COVID-19 Vaccine FAQ

Two COVID-19 vaccines (Pfizer and Moderna) have received emergency use authorization (EUA). Mammoth Hospital's infectious disease experts answer questions about these vaccines.

Q. Why should I get the COVID-19 vaccine?
A. In addition to preventing infection and death by reducing your chances of getting sick, the COVID-19 vaccines also will prevent many long-lasting effects reported by COVID-19 patients. These include fatigue, shortness of breath, cough, muscle and joint pain, chest pain, difficulty thinking and concentrating ("brain fog"), depression, headache, and fever that comes and goes. Some people have also experienced heart, lung, kidney, skin, teeth and nervous system problems.

Q. Can the COVID-19 vaccines give me COVID?
A. None of the currently developed COVID-19 vaccines have the live SARS-CoV-2 virus. These vaccines cannot give you or anyone else COVID-19, nor do they make you contagious.

Q. Will I test positive for COVID-19 after being vaccinated?
A. No. The vaccine will not cause you to test positive with PCR or Antigen tests for COVID-19.

Q. What COVID-19 vaccines are now available?
A. Several companies are developing vaccines that work against SARS-CoV-2, the virus that causes COVID-19. Two have been tested in large-scale clinical trials and have received EUA by the Food and Drug Administration (FDA). They are:

- Pfizer-BioNTech mRNA vaccine
  - Granted Emergency Use Authorization (EUA) on 12/11/2020
  - Large-scale trial (44,000 participants) showed 95% efficacy
  - Two-dose vaccine, given 21 days apart
  - 50 million doses to the world by end of 2020 (6.5 million to U.S.)
  - 1.3 billion doses to the world in 2021
- Moderna mRNA vaccine
  - Emergency Use Authorization (EUA) status granted 12/18/2020
  - Large-scale trial (30,000 participants) showed 94% efficacy
  - Two-dose vaccine, given 28 days apart
  - 20 million doses to the world by end of 2020
  - 500 million to 1 billion doses to the world in 2021

Q. Who will get the first vaccines and when?
COVID-19 vaccination is one of the most important tools to end the COVID-19 pandemic. The State is prioritizing vaccines for equitable distribution to everyone in California who wants it. The state expects to have enough supplies to vaccinate most Californians in all 58 counties by summer 2021.

For a detailed schedule and list of who receives the vaccine and when, visit the link below:
https://covid19.ca.gov/vaccines/#When-can-I-get-vaccinated

Q. When will there be enough supplies for most people to get the vaccine?
A. Vaccine manufacturing is moving at a very fast pace. Hopefully, COVID-19 vaccines will be widely available for public consumption by mid-April 2021.
In addition to the Pfizer and Moderna vaccines, several other vaccines are in current trials to be completed in early 2021. Furthermore, vaccine trials in children under age 12 have also begun.

Q. What is the difference between Emergency Use Authorization (EUA) status and full FDA (Food and Drug Administration) approval for a vaccine?
A. When an effective vaccine has been demonstrated in a trial, it can apply for EUA status with two months of post-vaccine safety data. In order to apply for full approval, six 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.

Q. What is an mRNA vaccine?
A. Many types of COVID-19 vaccines are in development. The Pfizer and Moderna vaccines are made with messenger ribonucleic acid, otherwise known as mRNA, that can instruct your body to make a specific protein (the spike protein) found on the surface of the SARS-CoV-2 virus.
When your body makes this virus protein, it is recognized as not human, and your body develops antibodies to it. These antibodies help to protect you from becoming infected with COVID-19 .

The mRNA cannot mix with your DNA. After making the protein, your body destroys the mRNA, mRNA vaccines have been used in the past for flu, rabies, CMV (cytomegalovirus) and Zika viruses.

Q. Should I worry that the vaccine was made so quickly? Were steps skipped?
A. No steps were skipped. All COVID-19 vaccines being submitted for approval must meet high U.S. safety standards. All vaccines to be distributed in the U.S. were helped by funds from the government (e.g., Operation Warp Speed), large companies, or both. These funds helped speed three processes:

- Large scale trial showed 94% efficacy

Q. How well do the vaccines work?
A. The Pfizer and Moderna COVID-19 vaccines have been tested in large trials involving more than 70,000 people. Participants were randomly assigned to two study arms, one to receive the vaccine, the other a placebo injection. Since the trials are randomized, such large study groups help ensure that the type of human interactions in one study arm are similar in the other.
The trials reported a remarkable 94% and 95% efficacy in preventing COVID-19. An efficacy of 95% means the vaccine group had only 5% of the cases seen in the non-vaccine group. For example, if the placebo group had 95 cases of COVID-19, the vaccine group would have only five. The vaccine not only prevented COVID-19 cases overall, it also prevented severe cases of the disease.

Pfizer measured protection seven (7) days after the second dose; Moderna measured protection 14 days after the second dose. Summary results show:

- Pfizer COVID-19 vaccine trial (44,000 participants)
  - 95% protection
  - All COVID-19 cases: 162 total 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 trial (30,000 participants)
  - 94% protection
  - All COVID-19 cases: 185 total in placebo group vs. 11 in vaccine group
  - Severe COVID-19 cases: 30 total in placebo group vs. 0 in vaccine group

Both vaccines protected well across all ages of adults studied. Trials used different age groupings when providing summary data to the FDA.

- Pfizer
  - Ages 16 to 55: 96% efficacy
  - Over age 55: 94% efficacy
- Moderna
  - Ages 18 to 65: 96% efficacy
  - Over age 65: 86% efficacy *

* The difference between the efficacy of Pfizer and Moderna vaccines in older adults may be due to the cut-off age for the trial. For example, it is possible that the Pfizer vaccine would have a lower protection effect had they reported data for those over age 65.

