

COVID-19 VACCINE FAQ



How do COVID-19 vaccines work?

Two COVID-19 vaccines use messenger RNA (mRNA), which is a set of instructions that tells a cell to make a specific protein. For SARS-CoV-2 (COVID-19), this is the spike protein that is found on the surface of the viral envelope. The mRNA used in the vaccines don't enter the cell's nucleus and 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.

The other vaccine uses a modified adenovirus that contains DNA for the spike protein. The adenovirus is able to enter a cell and cause the spike protein to be made. Adenoviruses are a source of the common cold, but this particular virus can't replicate so it won't cause disease.

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 the vaccines 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.

The other authorized vaccine uses a modified virus that can't replicate and does not cause any disease, including COVID-19.



When will a vaccine be available?

The FDA has authorized three vaccines for COVID-19. The Pfizer-BioNTech mRNA vaccine was authorized for individuals 16 years and older. The Moderna mRNA vaccine and Janssen (Johnson & Johnson) adenovirus vaccine were authorized for individuals 18 years and older. All three vaccines were recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). They will review additional vaccines when authorized by the FDA.

The first groups of people, health care workers and residents of long-term-care facilities, began receiving vaccine doses in late December. Additional allocation phases included front-line essential workers, individuals over 75 years of age, and those at increased risk of severe disease. Local health departments can provide information on how remaining groups can get the vaccine.



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THINGS YOU NEED TO KNOW NOW (as of April 16, 2021)

1. The CDC and FDA recommended a pause in use of the single dose Johnson & Johnson vaccine. This is related to six cases of a rare blood clot associated with low platelet counts. The pause will continue until the CDC's ACIP has time to analyze data and determine if the recommendation should change.
2. There has been no link between the mRNA vaccines and the blood clot and low platelet counts seen with the Johnson & Johnson vaccine.
3. Follow vaccine schedules as recommended by the CDC. Pfizer-BioNTech and Moderna require two doses 3–4 weeks apart. Mild pain at the injection site, fatigue, headache, and muscle aches are common reactions.
4. The vaccines do not cause COVID-19.
5. Vaccines provide protection against COVID-19, but won't prevent infection. It's important to continue wearing a mask, wash hands and physically distance even after getting fully vaccinated.

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

Emergency use authorization (EUA) 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.

What are the differences between the vaccines authorized by the FDA?

Two of the vaccines are mRNA vaccines that have a piece of mRNA specific for the SARS-CoV-2 spike protein. They have similar efficacy and safety profiles. The third vaccine uses a non-replicating adenovirus to deliver the spike protein into nearby cells. None of the vaccines use live viruses so there is no risk of infection. The main differences between the vaccines include the ages of individuals eligible to get the vaccines, the length of time between doses, the number of doses, the cold chain requirements for storage, and the preparation of the vaccine. A side by side comparison is below.

| | Pfizer-BioNTech | Moderna | Janssen (J&J) |
|------------------------------|---|--------------------------------------|-------------------------------------|
| Ages eligible for vaccine | 16 and older | 18 and older | 18 and older |
| Length of time between doses | 21 days | 28 days | n/a single dose |
| Storage requirements | -80 C; stable at 4 C for 5 days | -20 C; stable at 4 C for 30 days | -20 C; stable at 4 C for 90 days |
| Preparation of vaccine | Reconstitution of lyophilized powder—5 doses per vial | No dilution needed—10 doses per vial | No dilution needed—5 doses per vial |

Why should I get a vaccine?

All COVID-19 vaccines are effective at preventing COVID-19, hospitalizations and death.

By getting vaccinated, you are reducing your risk of disease, hospitalization, severe complications, and even death. Reducing the risk of disease also prevents the health care system from being overwhelmed.

What does it cost to get the vaccine?

COVID-19 vaccines will be available at no cost to individuals, and clinicians administering the vaccine will be reimbursed for vaccine administration. [See guidance on coding and payment.](#)

Should I take any pain medications before getting the vaccine?

No, it is not recommended for people to take pain relievers before getting the vaccine as it is not known how these medications may affect how well the vaccine works. For tips on relieving pain and discomfort **AFTER** the vaccine, visit: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>.

How many doses are needed?

Both mRNA vaccines require two doses; the Pfizer-BioNTech vaccine should be given 21 days apart and the Moderna vaccine doses should be spaced 28 days apart to achieve an effective immune response. Recipients should get the second dose from the same manufacturer as their first dose. However, if they get a dose of a different vaccine, no additional doses are needed, and the series is considered complete. The Johnson & Johnson vaccine is a single dose.

What are the side effects of the vaccine?

Data from the clinical trials of all three candidates indicate that 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 in the trials. However, the CDC and the FDA are monitoring the adverse events or side effects as the vaccines are distributed to the public.

There have been reports of a few cases of severe allergic reaction to one of the components of mRNA vaccines. Individuals receiving any of the vaccines should be monitored for 15-30 minutes after injection.

*On 13, the FDA and CDC paused use of the Johnson & Johnson vaccine to review six reported U.S. cases of blood clots from the vaccine. These kind of clots are rare, and the vaccine hasn't been confirmed as the cause. More information will be available after further investigation. Patients can safely receive the Moderna or Pfizer vaccines in place of the Johnson & Johnson vaccine. Final updates at aafp.org/family-physician/patient-care/current-hot-topics/recent-outbreaks/covid-19/covid-19-vaccine/jj-vaccine-pause.html. The vaccines have not been associated with infertility or DNA modifications. Questions about vaccine side effects? Check with your family physician.

