

# COVID-19 Vaccine Discussion

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# How Vaccines Work

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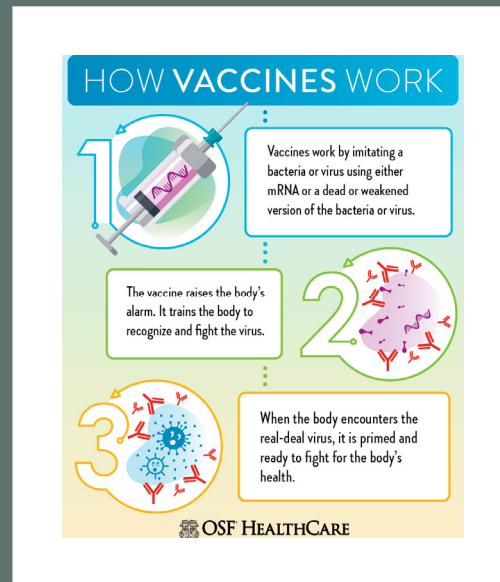


Image obtained from: <https://www.osfhealthcare.org/blog/how-vaccines-work-to-protect-us/>

Vaccines work by mimicking the infectious bacteria or viruses that cause disease. Vaccination stimulates the body's immune system to build up defenses against the infectious bacteria or virus (organism) without causing the disease. The parts of the infectious organism that the immune system recognizes are foreign to the body and are called antigens. Vaccination exposes the body to these antigens.

Some vaccines contain weakened versions of a bacteria or virus, other vaccines contain only part of the bacteria or virus. Some vaccines contain only the genetic material for a specific protein and direct the body to produce a small amount of that protein. The body's immune system reacts defensively once it detects this protein.

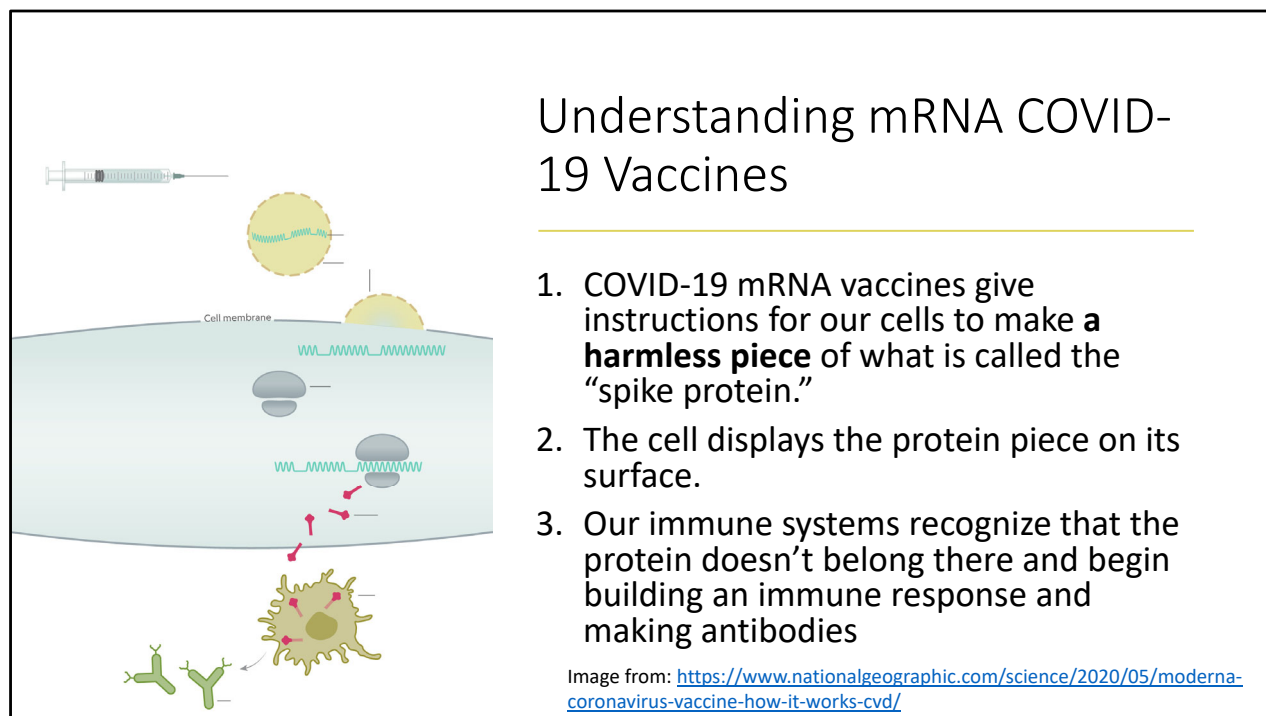
After vaccination, the immune system is prepared to respond quickly and forcefully when the body encounters the real disease-causing organism.

