

# COVID Vaccine Q&A

The FDA has authorized the emergency use of the Pfizer vaccine in individuals 16 years and older. See the [Pfizer Vaccine Fact Sheet](#).

## **Safety**

### **Is it safe?**

[COVID-19 Vaccine Safety](#): Two independent advisory committees [ACIP and the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC)] review vaccine safety data. ACIP also monitors post-market safety and effectiveness data for new vaccines. For COVID-19, ACIP has formed a separate Vaccine Safety Technical (VaST) Subgroup to provide timely evaluation of vaccine safety, both pre- and post-licensure.

[Enhanced Safety Monitoring for COVID-19 Vaccines](#): In addition to the Vaccine Adverse Events Reporting System (VAERS) and other systems routinely used by CDC and FDA to monitor vaccine safety, CDC is adding further monitoring programs for COVID-19 vaccines. Data on vaccinated healthcare workers will be collected through the National Healthcare Safety Network (NHSN) system. The Vaccine Safety Assessment for Essential Workers (V-SAFE) program, a smartphone-based active surveillance system, will collect text- or web-based health checks from early vaccine recipients who volunteer to report for 6 weeks post-vaccination. Any clinically important event(s) reported by the vaccine recipient will be followed up and a VAERS report will be submitted, as appropriate.

Learn more on CDC's [Ensuring the Safety of Vaccines](#).

### **How do we know the vaccine is safe, since it was “rushed” through the process?**

The biggest portion of the vaccine approval process that was “rushed” is the ramping up of vaccine production. Usually, pharmaceutical companies wait until full approval before starting manufacture, to avoid wasting money and resources if not approved. In the case of the COVID vaccines, the U.S. government paid pharmaceutical companies to go ahead and start ramping up production ahead of approval.

Emergency use authorization (EUA) approval was based on shorter term follow-up than normal. Normally, they like to follow trials for a year to see how long immunity lasts, so we don't yet know if a booster will be needed in the future. However, even six months immunity will help with getting back to normal.

The vast majority of vaccine side effects are immediate reactions like muscle aches. Late term adverse effects from vaccines are extremely rare, and there is no reason to think that would happen with the COVID vaccines.

### **If the COVID-19 vaccine is safe, why isn't Avera requiring it?**

The COVID-19 vaccines are approved by the FDA under what is termed an Emergency Use Authorization. The Emergency Use Authorization allows the FDA to help strengthen the public's health protections during a national emergency. The vaccine goes through many rigorous safety measures that are similar to a standard FDA approval, and Avera feels very comfortable that the COVID-19 vaccines approved under EUAs are safe and effective. However, the EUA is specific to each vaccine, and excludes certain groups because they have not been thoroughly tested. For that reason, Avera has not instituted a broad requirement that employees get the vaccine;

however, it is very strongly encouraged. If enough people get vaccinated, we can end this pandemic.

### **What are the side effects of the vaccine?**

According to Pfizer, early data on the vaccines show mild and temporary side effects like headache, fatigue and mild fever, which are all common signs that show a vaccine is working to help you build immunity.

There have been no serious side effects. The vaccine has shown no neurological problems (Guillain-Barre Syndrome) or allergic reactions at a rate higher than the placebo. The CDC encourages people with asthma, COPD, etc., to take the vaccine. [More...](#)

### **How should potential vaccine side effects impact scheduling of employee vaccinations?**

Because vaccine recipients may see mild and temporary side effects like headache, fatigue and mild fever - all common signs that show a vaccine is working to help build immunity – recipients are advised to get the vaccine at the end of shift and/or before a weekend. Departments may want to consider staggering vaccinations (such as half one day, half the next) to ensure workforce needs are met.

### **Is there a consent form for the vaccine or how do I agree to be vaccinated?**

In South Dakota, there is not a consent form for the vaccine in any care setting including long term care. Signing up and completing the screening process (answering yes you want to receive it) shows you agree to receive the vaccine. Avera is also required to give you the Emergency Use Authorization (“EUA”) Fact Sheet and other education, which will inform you of any contraindications, side effects and what to do if you have a reaction. Long term care facilities are advised to contact a Resident’s surrogate decision maker if the Resident is unable to provide consent prior to giving the vaccine, send them the EUA Fact Sheet, and will need to get phone agreement to vaccinate or decline on behalf of their Resident. A simple yes or no is sufficient and should be documented in the record.

In other states, a consent form may be required, check with your state department of health to learn more.

### **What are the differences between the Pfizer and Moderna vaccines?**

The biggest difference between Moderna and Pfizer is the minimum age:

- Moderna: 18 and over
- Pfizer: 16 and over

Another major difference is storage requirements; Pfizer must be stored at much colder temperatures than Moderna.

