# The **COVID-19 Vaccine** Frequently Asked Questions

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We are very optimistic about the COVID-19 vaccines and boosters that are currently available. Widespread immunization will help us eradicate the COVID-19 pandemic and get our lives back to normal more quickly. We are on our way, imagine the benefits of widespread vaccination so this crisis can end sooner.

We are part of a large network of quality-driven dermatology practices. Together with our 85 physician colleagues across 9 states, we have closely followed the vaccine and booster development, clinical trials and success of the ongoing vaccine campaign. Below are the answers we compiled to address our patients' most common questions about the vaccines, and we thought they might be helpful to you.

# How effective is the COVID-19 Vaccine?

FDA approved vaccines from Pfizer-BioNTech, Moderna, and Johnson & Johnson have all proven highly effective in reducing disease severity, hospitalization and death. In clinical trials and real world conditions, Pfizer and Moderna vaccines were initially about 95% effective in preventing symptomatic infection with the original coronavirus Alpha strain, while J&J was about 70%. All three vaccines are nearly 100% effective at preventing hospitalization and death, which is the primary goal of vaccination programs.

Because natural immunity from prior infection and the immune protection from vaccination has been shown to decline after 4-6 months, booster doses are now strongly recommended to pump up the immune system again. Booster doses are very common for vaccines, including most of our childhood immunizations as well as newer ones for chickenpox, HPV and shingles, and *do not indicate a failure*. COVID boosters were originally approved only for immunocompromised adults who may not have been able to develop a fully protective immune response. But given their proven safety and effectiveness, the FDA has recently approved an additional booster dose for all adults 18 or older for all three vaccines. A "mix-and-match" booster approach is recommended so people should choose a different vaccine for their booster than the one they started with in order to enhance the immune response against an additional viral target.

# Do the vaccines work against the Delta variant?

All three coronavirus vaccines currently show excellent effectiveness against the Delta variant, which is the most highly contagious virus variant yet identified. The Delta variant is the dominant strain in the US and worldwide and is most heavily impacting people and communities with low vaccination rates and those with falling immunity. Nearly every hospitalization and death during the 2021 summer and fall Delta surge occurred in the unvaccinated. We strongly recommend all eligible people be vaccinated immediately, even if you previously had COVID-19 or tested positive for coronavirus without symptoms. We also recommend all fully vaccinated adults receive a booster dose to further reduce the risk and severity of breakthrough infections from the highly contagious Delta strain. For those with natural immunity from known prior COVID-19 infection a single vaccine dose has proven to reduce the risk of re-infection, hospitalization and death.

Experts are currently studying how effective these vaccines protect against the new Omicron variant identified very recently in South Africa and other countries. If you have concerns or health issues, please discuss those concerns with your primary care physician so you can make the most informed decision.

# Should I be concerned about the side effects of the vaccine?

A small number of clinical trial participants experienced mild, short-term side effects such as fatigue, soreness at the injection site, and headaches. These side effects are similar to those that are experienced with other long-used vaccines such as MMR.

A reaction to the vaccine is typically not an allergy or a sickness. It is caused by your immune system working to pump out antibodies in response to the vaccine. These mild side effects show that your body is working hard to protect you from the virus. Many people experience no side effects from vaccines.

No serious widespread safety concerns have been observed for these vaccines.

The FDA placed a warning label on both the Pfizer and Moderna vaccines regarding a "likely association" with reported cases of heart inflammation in young adults. This inflammation may occur in the heart muscle (myocarditis) or in the outer lining of the heart (pericarditis) and is considered important but uncommon—arising in about 12.6 cases per million second doses administered. This is an extremely rare side effect, most cases are mild, and the young people generally recover on their own or with minimal treatment. In addition, we know that myocarditis and pericarditis are much more common if you get COVID-19, and the risks to the heart from COVID-19 infection can be more severe.

Use of the Johnson & Johnson vaccine was temporarily paused last spring due to a rare and serious adverse event—blood clots with low platelets. It occurs at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old. For women 50 years and older and men of all ages, this adverse event is extremely uncommon. The CDC and FDA did a thorough review of all available data and then recommended the use of the Johnson & Johnson vaccine resume, as the benefits outweigh its known and potential risks, and there remain alternative options for women under 50. The FDA has also placed another warning on the Johnson & Johnson vaccine after rare cases of the neurological disorder Guillain-Barré syndrome were reported in a small number of vaccination recipients. Most of the cases occurred within 42 days after vaccination and resulted in muscle weakness.

