

Center for Complex Diseases  
Covid19 Vaccine Statement  
12/20/2020

By:

Jennifer Curtin, MD  
Bela Chheda, MD  
David Kaufman, MD

We have received many questions from patients as to whether or not they should get the Covid19 mRNA vaccines made by Pfizer or Moderna. This document is a summary of what we know, what we don't, and what we are recommending based on the information available at this time.

Firstly, it is unlikely most of the general population (at least in the USA) will have access to the first or 2nd batches of vaccines being distributed. This is because over 40% of the US population has at least one risk factor for severe Covid19. Therefore the CDC is prioritizing who receives the doses based on risk of exposure, risk of death, and other key parameters. While this means that most Americans will not be eligible for the initial doses of the vaccines, it also gives us time to watch for unexpected side effects in the people receiving the first doses of the vaccines.

So far, the initial supply of vaccines made available in the USA have been designated for frontline healthcare workers, nursing home residents, and residents of long term care facilities.

According to the AARP, the "CDC advisory committee recommends that the next group of Americans to receive a COVID vaccine should be adults age 75 and older, as well as frontline essential workers, including first responders, postal workers, teachers, public transit workers and people who work in grocery stores."

So if you are not in one of the groups above, it is unlikely you will be able to obtain one of the early doses of either vaccine. The vaccines may be available to the larger population in the USA around March or April by some estimates, though it could be earlier or later.

For those living outside of the USA, the vaccine availability may be different for you and if you are able to obtain one of the early doses, then please reach out to your treating physician to discuss your individual case directly.

Can I get the vaccine if I have a history of severe allergies?

Although the ingredients for both mRNA vaccines are fairly simple: mRNA, some pH stabilizing minerals and salts, sugar, and lipids for the coating, there have been reports of severe allergic reactions to both vaccines so far, primarily occurring in people with a history of severe allergies. None of the reactions so far have been fatal, though at least one required hospitalization.

The most common side effects are injection site pain, fatigue, headache, muscle pain, and joint pain. Some people in the clinical trials have reported fever. Side effects are more common after the second dose; younger adults, who have more robust immune systems, reported more side effects than older adults. To be clear: These side effects are a sign of an immune system kicking into gear. They do not signal that the vaccine is unsafe. To date there are no long-term side effects associated with receipt of these vaccines, which will be closely monitored as their use expands.

Given that many of our patients have Mast Cell Activation and/or severe allergies, we are keeping our recommendations in line with the American College of Allergy, Asthma & Immunology in that the risk:benefit ratio of those with severe allergies still favors getting the vaccine vs. taking one's chances with getting Covid19. As with any vaccine, people with known allergies to any of the vaccine components (polyethylene glycol, etc.) should not receive vaccines containing those items. People with a history of severe allergies to things not necessarily present in the vaccines should receive the vaccine in a facility that is equipped to treat an anaphylactic reaction should it occur and should bring their epi-pens if they have been prescribed them previously (make sure they are not expired & the liquid is not cloudy). We would add that they should take their standard daily doses of allergy/mast cell medications at least an hour prior to receiving the vaccine. Patients should be observed by on site clinical personnel after receiving the vaccine for at least 20-30 minutes in case a reaction occurs so proper treatment and monitoring can be provided if needed. [1]

For patients with Mast Cell Activation or Mastocytosis, a discussion with your treating physician is recommended regarding vaccine administration. Our personal inclination would be that patients whose symptoms are stable on a medication regimen would be able to receive the vaccine with proper pre-medication & observation, however if one is still having frequent or severe allergic reactions, that discussion would be far more nuanced. Such patients would likely need to receive the vaccine in a hospital if they choose to receive it.

Is the vaccine safe for people with autoimmune diseases?

We do not have sufficient data at this time to say whether the vaccine aggravates or causes autoimmune illnesses, but there are studies in early stages trying to look at development of autoantibodies in early vaccine recipients. Hopefully more data will be available by the time the vaccines are more widely available.