## 3 Main Types of COVID-19 Vaccines

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- **mRNA vaccines -Pfizer-BioNTech and Moderna**
  - Instructs vaccinated persons' cells to make **a harmless piece of** COVID-19
- **Viral Vector – AstraZeneca and Janssen**
  - Uses weakened adenovirus as vector to transport COVID-19 virus genetic material into cell
  - Instructs vaccinated persons' cells to make COVID-19
- **Protein Subunit – Novavax**
  - Composed of proteins only, only mRNA or DNA

Currently, there are three main types of COVID-19 vaccines that have or will be undergoing large-scale (Phase 3) clinical trials in the United States



COVID-19 mRNA vaccines give instructions for our cells to make a **harmless piece** of what is called the “spike protein.” The spike protein is found on the surface of the virus that causes COVID-19.

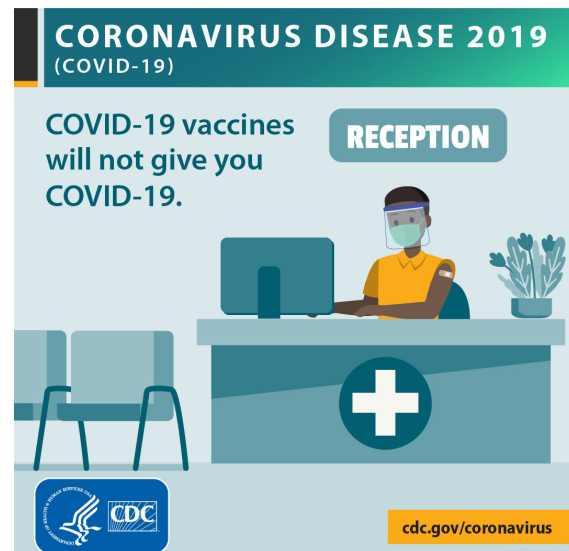
COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.

Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn’t belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.

At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

FAQ: Can a COVID-19 vaccine make me sick with COVID-19?

No. None of the COVID-19 vaccines contain the live virus that causes COVID-19 so a COVID-19 vaccine cannot make you sick with COVID-19, nor can you pass or infect someone else with COVID-19 being vaccinated.



Getting vaccinated yourself may also protect people around you, particularly people at increased risk for severe illness from COVID-19 (older adults & people with medical conditions)



## Vaccine Development

The U.S. Food and Drug Administration (FDA) is the regulatory authority that has oversight of the safety, effectiveness and quality of vaccines that are used in the United States.

Vaccines to prevent infectious diseases are given to millions of babies, children, adolescents and adults and it is critical that they are demonstrated to be safe and effective. Vaccines have prevented countless cases of disease and disability and have saved millions of lives. Ensuring the safety and effectiveness of vaccines is one of FDA's top priorities.

While more COVID-19 vaccines are being developed as quickly as possible, routine processes and procedures remain in place to ensure the safety of any vaccine that is authorized or approved for use.

## What do we know about the COVID-19 Vaccine?

- It will help keep you from getting COVID-19

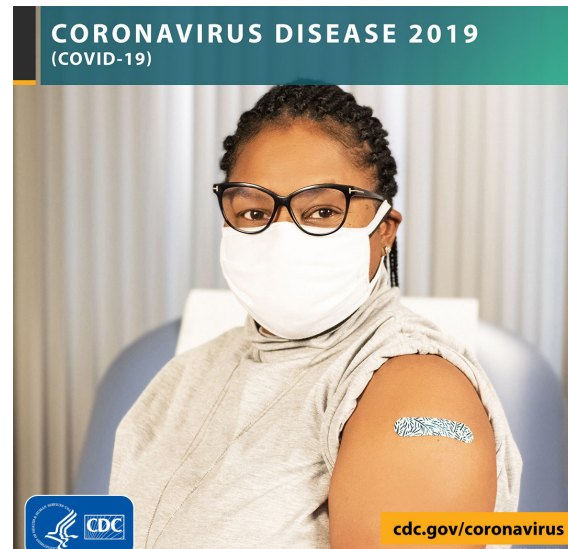


All COVID-19 vaccines currently available in the United States have been shown to be highly effective at preventing COVID-19.

