

## FAQ: COVID-19 Vaccine Information

Updated: Dec. 17, 2020

**\*\* We will continue to provide updates to this material as new information becomes available. Please look for our additional FAQs: Vaccine 101 and UCMC & BSD Employee Vaccination Logistics. \*\***

### 1. What vaccines will be available at UChicago Medicine?

Vaccination began Dec. 17 and will continue as we continue to get vaccine allotted to our organization by public health officials. UChicago Medicine will administer the COVID-19 vaccine in accordance with all requirements of the CDC and the CDC's Advisory Committee on Immunization Practice and will comply with all applicable FDA requirements, including, but not limited to any EUA that covers the vaccine. Only vaccines that have been reviewed by the FDA for safety and approved or authorized for use by the FDA will be widely offered to employees and our patients.

### 2. How was the vaccine developed so quickly?

Typically, it takes years to develop vaccines, assure their safety and efficacy, and then manufacture them on a mass scale. Because of the seriousness of the COVID-19 pandemic, the timeline was accelerated through national and international programs supporting the work of scientists around the globe, including teams here at UChicago Medicine. The research and development process was accelerated to allow scientists to perform many steps simultaneously rather than sequentially. The federal effort also provided funding to support the work of pharmaceutical companies to begin manufacturing vaccines before they are approved — allowing for quick distribution if and when the vaccines earn an FDA authorization.

### 3. Can you provide additional detail about the vaccine development process?

Here's a summary of the development process:

- After preliminary research in a lab, scientists tested the vaccines during clinical trials designed to make sure each immunization met or exceeded established safety and efficacy thresholds.
  - Trials began with small groups of people before expanding to include much larger numbers, making sure to include a wide range of people from across the country and around the world. This includes people of different ages, races, sexes, and health conditions. Scientists studied how well the vaccines worked when compared to a control group, which received a placebo version of the vaccine.
  - If clinical trial participants reported certain serious “adverse events” the trial may be placed on hold until the event(s) is investigated.
    - The trials are only restarted once scientists are confident it is safe to continue.
  - Pharmaceutical companies also tracked clinical trial participants after they received a vaccine to make sure they remained healthy and will continue to do so for up to two years.
- All of the research data collected in the vaccine's development is being reviewed by an independent advisory committee (Vaccine and Related Biological Products Advisory Committee) before the full FDA decides whether to issue an EUA.

For additional detail, [visit the FDA's website](#).

### 4. How effective is the COVID-19 vaccine?

Vaccines developed by Pfizer/BioNTech and Moderna have had an independent interim analysis performed on their vaccines. The Pfizer/BioNTech vaccine was reported to be 95% effective after two doses, and 52% effective after the first dose alone. The Moderna vaccine was reported to be 94.5% effective. In documents released December 8, the [FDA has evaluated the data provided by Pfizer/BioNTech](#) and determined that the vaccine is highly effective with even a single dose, with coronavirus cases quickly flatlining about 14 days after the first dose of the vaccine. This is true for all group of participants who were evaluated, regardless of age, weight, or race. The FDA is still awaiting data from the Moderna EUA application to determine the exact effectiveness of their vaccine, but the Moderna application on November 30 reported 94.1% efficacy.

## 5. Is the vaccine safe?

Only vaccines that meet standards for safety and effectiveness (known as efficacy) are approved for emergency use by the FDA. Vaccines are assessed to see whether and how well they can protect people from SARS-CoV-2, the virus that causes COVID-19. Any approved COVID-19 vaccine is tested in a trial of at least 30,000 volunteers and reviewed to make sure it is safe. Like any medical therapy, getting vaccinated is accompanied by some degree of risk. However, the reported potential risks and side effects of a COVID-19 vaccine are substantially lower than the risks and side effects associated with contracting SARS-CoV-2. When evaluating the data provided by Pfizer/BioNTech, the FDA concluded that there are no meaningful imbalances in adverse events between the placebo group and the vaccine group, meaning that there was no statistically significant increase in the risk of experiencing a serious health complication when receiving the vaccine. The FDA has not yet released their evaluation of the Moderna vaccine.

## 6. What are the vaccine's side effects?

All medical treatments have some degree of risk. For vaccines, that risk is typically small. Many vaccines have mild side effects, which usually range from soreness at the site of injection to a slight fever, body aches and a headache. [You can read more here](#). Clinical trials for the COVID-19 vaccine have shown they are 94-95% effective.

