COVID 19 Vaccines:

Vaccines for COVID19 infection prevention bring a real ray of hope to our current pandemic situation. Vaccines have the potential to protect the population from what continues to be the most deadly infectious disease threat in our lifetime.

Unfortunately, as with all things in times of crisis, our understanding of the virus and our efforts to combat it have had to evolve in real time leading to confusion and misinformation and fear and uncertainty. Vaccines will also not "cure" or eliminate the virus and current practices of mask wearing, social distancing and hand hygiene will still be central in our approach to dealing with the virus.

It may be helpful just to summarize what we know about the two leading candidate vaccines to help you make an informed decision in conjunction with your own understanding of your health situation and your personal healthcare provider's recommendations. The current information is overwhelmingly in favor of vaccination for most Americans however there remain personal health situation and limitations in any decision about healthcare that should be considered and discussed with your personal healthcare provider. This information is meant to summarize, the multitude of information about this issue to aid in our personal decision making efforts.

How Vaccines work in General?

Vaccines work by "pre-exposing" your immune system to either a part of the infectious agent or a deactivated (dead) form of the virus in order to allow it to prepare special disease fighting immune cells to attack the virus if you are exposed to it in the future and not allow it to infect you. It's a quite simple concept actually. The details of what is used and how much of a response the vaccine creates is what separates all the different vaccine technologies and effectiveness. The new vaccines use a novel mechanism that coaxes your own body's cells to produce a part of the virus instead of injecting a partial or inactivated virus into us.

Side Effects of Vaccines:

Because the vaccine is intended to cause an immune reaction, your body will experience similar symptoms as you might if you were infected by the virus, only to a much lesser degree. The vaccine and the immune response that follows cause fevers, chills, muscle soreness and sometimes mild respiratory symptoms in many people. The chance of a full blown allergic reaction is also possible, but very rare, similar in instance to trying a new type of food that you have never had before. Very rare. Long-term side effects of vaccines, those taking years to develop are hard to quantify or understand and very controversial, but what is clear that with existing vaccines these have been very rare and may not exist at all. There is no current data on long-term side effects of these COVID19 vaccines.

Development of COVID19 Vaccines

The development of the COVID19 vaccine has generated some controversy in terms of the speed in which it has arrived on the scene and if safety measures were compromised in its manufacture and development. Measures were taken in two broad categories to increase the availability of a safe and effective COVID19 vaccine: Manufacturing costs and regulatory requirements.

What we know is that measures were taken to eliminate some of the upfront costs to manufacturers in order to cut production time. These included giving money and guarantees of revenue that allowed manufacturers to make investments in infrastructure, manufacturing changes in equipment and production priorities to cover any potential lost revenue from moving resources from other products to the COVID vaccine efforts. This money allowed for a rapid shift of manufacturing and development that cut months and potentially years of development time. These efforts did not change the actual design and engineering of the vaccine itself however.

Companies were also paid in advance for millions of doses allowing them to manufacture large quantities of vaccine, at the same time as it was still being trialed (before approval) knowing that if it was ineffective or unsafe they would not lose money for their stockpile. Normally good business sense would necessitate that the vaccine be approved prior to its mass manufacture meaning a long delay from time of approval to time of availability. These and one regulatory change are actually the primary interventions that led to such rapid availability of the vaccine.

On the regulatory front, the government assisted the companies in moving forward with human trials and approval of the vaccine much more quickly than would normally be the case in vaccine or drug development. The data required to move forward from preliminary (test tube) trials to the final human trials was shortened, and emergency use approval was offered without long-term data on safety being available.

It is important to understand however that Phase 3, or final human trials were structurally the same as any previous vaccine efforts. A vaccine must prove safe and effective immediately (first 3 months) to even be considered for longer term studies.

The major difference in the COVID19 vaccine efforts is the requirement for long term efficacy (greater than 3 months) and long-term safety are being waived for “emergency use” of the vaccine. These studies and data will be collected and performed, but the vaccine is likely to be authorized for use prior to this information being available due to the positive initial studies and the dire need for a vaccine to save lives and help end the current devastating pandemic. This decision was based on a long history of vaccine technology being safe and effective without long term side effects, as well as the improvement in detection of problems earlier in drug/vaccine development.

