

COVID Vaccine FAQs

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

We all want this pandemic to end. By mid-May 2021, the COVID-19 pandemic reached 165 million cases and 3.4 million deaths worldwide. These striking numbers are underestimated since only people who have been tested are counted. In the United States, 33 million cases of COVID-19 have occurred and nearly 600,000 people have died from COVID-19. In the winter crisis, 3,300 lives were lost every day in the U.S. due to COVID-19. Widespread use of safe and effective vaccines can end the COVID-19 pandemic. Experts believe that 70-85% of people need to be vaccinated before the pandemic will end.

The fact that we have safe and highly protective vaccines should lead us all to want to be vaccinated. *By preventing infection, COVID-19 vaccines prevent not only death, but also the problems that occur after infection.* 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 receiving the vaccine. [*CLICK HERE TO GO BACK TO QUESTION LIST*]

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

With 165 million cases of COVID-19 worldwide and 33 million cases in the U.S., we should not wait to receive the vaccine. By mid-May, over **120 million** people in the U.S. have received a COVID-19 mRNA vaccine, and 10 million have received the J&J (Janssen) COVID-19 vaccine. With safe and highly protective vaccines, there is no reason why another person (including ourselves, our family, or our friends) needs to die from COVID-19. We should be urgently vaccinating. Being vaccinated enables us to protect our workplace and our close circle of friends and family. The sooner we can reach 70-85% vaccinated, the sooner the pandemic can come to an end. [*CLICK HERE TO GO BACK TO QUESTION LIST*]

3. What COVID-19 vaccines are currently available?

Vaccines can only be licensed in the U.S. if they have strong data from clinical trials. There are several COVID-19 vaccines that have data from well-designed large clinical trials. The below table (updated as of mid-May 2021) lists COVID-19 vaccines that are already authorized in the U.S. (top 3 rows in green) or are likely to seek U.S. authorization in the near future. The Pfizer and Moderna vaccines are both mRNA vaccines and both have shown an incredibly high level of protection (~95% protection) in large clinical trials. These vaccines have been given to over 100 million people in the U.S. It is unlikely that any of the other vaccines will be proven to be better at protecting against COVID-19 than these mRNA vaccines. Notably, the J&J (Janssen) vaccine has the benefit of being a single dose while giving 66% protection. All other vaccines listed in the table require two doses for full effect.

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| Vaccine | Туре | Doses | Efficacy | Trial Size | US Authorization |
|---------------|----------------------------|-------|------------------|------------------------|-----------------------|
| Pfizer | mRNA | 2 | 95% ¹ | 44K | Yes (12+) |
| Moderna | mRNA | 2 | 94% ² | 30К | Yes (18+) |
| J&J (Janssen) | Adenovirus vector (DNA) | 1 | 66% ³ | 44K | Yes (18+) |
| Astra-Zeneca | Adenovirus vector (DNA) | 2 | 62% | 9К | Pending Submission |
| Novavax | Protein | 2 | 89% | 15K in UK ⁴ | Pending Submission |

COVID-19 Vaccines Authorized or Likely to Seek Authorization in the U.S. (as of May 2021)

Green = authorized for use in the U.S.

¹ Polack FP et al NEJM 2020; 383(27): 2603-15

² Baden LR et al. NEJM Dec 30, 2020 (online)

³Sadoff J et al. NEJM Apr 21, 2021 (online)

⁴ 30K trial in US/Mexico pending

For a detailed comparison of the top 3 rows of vaccines (Pfizer, Moderna, J&J (Janssen), see **Question 9.** [*CLICK HERE TO GO BACK TO QUESTION LIST*]

4. What is an mRNA vaccine and what is an adenovirus vector vaccine?

mRNA Vaccines (Pfizer, Moderna)

The Pfizer and Moderna vaccines authorized for use in the U.S. are both mRNA vaccines. mRNA stands for "messenger ribonucleic acid," and it is an instruction set to make proteins. Every cell in our bodies has mRNA in it because we need proteins to survive. The mRNA in the Pfizer and Moderna COVID-19 vaccines provide 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. These antibodies protect you if you later encounter the virus. 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 to be created. mRNA vaccines have been made for flu, rabies, CMV (cytomegalovirus), and Zika viruses. Full ingredients in the vaccine are found in **Question 30**.

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Adenovirus Vector Vaccines (J&J (Janssen), AstraZeneca)

Adenovirus vector vaccines have the same goal as the mRNA vaccines which is to have your body make a specific protein (Spike protein) on the surface of the SARS-CoV-2 virus. To do this, it uses a harmless adenovirus, a virus that is not related to the SARS-CoV-2 virus. The adenovirus that is used in the vaccine cannot cause any disease. It just provides a way for the instruction set to make Spike protein to be provided to your body. When your body makes this viral protein, it is recognized as not human, and your body develops antibodies to it. [CLICK HERE TO GO BACK TO QUESTION LIST]

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

None of the currently developed COVID-19 vaccines involve live SARS-CoV-2 virus. None of the vaccines can give you or anyone else COVID-19. The vaccine does not make you contagious. [*CLICK HERE TO GO BACK TO QUESTION LIST*]

6. 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 four things to speed up:

