COVID-19 Vaccine Update

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On December 11, 2020, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to one COVID-19 vaccine produced by Pfizer Inc./BioNTech. In addition, the vaccine produced by Moderna is approved by the FDA on 12/18/ 2020 and received the EUA approval 12/19/20.

The Pfizer and Moderna vaccines contain:

- mRNA – the main, active ingredient that elicits an immune response and the production of antibodies against COVID-19.
- Lipids – an outside coating or shell of fat that protects the mRNA from destruction as it is being stored, administered and delivered to cells
- Potassium chloride; monobasic potassium phosphate; sodium chloride (salt); dibasic sodium phosphate dehydrates– salts that are used to maintain proper levels of acidity (pH)
- Sucrose – a sugar that stabilizes the suspension
- Each vaccine sponsored by the U.S. Department of Health and Human Services' Operation Warp Speed uses a slightly different approach with the same goal: to induce an immune response in the body against COVID-19. The vaccines produced by Pfizer and Moderna are both mRNA vaccines.
- This type of vaccine operates somewhat differently than other types, like the seasonal flu vaccine. mRNA vaccines contain a message from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus.
- After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies also recognize that the protein should not be there and build immune cells that will remember how to fight the virus that causes COVID-19 if we are exposed in the future.
- Most of the vaccines will require two shots, with the second shot received 21 to 28 days after the first, depending on the vaccine.

Producing a vaccine against COVID-19 has been the top priority of scientists and governments around the world to help bring an end to the pandemic. With the coordinated investment of resources, development of these vaccines has been accelerated, all while maintaining standards for safety and efficacy. Rather than eliminating steps from traditional vaccine development timelines, steps are proceeding simultaneously, such as scaling up manufacturing while safety and efficacy data are being collected. Pfizer recently completed their clinical trial, which included more than 43,000 people.

Health care professionals and researchers are still learning about COVID-19 infection and about how long the vaccines will protect against Covid infection. Because COVID-19 is still a

relatively new virus, it is difficult to know exactly how the virus affects the body long-term and how long immunity from natural infection lasts. So, it is also difficult to predict how long a vaccine will provide protection against the virus. As the vaccines are administered and new information is gathered, additional data about how long it will protect against the virus will be available. Based on the experience with other vaccines and early data from the COVID-19 vaccines, it is likely that people who are vaccinated will have enough immunity where they will not pass the virus to others if exposed, but this is not 100 percent certain.

While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others.

Before receiving approval for emergency use, pharmaceutical companies must provide evidence that their vaccines are safe. A team of experts from the FDA and the CDC's Advisory Committee on Immunization Practices reviewed all available data on the safety and efficacy of the vaccines before recommending them for use.

Side effects that have been reported with the Pfizer-BioNTech and Moderna COVID-19 Vaccines include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

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Because we expect to get limited supply of the vaccines initially, the COVID-19 Vaccine & Therapeutics Taskforce is identifying the first groups of employees who will be invited to get the

vaccine in the first couple weeks. These first groups are being identified based on the recommended prioritization guidelines from CDC and MDHHS. The goal is to administer the initially limited supply of vaccines to those most at risk, following state and CDC guidelines for a phased rollout. We will continue to get more and more vaccine supply each week and eventually have enough supply for all who want the vaccine.

Starting sometime the week of December 13, 2020, health care organizations across the country, including Michigan Medicine, will begin vaccinating people based on the recommended prioritization guidelines from CDC and MDHHS.

According to CDC, vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Current evidence suggests that people who have had COVID-19 may be protected for up to 90 days after their initial infection, so they may decide to wait until after this period, if desired.

For people with CF:

Initially, there will be a limited supply of authorized vaccines. When a vaccine becomes available, you will likely have only one option.

People with CF (ages 16 and older), may be eligible to receive a vaccine based on their health status in consultation with their doctor. Vaccine distribution is determined by the Centers for Disease Control and Prevention (CDC).

There are many things you can do to protect your health and that of your household until a vaccine is available and, more importantly, until infection rates are reduced. Everyone — even those who have been vaccinated —should continue doing what they can to protect their health and the health of everyone around them. Until infection rates are getting low, everyone — even those who have been vaccinated — should continue doing what they can to protect their health and the health of everyone around them. People who have been vaccinated can still have the virus that causes COVID-19 and infect others, even if they themselves are not ill. Enough of the population will need to be vaccinated in order for us to learn how well the vaccines provide long-term protection under real-life conditions

Most people will be able to get a vaccine without paying out of pocket (the cost of the vaccine itself is covered by the U.S. government).

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