1. Why should I get the COVID-19 vaccine?

We all want this pandemic to end. A safe and effective vaccine can end the COVID-19 pandemic. Experts believe that at least 70% of people need to be vaccinated before the pandemic will end.

In addition to preventing death, by reducing your chances of getting sick with COVID-19 through vaccination, you will also prevent long lasting effects of infection that have been reported. COVID-19 infection has been reported to cause long lasting problems related to fatigue, shortness of breath, cough, joint pain, chest pain, difficulty thinking and concentrating (“brain fog”), depression, muscle pain, headache, and intermittent fever. In addition, some people have reported problems with their heart, lung, kidney, skin, teeth, and nervous system after COVID infection. These complications of infection can be prevented by the vaccine.

2. Is the vaccine required for healthcare personnel or UC employees?

No. The vaccine is voluntary, but highly recommended.

3. What COVID-19 vaccines are currently available?

Several companies are working on COVID-19 vaccines that work against the virus that causes COVID-19, SARS-CoV-2. Two have been tested in large-scale trials and are authorized for use in 2020 by the FDA (Food and Drug Administration). These two include:

- Pfizer mRNA vaccine
  - Emergency Use Authorization (EUA) approved 12/11/2020
  - Large scale trial (44,000 participants) showed 95% efficacy
  - Two dose vaccine

- Moderna mRNA vaccine
  - Emergency Use Authorization (EUA) approved 12/18/20
  - Large scale trial (30,000 participants) showed 94% efficacy
  - Two dose vaccine

4. What is the difference between Emergency Use Authorization (EUA) status and full FDA (Food and Drug Administration) approval for a vaccine?

When an effective vaccine has been demonstrated in a trial, it can apply for EUA status with 2 months of post-vaccine safety data. In order to apply for full approval, 6 months of post-vaccine safety data must be provided. The FDA is encouraging companies who receive EUA status to apply for full approval as soon as possible. Both mRNA vaccines have reported outstanding safety data with no serious side effects (see Question 13).

5. What is in the vaccine? What is an mRNA vaccine?

There are different types of COVID-19 vaccines under development. The two vaccines that have received EUA status are both mRNA vaccines. mRNA stands for “messenger ribonucleic acid” and it encodes the instructions for your body to make a specific protein (Spike protein) on the surface of the SARS-CoV-2 virus. When your body makes this viral protein, it is recognized as not human, and your body develops antibodies to it. Some vaccines inject the protein itself, but mRNA vaccines inject the instructions needed for your body to make the protein.

After making the protein, your body will destroy the mRNA. The mRNA does not stay in your body. It is temporary and does not mix into your genetic code. The COVID-19 vaccines are not the first mRNA vaccines. mRNA vaccines have been made for flu, rabies, CMV...
(cytomegalovirus), and Zika viruses. Besides the main ingredient, the mRNA, the other listed ingredients include lipid nanoparticles (such as polyethylene glycol and polysorbate) which are the delivery mechanism of the mRNA, salts which help balance pH and sugar (sucrose) which protects the vaccine while it is frozen. Detailed ingredient lists can be found here:

- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines (CDC)

6. Can the COVID-19 vaccine give me COVID? Is there live virus in the vaccine?

None of the currently developed COVID-19 vaccines involve live SARS-CoV-2 virus. The mRNA vaccines are not live and cannot give you or anyone else COVID-19. The vaccine does not make you contagious.

7. Will getting the COVID-19 vaccine make me test positive for COVID-19 if I am tested after being vaccinated?

No. The vaccine will not cause you to test positive on viral tests for COVID-19, such as PCR tests or antigen tests. However, the vaccine will likely cause you to test positive for antibody tests (also called serology) since the vaccine helps build antibodies to COVID-19.

8. Should I worry that the vaccine was made so quickly? Were steps skipped?

No steps were skipped. All of the COVID-19 vaccines that are being distributed in the U.S. were either helped by government funds (e.g. Operation Warp Speed) or were funded by large companies, or both. These funds enabled two things to speed up:

- **Trial enrollment.** If you can increase the number of staff that are recruiting patients, you can enroll a lot of people into a trial in a shorter time period. For example, you can have one person recruit 1,000 people into a trial, or you can have 1,000 recruiters each enroll one person into a trial. The more staff recruiters you have, the faster your enrollment. The funds helped the trials quickly enroll tens of thousands of participants.

- **Manufacturing.** Funds help increase the number of manufacturing plants, warehouses, and employees. In addition, mRNA vaccines are fast to manufacturer because they don’t involve a step such as growing the virus in eggs to ultimately produce virus proteins used in the vaccine. These vaccines do not involve any live virus step. They are molecular based and can be rapidly manufactured.