- **Development:** Current vaccines benefitted from advances in science that allowed rapid development. For example, mRNA vaccines use a technology that creates the instruction set to build proteins. It also benefits from technology that keeps the instruction set stable, including cooling it.
- **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 hire one person to recruit 30,000 people for a trial which would take years, or you can hire 1,000 recruiters to find 30 people each, which might take just a few weeks. 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, these vaccines can be made quickly because they don't involve a step such as growing the virus to ultimately produce virus proteins. For example, some flu vaccines require a step where the vaccine protein is made from live virus in chicken eggs. These vaccines do not involve any live virus step. They are molecular based and can be rapidly manufactured.
- **Distribution:** Funds enable produced vaccines to be shipped rapidly around the U.S. and around the world on a regular basis. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

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

Companies that prove that a vaccine is highly protective in a trial 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. For the mRNA vaccines, 6 months has passed as of end April 2021. The FDA is encouraging companies who receive EUA status to apply for full approval as soon as possible. As of mid-May, Pfizer has initiated its application for full approval, and Moderna anticipates submitting for full approval soon. The review process for full approval is lengthier, but given the success and safety profiles so far, we anticipate starting to see fully approved vaccines beginning in July 2021. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

8. Who pays for the vaccine?

The COVID vaccines are free in the U.S. because the government has purchased enough doses for everyone to be vaccinated. Your health insurance may be charged for the administration fee (cost of having a nurse or pharmacist give you the vaccine), but if you do not have insurance, the administration fee will be covered by the government. No one should pay any out-of-pocket costs to receive a COVID-19 vaccine. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

9. Which vaccine should I get? How well do they work? Are they safe?

All vaccines that are FDA authorized in the U.S. have been tested in large vaccine trials involving tens of thousands of participants and provide significant protection against COVID-19. The U.S. will only authorize and approve vaccines that have at least a 50% protection against COVID-19 disease. This 50% cut off was chosen because it provides a large amount of protection against a deadly virus. In these trials, participants were randomized to receive the vaccine or a placebo injection. Then, they were allowed to live their lives and mix with their communities as they normally would. Since the trial is randomized, large numbers should ensure that the types of human interactions in the vaccine group are similar to the placebo group.

Comparing the mRNA vaccines (Pfizer and Moderna)

The Pfizer and Moderna vaccines are essentially twin vaccines. They are both mRNA vaccines, made by two different companies which tested them in two large clinical trials, and both were found to be ~95% protective. This is the best result that scientists could hope to see. Nearly identical results from two completely different large trials.

Both trials reported a remarkable 94-95% efficacy in preventing COVID-19 cases. 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 vaccines not only prevented COVID cases overall, but they prevented severe COVID-19 disease.

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Protection was measured after the second dose for both vaccines. Pfizer studied the amount of protection 7 days after the second dose, and Moderna studied the amount of protection 14 days after the second dose.

- 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)
 - $\circ~$ All COVID-19 cases: 185 in placebo group vs. 11 in vaccine group
 - \circ Severe COVID-19 cases: 30 in placebo group vs. 0 in vaccine group

Both mRNA vaccines performed well across the age spectrum. Note that they used different age groupings when providing summary data to the FDA. It is likely that if they used the same age groupings, that the results would be very similar.

- Pfizer
 - o 16-55 years old: 96% efficacy
 - >55 years old: 94% efficacy
- Moderna
 - 18-<65 years old: 96% efficacy
 - o 65+: 86% efficacy

These two vaccines have outstanding safety profiles. Like many vaccines that are designed to help your immune system protect you with antibodies and immune fighter cells, you may feel like you have a cold or flu-like symptoms for a few days after receiving the vaccine, but this is your immune system working, and you are not contagious or ill with COVID-19. See **Question 28** for more details on side effects after receiving mRNA vaccines.

The results of the mRNA vaccine trials were submitted to the FDA in December 2020, shared with the CDC's Advisory Committee on Immunization Practices (ACIP), and published in the New England Journal of Medicine (<u>https://www.nejm.org/doi/full/10.1056/NEJMoa2034577;</u> <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2035389</u>).</u>

Comparing the J&J (Janssen) vaccine to the mRNA (Pfizer, Moderna) vaccines

All vaccines authorized in the U.S. prevent COVID-19, including complications such as hospitalization and death. In preventing COVID-19, they also prevent complications of this virus such as brain fog, chronic muscle/joint pain, and heart and lung problems.

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Selecting a vaccine is a personal choice. *All vaccines offered are very safe and protect against serious disease and hospitalization.* The two-dose mRNA vaccines (Pfizer, Moderna) provide strong protection against COVID-19, and work well in the elderly and in those with chronic illness. These vaccines require a personal willingness to pursue a second dose. The one-dose J&J (Janssen) vaccine is highly convenient, and you can be done in one visit. While it protects very well against severe disease and hospitalization, it is less protective in those who have diabetes and older (>60) patients with chronic diseases. Overall, if maximal protection is important to you, then the two-dose mRNA vaccines may be for you. If maximal convenience is important to you, then the one-dose J&J (Janssen) vaccine may be for you.

