

## COVID-19: Vaccine Information

### Frequently Asked Questions (FAQs)

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

We all want this pandemic to end. By mid-December, the COVID-19 pandemic caused 75 million cases and 1.7 million deaths worldwide. Because these numbers are based on people who have been tested and since not everyone who is sick is tested, the truth is likely even higher. In the United States, 310,000 people have died due to COVID-19. Right now, 2,500 lives are lost every day in the U.S. due to COVID-19. A safe vaccine that works well can end the COVID-19 pandemic. Experts believe that at least 70% of people need to be vaccinated before the pandemic will end.

***By preventing infection with COVID-19, the vaccine prevents death, and the long lasting effects of infection that have been reported.*** COVID-19 infection has been reported to cause long lasting problems that some people have after recovering from COVID-19. These include being tired, having shortness of breath, cough, joint pain, chest pain, difficulty thinking and concentrating (“brain fog”), depression, muscle pain, headache, and fevers that come and go. 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. Who gets the vaccine first? How many doses are arriving in 2020?

The following groups will be the first to get the COVID-19 vaccine:

- Healthcare personnel (e.g. hospitals, nursing homes)
- People living in nursing home, assisted living and other long-term care facilities.

Combining the availability of both vaccines, it is anticipated that 40 million doses will be provided to the U.S. before the end of 2020. This is enough to start the two-dose series in 20 million people by end-December, with millions more to follow in 2021.

#### 3. Is the vaccine required for healthcare personnel?

No. The vaccine is voluntary, but highly recommended.

## 4. What COVID-19 vaccines are currently available?

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

- Pfizer mRNA vaccine
  - Emergency Use Authorization (EUA) granted on 12/11/2020
  - Large trial (44,000 participants) showed 95% protection from COVID-19 disease
  - Two dose vaccine, requires ultra-cold storage (-70 Celsius)
  - First shipments mostly to hospitals, which can handle cold storage
  - 50 million doses to the world by end 2020 (6.5 million to US)
  - 1.3 billion doses to the world in 2021
- Moderna mRNA vaccine
  - Expected Emergency Use Authorization (EUA) status 12/18/2020
  - Large trial (30,000 participants) showed 94% protection from COVID-19 disease
  - Two dose vaccine, requires standard cold storage (-20 Celsius)
  - First shipments to hospitals and pharmacies serving long-term care
  - 20 million doses to the world by end 2020
  - 500 million to 1 billion doses to the world in 2021

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

When an effective vaccine has been demonstrated in a trial, it can apply for EUA status with 2 months of post-vaccine safety data. In order to apply for full approval, 6 months of post-vaccine safety data must be provided. The FDA is encouraging companies who receive EUA status to apply for full approval as soon as possible. Both mRNA vaccines have reported outstanding safety data with no serious side effects (see Question 14).

## 6. What is in the vaccine? What is an mRNA vaccine?

There are many different types of COVID-19 vaccines being made. The two vaccines that are being currently released for use in the U.S. are mRNA vaccines. mRNA stands for “messenger ribonucleic acid” and it encodes the instructions for your body to make a specific protein (Spike protein) on the surface of the SARS-CoV-2 virus. When your body makes this viral protein, it is recognized as not human, and your body develops antibodies to it. 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. mRNA vaccines have been made for flu, rabies, CMV (cytomegalovirus), and Zika viruses.

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

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

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

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

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

No steps were skipped. All the vaccines going for approval must meet the high U.S. standards of safety for making vaccines. All of the COVID-19 vaccines that could be used in the U.S. were supported by funds from the government (e.g. Operation Warp Speed), large companies, or both. These funds enabled three things to speed up:

- **Trial Enrollment:** If you can increase the number of staff that are recruiting patients, you can enroll a lot of people into a trial in a shorter time period. For example, you can have one person recruit 1,000 people into a trial, or you can have 1,000 recruiters each enroll one person into a trial. The more staff recruiters you have, the faster your enrollment. The funds helped the trials quickly enroll tens of thousands of participants.
- **Manufacturing:** Funds help increase manufacturing buildings, warehouses, and employees. In addition, mRNA vaccines can be made quickly and easily because they do not involve growing the virus to make the virus protein for a vaccine. 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. How well does the vaccine work?

The Pfizer and Moderna COVID-19 vaccines have both been tested in large vaccine trials involving tens of thousands of people. Those in the trials 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 trials were randomized, large numbers should ensure that the types of human interactions in one arm were similar to the other. The 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 vaccine not only prevented COVID cases overall, but it prevented severe COVID-19 disease.

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

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

Both vaccines protected well across all adult ages that were studied. Note that they used different age groupings when providing summary data to the FDA.

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

\*Note that this difference between Pfizer and Moderna may be because of the age cut off selected. For example, it is possible that the Pfizer vaccine would have a lower protection effect if they reported data for those 65+ years old.