Based on what we know about vaccines for other diseases and early data from clinical trials, experts believe that getting a COVID-19 vaccine may also help keep you from getting seriously ill even if you do get COVID-19.

## What do we know about the COVID-19 Vaccine?

- It will help keep you from getting COVID-19
- It is a safer way to help build protection



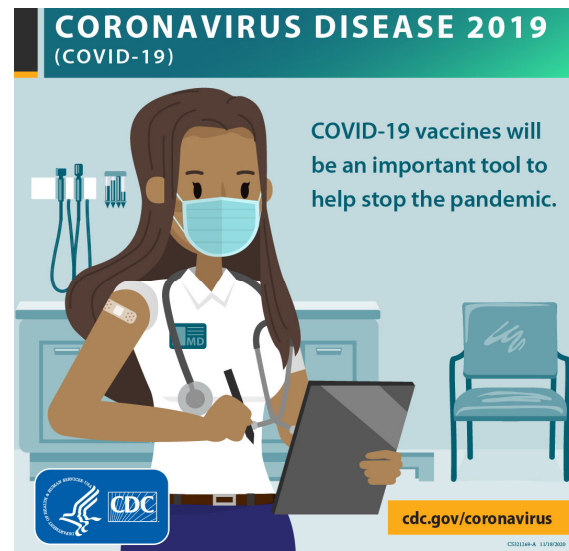
COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect you. And if you get sick, you could spread the disease to friends, family, and others around you.

Clinical trials of all vaccines must first show they are safe and effective before any vaccine can be authorized or approved for use, including COVID-19 vaccines. The known and potential benefits of a COVID-19 vaccine must outweigh the known and potential risks of the vaccine for use. All COVID-19 vaccines that are in development are being carefully evaluated in clinical trials and will be authorized or approved only if they make it substantially less likely you'll get COVID-19.

Getting COVID-19 may offer some natural protection, known as immunity. Current evidence suggests that reinfection with the virus that causes COVID-19 is uncommon in the 90 days after initial infection. However, experts don't know for sure how long this protection lasts, and the risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity. COVID-19 vaccination will help protect you by creating an antibody (immune system) response without having to experience sickness.

## What do we know about the COVID-19 Vaccine?

- It will help keep you from getting COVID-19
- It is a safer way to help build protection
- It will be an important tool to help stop the pandemic

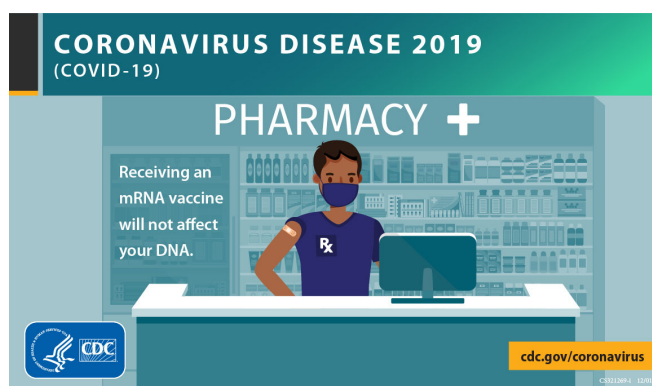


Wearing masks and social distancing help reduce your chance of being exposed to the virus or spreading it to others, but these measures are not enough.

Vaccines will work with your immune system so it will be ready to fight the virus if you are exposed.

The combination of getting vaccinated and following recommendations to mitigate the spread (mask wearing, social distancing and hand washing) will offer the best protection from COVID-19.

## Ensuring the Safety of COVID-19 Vaccines



- COVID-19 vaccines are **safe and effective**
- Some people do not have any side effects, and some will have mild side effects – these reactions are normal and show vaccine is working
- A small number of people have had a severe allergic reaction (called “anaphylaxis”) after vaccination, but this is extremely rare

COVID-19 vaccines are **safe and effective**. Millions of people in the United States have received COVID-19 vaccines, and these vaccines have undergone the most intensive safety monitoring in U.S. history.

Results from these monitoring efforts are reassuring. While some people don’t have any side effects after getting a COVID-19 vaccine, some people will have mild side effects after COVID-19 vaccination, like pain or swelling at the injection site, a headache, chills, or fever. These reactions are normal and show the vaccine is working.

