

FAQ: COVID-19 Vaccine Information

Updated: June 11, 2021

* 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?

UChicago Medicine is currently providing Pfizer vaccines to most patients, however in certain cases we are providing the Johnson & Johnson Janssen vaccine. 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 were the vaccines 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 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 are the COVID-19 vaccines?

COVID-19 vaccines were required to undergo an independent interim analysis on their safety and efficacy. The <u>Pfizer/BioNTech</u> vaccine was reported to be 95% effective after two doses, and 52% effective after the first dose alone. The <u>Moderna</u> vaccine was reported to be 94.5% effective and the <u>Johnson & Johnson</u> vaccine was reported to be 66.9% effective.

5. Are the vaccines 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.

6. What are the vaccines' 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.

- **Pfizer**: Side effects including injection site pain, fever, chills, fatigue, muscle pain, joint pain, headache and swollen lymph nodes. <u>Data from Pfizer's clinical trial, published December 10</u>, 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 <u>data from Moderna's clinical</u> 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.
- Johnson & Johnson: Side effects to the Johnson & Johnson vaccine <u>are similar</u> to other vaccines, and include pain at the injection site, redness, swelling, fatigue, headache, muscle pain, chills, fever and nausea. In rare cases, thrombosis with thrombocytopenia syndrome (TTS) has been reported among Johnson & Johnson COVID-19 vaccine recipients. Most events occurred within 1-2 weeks of receiving the vaccine, and were more common among women between 18-49 years of age. The FDA's EUA now includes a warning that rare clotting events might occur after vaccination, primarily among women ages 18–49 years.

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. However, the FDA has determined that there is no increased risk of serious adverse events within the first two months following vaccination. The clinical trials will continue after EUA is issued to collect long-term safety data on these vaccines. The most noteworthy issue seen was Bell's Palsy, a temporary paralysis of muscles in the face; however, the rate at which it occurred in the vaccine and placebo groups was not greater than the rate of incidence in the general population and therefore there is no evidence that these cases were linked to the vaccine. Some people who had had lip filler injections also experienced lip swelling after the vaccine.

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

At this time, you should not get the a 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 Pfizer ingredient list here, the Moderna ingredient list here, and the Johnson & Johnson ingredient list here. The Johnson & Johnson vaccine is not recommended for people with a history of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT. In those cases, you should get another FDA-authorized COVID-19 vaccine.

10. Can children be vaccinated?

The Pfizer/BioNTech vaccine is currently the only vaccine approved for use in children 12 and up. We expect the other vaccines to be approved for adolescents and children in the coming weeks and months.

11. 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 <u>professional</u> <u>societies</u> have <u>advocated</u> 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.

You can read more from UChicago Medicine reproductive health experts in an FAQ here.

12. How long will it take for me be protected from the 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.

13. 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. These typically last for 24-48 hours. 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. Some people may have no side effects. However, others people may have severe, short-lived reactions. You may continue to work after getting your second dose even if you have mild side effects. If you do not feel well enough to work after your vaccine, please use your sick leave. You will need to stay home from work if you have any of the following symptoms and you may need to get a COVID-19 test:

- Cough
- Fever of more than 100.0F
- Loss of taste and smell
- Runny or stuffy nose
- Shortness of breath
- Side effects that get worse after two days or 48 hours
- Sore throat

You can request a test through MyChart or by calling our COVID-19 testing triage line at 773-702-6819 (employees only).

If you are concerned about your side effects, please contact your personal physician first. If you don't have a doctor and are employed by UChicago Medicine, you can call Occupational Medicine (UCOM) at 773-702-

9647. UCOM is available to answer questions from 7:30 a.m. - 4:30 p.m. on weekdays and 8 a.m. - 12 p.m. on weekends to answer questions.

If you believe you are experiencing a medical emergency, dial 911 or go to the closest emergency room.

We will continue to require all employees to wear a mask and follow our current social distance requirements while working on the medical campus, regardless of whether they've been vaccinated..

14. Will I need one dose or two?

The Pfizer vaccine requires two doses, which are given three weeks apart. The Moderna vaccine also requires two doses, which are given four weeks apart. These vaccines are not interchangeable. **Not taking the second injection could leave you unprotected**. (*See details above*.) The Johnson & Johnson vaccine requires a single dose.

15. 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 and Moderna vaccines, the vaccines appear to provide strong protection against the virus for at least six months. Both clinical trials will continue to further study the long-term safety and effectiveness of the vaccines.

16. 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.

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

While on hospital property, please continue to follow all of our organization's masking and social distancing requirements. Outside hospital property, we recommend following <u>the CDC's latest guidance</u> for those who are fully vaccinated (ie: more than two weeks past the second/only dose). You should expect some COVID-19 precautions to remain in place until we've reached <u>herd immunity</u>. 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.

18. 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).

19. 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.

20. Does the vaccine cause Bell's palsy?

There were four incidences of Bell's palsy in the Moderna clinical trial (three in the vaccine group and one in the placebo group. There were four cases in the Pfizer vaccine trial, all of which were in the group that received the vaccine. However, the incidence in the trials was less that that reported in the general population. As with any adverse event that is reported in a clinical trial it is being monitored as a special interest adverse effect.

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. Vaccine availability will depend on supply and the location where you receive your vaccine.

23. Will I need to get an antibody test before or 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?

Yes. It is OK to receive other vaccines at the same time or shortly around the time of your COVID-19 vaccine.

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 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 <u>return-to-work criteria</u>, 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.

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