9. How well does the vaccine work?

The Pfizer and Moderna COVID-19 vaccines have both been tested in large vaccine trials involving tens of thousands of participants. The trials reported a remarkable 94-95% efficacy. 95% efficacy means that the vaccine group had only 5% of the cases seen in the placebo (non-vaccine) group. For example, if the placebo (non-vaccine) group had 100 cases of COVID-19, the vaccine group would only have 5. Importantly, the vaccine not only prevented COVID cases overall, but it prevented severe COVID-19 disease.

- Pfizer COVID-19 vaccine Phase 3 trial (~44,000 participants)
  - 95% efficacy (protection)
  - All COVID-19 cases: 162 in placebo group vs. 8 in vaccine group
  - Severe COVID-19 cases: 9 in placebo group vs. 1 in vaccine group

- Moderna COVID-19 vaccine Phase 3 trial (~30,000 participants)
  - 94% efficacy (protection)
  - All COVID-19 cases: 185 in placebo group vs. 11 in vaccine group
  - Severe COVID-19 cases: 11 in placebo group vs. 0 in vaccine group

10. How many doses is the vaccine and how far apart?

Both the Pfizer and Moderna vaccines are a two-dose series. This means that you must receive both doses to achieve the 94-95% protection that was seen in the trials.
• In general, the second dose may be scheduled approximately 21 or 28 days after the first dose, but CDC guidance says the second dose can be scheduled up to six weeks after the first dose.
  ○ CDC Guidance: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

11. Am I protected as soon as I receive the vaccine? Can I stop wearing a mask?

No. The full protection provided by both Pfizer and Moderna vaccines occurred 7 days after the second dose, though some protection may occur as early as 10 days after the first dose. In addition, even after you are vaccinated, all policies, protocols, and public health orders related to COVID-19 will remain in place until you are notified otherwise. Experts believe that 70% of the population needs to be vaccinated before the pandemic will be over.

12. What side effects do the vaccines have? Do I have to do any planning?

Thus far, vaccines trials have shown that COVID-19 mRNA vaccines are highly protective and generate a strong immune response. Sometimes when vaccines produce an immune response, there may be side effects that feel like the flu, but do not mean you are infected or contagious. Instead, these symptoms are simply a sign that your body is successfully generating an immune response to provide you protection.

• Expect some symptoms after vaccination. Both mRNA COVID-19 vaccines commonly cause mild-to-moderate non-infectious “flu-like” symptoms. Data are being reviewed by the FDA and will be increasingly available
  • Smart scheduling
    ○ Recommend trying to schedule vaccination when you do not have anything important planned in the next day or two, including work shifts
    ○ Recommend ensuring that staff who have specialized skill sets do not get vaccinated on the same day. Separating by at least 3 days will ensure that you don’t have a loss of skill set if they call off work for vaccine-related side effects
  • Do not pre-medicate. For advice on use of over-the-counter medications such as aspirin, acetaminophen (e.g. Tylenol) and ibuprofen (e.g. Motrin, Advil), see Question 14.

• Pfizer mRNA vaccine
  ○ Any symptoms: 59% after 1st dose, 70% after 2nd dose
  ○ Mild to moderate symptom types: fatigue 63%, headache 55%, muscle aches 38%, chills 32%, joint pain 24%, fever 14%
  ○ Few grade 3 (severe) side effects: fatigue 4%, headache 2%

• Moderna mRNA vaccine
  ○ Any symptoms 48-57% after 1st dose, 72-82% after 2nd dose. Both local and systemic symptoms were seen more frequently in those younger than 65 compared to those older than 65.
  ○ Fatigue, headache and muscle aches as well as local swelling/tenderness were the most common side effect
  ○ Grade 3 (severe) side effects: fatigue 10%, muscle aches 10%, joint pain 5%, headache 5% after dose 2

• Anticipate 5-10% call off of work for either vaccine due to side effects.

• Report Adverse Events
  ○ The CDC is strongly recommending all adverse events be reported through V-Safe, a new app created specifically for monitoring adverse events with the Covid-19 vaccines. Vaccine recipients can register at vsafe.cdc.gov (you can pre-register prior to receiving vaccine).

  ○ Serious adverse events must also be reported by the vaccine administrator through VAERS; https://vaers.hhs.gov/
13. Should I plan to take Tylenol or Motrin before my vaccine dose?

No. Do not pre-medicate. In general, pre-medicating with over-the-counter medications such as aspirin, acetaminophen (e.g. Tylenol) and ibuprofen (e.g. Motrin, Advil before receiving a vaccine reduces its ability to work and can blunt your immune response to the vaccine. The time to take these over-the-counter medications is if you have symptoms that make you uncomfortable after vaccination. If you are uncomfortable, don't hesitate to take an over-the-counter medication to help you feel better. If you have symptoms that keep you out of work, especially for more than 1-2 days, please reach out to your PCP for further guidance. For severe/long-term adverse events, the federal government has created an injury compensation program. Please see https://www.hrsa.gov/cicp for more information.