In addition, while all the vaccines have similar short-term side effects from receiving the shot (for example, arm soreness and brief cold or flu-like symptoms: See **Question 28**), they do have different rare serious effects. The mRNA vaccines have a rare risk of severe allergy (anaphylaxis) that is estimated to be about 5 per 1 million, or 1 in 200,000. The J&J vaccine also has a rare risk of severe allergy, but estimates are still being calculated. Severe allergies tend to occur within several minutes of vaccination. Every vaccine site requests that people be observed for 15 minutes (30 minutes if you have a serious allergic reaction to anything) so that they can administer life saving medication if a rare, but serious, allergic reaction occurs. All vaccine sites have these medications.

The J&J (Janssen) vaccine has also been linked to a rare, but serious, problem with blood clots. The problem involves a rare condition where a person makes antibodies against their own platelets. This condition can result in serious clots in the brain, lung, liver, or legs that can be life-threatening and require emergency treatment. Because it is rare, there is a very low chance that this happens with the vaccine, but it has been shown to be more common in women, especially those between the ages of 30-39 (see table). Nevertheless, even in that age group, the chance is very low, especially when you consider the protection it provides against the serious disease and chronic conditions that COVID-19 can cause. The FDA recommends that anyone who receives the J&J (Janssen) vaccine seeks medical attention if severe headache, abdominal pain, leg pain or shortness of breath occurs within 3 weeks of receiving the vaccine.

People should weigh their options between the mRNA and the J&J vaccine. The below table helps teach you about your choices when it comes to COVID-19 vaccines.

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| | mRNA Vaccine (Pfizer or Moderna) | J&J Vaccine | No Vaccine |
|--------------------------|---|--|------------|
| # Doses | 2 | 1 | 0 |
| Time between Doses | 3 weeks (Pfizer), or 4 weeks (Moderna) | | |
| Protection from COVID | 95% (Pfizer) 94% (Moderna) | 66% | 0% |
| Advantage | Greater protection | Greater convenience | None |
| Serious Side Effects | Rare allergic reaction 1 in 200,000 | Rare blood clots Females 18-29: 1 in 192,000 Females 30-39: 1 in 85,000 Females 40-49: 1 in 233,000 Females 50-64: 1 in 670,000 Females 65+ & males: no known risk | None |

[CLICK HERE TO GO BACK TO QUESTION LIST]

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

No. For mRNA vaccines, protection was measured starting 7 days after the second dose for the COVID-19 Pfizer vaccine and 14 days after the second dose for the COVID-19 Moderna vaccine. For the J&J vaccine, protection is active after two weeks. Until that time, you should assume you are not yet protected by the vaccine. 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.

As cases in the U.S. have sharply declined in response to the change in season and rising vaccinations, the CDC has provided general guidance for when it is safe to not wear a mask.

It is safe to **not** wear a mask if no one has symptoms of COVID and:

- When you and your immediate household are alone, both indoors and outdoors
- When vaccinated people from one household are with unvaccinated people from <u>one</u> other household, but all unvaccinated persons are low risk for serious COVID-19 disease.
- When you are in a room where everyone is fully vaccinated (at least 2 weeks past their last required dose)
- When you are outdoors and at a safe distance from other people (unless you are at an event that requires masking)

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• When you are eating at a restaurant and are at least 6 feet from other people who may not be vaccinated. In these moments, you should remove your mask only to eat and replace it as soon as you are done eating and drinking.

This is a contagious disease and we are all in this together. Guidance may change depending on the season and the number of people in your community who have COVID-19 since vaccine protection is not 100%. For example, SARS-CoV-2 is a winter virus and if we do not meet herd immunity levels of vaccination by winter, we may see cases begin to rise and outbreaks occur especially in areas where vaccination rates are less than 70%. Experts believe that 70-85% of the population will need to be vaccinated before the pandemic will be over. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

11. After vaccination, can I still spread COVID-19 to my friends and family?

While the vaccines work remarkably well, none provides perfect protection. Even with the mRNA vaccines (Pfizer, Moderna) which are ~95% protective, there is a 5% risk of breakthrough disease despite being vaccinated. This 5% risk can be important when there are a lot of people in the community with COVID-19. If you develop symptoms of COVID-19, you should be tested, and if you test positive, you are likely contagious to others. Fortunately, there is evidence that vaccination makes you less contagious to others if you are infected.

Will vaccination make me more likely to have asymptomatic disease and pass COVID-19 to others without knowing it? There are several reasons why this is unlikely to happen. First, both Pfizer and Moderna trials are evaluating the likelihood of asymptomatic disease and more data will be known over time. Moderna already reported that asymptomatic disease was greatly reduced at the time of the second vaccine dose. At UCI Health, our healthcare providers are routinely offered asymptomatic testing for COVID-19, and we have similarly found a marked reduction in both symptomatic and asymptomatic disease after vaccination. Second, there is no carrier state for COVID-19. The virus does not sit in the throat or nose waiting to infect someone. Third, there is no precedent for a highly effective vaccine against a virus that prevents symptomatic, but not asymptomatic, disease. This has not been shown to occur. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

12. How long will the vaccine protect me?

Participants in the COVID-19 vaccine trials will be followed for up to two years, including having blood drawn periodically to determine if protective levels of antibody are still present. Thus, more will be known as time goes by. Since immunity to other coronaviruses is known to last one to three years, it is widely anticipated that the COVID-19 vaccine will be an annual vaccine, possibly every other year at best. An annual vaccine may also help address variants, since the vaccines can be modified each year, similar to what is currently done for the flu vaccine. Although the mRNA vaccines are a two-dose series, it is likely that an annual vaccine or booster would be a single dose. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

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13. What is important to know about COVID-19 variants?

