FIRST WATCH
Helping the Helpers

# SARS-CoV-2 (COVID-19) Vaccine Update

As of the second week in December, the first vaccine against COVID-19 (**Pfizer**) was approved under an Emergency Use Authorization (EUA) and thousands of doses were transported to multiple areas of the country to begin vaccination of priority groups under FDA & CDC/APIC guidance, although states can accept the ACIP Priority Tiered Guidance system or develop their own Priority Group system at the state level. Just a little over a week later, the same process started for the second EUA-approved vaccine, **Moderna**, and its distribution and then vaccinations began too. At the end of the third week, more than half a million front line health care workers had received the first of two vaccinations needed to achieve the trial-found 94% +/- protection (Pfizer & Moderna require two doses 3 and 4 weeks apart, respectively). Also, in the APIC Recommendation's top tier, were vaccinating the elderly (and their professional care givers) in long term care facilities. The other group in the top tier, were EMS front line workers (considered healthcare workers by CDC & NIOSH). Many EMS workers are being offered access and are being vaccinated. Some states, however, have opted to put EMS workers in with other First Responders, such as Police and non-EMS Firefighters, which are in a lower tier with other Essential Workers, like teachers, grocery store workers, etc. Please consult your State Plan or with State or Local Public Health departments to determine what tier your job description falls in, educate yourself about the vaccine & vaccination process, and then make a decision about accepting or declining COVID vaccination. Make it a thoughtful one. The info available to us about COVID and the vaccines is changing all the time.

**First, some FAQs about COVID vaccines in general and then my personal feeling about the vaccinations. Spoiler alert. My opinion has changed from just a couple months ago.**

Everyone should make the decision about being vaccinated against COVID for themselves. There have been reports of both employees and employers asking whether the vaccination can be made mandatory. That's a loaded question and, quite honestly, one that we don't know the answer to…yet. So, let's go on the assumption that each individual is making the decision for themselves. Load yourself with valid information (not just what someone told you or you heard). Verify it with a known and valid source. If something is true, you should be easily able to find it in three (3) reliable places. Find a co-worker or two that have different opinions and have a nice debate, using what you have validated as accurate, as your arguments. You may still be on opposite sides but you will have heard the other side's arguments. Talk to your personal physician and/or your medical director, or a doctor that you have come to trust. Find out what he/she thinks. Ask them if they'll tell you what they chose or are going to choose.

1. The current COVID situation in the US (and Canada) has got to be considered in your decision. If there were only a few cases and life was normal again, traveling by plane, train or bus would not be considered risky. You could go out to dinner with your entire crew, station, or shift, and wouldn't have to wonder if you were going to get sick or pass it along to someone else. Someone who might be at risk for complications, severe disease, or death.



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2. There are a variety of vaccines with several different platforms (the way they actually work) being developed. There are currently two that have FDA EUAs to be used to vaccinate against COVID in the US. At least one more, and possibly two, are expected to be their presenting data, soon, to the various concerned bodies (experts) who then vote on whether an EUA should be given or, later on, if full-blown approval should be granted.

Normally, as you have been hearing, it takes years to develop a vaccine that is tested again and again and again, over years, to make sure that it is protective against the disease and safe, over a long enough period, to find any problems (short term, medium range, & long term). It is also tested in all the groups that might be receiving the vaccine, so that any group-specific problems become apparent during the trial, and not after full FDA approval when millions, including pregnant women, babies & small children, teens & young adults, those with chronic illnesses, compromised immune systems for one reason or another (cancer, elderly, immune system deficiencies, bone marrow, stem cell, or organ transplant, taking biologicals or high dose corticosteroid therapy, HIV positive, etc.) may be getting it. Instead of a few tens of thousands getting vaccinated during the trial, millions are. That's a much bigger slice of all kinds of people to test. Basically, everyone that is vaccinated becomes part of the "expanded trial". That's why those vaccinated are being monitored so closely. Moreover, everyone who gets vaccinated is being followed and can independently report any side effects or adverse reactions to an app site set up just for COVID-19 vaccination (called V-Safe), as well as the normal Vaccine adverse reporting system called VAERS. It's important that we build on what we know about these vaccines. ONLY when more are vaccinated, the results are fully known about side effects & adverse reactions, how long it takes to become protected from COVID and how long that protection lasts (going for multiple years rather than a couple of months). Only then, will the FDA consider giving an actual Standard FDA Approval of one or more of the vaccines.