A small number of people have had a severe allergic reaction (called “anaphylaxis”) after vaccination, but this is extremely rare and when it does happen, vaccination providers have medicines available that they can use to effectively and immediately treat the reaction. You will be asked to stay for 15–30 minutes after you get your vaccine so you can be observed and provided treatment in the rare case it is needed.

Cough, shortness of breath, runny nose, sore throat, or loss of taste or smell are **not** consistent with post-vaccination symptoms, and instead may be symptoms of COVID or another viral infection (i.e. influenza). Viral testing should be considered if someone has any of these symptoms

## COVID-19 Vaccines and Allergic Reactions



CDC has learned of reports that some people have experienced severe allergic reactions—also known as anaphylaxis—after getting a COVID-19 vaccine. As an example, an allergic reaction is considered severe when a person needs to be treated with epinephrine or EpiPen® or if they must go to the hospital.

If you have had a severe allergic reaction to any ingredients in an mRNA COVID-19 vaccine, **you should not get either of the currently available mRNA COVID-19 vaccines.** If you had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, **CDC recommends that you should not get the second dose.**

### If you have a non-severe allergic reaction to a COVID-19 vaccine

- CDC has also learned of reports that some people have experienced non-severe allergic reactions within 4 hours after getting vaccinated (known as immediate allergic reactions), such as hives, swelling, and wheezing (respiratory distress).
- If you have had an immediate allergic reaction—even if it was not severe—to any ingredient in an mRNA COVID-19 vaccine, **CDC recommends that you should not get either of the currently available mRNA COVID-19 vaccines.**
- If you had an immediate allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, **you should not get the second dose.**
- Your doctor may refer you to a specialist in allergies and immunology to provide more care or advice.

If you have had an allergic reaction to other types of vaccines

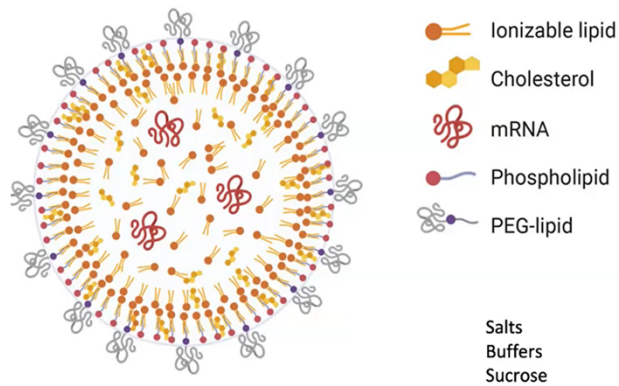
- If you have had an immediate allergic reaction—even if it was not severe—to a vaccine or injectable therapy for another disease, **ask your doctor if you should get a COVID-19 vaccine.** Your doctor will help you decide if it is safe for you to get vaccinated.

If you have allergies not related to vaccines

- CDC recommends that people with a history of severe allergic reactions not related to vaccines or injectable medications—such as food, pet, venom, environmental, or latex allergies—get vaccinated.
- People with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated.

## What is in the vaccines?

mRNA in a lipid (fat) nanoparticle



ACS Nano


Component	Potentially Allergenic?	PFIZER	MODERNA
Genetic material	Unlikely	mRNA (spike protein)	mRNA (spike protein)
Lipids	Unlikely	((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	heptadecan-9-yl 8-((2 hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino) octanoate (SM102)
PEG / polysorbate (polyethers)	Possibly	2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	polyethylene glycol 2000-dimyristoyl glycerol
Phospholipid	Unlikely	1,2-Distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
Sterol	No	cholesterol	cholesterol
pH Buffers & neutral salts	No	monobasic potassium phosphate dibasic sodium phosphate dihydrate potassium and sodium chloride	tromethamine tromethamine hydrochloride acetic acid / sodium acetate
Sugars	No	sucrose	sucrose

If you have had an allergic reaction to polyethylene glycol (PEG) or polysorbate - **People who are allergic to PEG or polysorbate should not get an mRNA COVID-19 vaccine.**

- These recommendations include allergic reactions to PEG and polysorbate.
- Polysorbate is not an ingredient in either mRNA COVID-19 vaccine but is closely related to PEG, which is in the vaccines.