When the SARS-CoV-2 virus causes infection, it enters the body and starts to grow. Each time the virus doubles, it can form mutations in its genetic code. This causes slightly different variants of the virus, and over time, many different variants now exist in the world. Finding these variants is made possible because we can sequence the virus' genetic code. There are several concerns related to variants, including whether some will be better at infecting people, spreading between people, or causing severe disease and death. One of the most important concerns about variants is whether the current vaccines will work on all of them.

What kind of information is most helpful about deciding if a variant will cause a vaccine to fail? Lots of media attention has been given to whether a variant might evade (or escape) a vaccine. Certain information is more helpful than others to decide whether that is likely to happen. So far, studies using blood from fully vaccinated people have shown that the Pfizer and Moderna vaccines are protective against the UK, Brazilian, and South African variants.

| Type of Information | Value for Proving Vaccine Failure | |
|--|--|--|
| Can cause outbreaks | Low | |
| Has mutations in spike protein | Low unless mutations proven to cause vaccine failure | |
| Blood from recovered persons (convalescent sera) doesn't work | Low. Infection is known not to protect well | |
| Blood from fully vaccinated persons doesn't work | High. Be attentive to this type of data which is the most valuable for showing that a vaccine may fail | |
| Variant COVID cases continue to occur in vaccinated people | High. If cases due to a variant keep occurring in fully vaccinated people, this would suggest vaccine failure. | |

Usefulness of Information on whether a Variant can Cause a Vaccine to Fail

What can we do to stop variants? Variants appear as more and more people become infected and the virus keeps growing in many people. The best solution is for as many people as possible to get vaccinated quickly to stop the spread and growth of the virus. [CLICK HERE TO GO BACK TO QUESTION LIST]

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

The distribution of race and ethnicity for the mRNA vaccine trials is found below.

- Pfizer
 - o Non-White Race: 10% African American, 4% Asian, 3% Other racial groups
 - Hispanic/Latino: 26%
- Moderna
 - Non-White Race: 10% African American, 5% Asian, <3% Other racial groups
 - Hispanic/Latino: 20%
- J&J (Janssen)
 - Non-White Race: 17% African American, 4% Asian, 14% Other racial groups
 - Hispanic/Latino: 45%

All vaccines are meant to get rid of germs and diseases that infect humans. These vaccines are meant to help humans fight off non-human pathogens. Thus, we do not expect a difference by race or ethnicity. In fact, there is no example of a vaccine where different ones are recommended based upon race or ethnicity. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

15. Will getting a COVID-19 vaccine make me test positive for COVID-19 if am tested after being vaccinated?

No. None of the vaccines will cause you to test positive on viral tests for COVID-19, such as PCR tests or antigen tests. However, the vaccine will cause you to test positive for certain antibody tests (also called serology) that look for antibodies against the spike protein since the vaccine helps build these antibodies to COVID-19. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

16. Who should get the COVID-19 vaccine? Who should not?

All eligible people should receive a COVID-19 vaccine to protect themselves and their loved ones from COVID-19. The only contraindication to the Pfizer, Moderna or J&J vaccines are if you have had a serious allergic reaction to that vaccine or its ingredients. If you do have a serious allergic reaction to one of COVID-19 vaccines, you may be able to safely receive one of the other vaccines. Discuss your plans with your doctor. In addition, if you have a serious bleeding disorder and your doctor has told you that you cannot get shots into the arm, then you need to consult with your doctor to ask if you can receive a vaccine. Because the vaccine provides outstanding protection against COVID-19, including protection from hospitalization and death, if you think you cannot get the vaccine, please discuss with your doctor to confirm whether or not you are truly unable to receive any of these vaccines. There are special circumstances that will affect the timing of when to get the vaccines (see next several questions). At this time, the vaccines are not authorized for children under the age of 12, but this is expected to change in early fall of 2021. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

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17. I already had COVID-19. Am I supposed to get the vaccine? If so, when?

Yes. Anyone who has had COVID-19 should still receive the vaccine. Unfortunately, having been infected with COVID-19 does not guarantee strong immunity to the virus. Usually protection is only reliable for 3 months after infection. Getting the vaccine will ensure you receive the protection found in the trials. You should not receive the vaccine while you are actively infectious, but after you return to normal activities, you can and should receive the vaccine. This can be as early as 10 days after your COVID-19 symptoms began. If you are eligible but your recovery is slow, you can wait up to 90 days after infection to receive your vaccine. During that period, you should still be protected from repeat COVID-19 infection. However, remember that full protection from vaccination only occurs 2 weeks after all doses are received, which can take over a month for the two-dose vaccines.

