

# COVID-19 Update and Vaccination Safety Concerns

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The pandemic that changed our lives is still going strong with hospitalizations at their highest (over 125,000 persons currently hospitalized). However, an end to the pandemic may be finally in sight with the newly and rapidly developed vaccines now being administered world-wide. I am pleased to say that none of my patient population have developed COVID-19 requiring admission to the Intensive Care Unit (ICU). I don't think that is a coincidence given that the patient population is a diverse group, ethnically, geographically and literally across every demographic element. Optimized hormones and Vitamin D, targeted supplements including Zinc and of course being safe and smart in going about your day has played a role in avoiding severe COVID.

The news is full of clips showing planes taking off and landing carrying the Pfizer and Moderna vaccines to hospitals and delivery points all over the United States. From the most recent data available on the Bloomberg vaccine tracker, over 22.1 million vaccine doses have been shipped to states across the country and over 9.27 million vaccine doses have been given. Keep in mind that for the level of protection mentioned in the clinical trial data, two doses have to be given, 3 weeks apart for the Pfizer, and 4 weeks apart for the Moderna vaccine.

Many of you have read my position on the general flu vaccine and might be assuming that my position is the same for the COVID-19 vaccine, but the common flu and COVID-19 are very, very different. Keep reading to learn my thoughts about the COVID-19 vaccines. First, let's quickly review my rationale for not being an advocate for the general flu vaccine. Keep in mind that for some individual situations in high-risk situations, the flu vaccine may still be the best approach.

**They aren't very effective.** Let's look at the medical studies and related data. In 2014, a very comprehensive review study of flu vaccine effectiveness was done. The study encompassed 90 previously completed studies, with several high-quality randomized, controlled studies. The entire study can be found here: <https://www.ncbi.nlm.nih.gov/pubmed/24623315>. The conclusion is stated verbatim below: *Influenza vaccines have a very modest effect in reducing influenza symptoms and working days lost in the general population, including pregnant women. No evidence of association between influenza vaccination and serious adverse events was found in the comparative studies considered in the review. This review includes 90 studies, 24 of which (26.7%) were funded totally or partially by industry. Out of the 48 RCTs, 17 were industry-funded (35.4%).*

**There are no guarantees that the vaccine even protects against the active strains for the upcoming season.** The flu shot's formula is based on the three or four

biggest strains that the experts "**believe**" will be the dominant viruses for the upcoming season. At best, this process is a very educated guess, as there is no way to be sure that the vaccine will cover the active strains for the coming year. There are hundreds to thousands of strains of the flu and there isn't much cross reactivity to the vaccine if the proper strains of the flu weren't covered in the vaccine.

## Covid-19 vs Severe-Covid-19

Coronaviruses are a family of viruses that can cause illnesses such as the common cold, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). In 2019, a new coronavirus was identified as the cause of a disease outbreak that originated in China. The virus is now known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease it causes is called coronavirus disease 2019 (COVID-19). In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic.

I feel it is important to differentiate between mild cases of COVID-19 and the severe cases, which I am defining as cases requiring hospitalization. According to Medscape and CDC data, approximately 86% of patients that get COVID-19 have mild to moderate cases that subside without medical intervention. That means that 14% require hospitalization. The rate of hospitalization and mortality increases dramatically with age and co-morbidity conditions and is higher amongst the African-American and Latino populations. From the same report, mortality is at the lowest, .1% for children 9 and younger without any complicating underlying conditions, and increases to 49.7% for patients that are 80 or more years of age that have complicating underlying conditions.

The reason why it is helpful to understand this data is because decisions that you make about getting a vaccine need to be informed about the risks and benefits both of getting the vaccine **and of not getting the vaccine**. COVID-19 is of minimal concern except for your ability to spread it, but severe COVID has to be a major concern of anyone regardless of age, gender or ethnicity.