- **Pfizer:** Side effects including injection site pain, fever, chills, fatigue, muscle pain, joint pain, headache and swollen lymph nodes. [Data from Pfizer's clinical trial, published December 10](#), showed that the most common side effect was injection site pain. That was followed by fatigue and headache that was primarily mild to moderate. Only 0.5% of those in the vaccine trial reported a severe reaction of which 3.8% had severe fatigue and 2% had severe headache. Fever was infrequently reported (3.7%). Side effects were more commonly seen in people between the ages of 18-55 than those who were 65-85. They were also slightly more likely to occur after the second dose. Side effects typically peaked within two days and were completely over within seven days.
- **Moderna:** Early [data from Moderna's clinical](#) trial also showed typical mild-to-moderate side effects, such as headaches, fatigue, muscle aches, chills, and injection site pain. The independent board that conducted the interim analysis of Moderna's large-scale trial found severe side effects included fatigue in 9.7% of participants, muscle pain in 8.9%, joint pain in 5.2%, and headache in 4.5%. Reactions typically occurred within 1-2 days of receiving the vaccine and tended to go away quickly. They were all resolved within seven days.

Different people can react differently to receiving a vaccine and some people have no reactions at all. However, it's important to know that risks reported in connection with the COVID-19 vaccine are significantly lower — and markedly less severe — than the risks associated with contracting COVID-19 itself.

## 7. Are there concerns about any long-term side effects?

Given the new nature of the COVID-19 vaccine, there hasn't been an opportunity to gather data on the vaccines' long-term side effects. With the Pfizer/BioNTech vaccine, within the first two months, the FDA has determined that there is no increased risk of adverse events following vaccination. The clinical trials will continue after EUA is issued to collect long term safety data on these vaccines. The FDA has not yet released their evaluation of the Moderna vaccine. In the FDA meeting on December 10, it was stated that the FDA's vaccine injury log showed that 6 weeks after vaccination was an appropriate timeframe to observe long-term side effects and for these vaccines no long-term side effects have been reported.

## 8. Can I get COVID-19 from the vaccine?

No. Much like you don't get influenza from a flu shot, it is not possible to get COVID-19 from a COVID-19 vaccine. You may feel unwell after getting vaccinated, and you will not have full protection from the virus until at least 14 days have passed from your second dose. Given our region's widespread community transmission, that means you could still catch COVID-19 after being immunized and before your body's immune system has reached its full ability to fight the virus. In addition, much like the flu vaccine, COVID-19 vaccines are not 100% effective, which means there is a chance you could contract COVID-19. However, researchers believe you may be less likely to get as sick as you would if you were unvaccinated.

**9. Will there be enough vaccine for everyone in the country? Who gets the vaccine first?**

Vaccine availability will be extremely limited for the first few months. However, federal officials say anyone who wants the vaccine will eventually be able to get immunized. Until then, the country will follow distribution guidelines developed by the [CDC](#), [National Academies of Sciences, Engineering, and Medicine](#), and the [Advisory Committee on Immunization Practices](#). This guidance gives priority to people who need the vaccine the most and organizations that administer the vaccine are obligated to follow those guidelines. It has been published that healthcare workers and nursing home patients will be among the first to be vaccinated. Healthcare workers have initially been sub-prioritized, giving priority to those who provide direct patient care to patients with COVID-19 or under investigation, as well as those who perform or attend aerosol-generating procedures. Internally, we are developing our own plan (*more below*) to guide our allocation decisions and ensure we're following scientific and regulatory guidelines while providing fair and equitable prioritization within our workforce. The general public, including the broader University community, likely won't be able to receive the vaccine until later in the distribution process. Updates on the federal allocation process and its impact on our patients and community will be widely communicated.

**10. Is there anyone who shouldn't be vaccinated?**

At this time, you should not get the Pfizer-BioNTech COVID-19 vaccine if you have had a severe allergic reaction after a previous dose of this vaccine or if you've had a severe allergic reaction to any ingredient of this vaccine. You can see [the ingredient list here](#).

**11. Can children be vaccinated?**

The Pfizer/BioNTech vaccine has been approved for use in children 16 and up. However, they are not expected to be vaccinated until later in the nation's vaccination process. Children have generally not participated in clinical trials for the vaccines, however we anticipate there will be more clinical trials that include children in the future. A Pfizer trial in adolescents 12 – 17 years old and another that's expected for children 5 – 11 years old expected to begin in April 2021.

**12. Can I get a COVID-19 vaccine if I'm pregnant, planning to become pregnant, or currently breastfeeding?**

The CDC has indicated that the vaccine may be administered to pregnant women and several [professional societies](#) have [advocated](#) for these individuals to be vaccinated. However, if you have questions or concerns, you should discuss with your healthcare provider. The CDC says those who are pregnant should weigh the following when deciding whether to get the vaccine:

- your individual risk of acquiring the virus (both to community transmission and occupation)
- the potential damaging health outcomes of contracting COVID-19 while you're pregnant
- the side effects that you may experience after receiving the vaccine
- the safety and efficacy data currently available.