Since the vaccines do not work immediately (see **Question 10**), some people will become infected with COVID-19 shortly after being vaccinated, including between the first and second doses of a two-dose vaccine, or even shortly after receiving the second dose. If this happens, there is no reason to worry that the vaccine won't work. In fact, it is likely that the combination of the vaccine and the infection will cause a strong immune response. However, for two-dose vaccines, it is still important to receive the second dose to ensure that immunity is locked in and the full 95% protection is achieved. The second dose can be received on time if you are no longer infectious, have not had a fever for at least 24 hours, and feel up to receiving the vaccine. If not, you should delay the second dose until those criteria are met. Even with a few weeks' delay, you should still expect to receive full benefit from the two doses.

Some people who have COVID-19 have received monoclonal antibodies or convalescent sera to help prevent severe disease. If so, you should not receive a COVID-19 vaccine for 90 days from the time you received the antibody therapy since those antibodies can bind the spike protein produced by the vaccine and prevent your body from making its own protective antibody. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

18. Are pregnant, breastfeeding, or immunocompromised persons supposed to get the vaccine?

Persons who were pregnant, attempting to become pregnant, breastfeeding, living with an immunocompromising condition, or taking medication that compromises the immune system are often not enrolled into initial vaccine trials. However, even though these persons were not enrolled in the initial trials, we know that pregnant and immunocompromised persons are at higher risk for serious COVID-19 disease. For this reason, persons with these conditions may want to make a personal choice to receive the vaccine.

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For those who are pregnant, breastfeeding, or trying to become pregnant, there are several factors to consider in your personal choice. First, consider your personal risk for becoming infected with COVID-19 because of the number of cases in your community, and your usual level of interaction with family, friends, and others in the community. Second, in general, concerns for any potential medication effects to a developing fetus are usually related to the first trimester when organs are forming. Third, the mRNA in the vaccines do not cross the placental barrier and will not reach the fetus. On the contrary, protective antibodies do pass to your baby through the placental barrier and through breastfeeding. Even though no trials yet exist that are specifically dedicated to pregnancy or immunocompromised individuals, there are at least 36 participants in the mRNA trials who became pregnant during the trials, including 18 in the vaccine group. They are being monitored for any effects. Discuss your desires and concerns with your doctor.

As of early May 2021, over 100,000 pregnant women have received a COVID-19 vaccine and 5,000 have signed up to be in a registry to be followed for any concerns. See updated information here:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html

The American College of Obstetricians and Gynecologists has released the following recommendation, suggesting that vaccine be offered to pregnant and breastfeeding women, and recommending against requiring women of childbearing age to have a pregnancy test before receiving the vaccine.

https://www.acog.org/clinical/clinical-guidance/practiceadvisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

In general, the concern for immunocompromised persons is not due to safety concerns, but rather that the vaccine may not generate as strong a protective response as in persons with a normal immune system. Nevertheless, a partial response may be an important benefit. Discuss your preferences and options with your doctor. For example, the American Society of Transplantation makes the recommendation that all transplant patients and their household members receive the COVID-19 vaccine when it becomes available.

https://www.myast.org/sites/default/files/2020%2012%2008%20COVID19%20VACCINE%20FA QS_FINAL.pdf

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19. When will children be able to be vaccinated?

As of mid-May, the status for vaccines authorized for children is as follows:

12 to <18 years old

- Pfizer is authorized to be used on children 12 years old and above as a two-dose vaccine, 3 weeks apart
- Moderna expects FDA review by June 2021 for children 12 years and above

2 to <12 years old

- Pfizer is currently enrolling children in this age range in a clinical trial and anticipates results by September 2021
- Moderna is currently enrolling children in this age range in a clinical trial and anticipates results by early 2022

6 months to <2 years old

- Pfizer is currently enrolling children in this age range in a clinical trial and anticipates results by end 2021
- Moderna is currently enrolling children in this age range in a clinical trial and anticipates results by early 2022

The authorization of a vaccine for children 12 and older means that tween and teen children can be vaccinated by the time school begins this fall, which is wonderful news. Because schools necessarily group same-aged children into classrooms, this means that children under 12 will be gathering in sizeable unvaccinated groups during school. Thus, other forms of protection will be important for this age group until they become eligible for a vaccine. The best way to protect children in this age range is for everyone who interacts with them who is eligible to be vaccinated (e.g., parents, teachers, older siblings, grandparents, aunts, uncles, and older cousins) to actually become vaccinated. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

20. Who is prioritized to get the vaccine?

As of May 2021, everyone who is 12 and older is prioritized to receive the vaccine in Orange County. There are active efforts to ensure that everyone hears about this opportunity. Efforts are being made by Orange County public health, insurers, hospitals, universities, and community centers to reach those who have limited access to vaccine centers or need help signing up. The goal is to ensure that everyone has access to receive a free vaccine. There are no costs to being vaccinated whether or not you have health insurance. The vaccine is free and if you don't have insurance to cover the nurse or pharmacist administration cost, that cost will be covered by the government.

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21. How many doses of vaccine does the U.S. have? Where can I get vaccinated?