At this point, let me interject that for the remainder of this paper, my focus is on severe COVID, not the so called "cases" that have been reported. The vast majority (86%) of the "cases" have none to mild symptoms and never require hospitalization. By severe cases, I am referring to cases that result in hospitalization, as it is hospitalizations that lead to mortality and the burden on the entire healthcare infrastructure. Here are some summary data that you can find on the CDC and other tracking sites:

**Cumulative COVID-19 cases in the United States:** 22.7 million

**Deaths (US): 379,255 (1)**

**Currently hospitalized (US):** 125,544 (as of 1/3/2021)

(1) *There are many troubling reports indicating that the death rate may be artificially high, and from my read, there are some valid concerns about the data. For example, the healthcare system, Medicare in particular, pays hospitals more for COVID-19 cases than for pneumonia or regular flu cases. Does this cause some over-reporting in favor of COVID-19? Other statisticians have analyzed some of the death certificates of persons classified as COVID-19 deaths, and question if COVID-19 or one of their underlying conditions was the actual cause of death. In other words, is every patient that dies from pneumonia for example that tested positive for COVID-19 properly classified as a COVID-19 death? I submit that for the purpose of my recommendations about the vaccine, it doesn't matter. Accordingly, I will not express any further concerns about the data, notwithstanding that I believe that there are some issues and inconsistencies.*

## The Pfizer and Moderna Vaccines

Both the Pfizer and Moderna vaccines are based on the use of mRNA or Messenger RNA. mRNA is genetic material that contains instructions for making proteins. mRNA vaccines for COVID-19 contain man-made mRNA. Inside the body, the mRNA enters human cells and instructs them to produce the "spike" protein found on the surface of the COVID-19 virus. Soon after a cell makes the spike protein, the cell breaks down the mRNA into harmless pieces. **At no point does the mRNA enter the cell's nucleus, which is where our genetic material (DNA) lives.** *(The point here is that mRNA does not change your DNA as has been speculated and published by non-authoritative sources on the internet).*

We know that approximately 44,000 people were studied in the Pfizer trial and another 30,000 in the Moderna trial. The adverse outcomes were few and very transient and the vaccines had approximately 95% efficacy. The 95% efficacy means that when compared to the "control group" (placebo – no vaccine) that in the vaccine group, only 5% as many patients tested positive for COVID-19 compared to the control group. While no vaccine is 100%, 95% is far better than the experts were expecting. The large size of these studies allowed them to have proper randomization between the vaccine and control cases and across multiple ethnicities, ages, and genders. In both cases, NONE of the participants that got the vaccine developed "severe" COVID. In both, there were a small number of participants that did develop COVID-19, hence the 95% reported effectiveness, but more importantly, NONE developed severe COVID-19.

Note that there are no long-term studies on these vaccines in particular, although the mRNA concept has been studied in reference to other vaccine projects and in animal studies. As a result, no material safety concerns have been found and reported. In fact, mRNA is one of the more promising medical technologies on the horizon for many diseases including infectious diseases such as Ebola, HIV and even some cancers.

At this point, it is important to note that neither of these vaccines have “full approval” from the FDA. Both are operating on a limited Emergency Use Authorization that has been granted by the FDA given the criticality of fielding the vaccine. This is probably the primary reason why employers including hospitals have for the most part not made vaccination mandatory.

**The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients:**

mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose. The Pfizer-BioNTech Covid-19 vaccine doesn't contain preservatives or the usual thimerosal, aluminum or mercury.

**The Moderna COVID-19 Vaccine contains the following ingredients:** messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose. The Moderna Covid-19 vaccine doesn't contain preservatives or the usual thimerosal, aluminum or mercury.

*The key point here is that you should be aware of the ingredients since the usual disclaimer is provided that you should not take the vaccine if you have allergies to any of the ingredients.*

As mentioned above, both the Moderna and the Pfizer vaccines are a new type called mRNA vaccines. Previous vaccines, such as the flu vaccine contain actual or synthetic versions of neutralized viruses. The mRNA vaccines work as described above without using any part of the actual virus.

*The key takeaway from the above paragraph is that mRNA vaccines do NOT contain any part of the virus as compared to conventional vaccines that use a genetically modified form of the virus to stimulate the immune response.*

The first dose, referred to as ‘priming the immune response’ is where your immune system learns to recognize the virus, and this process takes from two to three weeks. The second dose is when your immune system does the main work of building your long-term defenses against the virus.