While all medical treatments have potential adverse effects, the evidence clearly demonstrates these vaccines are overall very safe and effective. They prevent COVID-19 illness, and more importantly, hospitalization and death. They will help protect you and your family and keep your community safe. We strongly encourage every adult who is eligible to receive one of the three FDA approved vaccines and for children over 5 years old to receive a Pfizer vaccine (Emergency Use Authorization). The benefits of vaccination far outweigh any potential harm. Especially with the contagious Delta variant circulating and more readily impacting younger people, the risks of being unvaccinated are far greater than any rare side effects from the vaccines. If you get COVID-19, you could become severely ill and be hospitalized or even die. Even if your infection is mild, you or your child could face long-term symptoms following COVID-19 infection such as neurological problems or diminished lung function.

We recommend getting vaccinated right away if you haven't yet. It is the best way to protect yourself, your loved ones, your community, and to return to a more normal lifestyle safely and quickly.

# These vaccines were developed quickly. How do I know they are safe?

No corners were cut in the development of these vaccines, which have shown high levels of both protection and safety. The mRNA technology used in these new vaccines had been available for years and allowed companies a head start in the process. Additionally, the US government's Operation Warp Speed provided funding for companies to begin mass production of the vaccines at the same time they enrolled patients in clinical trials. Before a vaccine is approved for the US, it must undergo rigorous clinical trials, the final of which is Phase 3.

Phase 3 clinical trials for the COVID-19 vaccines involved *tens of thousands of volunteers* who were randomized to either receive the vaccine or a placebo, and then monitored for both side effects and for infection with SARS-CoV-2 (coronavirus). Study volunteers were closely monitored for any signs or symptoms that would indicate a problem with the vaccines. Fortunately, when the data showed great results, the vaccine was ready to ship out immediately.

For a vaccine to be approved for the US, a vaccine must reduce infection by at least 50%, and must not cause significant adverse events in those who receive it. *After a year and >450 million doses administered in the US, these three vaccines have all shown excellent safety profiles.* New studies also show in real life scenarios, the Pfizer and Moderna vaccines show 90% effectiveness in preventing infection in high-risk healthcare workers.



# I'm not in a high-risk group. Why should I take the vaccine?

This virus is highly contagious, therefore, even people who are not considered high risk should strongly consider being vaccinated. Furthermore, new variants like Delta have emerged that are even more highly transmitted, and may cause more serious infection even in healthier people. A vaccine is not the cure for COVID-19, widespread immunization is. All the US vaccines show effectiveness against the original Alpha strain and the more contagious Delta variant. Success in eradicating the pandemic and shortening the time it takes to return to 'normal' is completely dependent upon the acceptance of the science and data and a widespread willingness to be vaccinated. For many of us it is an opportunity to help keep our clinics fully staffed, our patients safer, and enable us to protect our communities, our families, including our grandparents, and those at high risk due to predisposing conditions, estimated to include as many as 1 out of 3 Americans.

# I have other health conditions. Is it safe for me to take the vaccine?

Individual health decisions are best made in conjunction with the advice of your physician. As with some other vaccines, some people are not good candidates for the COVID vaccine.

As a precautionary measure, it is advised that people with a history of severe allergies receive the vaccine under guidance of their physician. There were two instances of allergic reactions during the first day of the vaccine rollout in the United Kingdom. These individuals were National Health Services workers who had known significant allergies and were equipped with adrenaline auto-injectors to deal with their allergies.

Anaphylaxis after COVID vaccines is rare and occurred in approximately 2 to 5 people per million vaccinated in the U.S. This kind of allergic reaction almost always occurs within 30 minutes after vaccination, therefore, all vaccination sites monitor patients before leaving for any allergic reaction.

Women who are pregnant, lactating or plan to soon become pregnant should discuss vaccination options with their OB/Gyn but all the Obstetric specialty societies and CDC strongly recommend vaccination to pregnant women and those who may be planning a pregnancy. The risk of stillbirth and other complications is elevated with COVID infection and are significantly reduced by vaccination. Furthermore, numerous studies show that protective antibodies from both a prior infection AND a vaccination are transferred to the baby in utero and in breast milk, providing additional protection to the newborn.

#### There are several versions of the vaccine from different manufacturers. Which one is right for me?

Each FDA-approved vaccine will work well across all populations. Some vaccines, like Pfizer and Moderna, require a 2nd dose 3-4 weeks after the initial dose, while the Johnson & Johnson does not. Whichever vaccine you get, please follow the recommendations for boosters, if applicable, and any other directions provided by your medical provider.

# COVID-19 vaccines: What you need to know

The U.S. now has three vaccines in its arsenal against the coronavirus. Here's how they compare.