A third difference is the time between doses. Both vaccines are a two-dose series, but Moderna doses are separated by 25 to 28 days and Pfizer doses are separated by 21 days.

### **Are the Moderna and Pfizer vaccines “live” vaccines?**

No, neither the Moderna nor the Pfizer contain live virus.

### **Access and timing**

#### **Is this one dose or a series?**

The two initial vaccines projected for release are **two-dose series vaccines** and are not interchangeable. It’s important that you schedule your second dose while getting your first dose

because your booster must be from the same manufacturer. According to Pfizer, its second injection increases effectiveness from 50% after the first dose, to 94% after the second dose.

**Why can't I have the vaccine right now when others are receiving it?**

Unfortunately, at this time, there is not enough vaccine for everyone who is requesting it. Vaccine allocation to states and locations is being based on guidance from the Centers for Disease Control and Prevention (CDC), state health officials, National Academy of Sciences as well as the Catholic Healthcare Association. The best way to prevent COVID-19 is by wearing a mask, practicing social distancing and washing your hands frequently.

**How do I get the COVID-19 vaccine?**

Your location's Vaccine Coordinator will communicate details on how, when and where you can get the vaccine.

**If I am a frontline worker who is receiving the vaccine, is my family eligible to receive the vaccine also?**

At this time, only those on the allocation list are included in the vaccination group.

**If I cannot make the vaccine clinic this time, when is the next chance I will have?**

Depending on how much vaccine we are allocated, it could be a month or longer before you would be offered a second opportunity to be vaccinated. Avera strongly encourages all employees to sign up to be vaccinated as soon as they are eligible based on their role within the organization.

**How frequently will people need to be vaccinated?**

The flu is an annual shot, as it mutates each year. Coronaviruses don't mutate this same way, so the frequency of the COVID-19 vaccine is unknown at this time.

**I move in the winter months, can I get my first dose here and my second dose elsewhere?**

No. To receive your first dose with Avera, you must commit to scheduling your second dose at the same location.

**What should I do if I need to change my scheduled vaccine appointment?**

Patients who need to change appointments for their vaccines should email the COVID-19 Hotline at [covid19hotline@avera.org](mailto:covid19hotline@avera.org).

**Can I reschedule my vaccination appointment?**

To reschedule your first dose, refer to the link in your confirmation email, or visit <https://amcc.force.com/COVID19Vaccine/s/>.

When you receive your first dose, you are committing to your second dose appointment. Receiving your second vaccine dose is a top priority to ensure that you develop immunity. If you have made every effort to keep your second dose appointment but are unable, please contact the COVID-19 Hotline at [covid19hotline@avera.org](mailto:covid19hotline@avera.org) or your vaccine site coordinator.

**I already received my first dose, but I keep receiving invites. Do I need to sign up again?**

No, you do not need to sign up again. You may wish to contact your vaccine site coordinator to provide notification that you have received the first dose.

**I move in the winter months, can I get my first dose here and my second dose elsewhere?**

No. To receive your first dose with Avera, you must commit to scheduling your second dose at the same location.

**As we enter later phases of vaccine administration, is it too late for earlier groups (1A, 1C) to be vaccinated?**

No, those in earlier allocation groups are always welcome to schedule their vaccine appointment, as allocation allows.

**Vaccine and Test Results**

**Will the vaccine affect the results of my COVID-19 Diagnostic (PCR) testing or COVID-19 antibody testing?**

According to the CDC, the vaccine does not interact or cause false positives with COVID-19 diagnostic (PCR) tests. However, since the vaccine builds antibodies, your COVID-19 antibody test results may be positive.

**Allocation Questions**

**How were groups allocated?**

The state health departments have decided the order of vaccination with guidance from the CDC. Avera also consulted [CHA Guiding Principles](#), scientific research on vaccine allocation from the National Academies of Sciences, Engineering and Medicine, and Avera workflow/standard of care.

Categories were chosen based on risk of exposure to COVID, IE duration of exposure and care offered (aerosol-generating procedures, etc.).

**Why are you vaccinating some non-Avera employees first?**

Based on direction from our state health departments, we are vaccinating staff in both Avera and non-Avera emergency departments, ICUs, COVID units and long-term care facilities first. The people being vaccinated serve vital roles across our footprint, and it is the right thing to do.

**Are we vaccinating staff who are contracted, employed by a competitor, or who are students?**

Based on direction from our state health departments, a contracted worker, employee of independent competitor, or student would be treated the same as an Avera employee doing the same work.

**How do we handle residents of other states who come to our clinic to be vaccinated?**

Please vaccinate these patients if they schedule a vaccine appointment at your vaccine clinic. However, we will not be taking vaccine from one state to supply a site in another state.

**How long do we expect Phase 1 to last?**

We've had no indication how big the weekly allocations will be, so we are unable to predict.