**13. How long will it take for me be protected from the vaccine?**

How long it takes to gain immunity to the virus will depend on what vaccine you receive. The FDA has determined that the Pfizer/BioNTech vaccine is highly effective within 14 days of receiving the first dose of the vaccine; Pfizer has stated that the vaccine has an efficacy of about 52% following the first dose. The FDA has not yet released their evaluation of the Moderna vaccine. Generally, you should be protected about 14 days after you receive your second dose of the vaccine. The vaccine is not 100% effective, which means there is still a chance you could contract COVID-19. However, researchers believe you may be less likely to get as sick as you would if you were unvaccinated. Keep in mind: Skipping your second dose (if applicable) could leave you unprotected.

**14. Do I need to take any specific precautions after getting the vaccine, particularly if I'm going back to work or plan to spend time around others?**

Your vaccination poses no risk to others, so you can continue to interact safely with colleagues, patients, and family members. You may develop side effects such as site pain, fever, chills, fatigue, muscle pain, joint pain, headache and swollen lymph nodes. Most of these reactions will be mild to moderate and are a sign that your immune system is activating to protect you from the virus. However, some people may have severe, short-lived reactions. **If you have mild symptoms on Day 1, or improving symptoms on Day 2 after injection, you can return to work. If after two days, your symptoms continue or worsen you will need to stay home from work and get a COVID-19 test. You will need to stay home if at any time you**

**develop a fever of 100.0F or higher or if you have specific COVID-19 symptoms, such as cough, shortness of breath, runny nose, sore throat, or loss of taste or smell. Our Occupational Medicine team will operate a post-vaccination side effect hotline (773-702-9647) from 7:30 a.m. – 4:30 p.m. on Mondays through Fridays to answer your questions. If you believe your side effects are severe enough to need medical care, you should consult your primary care provider or other healthcare professional. If you believe you are experiencing a medical emergency, you should dial 911 or go to the closest emergency room.**

We will continue to require all employees to wear a mask and follow our social distance requirements, regardless of whether they've been vaccinated. You should continue to follow standard COVID-19 safety protocols outside of work until public health authorities relax those regulations.

**15. Will I need one dose or two?**

The Pfizer vaccine requires two doses, which are given three weeks apart (19–23 days after initial vaccination). Skipping the second dose could leave you unprotected. The Moderna vaccine also requires two doses, which are given four weeks apart. **Not taking the second injection could leave you unprotected.** (See *details above*.) We don't know yet which kind of vaccine we will be allocated or if we will receive multiple products. Regardless, all COVID-19 vaccines are intramuscular, meaning they are injected into the muscle of your upper arm.

**16. How long will I be protected by the vaccine? Will I need to get vaccinated multiple times over my lifetime?**

We don't know how long immunity to COVID-19 will last. Some vaccines produce a lifetime of immunity but others (like the annual flu shot) require regular immunizations to provide continued protection. In the FDA's evaluation of the Pfizer/BioNTech vaccine, the vaccine appears to provide strong protection against the virus for at least three months. The FDA has not yet released their evaluation of the Moderna vaccine. Both clinical trials will continue to further study the long-term safety and effectiveness of the vaccines.

**17. If I've received the vaccine, will it cause me to test positive for COVID-19?**

No. The vaccine will not produce a positive COVID-19 test result. If you test positive for COVID-19 after being vaccinated, it's because you have actually contracted the SARS-CoV-2 virus. You should self-isolate and report your diagnosis to Infection Control or Occupational Medicine as appropriate.

**18. Will I need to wear a mask and follow other restrictions after I get vaccinated?**

Yes. It will take months for the full roll out of the vaccine. It is also not yet clear whether or not people who have been vaccinated can still act as carriers for the virus. People will need to wear masks, practice social distancing, wash their hands, and take other precautions until we've reached [herd immunity](#). That occurs when a large portion of the population is vaccinated, making it difficult for infectious diseases to spread, because there are not many people who can be infected. Herd immunity works only if most people are vaccinated.

**19. Will I be able to care for patients with COVID-19 if I don't get the vaccine?**

Yes. If you do not get vaccinated, you will still be permitted to care for patients with COVID-19 and patients under investigation (PUIs).

**20. Will I need to have a COVID-19 test before I get my vaccine?**

No. However, if you have symptoms of COVID-19 before your vaccine, we recommend you get a test through our employee testing program and reschedule your appointment in MyChart.

**21. Can I still get COVID-19 if I've received my vaccination?**

Yes. The vaccine is not 100% effective, which means there is still a chance you could contract COVID-19. However, researchers believe you may be less likely to get as sick as you would if you were unvaccinated. Keep in mind: Skipping your second dose could leave you unprotected. If you continue to have COVID-19 symptoms that aren't improving on the second day after your vaccination, you should get a COVID-19 test.