If you should come in contact with the Covid-19 virus at a later date, your body will have readily prepared T cells and B cells that will attach to the outer covering spike proteins of the actual virus and thus neutralize it. These manufactured spike proteins will not be permanently embedded in your DNA, and they will not be permanently turning on your immune system. Thus, the effect of the vaccine is not long lasting.

Some of the scientific estimation models predict that the vaccine effect will only last for six to twelve months, with the possibility existing that yearly vaccinations will be necessary. Over the last few days, Moderna published a report suggesting (without proof) that their vaccine **may** last for up to **two years**. Many vaccines, such as the measles vaccine, confer lifelong immunity, but vaccines for respiratory infections like Covid-19 only confer immunity for a limited period of time. For this reason, the flu vaccine has to be given annually as well. Naturally occurring immunity seems to start to fall off after two to three months, with the possibility of getting a second infection rising after that period, especially as the virus appears to be mutating into more virulent forms.

## Potential Side Effects and Symptoms

Most of the reported side effects are “transient”, meaning that they last a day or two at the most and do not require any medical intervention. The reported side effects include injection site pain, fatigue, muscle and/or joint pain, headaches, chills and fever.

After the second injection, most of the immune defense building takes place and one may get some stronger side effects like a flu-like illness with low-grade fever, fatigue, and chills. Again, these symptoms are typically transient and subside within a short period of time. Some have reported that they needed to be away from work for a day for a more moderate amount of side effects.

It's important to note that with these symptoms, you're not getting a mild case of COVID. This is not possible as there is no actual virus in the vaccine. This is your immune system responding to a foreign antigen as it should by raising your metabolism and mobilizing all your immune system to build the necessary defenses.

Anaphylactic reactions are the most significant side effect, but they have been rare (around 10 per one-million doses). Both the Pfizer and Moderna COVID vaccines appear to be the only Polyethylene glycol (PEG)-based lipid nanoparticle encapsulated vaccine for use in humans. The side effects from this method of delivery have been known for some time. Conjugation of PEGs to proteins or drug delivery nanosystems is a widely accepted method to increase the therapeutic concentration of complex nano-biopharmaceuticals. It is believed that this aspect of the vaccine design may be responsible for the anaphylactic reactions that have been seen both in clinical trials and in the real vaccination effort. To date, of the millions that have been vaccinated world-wide, it is reported that there have been 21 anaphylactic reactions, and all responded to medical treatment (typically the EPI-PEN). In fact, 17 of the 21 the reported cases all had their own EPI-PEN indicating a history of anaphylactic reactions.

## What are the differences between the Pfizer and Moderna Vaccines?

Depending on many factors including your age, occupation, risk factors and geographic location, you may have a choice between the two vaccines that are currently available, or you may not. Accordingly, I will cover the differences between them in case you have a choice.

Scientifically, there are some minor differences between them, however none that merit discussion that would lead to a person favoring one versus the other in my opinion. There are a few differences that one can notice. The second dose of the Moderna vaccine is given twenty-eight days after the first, whereas the second dose of the Pfizer vaccine is administered twenty-one days later. Both vaccines have only been tested in the specifically authorized formats, 21 days (Pfizer) and 28 days (Moderna). I would recommend adhering to that schedule strictly as we do not know the impact of early or late administration of the second dose. ***In other words, don't get complacent and neglect to get the second dose – it is very essential to your protection.***

Although both vaccines use “PEG” encapsulation, Moderna uses a slightly different propylene glycol liposomal encapsulation and from the study data, the Moderna vaccine appears to be 100 percent effective against severe COVID.

Moderna is authorized for people eighteen years and older, while Pfizer's vaccine was authorized for people ages sixteen and up.