**Will independent LTC sites vaccinate all of their staff or just CNAs and nurses?**

Frontline, patient facing staff come first. If they are interacting with residents, they should be included.

**I already received my first dose, but I keep receiving invites. Do I need to sign up again?**

No, you do not need to sign up again. You may wish to contact your vaccine site coordinator to provide notification that you have received the first dose.

**The Vaccine and Your Health****If I've had COVID-19, do I need a vaccination?**

Yes, as long as you are not in a group for which the vaccine is not recommended, the CDC recommends that those who have completed isolation after a COVID-19 infection get the vaccine. According to the CDC, there is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.

**Can someone with active COVID be vaccinated?**

The CDC recommends that individuals currently under isolation for active COVID do not get vaccinated until their isolation period is complete. Similarly, those under quarantine for COVID close contact should not be vaccinated until their quarantine period is complete to avoid risking exposing vaccination workers.

**Can someone who has been exposed to COVID-19 (within 6 feet for a total of 15 minutes or more of someone who has tested positive for COVID-19) get vaccinated?**

Exposed individuals should wait until they complete their quarantine after COVID-19 exposure. This is not a safety-based recommendation; rather, it protects vaccine staff. The exceptions are long term care and congregate settings, in which vaccination is recommended for quarantining individuals using adequate PPE.

**Can immunocompromised patients receive this vaccine?**

The CDC recommends the vaccine for immunocompromised individuals, such as transplant and cancer patients. It may be less effective but is still recommended.

**Can pregnant or breastfeeding women receive this vaccine?**

ACOG (American College of obstetricians and gynecologists) recommends COVID-19 vaccines not be withheld from pregnant individuals who meet criteria for vaccination based on CDC-recommended priority groups. According to ACOG, while safety data on the use of COVID-19 vaccines in pregnancy is not available, there is also no data or signs the vaccine is unsafe that would indicate that the vaccines should be withheld. The vaccines do not enter your cells so do not alter human DNA; therefore they do not cause genetic changes. ACOG recommends pregnant women treat any mild vaccine side effects with acetaminophen. ACOG says other considerations include how much COVID-19 is in your community, how able you are to limit your exposure, and whether you have underlying health conditions that could mean COVID-19 would be more severe for you. No data is available on the effectiveness of the vaccine for pregnant women, but ACOG states it is likely similar to non-pregnant adults, in which the vaccine is 95% effective. For more discussion, pregnant women are encouraged to discuss with their physician.

According to the CDC, there are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. mRNA vaccines (the type of vaccine of the current COVID-19 vaccines in the market) are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

### **Does the COVID-19 Vaccine affect fertility?**

No, there is no evidence that the COVID-19 vaccine causes infertility because of the way the vaccine interacts with the body. Both Pfizer and Moderna use mRNA to persuade the body to develop antibodies. According to the [American Academy of Family Physicians](#), an mRNA vaccine uses a piece of messenger RNA — a set of instructions that tells a cell to make a specific protein. For SARS-CoV-2, this is the spike protein that is found on the surface of the viral envelope. The mRNA used in the vaccine does not enter the cell's nucleus and consequently has no interaction with a cell's DNA. It is also not a full virus and cannot replicate itself. The mRNA is rapidly broken down by the cell once the instructions have been transmitted, so it does not cause mutations or cellular defects, and has not been associated with infertility. Once the spike protein is made, it is put on the surface of the cell, where it is seen by the immune cells and causes them to become activated and respond. The result is the production of neutralizing antibodies. If a person who is immunized becomes infected with the virus, the neutralizing antibodies will bind to the virus and prevent it from entering cells and causing disease.

### **Can someone with underlying conditions get the vaccine?**

The CDC recommends that individuals with underlying health issues, such as COPD, asthma, diabetes, etc., get the vaccine.

### **Are there known interactions with any medications, monoclonal antibody therapies, or other vaccines?**

The CDC says the COVID-19 vaccine should be separated from other vaccines by at least 14 days before/after. If accidentally given closer to another vaccine, there is no need to repeat either vaccine.

There is also not a lot of data around other medications. However, the trial study had a number of clinical conditions (cardiac, HIV, diabetes), and those participants were on some medication, and that did not present an issue. Some medications may decrease immunity, however the added protection of the vaccine remains worthwhile. You should not receive this vaccine for 90 days after receiving convalescent plasma or monoclonal antibodies such as bamlanivimab or regeneron.

### **Are there any demographics who cannot receive the vaccine?**

The Pfizer vaccine did not receive emergency use authorization for individuals age 15 and younger. The Moderna vaccine did not receive emergency use authorization for individuals 17 and younger.

