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

We all want this pandemic to end. By mid-August 2021, the COVID-19 pandemic reached 205 million cases and 4.3 million deaths worldwide. These striking numbers are underestimated since only people who have been tested are counted. In the United States, 36 million cases of COVID-19 have occurred and 620,000 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 75-85% 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.

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

With 205 million cases of COVID-19 worldwide and 36 million cases in the U.S., we should not wait to receive the vaccine. By mid-August, over **a billion** doses of COVID-19 mRNA vaccine (Pfizer or Moderna) have been given around the world (**340 million** doses in the U.S.), and 26 million doses of J&J (Janssen) COVID-19 vaccine have been given worldwide (14 million doses in the U.S.). 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 75-85% vaccinated, the sooner the pandemic can come to an end.

3. Is it almost over? How should the upcoming months affect my desire to be vaccinated?

As of mid-August 2021, we should be bracing for what the upcoming 7 months will bring. There are likely 4 waves that we can expect – each compounding one another - meaning, that one wave is unlikely to return to zero before the next wave hits. It may start to decline a bit, but then the next wave will come. What are these waves?

- The first wave is now the wave of COVID-19 delta variant cases due to unmasked social activities, including gatherings and parties at people's houses, restaurants, bars, and breweries, that we had all hoped we could safely engage in when our cases were low throughout the spring and early summer.
- This wave that we are in will be compounded by the fact that schools opened in mid- August. Schools will necessarily gather groups of unvaccinated students into classrooms and while it is critical for learning, it does increase risk of transmission to other classmates and to parents, grandparents, and siblings at home or for after school care if students become sick with COVID-19.
- The third wave will be the change in season. The spring and summer are the safest months. We know from last year, that the winter season brings higher transmissibility and a 5-fold increase in cases compared to what we see during the summer.
- The fourth wave is from holiday gatherings. As Thanksgiving comes around and the end of year celebrations follow, we expect a large number of gatherings that will also increase the spread of this virus.

The time to get vaccinated is now in advance of the coming waves. Protect yourself, and your friends and loved ones, including children that you interact with.

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4. How should the delta variant affect my decision to be vaccinated?

First, what is the delta variant? Variants of COVID-19 arise when there are a large number of cases and the virus is replicating in many humans. During replication, as it doubles and doubles, virus mutations can arise. Sometimes these mutations make the virus weaker and sometimes they make the virus stronger (worse). In this case, the delta variant is a much more contagious version, and some studies suggest it can cause more severe disease.

Unfortunately, the delta variant went from a very uncommon form of the virus (around 5%) to nearly 90% of all U.S. cases in 5 weeks.

- What does this mean for the unvaccinated? Because the delta variant is more contagious, the chance that you get COVID if you are exposed to someone with COVID is incredibly high. Unmasked social or work encounters are risky for you, and when you get COVID, the chance you pass it on to others around you is high. Your best protection is to vaccinate, wear snug masks indoors and when in close contact with others outside of your household. Plus, carry hand sanitizer so you can clean your hands every time before you touch your eyes, nose, mouth, or mask.
- What does this mean for the vaccinated? For you, the vaccine has almost perfect protection against severe disease, including hospitalization and death. That's outstanding news. Unfortunately, mild breakthrough disease is occurring, ranging from a mild cold to a flu-like illness with fevers and chills. This mostly happens after exposure to a highly contagious person at home or at an unmasked social gathering. If you are exposed, you have 1/3 the chance of getting COVID-19 compared to an unvaccinated person, but it is no longer close to zero. For you, the combination of vaccination and masking keeps you well protected at around 88%. You should also clean your hands every time before you touch your eyes, nose, mouth, or mask.

5. If breakthrough disease can occur with the delta variant, why should I be vaccinated?

There are many reasons why you should be vaccinated even with reports of breakthrough infection with the delta variant.

- First, vaccination is the only protection you have after you've been exposed. That is, after the virus enters your body through your eyes, nose, or open mouth. Vaccination gives you an army in your body that is ready to fight any COVID-19 virus that enters. This includes both antibodies and fighter cells that recognize the virus and attack it. This is why vaccinated people are far less likely to become infected with delta virus (about 1/3 as likely as unvaccinated persons).
- Second, because vaccinated persons are less likely to become ill, they protect those around them. While vaccinated persons can become ill and shed a lot of virus, it remains to be seen whether the virus that vaccinated people shed may be less contagious than the virus shed by unvaccinated ill persons.
- Third, vaccination provides near perfect protection against severe disease, including hospitalization and death. The truth is no one thinks they are going to get severe disease until it happens. The vaccine protects you from the worst kinds of outcomes from this virus.
- Finally, vaccination can be very convenient. More and more workplaces, performances, and social events are requiring proof of vaccination.

6. 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-August 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. Over 340 million doses of these two mRNA vaccines have been given 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 below require two doses for full effect.

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

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

Light Blue = 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)

3 Sadoff 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 12.

7. 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 34**.