Pfizer's vaccine needs to be stored at -70 degrees Celsius requiring very expensive “super” ultra-freezers. It can be stored in a normal refrigerator for an additional five days but must be used within six hours if kept at room temperature. Moderna's vaccine still needs to be kept very cold, but the type of ultra-freezer it needs is much lower cost as it only needs to freeze to -20 degrees Celsius. After it thaws, it can be refrigerated for an additional thirty days. The bottom line is that the Moderna vaccine is much easier to transport, store and deliver, especially outside of hospital environments that have the super ultra-freezers.

Moderna's vaccine side effects were found to be more common after the second dose. Some experts are advising that people may want to consider taking the day off work after getting the second shot.

Both Moderna and Pfizer have noted through published work that those who received the vaccine had a much stronger response than those who acquired the immunity from the infection. Further, Moderna specifically published that their vaccine also protected against viral replication in lung and nose cells.

The other difference worth mentioning is that the Moderna vaccine was designed and is manufactured by Moderna in the United States. The Pfizer vaccine was actually created by their joint-venture partner BioNTech out of Germany. Essentially, BioNTech provide the biopharma design and Pfizer is providing logistic and production support. ***If I were to lean towards one or the other, I would lean to the Moderna vaccine due to knowing a single US-based company is responsible.***

## My Recommendation

Firstly, regardless of which decision you make regarding getting the vaccine, I recommend the following minimum approach to strengthening your immune system.

1. **Vitamin D.** Ensure your vitamin D level is optimized (50-80). Multiple studies have shown a correlation between suboptimal Vitamin D levels and severe COVID. Mainly, this means ensuring that you are taking your prescribed Vitamin D on a daily or weekly basis depending on which regimen you are on.
2. **Zinc.** I continue to recommend zinc supplementation in the amount of 25 mg daily. This was in one of my earlier recommendations and it continues to be a viable adjunct to strengthening the immune system. Remember that zinc specifically blocks viral replication even of corona viruses.
3. **Quercetin.** Quercetin is a nutraceutical product with anti-inflammatory and anti-histamine properties, so it is clinically useful in treating allergies, mast cell activation disorder and a host of other illnesses. But studies also show that Quercetin inhibits replication and reduces viral load of coronaviruses specifically. Here is a key study reference <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4808895/>
4. **Ivermectin.** Especially for high-risk patients, prophylactic Ivermectin has been shown in small studies to prevent severe COVID. Ivermectin is a medication that many of you have been prescribed if you have had parasites. It is a safe medication and again has been shown to prevent COVID and to reduce severity in cases where the patient already has COVID. Here is link to a key study reference: <https://covid19criticalcare.com/wp-content/uploads/2020/10/FLCCC-IVERMECTIN-Summary.pdf>

Now, regarding the vaccine, unfortunately I don't have a one size fits all recommendation. **Given the seriousness of severe COVID-19, the relatively high death rate for severe cases, and the burden on our regional health resources, recommending against getting a vaccine for all patients is not appropriate.**

On the other hand, there is a lot that is unknown about the vaccine. There are no long-term studies for obvious reasons, and we don't even know for sure how long the immunity conferred will last (seems to be less than one year). Also, we don't know if the vaccine will cover all of the eventual mutations of the virus that develop. We should also be somewhat concerned about the long-term impact of Polyethylene Glycol (PEG) with either of these two vaccines. Further, as we have all read recently, there is a new and more contagious strain out of the UK that has been found in several states in the US as well. Thus far, Moderna and Pfizer have postured that the vaccine "should" cover this variant, but no one can be certain. Finally, most of us have already lived through many prior viral scares including H1N1, Ebola, MERS and a few others. As the viral threats continue, we have to question if vaccines are the best defense against these perpetual long-term threats?