But a Pandemic is not normal. And, COVID is about as abnormal and destructive as an organism can be, as is the COVID Pandemic. Most infectious organisms have a sort of rule book – they act a certain way – they are predictable, even if it's a horrible predictability like Ebola has. COVID seems to either have a very long play book with lots of intricate plays or it functions like the old 8 Ball (ask it a question, shake it up, and read the answer whether it makes sense or not). So, we can't wait for years. We have to protect people as soon as it's known to be relatively safe. We know the short-term effects, and we have an idea of the mid-range effects. The scientists don't expect long-term adverse effects, but we just can't be sure at this point. Also, it wasn't trialed in all groups or ages. And yet, after a conversation with one's personal physician, most people will be eligible to get the vaccination, even if it wasn't tested in their group. In fact, only those that it's contraindicated in (known allergy to the components of the vaccine or a serious/severe reaction to the first shot precludes the second one) will be precluded from getting that particular vaccine but will likely be eligible for another type.

It just so happens that the first two utilize a brand-new platform (method) for a vaccine, although the process has been under development for a while. That platform is mRNA and basically, a very small piece of genetic material is altered and inserted into the body,



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via vaccination, to give direction to the cells in the body to not duplicate the virus. The scientists that developed this technique and the experts who understand it, have said that there is no way that the mRNA (the small bit of foreign genetic material) can be assimilated with the host's genetic code and cause a mutation of the host's DNA. Not Possible!! The body might identify it as a foreign protein and react to it (like a transfusion reaction after giving someone a unit of blood). The blood typing may be completely correct but the crossmatching missed a small part that was not going to tolerate it, and a reaction occurs. This has not been reported, except for a very few apparent allergic reactions with the FDA & CDC are all over it, trying to make sure it is completely understood.

3. So, we can agree that we would have rather had 5 years of development and testing but a lot of people can die of COVID in that time, so we jump faster and a "provisional" Emergency Use Approval (EUA) is given. For that EUA, the bar is much lower and basically only has to be probably better than not having the vaccination and no major serious/severe reactions. The bar was literally set at 50% not getting seriously ill and few to no serious adverse reactions. This is why most people, scientists or not, got excited. Preliminary data, which is analyzed & computed by an independent group, not associated with the manufacturer or any investors, who then give a report to the FDA, to the CDC/ACIP, and so on. The numbers were nearly double that low bar. 94% in one and 95% in the other. That's better than many vaccines out there now. And, other than a few moderate to serious allergic reactions, there has been no serious adverse effects reported. No one has died. Not during the trials and not since it has been given in multiple countries throughout the world. The next couple of vaccines that are expected to submit their data, and ask for EUAs, are platforms that have been used many times before. We hope their data is as good as that from Pfizer and Moderna.

4. A few words about side effect and adverse reactions. An adverse reaction is a reaction that is unexpected and not tolerated. Depending on the circumstances, an adverse reaction will often prevent others who might have the same type of adverse reaction, because they are in the same group, from getting the vaccine, drug, treatment, etc. because it may be considered too risky. Side effects are those things that are reported or observed during the trial, that may be annoying but are not dangerous and are usually transient. They are typically calculated as a percentage of how often that side effect occurs or are divided into common, uncommon, or rare.

With vaccines, many of what are called side effects are actually positive effects that show that an immune response is occurring and is desired after a vaccination. These include fever, chills, headache, musculoskeletal aches, fatigue, sore throat, congestion. Basically, it's what you might see if you actually got sick with the infection but usually much milder. It means that your body is capable of mounting a defense against the organicism that needs to be protected against. It's why so many in the trial have few signs of an immune response until after the second shot, when it becomes more common. Still, most have reported that at around 36 hours after the time of the shot, the symptoms just disappear, as if a light switch got turned off.



