AMERICAN ACADEMY OF FAMILY PHYSICIANS

COVID-19 Vaccine FAQs

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What is an mRNA vaccine and how does it work?

An mRNA vaccine uses a piece of messenger RNA — a set of instructions that tells a cell to make a specific protein. For SARS-CoV-2, this is the spike protein that is found on the surface of the viral envelope. The mRNA used in the vaccine does not enter the cell's nucleus and consequently has no interaction with a cell's DNA. It is also not a full virus and cannot replicate itself. The mRNA is rapidly broken down by the cell once the instructions have been transmitted, so it does not cause mutations or cellular defects, and has not been associated with infertility.

Once the spike protein is made, it is put on the surface of the cell, where it is seen by the immune cells and causes them to become activated and respond. The result is the production of neutralizing antibodies. If a person who is immunized becomes infected with the virus, the neutralizing antibodies will bind to the virus and prevent it from entering cells and causing disease.

Can an mRNA vaccine cause COVID-19?

No. An mRNA vaccine is not a virus and can't cause disease. Because it activates the immune system, it can cause mild symptoms in some people (e.g., fatigue, achiness, fever). Based on data from the clinical trials, the most common reactions to the vaccine are pain at the injection site, fatigue, headache, and muscle aches. These symptoms are very common with other vaccines, including the flu shot, and are a sign that the body is responding to the vaccine.

When will a vaccine be available?

The FDA has authorized the Pfizer-BioNTech mRNA vaccine for individuals 16 years and older. Another vaccine (Moderna) has also applied for potential emergency use authorization for use in the U.S. The FDA will meet Dec. 17 to review the clinical trial data for the second vaccine. Once the data are reviewed, and if there are no safety concerns, the FDA may grant emergency use authorization (EUA) resulting in two available vaccines.

The CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend use of the Pfizer-BioNTech mRNA vaccine in individuals aged 16 years and older on Dec. 12, 2020. They will review additional vaccines once they are authorized by the FDA.

It is anticipated that the first groups of people will receive the first vaccine doses at the end of December or in early January 2021. Health care workers and residents of long-term-care facilities will be

the first groups to receive the vaccine. Given the requirement for extreme cold to store the vaccine, there will be limited sites able to administer the vaccine initially.

What is the difference between the emergency use authorization and licensure (approval) by the FDA?

Emergency use authorization is a process by which the FDA can authorize use of a medication or vaccine with less data if the benefit of the vaccine has been shown to outweigh the risk. EUAs can be issued only during a declared emergency, such as the COVID-19 pandemic. Vaccines issued an EUA will continue to be studied and have additional safety monitoring and informed consent and education associated with them.

Why should I get a vaccine?

The trial results for one of the vaccine candidates indicate 95% efficacy at preventing COVID-19. By getting vaccinated, you are reducing your risk of disease, hospitalization, severe complications, and even death. Getting vaccinated and reducing the risk of disease also helps prevent the health care system from being further overwhelmed.

What does it cost to get the vaccine?

Any COVID-19 vaccine will be available at no cost to individuals, and clinicians administering the vaccine will be able to be reimbursed for vaccine administration (see guidance on coding and payment).

How many doses are needed?

Both mRNA vaccines under consideration require two doses, with around three to four weeks between each, to achieve an effective immune response. This is typical for most vaccines, with some needing three or more “booster” shots to maintain immunity.

What are the side effects of the vaccine?

Data from the clinical trials of one of the candidates indicate the most common reactions were pain at the injection site, fatigue, headache, and muscle aches. These symptoms are commonly seen with other vaccines. A few people also reported fever and nausea. No serious side effects were seen in the data reported from the trials. However, the CDC and the FDA will monitor for any adverse events or side effects as the vaccine is distributed to the public.

The vaccine has not been associated with infertility or modifications to recipient DNA.

If you have concerns or questions about any side effects after receiving the vaccine, check with your family physician.

How long does immunity last?

It is not known how long immunity will last from the vaccine. In the clinical trials that have been conducted to date, the median length of follow-up was two months for vaccine recipients. It is also not known how long immunity from natural infection lasts; there are reports of waning antibody levels

around three months after infection, and a few cases of reinfection have been reported. We do know that seasonal coronaviruses (a source for the common cold) do not induce a robust immune response, which leads to limited immunity to these viruses.

Do I still need to wear a mask and physically distance if I have the vaccine?

Yes! While the vaccines provide protection against COVID-19 disease, they have not been shown to prevent infection, so people who are immunized may still be able to transmit the virus. Additionally, the 95% efficacy in preventing disease was not observed until several weeks after the second dose. Everyone will still need to wear a mask and practice physical distancing until a large section of the population have developed immunity, which may not be until late 2021. Even then, more data will be needed to see how long immunity lasts. Additional rounds of immunizations may be needed.

Can I get the vaccine if I've already had COVID-19?

Yes, although there are not enough data currently to determine how prior infection with COVID-19 affects the efficacy of the vaccine. It is known that natural immunity to the virus wanes over time, so currently, under the EUA, individuals who have previously been infected are eligible for receiving the vaccine.

Who *can't* get the vaccine?

Children and adolescents under age 16 are not eligible to receive the vaccine as there are not data on the safety and efficacy in this population. While pregnant individuals were also not included in the first round of trials, patients who are pregnant or lactating are able to determine if they wish to receive the vaccine. These patients are encouraged to have a discussion on the potential benefits and risks with their family physician.

As with other vaccines, anyone who has a fever or other symptoms may not be able to get the vaccine until their symptoms resolve. This includes those who have symptoms or are positive for COVID-19. There is also caution for people with documented anaphylactic reactions to vaccines.

Can I get other vaccines, like the flu shot, at the same time as the COVID-19 vaccine?

No, you will need to wait two weeks after getting the COVID-19 vaccine before getting other immunizations.

How do I report symptoms after the vaccine?

As with other vaccines, vaccine recipients are encouraged to report side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). This is a nationwide program that collects data to use as signals of unexpected events from a vaccine. If you have a question on what might be considered a side effect related to the vaccine, talk with your family physician.

Because any COVID-19 vaccine will be provided under EUA, clinicians will have additional reporting requirements that will be outlined in the EUA fact sheet from the FDA. Each state and jurisdiction have plans in place for handling the reporting.

In addition to VAERS, the CDC will implement a new, smartphone-based tool called **v-safe** that will send text messages to encourage reporting of adverse events or impacts to quality of life. This system will require the use of a smartphone, and recipients must opt into the system. Information on v-safe will be provided to anyone who gets the vaccine, along with a card indicating which vaccine and dose was given, and the EUA fact sheet.

Additional Resources

- AAFP COVID-19 vaccine webpage: www.aafp.org/covidvaccine
- Familydoctor.org vaccine page: https://familydoctor.org/vaccines/
- CDC COVID-19 vaccine webpage: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
- FDA EUA fact sheet: https://www.fda.gov/media/144413/download

References

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3. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee Meeting, Dec. 10, 2020 FDA Briefing Document, Pfizer-BioNTech COVID-19 vaccine. https://www.fda.gov/media/144245/download. Accessed Dec. 12, 2020