According to the CDC, you should not get the vaccine if you have had a severe allergic reaction (anaphylactic, swelling of the face, mouth or throat) to a previous dose of this vaccine, to any ingredient of this vaccine, to another vaccine, to other subcutaneous, intramuscular or intravenous injections.

### **Are there long-term effects from this vaccine?**

According to the CDC, this vaccine was developed using mRNA and does not interact with DNA in any way – it is quickly broken down in the cell and never enters the nucleus, and thus won't cause long-term effects. [More...](#)

**Does the flu shot increase my chance of getting COVID?** The flu shot does not increase your chance of getting COVID-19. It actually decreases your chance of getting sick. A flu

vaccine will not protect you from getting COVID-19, but it can prevent you from getting the flu at the same time as COVID-19. This can keep you from having a more severe illness. While it's not possible to say with certainty what will happen in the fall and winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading during that time. That means that getting a flu vaccine will be more important than ever.

### **Should I take ibuprofen or acetaminophen before my vaccination?**

Until we learn more, at this time, we are not recommending that vaccine recipients pre-medicate for anticipated side effects. However, recipients may choose to use ibuprofen or acetaminophen to treat side effects if they develop after they receive the vaccine.

### **What if I get my second dose in a two-dose series late, do I need to restart the series?**

No. The CDC says you can consider your series complete.

### **If a patient has COVID or has been exposed, how does that impact the second dose in a two-dose series?**

According to the CDC, if a patient contracts COVID-19 after getting their first dose in a two-dose series, wait until they are out of their isolation period before administering the second dose.

- COVID-positive patients must isolate for 10 days after symptoms first appear. They may then receive the second dose if their symptoms are improving and they've had no fever for 24 hours.
- Asymptomatic positive COVID patients must wait 10 days after a positive test to exit isolation and receive their second dose.

Similarly, if a patient is exposed to someone who has tested positive for COVID-19 (within 6 feet for a total combined 15 minutes or more), they can get a vaccine after ending quarantine.

- Patients must quarantine for 10 days after exposure, then if they remain asymptomatic, they may exit quarantine.
- Patients may exit quarantine in 7 days if they have a negative test on day 5 or after.
- Continue to watch for symptoms for 14 days after exposure.

There is no need to re-administer the first dose; after quarantine or isolation has ended and second dose is administered, the vaccine course is considered complete.

### **Should the person giving me my vaccine be wearing gloves?**

Gloves are not required PPE for vaccinators. Giving vaccinations without gloves is safe for both you and your vaccinator.

### **After I am fully vaccinated, is it safe for me to be around those who have not had their vaccinations?**

Even after you are vaccinated, you may still be able to spread COVID-19 to others. To protect those around you, continue masking and social distancing until we learn more.

### **What happens if I contract COVID-19 after I have been vaccinated?**

If you are exposed to COVID-19 after you have been vaccinated, your body may be able to quickly fight it off. You may have either minimal symptoms or none at all, especially when compared to not having been vaccinated. Vaccines are 94-95% effective so there is a small chance you could contract COVID-19.

## **Ethical Questions**

**Are there ethical concerns with the COVID-19 vaccine? Was it developed using embryonic stem cells?**

Neither the Pfizer nor Moderna vaccine involved the use of fetal cell lines connected to abortions in their design, development or production. [More...](#)

**Avera Policy Questions**

**Will PPE guidelines be relaxed if I get the vaccine?**

According to the CDC, the vaccine takes effect in two weeks and you need two doses for the most effectiveness. Data does not yet confirm how effective the vaccine is at preventing asymptomatic spread or how long the vaccine will protect you, so it is important to continue social distancing, masking and PPE for now.

**Will visitation guidelines be relaxed after a large amount of people are vaccinated?**

Because we do not know how effective the vaccine is at this point, visitation guidelines will not be relaxed right now.

**Can my employer require that I get it?**

Because this is an Emergency Use Authorization by the FDA, Avera will not require the vaccine at this time. Avera strongly encourages employees who are not in excluded populations to get the vaccine and is offering it first to those employees at most risk of being exposed. Avera employees will be paid for the time spent obtaining the vaccine at a designated inoculation site. Expected time would be no more than 30 minutes.

**Will Employee Health require staff to stay home if they have symptoms after vaccination?**

Employee Health will provide additional guidance about this soon.

**Vaccine Cost**

**What is the cost of the vaccine?**

At this time, there is no out-of-pocket cost of the vaccine to the vaccine recipient.

**Does it matter what health insurance provider I have when it comes to seeking vaccination? What happens if I am vaccinated by an “out-of-network” health care system?**

Regardless of where you access your COVID-19 vaccine, there is no out-of-pocket cost to you. In South Dakota, our health systems have been contracted to administer the vaccine on behalf of the state. If you are offered vaccine, you are encouraged to take advantage of it.