## Do other vaccines contain PEG/polysorbate?

Human Papillomavirus (HPV) (Gardasil 9)	10/2018	amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Quadrivalent	12/2019	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, hydrocortisone thimerosal (multi-dose vials)
Influenza (Fluad)	4/2019	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Quadrivalent	©2019	octoxynol-10 (TRITON X-100), $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Quadrivalent	4/2019	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and <i>Spodoptera frugiperda</i> cell proteins, baculovirus and cellular DNA, Triton X-100
Influenza (Flucelvax) Quadrivalent	8/2019	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and $\beta$ -propiolactone, Thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent	2/2020*	ovalbumin, formaldehyde, sodium deoxycholate, $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent	2019	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)
Influenza (Fluzone) High Dose	1/2019	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent	8/2019	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	9/2018	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, Vero cell DNA, sodium metabisulphite, Vero cell protein



## Vaccination Considerations for People who are Pregnant

- Pregnant people are at increased risk for severe illness from COVID-19
- There are limited data about the safety of COVID-19 vaccines for people who are pregnant
- People who are pregnant and part of a group recommended to receive the COVID-19 vaccine (frontline essential workers) may choose to be vaccinated.
- To date, pregnant health care workers who received the vaccine are doing well.

Observational data demonstrate that, while the chances for these severe health effects are low, pregnant people with COVID-19 have an increased risk of severe illness, including illness that results in ICU admission, mechanical ventilation, and death compared with non-pregnant women of reproductive age. Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm birth, compared with pregnant women without COVID-19.

mRNA vaccines do not contain the live virus that causes COVID-19 and, therefore, cannot give someone COVID-19. Additionally, mRNA vaccines do not interact with a person's DNA because the mRNA does not enter the nucleus of the cell. Cells break down the mRNA quickly. Based on how mRNA vaccines work, experts believe they are unlikely to pose a specific risk for people who are pregnant. However, the actual risks of mRNA vaccines to the pregnant person and her fetus are unknown because these vaccines have not been studied in pregnant women.

## References

- Understanding How COVID-19 Vaccines Work from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>
- Different COVID-19 Vaccines from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>
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- Ensuring the Safety of COVID-19 Vaccines in the United States from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>
- COVID-19 Vaccines and Allergic Reactions from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html>
- Vaccine Development – 101 from <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101>
- Vaccination Considerations for People who are Pregnant or Breastfeeding from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>



## If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine?

- Yes. Due to the severe health risks associated with COVID-19 and the fact that reinfection with COVID-19 is possible, you should be vaccinated regardless of whether you already had COVID-19 infection.
- If you're actively sick with COVID-19, or if you've just recovered, hold off for a while before getting vaccinated. **Experts recommend that you wait until you are fully recovered from your infection and are no longer in isolation before you receive a COVID-19 vaccine.**
- **If you were treated for COVID-19 symptoms with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine.** Talk to your doctor if you are unsure what treatments you received or if you have more questions about getting a COVID-19 vaccine.

Experts do not yet know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called “natural immunity,” varies from person to person. It is rare for someone who has had COVID-19 to get infected again. It also is uncommon for people who do get COVID-19 again to get it within 90 days of when they recovered from their first infection. We won't know how long immunity produced by vaccination lasts until we have more data on how well the vaccines work.

Given the limited vaccine supply and your natural immunity following your COVID infection, you may wish to wait up to 90 days for the vaccine (so that others – who have no immunity – can receive their vaccine now). However, you are not required to wait 90 days.

## Will side effects of a COVID-19 vaccine be worse in someone who has recovered from COVID-19?

- Data from clinical trials indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection and has not shown that worse side effects are seen among people who received the COVID-19 vaccine and have recovered from a SARS-CoV-2 infection.
- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
- While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity.

For more information: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

## COVID-19 vaccine for those with SCD, rare diseases or compromised immune systems?

- [COVID-19 Vaccines Pose Little Risk to Rare Disease Patients, FDA, CDC Say](#) - The two COVID-19 vaccines are expected to pose little risk to the rare disease community, including to patients with compromised immune systems or those participating in gene.
- [Based on current information, Medical Research and Advisory Committee \(MARAC\) recommends that people with sickle cell disease receive COVID-19 vaccination.](#) - The benefits of vaccination outweigh the risks for people with SCD. Vaccination is worthwhile compared to the risks of having COVID-19 disease in people with SCD.
- [Webinar: COVID-19 Vaccines and Sickle Cell Patients](#) – The COVID-19 Vaccine & The Adult Living with Sickle Cell Disease given by Mandy S. David, MPH, PA-C from John Hopkins