	Johnson & Johnson	Pfizer	Moderna
Type of vaccine	Viral vector	RNA	RNA
How it works	Teaches the immune system to attack the protein the virus uses to infect other cells. The instructions are carried by a non-dangerous virus.	Uses RNA to teach the immune system to target the virus's surface, preventing infection.	Uses RNA to teach the immune system to target the virus's surface, preventing infection.
Effectiveness*	66%	95%	94.5%
Storage conditions	At least three months at refrigerator temperatures	Two weeks at freezer temperatures (-4°F), five days in the refrigerator (36° to 46°F)	One month at refrigerator temperatures
Doses needed per person	One shot	2 shots, three weeks apart	2 shots, four weeks apart
Status of availablity	FDA authorized	FDA authorized	FDA authorized

\*Note: The Johnson & Johnson vaccine was tested at a time when faster-spreading viral variants were common and in countries where these strains are known to exist.

Sources: Pfizer; Moderna; Johnson & Johnson; U.S. Food and Drug Administration; World Health Organization

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#### When will I be able to get the vaccine?

All 50 states are now offering vaccines to any resident age 16 or above and they are widely available. Currently, only the Pfizer vaccine is approved by Emergency Use Authorization for children ages 5 - 15 years old. Most U.S. pharmacies are accepting walk-ins for COVID-19 vaccines, given abundant supply.

# Will the vaccine alter my DNA or give me COVID? How do they work?

No. None of the vaccines currently available in the US have active viruses in them. Therefore, <u>there is no possibility of getting</u> <u>infected with COVID-19 by taking the vaccine.</u> COVID vaccines will not alter your DNA, which is found in your chromosomes inside the cell nucleus. The new COVID vaccines are based on RNA technology, which has no impact on your DNA. The human body is already full of messenger RNA (mRNA), which translates the genes from your DNA to build proteins that our bodies need.

The Pfizer and Moderna mRNA vaccine delivers a tiny piece of genetic code from the SARS CoV-2 virus to host cells in the body, essentially giving those cells instructions, or blueprints, for making copies of spike proteins (the spikes you see sticking out of the coronavirus in pictures online and on TV). The spikes do the work of penetrating and infecting host cells. These proteins

stimulate an immune response, producing antibodies and developing memory cells that will recognize and respond if the body is infected with the actual virus.

The Johnson & Johnson is a carrier vaccine, which uses a different approach than the mRNA vaccines to instruct human cells to make the SARS CoV-2 spike protein. Scientists engineer a harmless adenovirus (a common virus that, when not inactivated, can cause colds, bronchitis, and other illnesses) as a shell to carry genetic code on the spike proteins to the cells (similar to a Trojan Horse). The shell and the code can't make you sick, but once the code is inside the cells, the cells produce a spike protein to train the body's immune system, which creates antibodies and memory cells to protect against an actual SARS-CoV-2 infection.

# There is a lot of conflicting information about the vaccine. How do I know what to trust?

There is no shortage of information, opinions and falsehoods about the COVID vaccines. To ensure you are getting the most accurate information, we recommend that you rely on licensed medical professionals as well as local, state and federal healthcare agencies and other resources that are experienced in evidenced-based science and medicine.

The CDC keeps regularly updated COVID vaccine facts and information on their website. You can access that information here: <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html</a>

# Patient Safety is Our Priority

As the country begins to move toward normalcy, we ask for your help a while longer. The CDC strongly recommends that medical practices continue to follow the current safety protocols. This is in order to protect our vulnerable patients and staff who are not able to be vaccinated. Our mission is to provide ALL patients with the highest quality, safest care possible – right now, that necessitates:

- Continuing to recommend our staff get vaccinated to join the majority of staff who have already been immunized
- Screening all staff, patients and visitors consistent with updated guidelines
- Rescheduling patients who have been exposed to or are experiencing COVID-19 symptoms
- Requiring staff to wear medical-grade face masks and asking patients to do the same
- Thoroughly and frequently sanitizing the entire office and exam rooms
- Limiting visitors according to the most recent local and federal guidelines
- Promoting physical distancing in waiting areas and minimizing in-office wait times
- Offering telehealth appointments to high-risk patients and others, as needed

Here are some ways you can reduce your risk and avoid exposing others if you have been exposed or contracted COVID-19:

- Get vaccinated and boosted
- Talk to your primary care physician about getting a COVID-19 vaccine if you have questions or concerns
- Stay at home if you have tested positive for COVID-19, have been exposed to the virus or exhibit symptoms
- Frequently wash your hands
- Wear a mask , preferably a medical-grade mask for better protection
- Follow appropriate physical distancing protocols

# Thank you for trusting us with your care.