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.

8. 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.

9. 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.

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- 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.

10. 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. Pfizer applied for full approval in May 2021 and Moderna applied in June 2021. The review process for full approval is substantially lengthier, but FDA is prioritizing full approval with an anticipated approval date for at least one, if not both, of the mRNA vaccines in late August 2021 or early September 2021.

11. 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.

12. 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) using clinical trial data

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 in the trials. This is the best result that scientists could hope to see. Nearly identical results from two completely different large trials. The clinical trial data are discussed below. For the effect of these vaccines on the delta variant, see **Questions 4 and 5**.

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.

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.

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- Pfizer COVID-19 vaccine Phase 3 trial (~44,000 participants)
 - o 95% efficacy (protection)
 - o All COVID-19 cases: 162 in placebo group vs. 8 in vaccine group
 - o Severe COVID-19 cases: 9 in placebo group vs. 1 in vaccine group
- Moderna COVID-19 vaccine Phase 3 trial (~30,000 participants)
 - o 94% efficacy (protection)
 - o All COVID-19 cases: 185 in placebo group vs. 11 in vaccine group
 - o 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 o >55 years old: 94% efficacy
- Moderna
- o 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 32** 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 (https://www.nejm.org/doi/full/10.1056/NEJMoa2035389).

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.

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 32), 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.

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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.

The J&J (Janssen) vaccine has also been linked to a rare neurologic disorder called Guillain-Barré syndrome. This condition occurs when the immune system attacks nerves and can cause muscle weakness and sometimes paralysis. Nearly all cases require hospitalization for treatment and recovery. Sometimes permanent nerve damage can occur. The chance of Guillain-Barré is quite rare and generally occurs within 6 weeks of receiving the vaccine. About 100 suspected cases have occurred for a risk of approximately 8 cases per million who have received this vaccine, and continued monitoring is occurring.

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.

	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

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

No. Protection doesn't fully occur until at least 14 days after the last required dose of the vaccine. 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 still apply to you unless stated otherwise.

As cases in the U.S. have sharply risen due to the delta variant, and with the coming change in season, CDC has recommended that everyone in communities with a high amount of cases should mask when outside the home in an indoor area. In addition, be careful even when outdoors at crowded gatherings, and anytime your mask is off to eat or drink. It is especially important to socially distance when eating or drinking since your mask is not protecting you.

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 75%. Experts believe that 75-85% of the population will need to be vaccinated before the pandemic will be over.

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

While the vaccines work remarkably well, none of them provides perfect protection. Even before the delta variant, the mRNA vaccines (Pfizer, Moderna) were 95% protective, with a 5% risk of breakthrough disease despite being vaccinated. Now, with the delta variant, the vaccine is still >90% protective against severe disease and hospitalization, but more vaccinated persons can get mild breakthrough disease. If you develop symptoms of COVID-19, you should be tested, and if you test positive, you should assume you are 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.

15. 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.

16. 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 alpha (B.1.1.7, UK), beta (B.1.351, South African), gamma (P1, Brazilian), delta (B.1.617.2, Indian), and lambda (C.37, Peruvian). For more information on the delta variant see **Questions 4 and 5**.

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Usefulness of Information on Whether a Variant Can Escape a Vaccine

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 escape. The question will then be how often this can happen and whether the vaccine still protects against severe disease, such as hospitalization or death.

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.

17. When will COVID vaccine boosters be available? Why are they needed?

FDA authorization for extra vaccine doses for immunocompromised patients is underway. There is also active discussion on whether extra vaccine doses for older adults will be needed.

In addition, both Pfizer and Moderna have stated they will seek FDA authorization for 3rd doses for their vaccines as early as September (Pfizer) and later this fall (Moderna).

Similar to the flu shot, it was widely anticipated that the protection from COVID-19 vaccines would wane, likely after a year. This is consistent with human immunity to cold viruses, which generally lasts 1-3 years. While there is good evidence that the COVID vaccines generate protective antibody levels for at least 9 months, there is also evidence that they do slowly wane over time. We also know that vaccines generate not only antibodies, but also fighter cells against the COVID-19 virus, but no one wants to risk waning immunity when winter is around the corner. For that reason, it is still expected that a booster shot will be made widely available this fall.

18. 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
 - o Hispanic/Latino: 26%
- Moderna
 - o Non-White Race: 10% African American, 5% Asian, <3% Other racial groups
 - o Hispanic/Latino: 20%
- J&J (Janssen)
 - o Non-White Race: 17% African American, 4% Asian, 14% Other racial groups
 - o 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.

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19. 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.

20. 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.

21. 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 13**), 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.