**22. Does UChicago Medicine recommend one vaccine over another?**

No. The vaccine you receive will be based solely on what type of vaccine is allocated to us by public health officials at the time.

**23. Will I need to get an antibody test after receiving the vaccine?**

No. Antibody (serologic) testing was not recommended by the CDC's Advisory Council on Immunization Practices.

**24. I just had a flu shot or another immunization or I still need to get one. Can I also get a COVID-19 vaccine?**

It's recommended that you don't get any another vaccine within 14 days before or after getting your COVID-19 vaccination. If you've recently received a vaccine (such as an annual flu shot) you should wait to schedule your COVID-19 vaccine until you've finished that two-week window.

**25. Will I be able to get vaccinated if I've already tested positive for COVID-19?**

Yes, with the following exceptions:

- If you are symptomatic and infectious, you should postpone getting your vaccine until you are well and no longer contagious.
- If you've had COVID-19 in the proceeding 90 days, you should postpone getting your vaccine until that 90-day window has elapsed.
- If you've been treated for COVID-19 with monoclonal antibodies or convalescent therapy in the past 90 days, we recommend you postpone your vaccine until after the three-month window has passed.

**26. I've had a high-risk exposure and have had to furlough from work. Can I get vaccinated during that time?**

No. Delay getting your vaccine until you have met our [return-to-work criteria](#), which is remaining asymptomatic and testing negative on Days 5-7. If you meet that criteria, you can schedule your test on Day 8 or after.

**27. I participated in a clinical trial for a vaccine candidate. Will I be able to get a vaccine through the employee program?**

If you have enrolled in a COVID-19 Vaccine trial (at UChicago Medicine or elsewhere), please contact the principal investigator about risks and benefits of withdrawing from the study to receive COVID-19 vaccination through the University of Chicago Medicine's employee vaccination program. The study team does not know whether or not you received active vaccine or placebo and would need to have the sponsor break the blind (i.e. access the trial data and determine if you received a vaccine or a placebo).

• **Moderna Trial**

If you are an enrolled participant in the **Moderna** trial, the study plan is to perform a blinded cross-over study design. This means that you will be given the opportunity to withdraw from the trial, should you desire to do so, or to remain in the trial and receive investigational product from the study arm into which you were not originally randomized. If you were originally randomized to receive active vaccine, you will be given 2 doses of the placebo study product. On the other hand, if you were randomized to receive placebo study product, you will be given 2 doses of the Moderna vaccine (if you received active vaccine you will **not** be given active vaccine again and if you received placebo study product, you will **not** receive the placebo study product again). There are several important reasons that this is the study plan.

1. First and foremost, it means that all persons who volunteered for the trial will receive active Moderna SARS-CoV-2 mRNA vaccine
2. This design will insure the integrity of the study blind will allowing all participants to receive active vaccine.
3. In monitoring for the incidence of adverse events associated with receipt of the vaccine, subjects will serve as their own control. This means that in a blinded and an unbiased fashion subjects will report adverse experiences they experienced both with the vaccine and the placebo normal saline injection.
4. It will allow consistent long-term monitoring of the durability of efficacy and any adverse events directly associated with the vaccine.

5. Finally, because stores of investigational product are reserved for study use, the vaccine that will be given through the study will not take away from the EUA stock that the University has been allotted.

It is anticipated that participants in the Moderna trial will start to be scheduled to come back for vaccine /placebo doses within the next 2 weeks. Study subjects who are essential healthcare workers will be scheduled first followed by the other study participants.

It is not recommended that employees who received the Moderna vaccine through a clinical trial participate in our employee vaccination program.

- **Janssen Trial**

**Janssen** trial participants will also have opportunity to receive active vaccine if they were randomized into the placebo arm of the study. However, this cannot occur until there is safety and efficacy data to support an EUA for Janssen. The earliest this could occur is estimated to be February 2021.

It is important to know there is no safety data on receiving a second vaccine (such as the Pfizer vaccine) after receiving any other company's COVID-19 vaccine. If a person was given the experimental trial vaccine in Janssen's trial and the participant has received the full trial regimen or incomplete regimen (i.e., only the first dose of a two-dose regimen) please be advised that **Janssen** do not have information on the safety of the newly authorized mRNA vaccine following administration of the **Janssen** experimental vaccine. The risks of receiving another deployed vaccine after a full regimen of Janssen's trial vaccine are unknown. **Janssen** encourages participants to stay in the study for the safety and follow up testing but individuals are free to leave at any time as this is a personal choice.

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