On December 10, 2020 the vaccine developed by Pfizer/BioNTech was reviewed by a panel of experts who recommended that the FDA issue an Emergency Use Authorization (EUA) for people age 16 and older. The FDA approved this EUA, allowing immediate distribution throughout the US and vaccinations began on Monday December 14, 2020. This novel vaccine prevented the virus in 95% of clinical trial participants.

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.

We are optimistic about the COVID-19 vaccines that are currently and soon-to-be available. Widespread immunization will help us eradicate the COVID-19 pandemic and get our lives back to normal more quickly.

We are part of a large network of quality-driven dermatology practices. Together with our 66 physician colleagues across 8 states, we have closely followed the vaccine development and clinical trials. Below are the answers we compiled to address our patients’ most common questions about the vaccine and we thought they might be helpful to you.
From what we have learned, 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. Even after FDA approval, the COVID-19 vaccines will continue to be monitored as they are used in larger populations to ensure that any indication of rare complications from its use are detected as soon as possible and evaluated to see if they were caused by the vaccine.

**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. A vaccine is not the cure for COVID-19, widespread immunization is. 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 the 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, 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.

Women who are pregnant, lactating or plan to soon become pregnant should discuss vaccination options with their OB/Gyn.

**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. At least during the early stages of vaccine availability, individuals will not be able to choose which vaccine they receive. Some vaccines, like the two mentioned above, will require a booster dose 3-4 weeks after the initial dose. Whichever vaccine you get, please follow the recommendations for boosters, if applicable, and any other directions provided by your medical provider.
There is a lot of conflicting information about the vaccine. How do I know what to trust?

There is no shortage of information and opinions 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 Mayo Clinic is one reputable source of information. They recently published a Myth/Fact document to help clarify information about the vaccine. That document can be found here:


Will I get COVID if I take the vaccine? Will the vaccine alter my DNA?

No. As of now, none of the vaccines that are in Phase 3 clinical trials and FDA emergency use approval have active viruses in them. Therefore, there is no possibility of getting infected with COVID-19 by taking the vaccine.

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. These proteins stimulate antibodies to the virus to protect the recipient against contracting the disease.

How the Pfizer-BioNTech vaccine works

mRNA vaccines give the immune system genetic instructions to recognize the virus

![Diagram of mRNA vaccine process]

Scientists focus on the genetic sequence for the virus’s ‘spike’ protein. This is used to synthesize an mRNA sequence-instructions that cells can use to make the “spike” protein.

The synthetic mRNA is packaged in a lipid nanoparticle that delivers the instructions to a cell.

Once inside the cell, its cellular machinery follows the mRNA instructions to produce the viral protein. This is displayed on the surface of the cell and stimulates an immune system response.
Your Safety is Our Priority

Even as the COVID vaccine becomes available, we will remain vigilant about safety, and recommend that our patients do the same. According to the CDC, transmission risk for COVID-19 is extremely low in the health care setting under proper protective conditions like we provide:

- Screening all staff, patients and visitors
- Rescheduling patients who have been exposed to or are experiencing COVID-19 symptoms
- Requiring staff to wear 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
- Helping our staff receive flu vaccinations now and strongly recommending COVID-19 vaccinations when available

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

- 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
- Follow appropriate physical distancing protocols
- Talk to your primary care physician about getting a COVID-19 vaccine when it becomes available to you

Thank you for trusting us with your care.