14. What if I have a history of allergies? Should I not get the vaccine?

Based on the latest CDC guidelines, if you have severe allergic reaction (i.e. anaphylaxis) to a dose of a Covid-19 mRNA vaccine, or one of its components such as polyethylene glycol (PEG) or polysorbate, you should not receive the vaccine (unless cleared by an allergist/immunologist in certain cases). If you have a history of severe allergic reaction/anaphylaxis to any other trigger such as injectable medications/vaccines you may receive the vaccine if warranted, but with an observation period of up to 30 minutes after vaccination. If you have a history of severe allergic reactions (i.e. anaphylaxis) to food, latex, oral medications etc. you will need to be observed for 30 minutes after vaccination. For more minor reactions to food, pets, oral medications you will be observed for 15 minutes, as well others receiving the vaccine who do not have a history of allergies. Epinephrine and other medications will be available at the vaccine administration site in case of a severe reaction, but if you have an Epi-pen you should bring it with you. Currently the CDC is not recommending pre-medication with Benadryl or other antihistamines. There are some indications from the FDA that those with a prior history of dermal fillers (such as Juvederm) may experience swelling in these areas after receiving the Moderna vaccine. It is also possible this reaction may occur with the Pfizer vaccine. If you have a history of dermal fillers in the face and/or the vocal cords, please discuss with your doctor prior to receiving the vaccine and also notify the staff at the vaccine clinic so they can counsel and monitor you appropriately.

15. What if I get the first dose and then don’t want the next dose?

You must complete both doses of the mRNA vaccine to gain the full benefit of 94-95% protection shown in the vaccine trials. This is the reason why you should not start the vaccine series unless you intend to complete it. It is also important to anticipate that the COVID-19 vaccine often causes a mild flu-like illness after each dose, though it appears such symptoms are more pronounced after the second dose. This was a normal effect seen in studies and not a cause for concern. These symptoms do not mean that you have an infection or are sick with COVID-19. Instead, these vaccine-related symptoms are a sign that your body is working hard to build an immune response to protect you from future infection. Thus, developing these symptoms after the first dose does not mean you shouldn’t receive the second dose.

16. What if I missed my second dose? Can I get it late?

Although second doses may be scheduled as soon as 21 or 28 days after the first dose, the CDC has said it can be scheduled up to six weeks after the first dose with no decrease in effectiveness.

17. Should I get the COVID-19 vaccine now or wait?

The best time to get the vaccine is now when the pandemic is at its peak and people are becoming sick and dying from COVID-19 every day. The best way to end the pandemic is for 70% of people to get vaccinated. The fact that two large trials with over 70,000 combined
participants have shown that mRNA COVID-19 vaccines are highly protective with only brief temporary mild side effects is very reassuring for vaccine safety and benefits.

18. What if I have recently received or am planning to receive a different vaccine? How will this impact my Covid-19 vaccination?

The CDC has published interim guidance on this and many other topics (linked below). Currently, their guidance is to leave 14 days between administration of another vaccine and the Covid-19 vaccines with the important caveat: “However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/ upon admission or onboarding).” More information can be found at this link:

- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines (CDC)

19. When will the general public get the vaccine? How many doses will the U.S. eventually receive?

Vaccine manufacturing is moving at a very fast pace. Hopefully, COVID-19 vaccines will be widely available for public consumption by mid-April. In addition to the Pfizer and Moderna vaccines, several other vaccines are in current trials that will complete in early 2021. Furthermore, vaccine trials in children under 12 years old have also begun. The 40 million doses of the mRNA vaccines that are anticipated to arrive in the US by December will provide the two-dose series for 20 million people. Millions of additional doses will arrive in January and thereafter.

20. Who pays for the vaccine?

At this time, public health is distributing these mRNA vaccines for free because the government has purchased millions of doses. In the future, this may change. The government may purchase more doses, your insurance may cover the cost, or you may be able to pay out of pocket.

21. I already had COVID-19. Am I supposed to get the vaccine?

Yes. Persons who have had COVID-19 should still receive the vaccine. Immunity to COVID-19 following COVID-19 infection is highly variable, and we do not have much data beyond 90 days. The vaccine will ensure you are protected with the benefit found in the trials. You should not receive the vaccine while you are actively infected, but after full recovery (usually 14 days after symptom onset and clearance to end your isolation), you can receive the vaccine. In some cases, it may be reasonable to delay vaccination until the end of your 90 day period from symptom onset if desired. It is recommended you discuss this with your PCP. These recommendations also apply to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

22. Are pregnant, lactating or immunocompromised persons supposed to get the vaccine?

Pregnant, lactating and immunocompromised persons were not enrolled in the mRNA trials. Thus, data are not currently available to provide a recommendation for either efficacy or safety. While awaiting further studies and guidance, we understand that pregnant or immunocompromised persons are at higher risk for more serious disease and may make the personal choice to receive the vaccine. More information can be found at these sites:

- Vaccinating Pregnant and Lactating Patients Against COVID-19
- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines