase 1a**

The Advisory Committee on Immunization Practices has recommended that the vaccine roll-out happen in phases. On Dec. 1, 2020, Phase 1a of the vaccine program was rolled out to healthcare workers and long-term facility residents, such as people in nursing homes. Phase 1a includes approximately 24 million people across the United States. In Arkansas, this group will include primary and urgent care workers, providers at college/university student health centers, K-12 health clinics and school nurses, dental clinics, EMS, fire, and law enforcement who serve as first responders, pharmacies, home health, private care/personal care, hospice care, dialysis centers, correction officers, and blood donation centers, comprising approximately 180,000 Arkansans.

As of Jan. 5, 2021, Gov. Asa Hutchinson and Dr. Jose Romero, Arkansas secretary of health, have moved first responders into the vaccine roll-out Phase 1a.

**Phase 1b**

On Dec. 20, 2020, ACIP recommended that in Phase 1b, vaccines should be offered to people ≥75 years of age and to frontline essential workers (non-health-care workers). ACIP has classified the following personnel as Phase 1b workers: first responders (such as firefighters, fire fighters and police officers), corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the education sector (teachers and support staff members) as well as child-care workers. Phase 1b includes approximately 49 million people across the United States.

In Arkansas, this group includes teachers and school staff, food and agricultural workers, firefighters/police not in Phase 1a, manufacturing workers, grocery store workers, public transit workers, child-care

workers, U.S. Postal Service workers, and essential government workers, comprising approximately 400,000 Arkansans.

As of Jan. 5, 2021, Gov. Hutchinson and Health Secretary Romero, have adjusted Phase 1b to reflect that persons who are  $\geq 70$  years of age are to be included in this phase.

### **Phase 1c**

As of this writing, Phase 1c does not yet have a timeline. However, Phase 1c will see the vaccine offered to persons aged 65-74 years, persons aged 16-64 years with medical conditions that increase the risk for severe COVID-19 disease, and essential workers not previously included in Phase 1a or 1b. Phase 1c includes approximately 129 million people across the United States. In Arkansas, this group includes people who are aged 65-69, people who are 16-64 with high-risk medical conditions, and essential workers such as: transportation and logistics, water and wastewater, food service, shelter and housing, public safety, finance, IT and communications, energy, media, and public health workers.

### **Phase 2**

Phase 2 includes all other persons aged  $\geq 16$  years not already recommended for vaccination in Phases 1a, 1b, or 1c. Currently, in accordance with recommended age and conditions of use (1), any authorized COVID-19 vaccine may be used. ACIP is closely monitoring clinical trials in children and adolescents and will consider recommendations for use when a COVID-19 vaccine is authorized for use in persons aged  $< 16$  years.

### **Question 10: Will there be enough doses for everyone?**

At first, no. Each week, more and more vaccine doses are becoming available in the United States and across Arkansas. The roll-out of the vaccine will progress according to the Arkansas Department of Health COVID-19 Vaccination Phased Plan. It will progress according to the plan laid out in Question 9 above. Once we have progressed through Phases

1a, 1b, and 1c, which will take some time, and the vaccine is available for everyone, then yes, there will be enough vaccine doses for everyone who wants the vaccine to have the vaccine. You can check the number of vaccine doses sent to Arkansas by following this link to the Arkansas Department of Health's COVID-19 Vaccination Plan Dashboard.

### **Question 11: Where can I get the vaccine?**

While decisions are still being made about where the general public can receive their vaccine once it becomes available, it is likely that you will be able to receive the vaccine at your local pharmacy store and/or your local clinic, doctor's office, or care clinic.

### **Question 12: Can I get a vaccine without insurance? Is there a cost?**

There is not expected to be any cost associated with getting the vaccine. In other words, the vaccine will be free of charge. This means you will be able to receive the vaccine even if you do not have insurance coverage. While eventually the COVID-19 vaccine(s) may be covered by your insurance provider, currently the vaccine is being rolled-out free of charge.

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The above information was written with evidence-based information from the Centers for Disease Control and Prevention (CDC), the United States Food and Drug Administration, (FDA), and the CDC's Advisory Committee on Immunization Practices (ACIP).

For further information, please visit the following websites:

- [Understanding How COVID-19 Vaccines Work](#)
- [Information about the Pfizer/BioNTech COVID-19 Vaccine](#)
- [Information about the Moderna COVID-19 Vaccine](#)
- [Understanding mRNA COVID-19 Vaccines Vaccination Considerations for People who are Pregnant or Breastfeeding](#)
- [Advisory Committee on Immunization Practices \(ACIP\) Recommendations for Allocation of COVID-19 Vaccine](#)