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

The Centers for Disease Control and Prevention (CDC) has issued a recommendation that pregnant persons be vaccinated due to strong evidence of safety and the rising number of cases in pregnant individuals. Data from the v-safe pregnancy registry has not found any associated risk of the vaccine with miscarriage or infertility.

https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html

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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 mid-August 2021, over 150,000 pregnant women have reported receiving a COVID-19 vaccine and 5,100 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 (ACOG) and the Society for Maternal- Fetal Medicine (SMFM) have jointly recommended that all pregnant and breastfeeding women be vaccinated.

https://www.acog.org/news/news-releases/2021/07/acog-smfm-recommend-covid-19- vaccination-for-pregnant-individuals

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.

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

23. When will children be able to be vaccinated?

As of mid-August, 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 in the near future 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
- FDA anticipates emergency use authorization of a vaccine for the 5 to <12 year old age group by mid-winter (2021-22), and for the 2 to <5 year old age group, a few months later

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
- FDA anticipates emergency use authorization of a vaccine for this age group in early 2022

The authorization of a vaccine for children 12 and older means that tween and teen children have had the opportunity to vaccinated in time for the start of school, which is wonderful news. Because schools necessarily group same-aged children into classrooms, this means that children under 12 are 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.

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24. Who is prioritized to get the vaccine?

As of August 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.

25. 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 https://myturn.ca.gov/. In addition, vaccines are available on a walk in basis at local pharmacies and grocery stores. Vaccines are also available directly from medical providers, and through community events.

26. 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 made COVID-19 vaccination a requirement for staff, faculty, and students by fall term 2021. Many other colleges and universities have declared COVID vaccination a requirement for students this fall. 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 (75-85%) may risk disease, outbreaks, hospitalizations, and deaths due to winter resurgence of COVID-19.

Timing of Doses

27. 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

28. 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.

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 12**).

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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.

29. 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.

30. 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.

31. 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 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 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 symptoms (see **Question 37**) and would need to be tested, and if positive, you will need to quarantine.

32. Who needs a 3rd COVID-19 Vaccine dose?

People who are moderately to severely immunocompromised are especially vulnerable to COVID-19 and are at more risk of serious, prolonged illness. As of mid-August, the CDC recommends that for people who received an initial 2 doses of an mRNA COVID-19 vaccine, they receive an additional dose of the same vaccine at least 4 weeks (28 days) after the initial 2 doses.

33. Am I eligible for a 3rd vaccine dose?

As of mid-August, the CDC is recommending that moderately to severely immunocompromised people receive an additional dose. These are people who have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (e.g. CD4 count <200)
- · Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

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34. How long after getting my initial COVID-19 vaccines can I get the additional dose?

CDC recommends the additional dose of an mRNA COVID-19 vaccine be administered at least 4 weeks (28 days) after the second dose of Pfizer or Moderna COVID-19 vaccine.

35. Can you mix and match the vaccines?

For people who received either Pfizer-BioNTech or Moderna's COVID-19 vaccine series, a third dose of the same mRNA vaccine should be used. An alternative product can be used only if the primary series is unavailable. A person should not receive more than three mRNA vaccine doses. If you did not receive your initial vaccinations from UCI Health, please bring your CDC vaccination card.

I am immunocompromised and received the J&J/Janssen vaccine

The FDA's recent EUA amendment only applies to mRNA COVID-19 vaccines, as does CDC's recommendation. An additional vaccine dose is not currently recommended for patients who received J&J as the primary vaccine at this time. There is not enough data at this time to determine if immunocompromised people who received the J&J/Janssen vaccine receive the same benefit from an additional dose of J&J/Janssen vaccine as those who got an mRNA vaccine, nor if receiving an mRNA vaccine after J&J will provide additional benefit either. The FDA and CDC are actively working to provide guidance on this issue and we anticipate future updates.

37. Do I need a physician order to obtain the third vaccine dose?

No physician order is required. You will be required to confirm that you meet the criteria for being moderately to severely immunocompromised (as listed above), before receiving the third dose.

Safety and Side Effects

38. 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.

39. 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. The COVID-19 mRNA vaccines (Pfizer and Moderna) have not been linked to this disorder. The J&J (Janssen) vaccine has been linked to this Guillain-Barré syndrome. Sometimes permanent nerve damage can occur. The chance of Guillain-Barré is quite rare and generally occurs within 6 weeks of receiving the vaccine. About 100 suspected cases have occurred for a risk of approximately 8 cases per million who have received this vaccine, and continued monitoring is occurring.

40. 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.

41. 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 150,000 pregnant people in the U.S. have chosen to receive the COVID-19 vaccine and, so far, there is no evidence of infertility or harm to the baby (See Question 22).

42. 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 34**). 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.

43. 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 to over a thousand health care professionals, and we found a marked reduction in both symptomatic and asymptomatic disease after vaccination (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781727). 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.

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44. 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-August, over a billion doses of COVID-19 mRNA vaccine (Pfizer or Moderna) have been given around the world (340 million doses in the U.S.), and 26 million doses of J&J (Janssen) COVID-19 vaccine have been given worldwide (14 million doses in the U.S.). 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-August 2021, there were 600,000 COVID cases diagnosed every day across the world. Many places around the world are still 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.