How long does immunity last?

It is not known how long immunity will last from the COVID-19 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. It is likely that a vaccine will have a stronger and more lasting immune response, but data are limited and the research is ongoing.

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. In patients who received the Pfizer-BioNTech or Moderna vaccine, the high rate of efficacy in preventing disease was not observed until several weeks after the second dose of the vaccines. Everyone will still need to wear a mask and practice physical distancing until a large section of the population has been immunized, or 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.

If I am vaccinated against COVID-19, can I still spread the virus to others?

The vaccine trials conducted did not look at the vaccine's ability to prevent virus transmission. We do know the vaccine is very effective at preventing illness in those receiving the vaccine. Because there are not data demonstrating the ability of the vaccines to prevent viral transmission, it is important to continue to wear a mask and socially distance even after getting vaccinated.

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.

If more than one vaccine is available, would taking two different vaccines be less effective?

There have been no studies conducted looking at the effectiveness of the use of different vaccine products to complete the COVID-19 series. Current guidance states the same vaccine should be given for both dose one and two. If different vaccines are given, the recipient **does not** need to receive an additional vaccine.

Who can't get the vaccine?

Children and adolescents under age 16 are not eligible to receive the Pfizer-BioNTech vaccine. Those under age 18 are not eligible to receive the Moderna or Johnson & Johnson vaccines as there are not data on the safety and efficacy in this population. While pregnant or immunocompromised individuals were also not included in the first round of trials, patients who are pregnant, lactating, or immunocompromised **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 have tested positive for COVID-19. There is also caution for people with documented anaphylactic reactions to vaccines. Individuals with a known allergy to any of the vaccine components should not be immunized.

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 outlined in the EUA fact sheet from the FDA. Each state and jurisdiction has plans in place for handling reporting.

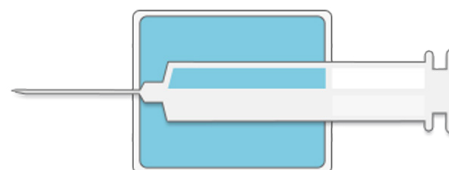
In addition to VAERS, the CDC implemented a new, smartphone-based tool called **v-safe** that sends text messages to encourage adverse events reports or impact to quality of life. This system requires the use of a smartphone, and recipients must opt into the system. Information on v-safe is provided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

If I have allergies, can I get the COVID-19 vaccine?

Yes! Seasonal allergies and even food allergies, including allergies to shellfish and peanuts, do not exclude you from getting the COVID-19 vaccine. Individuals who had severe reactions, like anaphylaxis, after a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]) should not get another dose of the Pfizer or Moderna vaccine. Instead they should receive a dose of the Johnson & Johnson vaccine if it becomes available again. Individuals who have an allergy to polysorbate or have had a reaction to an injectable medication or vaccine are not precluded from getting the COVID-19 vaccine, but should be monitored closely after administration. See more information at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

Can I get the COVID-19 vaccine if I am pregnant or breastfeeding?

There has been no data on the use of EUA approved COVID-19 vaccines in pregnant or breastfeeding women. However, these individuals are not excluded from getting the vaccine and they should talk with their family physician about the risks and benefits of being vaccinated.



Additional Resources

- AAFP COVID-19 vaccine webpage: www.aafp.org/covidvaccine
- AAFP's Johnson & Johnson COVID-19 Vaccine FAQs: <https://www.aafp.org/family-physician/patient-care/current-hot-topics/recent-outbreaks/covid-19/covid-19-vaccine/j-j-vaccine-pause.html>
- Familydoctor.org vaccine article: <https://familydoctor.org/covid-19-vaccine/>
- CDC COVID-19 vaccine webpage: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>
- Pfizer-BioNTech EUA fact sheet: <https://www.fda.gov/media/144413/download>
- Moderna EUA fact sheet: <https://www.fda.gov/media/144638/download>
- Janssen (Johnson & Johnson) EUA fact sheet: <https://www.fda.gov/media/146305/download>
- Coding and payment resources:
 - a. COVID-19 Vaccine Coverage Requirements and Preliminary Payment Guidance: <https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/vaccines/ES-COVIDVaccineCoveragePayment-121020.pdf>
 - b. First COVID-19 Vaccine CPT Codes Published: https://www.aafp.org/journals/fpm/blogs/gettingpaid/entry/covid_vaccine_codes.html

References

1. Centers for Disease Control and Prevention. Understanding mRNA vaccines. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>. Accessed Dec. 12, 2020.
2. Centers for Disease Control and Prevention. Frequently asked questions about COVID-19 vaccine. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>. Accessed Dec. 12, 2020
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. 10, 2020.
4. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee Meeting, Dec. 17, 2020 FDA Briefing Document, ModernaTX COVID-19 vaccine. <https://www.fda.gov/media/144434/download>. Accessed Dec. 17, 2020.
5. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee Meeting. February 28, 2021. FDA Briefing Document. Janssen COVID-19 vaccine. <https://www.fda.gov/media/146217/download>. Accessed February 26, 2021.