All of that being said, here are my recommendations:

1. **If you are under 16, there are no approved vaccines for you.** The Moderna vaccine is approved for 18 or over and the Pfizer is approved for 16 or over. Both promise to have vaccines later in the year for the younger groups.
2. If you are on the “**front line**” (first responders, restaurant workers, health care workers, others in frequent and direct contact with the public) in your occupation, **I would highly recommend the vaccine** unless you are in the group of persons who should not get the vaccine (point 6 below)
3. If you are over 75, or between 60 and 75 and have one or more of the reported comorbidity conditions (see CDC Comorbidities below), **I again highly recommend the vaccine** unless you are in a group that should not get the vaccine (point 6 below).
4. Healthy individuals between 18 and 60 years without significant comorbidities. Many of you fit into this group and I have thought long and hard about what to recommend. After considering everything known and some of what is unknown, **I recommend that you consider the vaccine both for your own protection and for the overall “greater good”.**

Consider that many of you have family or friends that have been severely impacted by COVID-19. Further, if this broad group doesn't get vaccinated, it will be difficult to achieve herd immunity needed to end the pandemic and that means that many of the elderly and high-risk persons that are a part of your life will continue to be at risk. Again, the recommendation is still subject to each of your own personal beliefs and unique health situations not covered in this letter. **However, the point is that you need to think about your loved ones, and not just what is best for you personally.**

5. **Female patients who are pregnant or considering a near-term pregnancy.** Since pregnant women were excluded from the initial placebo-controlled studies, the CDC says there are not sufficient data to make any recommendations for women considering near-term pregnancies. However, the CDC does say that based on the available data that pregnant women are at increased risk for severe COVID. Accordingly, females that are considering pregnancy are best advised to hold on the pregnancy until more data is available. If you are committed to the near-term pregnancy, then shelter in to avoid exposure and postpone taking the vaccine until more data is available to make an informed choice. **With no data on the impact of the vaccine on an active pregnancy, it is hard to recommend getting a vaccine.** If you are already pregnant, you should again consider all of the other risk factors mentioned in making an informed decision. Studies are underway and perhaps in a few months, the answer will be more clear.
6. **Patients who should NOT get the vaccine.**



- a. **Patients that are allergic to any of the listed ingredients.** I know, most people have no idea if they are allergic to the mentioned ingredients, but this is the only absolute exclusion case.
- b. Patients with a history of anaphylactic reactions should only take the vaccine if recommendation #2 (front line worker) or #3 (high risk by age/comorbidity) above applies due to the probability of a severe reaction. **If you do decide to take it, be sure that your EPI-PEN is not expired and keep it on your person when you go to get the vaccine.** Further, it is highly recommended that you only get vaccinated at sites that have EPI-PEN and other life-saving equipment available such as hospitals.
- c. Patients that have been diagnosed and not yet fully treated for Mast Cell Activation Disorder (MCAD) should generally avoid the vaccine until their MCAD is well-managed. Mast Cell Activation Disorder (MCAD) is a disorder where components of the blood stream, namely mast cells, secrete various substances including histamine, interleukins, prostaglandins, cytokines, chemokines, and heparin, which can be then involved in an aggressive allergic reaction or significant inflammatory response. MCAD patients frequently have extreme reactions to chemicals, perfumes, many other environment substances.

MCAD patients with significant comorbidity factors that make the risk too great to not get it right away should consult specifically with Dr. Lawson. It should be noted that patients appearing for the studies with symptoms of MCAD were excluded from the study, hence there is no evidence to indicate that it is safe for patients with MCAD. Scientifically, there are many areas of concern for a patient with MCAD being given the vaccine. If a person with MCAD does elect to get a vaccine, it is highly recommended that this person only get vaccinated at sites that have EPI-PEN and other life-saving equipment available such as hospitals.

- d. Patients with a prior COVID-19 positive diagnosis should not get the vaccine for at least 90 days after the positive test.
  - e. Patients who received convalescent plasma or one of the available commercial antibody treatments should wait for 90 days from cessation of treatment prior to getting the vaccine
7. **CIRS (Chronic Inflammatory Response Syndrome/Mold Illness) patients.** Once again, there is not a singular answer. CIRS patients should consider which categories are applicable from the above list and make their decisions accordingly. It is true that your immune system is weakened and as such, there are reasons why you should get the vaccine as well as reasons why you should not get one. On the pro-vaccine side, it is my opinion that CIRS is another unlisted comorbidity factor that increases risk of severe COVID. On the anti-vaccine side, many of you also have mild or more significant cases of MCAD

and this would be a reason to consider NOT for getting the vaccine, at least until your MCAD is well-managed.