However, it does appear from some initial pre-print studies that Covid19 itself may either cause or worsen autoimmunity by some mechanism with a slew of autoantibodies being detected in those infected. There is a possibility the development of anti phospholipid antibodies may be contributing to the development of blood clots in Covid19 patients, though more research will be needed to confirm this. Thus it may end up being the case that risk of autoimmune exacerbations by the vaccines may be less than from Covid19 itself, but only more research will tell. [3-6]

What is an mRNA vaccine and is it safe?

First of all, let's go through a quick review of cell biology to set the context:

In the nucleus of our cells, we have DNA that contains the blueprint for all of the proteins that our cells make and more. In order to go from DNA to protein, the DNA must be transcribed into "messenger RNA (mRNA)" first. That mRNA then leaves the nucleus (where the DNA resides) and goes into the cytoplasm of the cell where the mRNA may be copied a few times (a process called 'amplification') and connect with other proteins called ribosomes that read the mRNA and translate the code it contains into a protein. The mRNA may be translated a few times before it bumps into a ribonuclease protein and gets chopped up into its original building blocks and recycled.

The SARS-CoV2 virus that causes the Covid19 illness is a single stranded RNA virus, which means that it doesn't have a DNA blueprint inside like humans do, it just has one strand of RNA to serve as its blueprint. (Of note: Some viruses have DNA, some have a double strand of RNA, some have a single strand of RNA to carry the blueprint for all the pieces and parts required to assemble new viruses.)

Viruses are very efficient organisms, in that they don't carry the machinery to make copies of themselves with them, they infect cells of other organisms and use the cells' machinery to make the virus proteins and copies of their blueprints for them. However, viruses have been around a very long time and life on earth has evolved some protections against strategies viruses use to infect our cells and hijack our cellular machinery - though viruses can evolve faster than we can.

So when a person gets infected with the SARS-CoV2 virus, the virus RNA enters their cells, gets copied, and some gets translated by the cells' ribosomes into virus proteins, some gets chopped up by ribonucleases, and some gets packaged into the newly assembled viruses prior to their release from the cell.

What the mRNA vaccines are doing is taking the RNA blueprint for *just* the SARS-CoV2 viral spike protein (without any of the other proteins that would come along with an actual infection by the SARS-CoV2 virus itself) wrapping it in a layer of fat molecules that help deliver the RNA to the cytoplasm of our cells where that spike protein RNA can be copied and translated into the spike protein. Our cells will recognize the spike protein as foreign, chop it up and stick pieces of it on the surface of the cells cradled in a special MHC protein that presents the pieces of the viral spike protein to our immune cells so we can make an immune response to multiple parts of the spike protein. The spike protein RNA was chosen for the vaccine because it was the target of neutralizing antibodies (antibodies that were able to block the virus from infecting cells) found in Covid19 survivors.

Both vaccines appear to induce a robust B and T cell immune response, though we will not know how long the immunity lasts as that knowledge requires time and observation of infection rates in the vaccinated trial participants over the course of a longer time period.

So far, the efficacy of both the Pfizer and Moderna vaccines have been similar in the 94-95% range. The vaccine was not 100% effective in preventing infection, meaning one can still get Covid19 despite getting the vaccine, but the risk of getting severe Covid19 was dramatically lower in the vaccinated vs. placebo groups in the trial. So masks, social distancing, and hand hygiene will still be needed after vaccination at least until we reach herd immunity.

Refs:

1. <https://acaai.org/news/american-college-allergy-asthma-and-immunology-releases-guidance-risk-allergic-reactions-pfizer>
2. <https://www.aarp.org/health/conditions-treatments/info-2020/coronavirus-vaccine-research.html>
3. Prothrombotic antiphospholipid antibodies in COVID-19. Yu Zuo, et. al. medRxiv 2020.06.15.20131607; doi: <https://doi.org/10.1101/2020.06.15.20131607>
4. Diverse Functional Autoantibodies in Patients with COVID-19. Eric Y. Wang, et. al. medRxiv 2020.12.10.20247205; doi: <https://doi.org/10.1101/2020.12.10.20247205>