The vaccine supply to the U.S. is plentiful for everyone in the U.S. to become vaccinated. You can receive a vaccine by signing up at <u>https://myturn.ca.gov/</u>. In addition, vaccines are available at local pharmacies, groceries, medical providers, and community events. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

22. Will the COVID-19 vaccine be required?

Currently, a variety of vaccines, such as measles-mumps-rubella, chickenpox, and polio are required in certain settings – for school, college, and in healthcare settings. The University of California and California State campuses have declared the intent to make COVID-19 vaccination a requirement for staff, faculty, and students by fall term 2021. Many colleges and universities have declared COVID vaccination a requirement for students this fall. The ability to require the COVID-19 vaccine assumes that at least one COVID vaccine will receive full FDA approval (instead of Emergency Use Authorization – see **Question 7**). Full authorization is expected to occur for Pfizer and Moderna vaccines by summer 2021. Places requiring COVID-19 vaccination wish to create a safe campus/workplace where individuals can rely upon herd immunity and can return to pre-pandemic activities, interactions, learning, and collaboration that is important to a healthy society. It will also assure that the campus/workplace is maximally protected for the upcoming winter season. Since COVID-19 is a highly seasonal virus, places (e.g., zip codes, schools, nursing homes) that do not reach high levels of population vaccination (70-85%) may risk disease, outbreaks, hospitalizations, and deaths due to winter resurgence of COVID-19. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

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

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

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

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24. What if I get the first dose and then don't want the next dose?

It is important to remember that the two large Pfizer and Moderna trials were not designed to assess the benefit from a single shot. For example, everyone in the Pfizer vaccine group received two shots, 21 days apart. Thus, for each vaccine participant, there were only 21 days between doses that provided any information about the effect of the first dose alone. Nevertheless, evidence from Scotland and Israel have shown that after 14 days from the first dose of the Pfizer vaccine, there is evidence of 85-90% protection from symptomatic disease and hospitalization. However, these studies do not tell us how long that protection would last if the second dose isn't given to lock in protection.

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The large clinical trials will be following participants who received both doses for 2 years. These trials are providing scientific evidence that two doses provide continued protection. Currently, strong evidence of immunity persists at least 9 months, and longer time periods are currently under study. In addition, those who begin a two-dose vaccine series will not be considered fully vaccinated until two weeks after both doses are complete. This is the reason why you should not start the vaccine series unless you intend to complete it. Or, strongly consider obtaining the J&J (Janssen) vaccine instead if there is a high chance you will not get the second dose (For a detailed comparison of the Pfizer, Moderna, and J&J (Janssen) vaccines, see **Question 9**).

It is also important to remember that the COVID-19 vaccines often cause a mild flu-like illness after each dose. 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. You should expect similar symptoms after each dose. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

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

Ideally, you should try to be on time with your second dose because the data on vaccine benefit from the clinical trials were based upon a fixed number of weeks between doses (3 weeks between Pfizer doses; 4 weeks between Moderna doses). However, in real life, there may be reasons that prevent you from getting your second dose on time. All recommended vaccines have a window of 4-6 weeks that a dose can be given late without being considered delayed. Even beyond that time, you should still receive the second dose. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

26. Can I get my second dose a day or two early?

In both Pfizer and Moderna trials, participants were allowed to get their second dose up to two days early. Earlier than that is not recommended given the time needed for the first dose to take effect. In general, it is preferable for the second dose to be given on time or later. Importantly, many vaccine centers will not give the second dose early, so be sure to check if that is a special request. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

27. What if I have been exposed to someone with COVID-19 close to the time of my scheduled dose? Should I reschedule?

If you have had a known exposure to someone with COVID-19 within 10-14 days of your scheduled dose, you should consider rescheduling to avoid being infected at the time of your dose. The risk of this is likely to be greatest with a household exposure or other conditions of prolonged close contact without masking. If this is the case and you are able to reschedule, it

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would be advisable to do so. If you are unable to reschedule, you can go ahead and receive your vaccine as long as you have no symptoms at the time of the vaccine. Just be aware that you may still develop COVID-19 around that same time (see **Question 33**) and would need to be tested, and if tested, you will need to be quarantined. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

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

So far, clinical trials have shown that COVID-19 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.** All COVID-19 vaccines commonly cause mildto-moderate non-infectious "flu-like" symptoms. This occurs commonly for one day, sometimes for two days, and less commonly for 3 or more days.
- Pick a good time
 - Get your vaccine when you do not have anything important planned in the next day or two, including work shifts. This is more important after the second dose since symptoms are more common after the second dose.
 - If you can, have staff who have highly specialized skill sets separate their vaccines by at least 3 days in case one needs to miss work for vaccine-related side effects
- Pfizer mRNA vaccine
 - Percent of people with any symptoms: 59% after 1st dose, 70% after 2nd dose
 Note: in placebo (no vaccine) group: 47% symptoms after 1st dose, 34% after 2nd
 - Types of symptoms: fatigue 63%, headache 55%, muscle aches 38%, chills 32%, joint pain 24%, fever 14%
 - Percent of people with severe side effects: fatigue 4%, headache 2%
- Moderna mRNA vaccine
 - Percent of people with any symptoms: 55% after 1st dose, 79% after 2nd dose
 Note: in placebo (no vaccine) group: 42% symptoms after 1st dose, 37% after 2nd
 - Types of symptoms: fatigue 69%, headache 63%, muscle aches 60%, joint pain 45%, chills 43%
 - Percent of people with severe side effects:
 - First dose: fatigue 1%, muscle aches 1%, joint pain <1%, headache 2%, chills <1%, fever <1%
 - Second dose: fatigue 11%, muscle aches 10%, joint pain 6%, headache 5%, chills 2%, fever 2%
- J&J (Janssen) vaccine (one dose vaccine)
 - Percent of people with any symptoms: 55%

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Note: in placebo (no vaccine) group: 35%

- Types of symptoms: headache 39%, fatigue 38%, muscle aches 33%, nausea 14%, and fever 9%
- Percent of people with severe side effects: fatigue 1%, muscle aches 1%

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29. Should I plan to take Tylenol or Motrin before my vaccine dose?