I recognize that this isn't as straight-forward as some would like, but under the circumstances the decision is not straight-forward for any patient. Patients have to consider the totality of their own situation, exposure risks, risks to elderly that live with them or close to them, the impact of the pandemic itself, economics and many other factors. I do hope that this paper has given you a framework for an informed decision.

In the end, there just are no easy answers here. There are plenty of questions that each of us needs to answer in order to make an informed decision. Some of you may effectively not have a choice. I have spoken to many where their employer has strongly "urged" them to get the vaccine. In the coming months, some employers will likely require it, as many hospitals require flu vaccines for their staff. In my early medical career, I was required by my employer to take the annual flu shot even though personally, I didn't agree with it. Here is an additional thought that may help if you are on the fence.

*Has the pandemic had adverse consequences on how you are able to live your life? Most will answer yes, hence taking the vaccine to help end the pandemic may be a noble thing to do even if you don't personally believe it is the best thing for you. Consider your loved ones and the ability to return to a time where you can freely spend time with them "without a mask".*

**With few exceptions, I will not be preparing medical letters to get patients excluded from the vaccine.** The exception would be for patients with a current MCAD diagnosis that was made by this office. If any of the other exceptions apply to you, please consult with your primary care or other physician.

In closing, I do hope and pray for the health and well-being of all of us, that the end to the pandemic is near. I thank you for the confidence that all of you place in me and my practice, and we promise to continue delivering our best to each of you in the years ahead.

**In health,**

**Lynese L. Lawson D.O.**

**Medical Director**

## CDC Comorbidity Conditions

Adults of any age with **certain underlying medical conditions** are at increased risk for severe illness from the virus that causes COVID-19. Severe illness from COVID-19 is defined as hospitalization, admission to the ICU, intubation or mechanical ventilation, or death.

Adults of any age with the following conditions **are at increased risk** of severe illness from the virus that causes COVID-19:

- [Cancer](#)
- [Chronic kidney disease](#)
- [COPD \(chronic obstructive pulmonary disease\)](#)
- [Down Syndrome](#)
- [Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies](#)
- [Immunocompromised state \(weakened immune system\) from solid organ transplant](#)
- [Obesity \(body mass index \[BMI\] of 30 kg/m<sup>2</sup> or higher but < 40 kg/m<sup>2</sup>\)](#)
- [Severe Obesity \(BMI ≥ 40 kg/m<sup>2</sup>\)](#)
- [Pregnancy](#)
- [Sickle cell disease](#)
- [Smoking](#)
- [Type 2 diabetes mellitus](#)

COVID-19 is a new disease. Currently there are limited data and information about the impact of many underlying medical conditions on the risk for severe illness from COVID-19. Based on what we know at this time, adults of any age with the following conditions **might be at an increased risk** for severe illness from the virus that causes COVID-19:

- [Asthma \(moderate-to-severe\)](#)
- [Cerebrovascular disease \(affects blood vessels and blood supply to the brain\)](#)
- [Cystic fibrosis](#)
- [Hypertension or high blood pressure](#)

- [Immunocompromised state \(weakened immune system\) from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines](#)
- [Neurologic conditions, such as dementia](#)
- [Liver disease](#)
- [Overweight \(BMI > 25 kg/m<sup>2</sup>, but < 30 kg/m<sup>2</sup>\)](#)
- [Pulmonary fibrosis \(having damaged or scarred lung tissues\)](#)
- [Thalassemia \(a type of blood disorder\)](#)
- [Type 1 diabetes mellitus](#)

the inappropriate release of mast cell mediators including: histamine, interleukins, prostaglandins, cytokines, chemokines, and heparin (There are more than 200 chemical mediators associated with mast cells.)

Mast Cell Activation Disorder (MCAD) is a disorder where components of the blood stream, namely mast cells, secrete various substances including histamine, interleukins, prostaglandins, cytokines, chemokines, and heparin, which can be then involved in an aggressive allergic reaction or significant inflammatory response.