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**So, as promised, here is the personal thought process I went through to decide if I wanted the vaccine and if I was going to recommend it to family and friends who asked me what to do. It does not, in any way, reflect the thoughts or philosophy of anyone at FirstWatch, but myself.**

My initial reason for not liking the idea of the vaccine in the summer and early fall was that it was moving really fast, with a lot of pressure to have it in people's arm in the beginning of November. There were a lot of non-scientists and non-physicians that were involved in the process and we really try to make sure that it's the scientists and doctors that make the decisions looking only at the relevant data. The decisions are actually made by several boards who don't have any conflict of interest financial or career interest in any component of the vaccine except for science to prevail. In other words, the only goal of the data reviewers is a safe and effective vaccine.
So, when there was a push to have the data released and the vaccinations begun by the beginning of November, when the Phase 3 trials had just begun (some of them) in late July, it just didn't seem smart or safe. It would be reported that the trial was 43,448 people so most people thought that meant that 43, 448 people received the vaccine. But that's not blinded, randomized trials work. Only half (21,720) got the real vaccine and the rest (21,728) got the placebo and become the control group. For a trial, that's a pretty small phase 3 trial. And, since the two vaccines in contention in that time frame required 2 injections, 28 days apart (with permission, one was moved to 21 days so that the data could be collected quicker), and a full immune response wouldn't be expected until 1-2 weeks after the 2$^{nd}$ shot, there was just not enough time for good data on efficacy or adverse events. Every medical person or scientist I discussed it with or heard discuss it, was concerned, and likely to refuse being immunized if it was approved under those circumstances. I was in that same corner.

Then, the Pfizer and Moderna CEOs announced that they were not seeking to speed up the data and would not be allowing political or crowd pressure to interrupt the scientific process. And, Dr. Hahn, from the FDA wrote that he wanted a promise that the companies would not seek an EUA until data had been collected for two months after the second shot. That interval would allow close and mid-range adverse effects to be known and would be a better indicator of how well the vaccine worked at preventing COVID infection, serious or severe disease, etc. When early November passed without the data being released and no vaccinations occurring outside the trial, I was much more comfortable that the scientists at the companies and at the FDA, NIH, and CDC were running the show and looking for the proper benchmarks. When the independent experts (a secret panel so no one can add undue influence) reported the greater than 90% efficacy, the benchmark that was going to get approval at 50% was in the rear window. Now, healthcare people that I talked to and relied on for the truth and the scientists were all saying what I was thinking. We were all leaning towards it. When the numbers of COVID cases started climbing and it became obvious that many people just had so much COVID fatigue that they were wearing masks or not wearing them properly, they weren't distancing and they were traveling on planes, ships and trains. It seemed like the vaccine was going to be the only way to decrease cases and keep those at greatest risk from becoming seriously ill or dying.



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So, I want the vaccine. **Which brings me to the question that I suggested you ask yourself. If they told you that you couldn't have the vaccine, would you be disappointed or glad?** I ask that because, after I decided I would take the vaccine when my turn came, I probably won't be able to take the Pfizer or Moderna vaccines because I've had anaphylaxis to injectable medications and severe reactions to previous vaccinations, so it's likely contraindicated, at least for the Pfizer. I was disappointed.

There is a lot of information available about both of the currently EUA-granted vaccines, some of it essential to know before making a decision about getting a COVID-19 vaccination and other info that may answer some curiosity or just add to one's knowledge. There is also general info that pertains to the COVID vaccines and vaccine guidance in general, access to the complete US Plan for COVID vaccination rollout, and another document that has links to each state's plan. In an ideal situation, everyone would be following the same, or very similar plan, as was done during the 2009 H1N1 pandemic vaccine rollout.

Instead, there is guidance/recommendations from the recognized experts in the field of vaccines & vaccination, but each state was free to either adopt the ACIP Guidance for prioritizing the groups receiving the vaccine or adopt their own plan. All the links to the general documents, including the one with links to each state plan, are listed in a document titled, ***SARS-CoV-2 (COVID-19) Vaccine Update - Resources & Links***

**An attachment to this page will have a labeled list of URL links.**

Those titles containing an *means that the info could be very helpful and should be considered for reading. The same applies for all the titles in that section if the * is at the beginning of a bolded, underlined **Section Title**. Vaccine-specific materials will be indicated by **Pfizer** in a darker red and **Moderna** in mauve; they each have their own section.



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