If you regularly take aspirin, acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Motrin, Advil) for other medical conditions, please continue to do so as directed by your physician or as needed. Otherwise, *do not pre-medicate*. In general, pre-medicating with over-the-counter medications that reduce fever or inflammation such as acetaminophen (e.g., Tylenol) and ibuprofen (e.g., Motrin, Advil) before receiving a vaccine may reduce its ability to work and can blunt your immune response to the vaccine. The time to take these over-the-counter medications is after 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 usually take these medications for other medical reasons, continue to take them per your normal routine. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

30. What ingredients are in the vaccines?

The Pfizer BioNTech COVID-19 vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

The Moderna vaccine includes the following ingredients: mRNA, lipids (SM-102, 1,2-dimyristoylrac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replicationincompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

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

Allergies are generally linked to specific items. Having a significant allergy to a food or different medication does not necessarily mean that you are at higher risk for an allergic reaction to the COVID vaccine. The only definite reason to not give the COVID-19 vaccine to someone is if that person has a known allergy to the COVID vaccine (from prior doses) or an ingredient in the vaccine. For example, the COVID-19 vaccines are not made in chicken eggs and there should not be any additional risk for people with allergies to eggs. For individuals who have a lot of serious allergies, please consult with your doctor. If you have been told to carry epinephrine (Epipen) for any reason, we recommend that you continue to do so, including when you receive the vaccination. All vaccination distribution centers are required to have emergency allergy medications on site, and the CDC is recommending that everyone who receives the vaccine be observed for 15 minutes, or 30 minutes if you have any history of anaphylaxis for any reason. If you are unable to wait that duration of time, we recommend that you remain around other people for the 15 minutes immediately after receiving the vaccine, or are on the phone with someone who is aware that you have just been vaccinated and knows your location. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

32. Will my medication interfere with the vaccine?

There are no medications that are contraindications to the COVID-19 vaccine. In fact, we recommend that you take all your medications as prescribed to ensure your health is in the best condition before vaccination. Nevertheless, there are some special circumstances to consider:

- If you are taking a blood thinner, check with your doctor if you are able to get a vaccine shot without a bleeding risk
- If you are on immunosuppressant medication or chemotherapy, check with your doctor about the best timing for you to receive your vaccine. If medication is taken in a periodic fashion, there may be better times in the cycle to be vaccinated than others.

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33. What if I get COVID-19 after receiving my first dose? Is that dangerous?

As millions are vaccinated across the United States, some persons happen to become sick with COVID-19 before their vaccination sequence is complete. Remember, you do not reach the protection seen in the clinical trials until 14 days after your last dose of COVID vaccine (two doses for Pfizer and Moderna, and one dose for J&J). Some people have been exposed to persons who have COVID-19 before or shortly after receiving the vaccine. If you become infected and have been vaccinated at the same time, your body will work to both fight the infection and respond to the vaccine by making more antibodies. You will likely experience the

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symptoms related to both, but the vaccine will still be working to help you make the right antibodies to prevent future infection.

For two-dose vaccines (Pfizer and Moderna), if your infection is close to your second dose, you will need to delay your dose if your symptoms started within 10 days of your appointment or if you have a fever within 24 hours of your appointment. After you are no longer infectious, you are able to receive your second dose. Some have suggested that a second dose may not be necessary in those who have been infected. However, it has not been proven that infection plus a single dose is equivalent to two doses of an effective vaccine in the long run. While it may be true for some select individuals, it is unlikely to be true for most or all individuals. Because it is not possible to know, the recommendation is that people who have had COVID-19 should still receive a full course (either one dose of J&J, or two doses of Pfizer or Moderna). Two things are well understood at this time. First, that infection does not provide trustworthy immunity beyond 3 months. Second, the mRNA vaccines require two doses to achieve the 95% protection seen in two large trials. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

34. If I have had COVID-19, should I delay getting the vaccine? When is it safe to get it?

If you have had COVID-19, you can and should receive the vaccine. This can be as early as 10 days after your COVID-19 symptoms began if you have not had a fever for the past 24 hours. In general, if you have an opportunity to receive the vaccine, you should take advantage of the opportunity. However, you may choose to delay your vaccine for up to several weeks for the following reasons:

- If you still don't feel well enough to get a vaccine because you are still recovering from the effects of COVID-19
- If you are certain you can schedule a dose within 2 months of your infection. Remember, infection only generates protection for about 3 months, and it takes two weeks to become protected after the one-dose J&J vaccine, and over a month to receive both doses of a two-dose vaccine series plus two more weeks to develop full protection.