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

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

- Pfizer
  - Non-White Race: 10% African American, 4% Asian, 3% Other racial groups
  - Hispanic/Latinx: 26%
- Moderna
  - Non-White Race: 10% African American, 5% Asian, <3% Other racial groups
  - Hispanic/Latinx: 20%

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

Both the Pfizer and Moderna vaccines are two-doses. 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

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

No. The 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. Until that time, you should assume you have no proven benefit from 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. Experts believe that 70% of the population needs to be vaccinated before the pandemic will be over.

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

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

- **Expect some symptoms after vaccination.** Both mRNA COVID-19 vaccines commonly cause mild-to-moderate non-infectious “flu-like” symptoms.
- **Picking a good time**
  - Get your vaccine when you do not have anything important planned in the next day or two, including work shifts
  - If you can, have staff who have special 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 1<sup>st</sup> dose, 70% after 2<sup>nd</sup> dose  
Note: in placebo (no vaccine) group: 47% symptoms after 1<sup>st</sup> dose, 34% after 2<sup>nd</sup>
  - 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 1<sup>st</sup> dose, 79% after 2<sup>nd</sup> dose  
Note: in placebo (no vaccine) group: 42% symptoms after 1<sup>st</sup> dose, 37% after 2<sup>nd</sup>
  - Types of symptoms: fatigue 69%, headache 63%, muscle aches 60%, joint pain 45%, chills 43%
  - Percent of people with severe side effects (mostly second dose): fatigue 10%, muscle aches 9%, joint pain 5%, headache 5%
- Anticipate 10-20% to call off of work for either vaccine due to side effects.

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

If you regularly take aspirin, acetaminophen (e.g. Tylenol) and 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 if you have symptoms that make you uncomfortable after vaccination. If you are uncomfortable, don't hesitate to take an over-the-counter medication to help you feel better. If you usually take these medications for other medical reasons, continue to take them per your normal routine.

## 16. 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. 21 days is barely enough time for that dose to have its full immune effect. Thus, even though the overall data suggests that benefit may have started to be seen after the first dose, there is insufficient data in that time to make any conclusions.

All that can be known from the scientific evidence is that two doses are needed to see the 94-95% protection. This is the reason why you should not start the vaccine series unless you intend to complete it. It is also important to anticipate that the COVID-19 vaccine often causes a mild flu-like illness after each dose. 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.

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

Try to be on time with your second dose because the data on vaccine benefit was based upon a fixed number of weeks between doses (3 weeks between Pfizer doses; 4 weeks between Moderna doses). If you are late, you should still receive the second dose. Most vaccines have rules for how many weeks you can be late before you should start the vaccine series again. In the case of the COVID-19 vaccine, doses will be given late until CDC or published data provide guidance on when it is too late to give the second dose.

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

Now is the best time to get the vaccine because the pandemic is at its peak and people are becoming sick and dying from COVID-19 every day. By mid-December, the U.S. is experiencing 2,500 deaths due to COVID-19 **every single day**. The vaccine will prevent not only disease, but the downstream effects of disease such as hospitalization, death, and long-term effects like brain fog, lasting muscle and joint pains, and heart and lung problems. The best way to end the pandemic is for at least 70% of people to get vaccinated. The fact that two large trials with over 70,000 combined participants have shown that mRNA COVID-19 vaccines are highly protective with only brief mild side effects is very reassuring for vaccine safety and benefits.

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

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



## 20. Who pays for the vaccine?

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

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

Yes. If you have had COVID-19, you should still receive the vaccine. Natural immunity to COVID-19 following COVID-19 infection is unpredictable. The vaccine will make sure you are protected with the benefit found in the trials. You should not receive the vaccine while you are infected, but after you recover and return to normal activities, you can and should receive the vaccine.

## 22. 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 were not enrolled in the mRNA trials. Thus, information is not available to provide a recommendation for either protection or safety. So far, there are 36 participants in the mRNA trials who became pregnant during the trials, 18 in the vaccine group. They are being monitored for any effects. While awaiting further data and guidance, we understand that pregnant or immunocompromised persons are at higher risk for more serious COVID-19 disease and can make the personal choice to receive the vaccine.

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 your usual interactions in with family, friends, and in the community. Second, in general, concerns for any potential medication effects to a developing fetus are usually for the first trimester when organs are forming. Third, the mRNA in the vaccines do not cross the placenta and will not reach the baby. On the contrary, protective antibodies do pass to your baby through the placental barrier and through breastfeeding. Discuss your desires and concerns with your doctor.

The American College of Obstetricians and Gynecologists has released the following recommendation, suggesting that the COVID-19 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/practice-advisory/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 good of 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%20FAQS\\_FINAL.pdf](https://www.myast.org/sites/default/files/2020%2012%2008%20COVID19%20VACCINE%20FAQS_FINAL.pdf)

### **23. 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, mRNA 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.

### **24. 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 contains the following ingredients: mRNA, lipids (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2-

distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

## **25. How do I get the vaccine?**

The first vaccine doses will be given to healthcare personnel and residents of long-term care facilities. Hopefully, vaccine will be widely available to the public by mid-April if not sooner.