Q. Were different races and ethnicities included in the vaccine trials?

A. The people in the COVID-19 mRNA trials were of the following race and ethnicity:

- Pfizer
  - 57% white
  - 26% Hispanic/Latinx
  - 10% Black
  - 4% Asian
  - 3% other racial groups
- Moderna
  - 62% white
  - 20% Hispanic/Latinx
  - 10% Black
  - 5% Asian
  - < 3% other racial groups

Q. How many doses do I need?

A. Both the Pfizer and Moderna vaccines are a two-dose series. This means that you **must** receive both doses to achieve the 94% and 95% protection levels seen in the trials.

- The Pfizer vaccine is two doses given 21 days apart.
- The Moderna vaccine is two doses given 28 days apart.

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

A. No. The protection provided by the vaccine starts seven (7) days after the second Pfizer dose and 14 days occurs after the second Moderna. Until then, you should assume you have no proven benefit from the vaccine.

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.

Q. What side effects do the vaccines have?

A. So far, trials indicate 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. This does not mean you are infected or contagious. Instead, these symptoms are a signal that your body is successfully generating an immune response to protect you from the virus.

Data are being reviewed by the FDA and more details will become available. Here's what we know so far about side effects:

- Pfizer mRNA vaccine
  - Any symptoms: 59% after first dose, 70% after second dose
  - Mild to moderate symptom type following the second dose: 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: 57% after the first dose, 82% after the second dose: fatigue 67.6%, headache 62.8%, muscle aches 6.1%, chills 48.3%, and fever 17.4%.
- Few grade 3 (severe) side effects: fatigue 10.6%, headache 5%

Schedule your vaccinations when you do not have anything important planned for the next day or two, including work.

- To get the full benefit from the vaccine, do not take Tylenol or Ibuprofen prior to receiving the vaccine. Once you have been vaccinated (especially with the second dose), you may take ibuprofen or Tylenol to help decrease any potential side effects.

Q. If I have food or medication allergies, should I worry about an allergic reaction to the vaccine?

A. Having a significant allergy to a food or medications does not necessarily mean you are at higher risk for having an allergic reaction to the COVID-19 vaccine. The risk of an allergic reaction exists for those who have a known allergy to the vaccine (from prior doses) or a known allergy to an ingredient in a vaccine. As an example, mRNA vaccines are not made in chicken eggs and there should not be any additional risk for people with known allergies to eggs.

The following table helps determine who is and who is not a candidate to receive the vaccine:

Algorithm for the triage of persons presenting for mRNA COVID-19 vaccine

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** • Do not vaccinate

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

Please consult your doctor before being vaccinated if you have many serious allergies. If you have been told to carry epinephrine (Epipen) for any reason, you should continue to do so, including at the time of vaccination.

All vaccine distribution centers must have emergency allergy medications on site. The CDC also recommends that everyone vaccinated be observed for 15 minutes, and 30 minutes for anyone with a history of anaphylaxis.

Q. Should I take Tylenol or Motrin before my vaccination?

A. If you regularly take aspirin, acetaminophen (e.g., Tylenol) and ibuprofen (e.g., Motrin, Advil) for other medical conditions, continue to do so as directed by your physician or as needed. Otherwise, do not pre-medicate.

Taking over-the-counter medications such as acetaminophen and ibuprofen before receiving a vaccine may reduce its ability to work and blunt your immune response to the vaccine. After the vaccination, don't hesitate to take an over-the-counter medication if you have symptoms that make you uncomfortable.

Q. What if I get the first dose then don't want the second?
A. The Pfizer and Moderna trials were not designed to assess the effectiveness of a single shot. For example, everyone in the Pfizer vaccine group received two shots, 21 days apart. Even though overall data suggest that benefits may start after the first dose, we don't know enough to make any conclusions.
The scientific evidence so far shows that two doses are needed to achieve 94% to 95% protection. For these reasons, you should start the vaccine series unless you intend to complete it.

Q. What if I missed my second dose?
A. Try to get the second dose on time. Data on vaccine benefit was based on a fixed number of weeks between doses (three weeks between Pfizer doses; four between Moderna doses). If you are late, you should still receive the second dose.
Most vaccines have rules for how many weeks you can be late before you should start the vaccine series over. For the COVID-19 vaccines, doses will be given late until the CDC or published clinical data provide guidance on when it is too late to give a second dose.

Q. If I already had COVID-19, do I need the vaccine?
A. Yes. People who have had COVID-19 should still get the vaccine. Natural immunity to COVID-19 after infection is unpredictable. The vaccine ensures you receive the same protection levels found in the trials. Vaccines should not be given to anyone who is actively infected. After full recovery, you can and should receive the vaccine.

Q. Can pregnant, breastfeeding or immunocompromised persons get the vaccine?
A. Pregnant, breastfeeding and immunocompromised persons were not enrolled in the mRNA vaccine trials so there are no data currently available to make a recommendation. What is known is that the mRNA in the vaccines do not cross the placenta to reach your baby. But protective antibodies you produce do pass to your baby through the placenta and breastfeeding.
The American College of Obstetricians and Gynecologists recommends that the COVID-19 vaccine be offered to pregnant and breastfeeding women, and does not recommend women of childbearing age to have a pregnancy test before receiving the vaccine.

The concern for immunocompromised persons receiving the vaccine is not for safety, but rather the vaccine may not generate as strong a protective response as in persons with a healthy immune system. Nevertheless, a partial response may be an important benefit. Discuss your preferences and options with your doctor.

Q. Who pays for the vaccine?
A. At this time, the two mRNA vaccines are free because the U.S. 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.