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35. What is Bell's palsy or Guillain Barré? Do the COVID vaccines cause this?

Bell's palsy is a temporary facial nerve paralysis that occurs in 40,000 people in the U.S. every year (110 people every day). Its cause is often unknown, but it is linked to stress and infection, including COVID-19. There were cases of Bell's palsy among participants in the large clinical Pfizer and Moderna trials with a few more in the vaccine versus placebo group in both trials. However, the FDA did not determine that the vaccines were a cause of Bell's palsy because the number of cases in the trials was less than the expected number of cases that would normally occur in the number of people in the trials over the time period of the trials.

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Guillain Barré is a rare disorder that involves weakness and paralysis. It usually requires hospitalization and slow recovery with treatment. While Guillain Barré is rarely associated with the flu vaccine, it has not been associated with the COVID-19 vaccines. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

36. Do the COVID vaccines cause cancer?

The COVID vaccines do not cause cancer. In fact, scientific advancements have allowed these types of vaccines (mRNA vaccines and adenovirus vector vaccines) to treat cancer. The way these vaccines work is to provide an instruction set to make a protein. When used to treat cancer, these vaccines work to create proteins similar to those on the surface of cancer cells so that the body learns to recognize them as non-human and fights against them. In the same way, the COVID vaccines make the COVID-19 spike protein and help the body make antibodies and fight against the virus. The vaccine is not alive and cannot infect or change our cells. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

37. Does the vaccine cause infertility or affect our genes?

The vaccines do not cause infertility or affect any of our genetic code. The COVID-19 vaccines do not enter the part of the cell where DNA is housed, and do not and cannot affect our genetic material. In addition, the vaccine only stays in the body very briefly and is taken up by the cells in our arm. It does not move from the arm to the reproductive organs. During the vaccine trials when participants were asked to refrain from becoming pregnant, over 20 people who received the vaccine became pregnant during the trials, suggesting the vaccine does not cause infertility. If you are pregnant when you receive the vaccine, the vaccine ingredients do not cross the placenta. The only thing that crosses to the baby are the protective antibodies that your body makes in response to the vaccine. Over 100,000 pregnant people in the U.S. have chosen to receive the COVID-19 vaccine and, so far, there is no evidence of harm to the baby (See **Question 18**). *[CLICK HERE TO GO BACK TO QUESTION LIST]*

38. Does the vaccine cause me to be tracked? Does it inject a microchip?

The COVID-19 vaccines do not contain any tracking or surveillance device. The vaccines only contain clear liquid, and the ingredients are known (see **Question 30**). There is no microchip in the vaccine, and there is no such device that could fit through the tiny needle that is used to inject the vaccine. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

39. Does the vaccine cause me to shed COVID-19 due to asymptomatic infection?

This is unlikely to happen. First, both Pfizer and Moderna trials are evaluating the likelihood of asymptomatic disease and more data will be known over time. Moderna already reported that asymptomatic disease was greatly reduced at the time of the second vaccine dose. At UCI Health, our healthcare providers routinely offered weekly asymptomatic testing for COVID-19 COVID-19 Vaccine Q&A Document Created: 12/07/20

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to over a thousand health care professionals, and we found a marked reduction in both symptomatic and asymptomatic disease after vaccination. Second, there is no carrier state for COVID-19. The virus does not sit in the throat or nose waiting to infect someone. Third, there is no precedent for a highly effective vaccine against a virus that prevents symptomatic, but not asymptomatic, disease. This has not been shown to occur. Importantly, the opposite has been shown with viral vaccines where breakthrough disease results in less shedding, even when infected. **[CLICK HERE TO GO BACK TO QUESTION LIST]**

40. Is it better to wait to get the vaccine? What does waiting tell me?

When a vaccine is authorized for use, it is understandable that people may want to wait to see how the vaccine performs in others before they agree to get the vaccine themselves. For the COVID-19 vaccines authorized in the U.S., there were over 45,000 individuals in the combined trials who received the vaccines. These large trials helped define common side effects expected from the vaccines. Post-authorization use in millions of people has helped confirm these side effects and define increasingly rare events. Due to the pandemic, the number of vaccines given far exceeds what other vaccines experience in many years. By mid-May 2021, over 150 million people in the U.S. have received at least one dose of a COVID-19 vaccine. In addition, nearly a billion doses of Pfizer and Moderna COVID-19 vaccines have been given to other countries worldwide. Pfizer alone has a goal of 2.5 billion doses produced by the end of 2021. The experience of millions of people has confirmed that severe allergic reactions are very rare, and side effects are mild and temporary. In contrast, by mid-May 2021, there were over **700,000 COVID cases diagnosed every day across the world**. Many places around the world are eagerly awaiting the type of access to vaccines that the U.S. has. In the U.S., we are trying to rapidly vaccinate everyone to ensure the end of the pandemic here at home. The risk of COVID-19 hospitalization, death, and post-infectious chronic fatigue, confusion, and pain far outweighs the minor side effects of the vaccine, with millions and millions of people experiencing safe and effective vaccination and the reassurance of highly effective protection from COVID-19. [CLICK HERE TO GO BACK TO QUESTION LIST]