Specifics about the vaccine we are likely to see here in SW Michigan :

Pfizer/BioNTech

This vaccine is based on plans for a pandemic vaccine drawn up many years ago, and was easily implemented by a large company with many years of experience in safe vaccine development. Instead of introducing a dead or partial virus the Pfizer vaccine gives instructions (mRNA) to the cells of your

body which encourages them to make the major “spike” protein found on the surface of the virus. Thus your body makes a part of the virus that your immune system recognizes and prepares itself to kill off this protein on any virus that enters your system in the future. This immune response appears to last at least 3 months for certain and likely lasts 6 months or longer. Only time will tell how long the immunity will last after 6 months.

With this vaccine there are two doses given 28-30 days apart. The first dose is the initializing dose and does produce some immunity and generally has a mild immune response. The second or “booster” dose produces a dramatic immune response and is thought to be the main source of what is hoped to be prolonged protection. That is why getting the second dose is so important and why there is more side effects of fever, sore muscles etc. with the second dose.

Pfizer tested this vaccine in 30,000, mostly younger healthy volunteers, giving 15,000 of them the vaccine and 15,000 of them a placebo saline solution. Of the vaccine group only 8 people later went on to have COVID19 infection compared to 162 in the saline group, giving the vaccine it’s upwards of 95% effectiveness rate. There were no serious reportable side effects in the vaccine group. The company is now proceeding to test the vaccine on children, and continues to monitor the initial vaccine group for longer term immunity and side effects.

Moderna Vaccine

The Moderna vaccine uses the same mechanism as the Pfizer vaccine delivering messenger RNA instructions to the body’s cells to produce the viral spike protein and trigger an immune response. It also requires two doses and has been shown to be over 94% effective in similar trials. The main difference between the two vaccines is the Moderna vaccine is concentrated in a more stable solution that does not require super cold refrigeration for distribution and may be more easily transported and supplied across the planet.

Both Vaccines are likely to be approved by emergency use authorization and likely will be available for distribution prior to Christmas.

Approval and Distribution:

The FDA requires only 50% efficacy for vaccines. The efficacy of both these vaccines surpasses 90%, which is quite remarkable. Over the following 2 months of vaccine trials there have been no serious reactions or side effects, which is reassuring.

One or the other vaccine is likely to become available in our community in the coming month. Distribution will likely be based on risk. Currently healthcare workers and residents of long term care facilities are considered the first tier to receive the vaccine. Next are designated essential workers for infrastructure and public safety and after that those with high risk health conditions or over the age of 65. Vaccination for the general population and children likely remains months away.

So is this the answer to our prayers?

Yes and no. It is important to understand that the vaccines will be critical to a return to normalcy in interactions and business. The vaccines are not a cure for COVID19 and the virus will remain in our community likely for years to come. Vaccinated people may be immune to getting sick, but may still be able to carry the virus and spread it to others. More study of this is needed and likely more recommendations will come in the future. At this time however, it is critical that current mask wearing, social distancing and hand hygiene be continued indefinitely into the future, whether you have been vaccinated or not. It is likely that you can still carry the virus on your hands, or in your nose after vaccination. You just may not yourself get sick.

What about possible long-term side effects of vaccination?

There is no data to make predictions or assurances of the lack of long-term side effects of these new vaccines. What we know is the stimulation of the immune system to create temporary immunity is not new and is similar to all vaccines currently in use and that those currently used vaccines have been proven to have long-term safety. The new messenger RNA technology is felt to be theoretically safer as it does not expose the body to any part of the foreign virus in any form (dead or fragmented). Only long-term monitoring for side effects will answer these questions with certainty.

What might we experience if we get the vaccine?

The initial shot (there is no oral or nasal form) is likely to produce only mild symptoms of respiratory illness if anything at all. There have been fairly clear reports of greater symptoms after the booster (second) vaccination at 30 days. These have included fever, soreness and redness at the vaccination sight, chills, cough congestion and headache. The symptoms have been described as minor to moderate and generally have resolved within 24 hours. No serious reactions or dangerous side effects were found during the 2 months of post vaccination data we have so far.

What if I have had COVID19? Do I still need to get vaccinated?

The answer here is yes, because of the uncertainty of a prolonged immunity after infection. Some people who had minor symptoms of infection, but tested positive, do not go on to produce any protective immunity. This is thought to explain why we have seen some “repeat” infections in people. The vaccines have proven to provide over a 90% chance of producing a true immunity that will last at least 3 – 6 months. For this reason the current recommendation is to get vaccinated to ensure immunity even if you have tested positive in the past.

When might HCSWMi employees have the chance to be vaccinated?

The COVID19 team is currently in touch with the Kalamazoo Health Department and have requested to be part of the initial rollout of vaccination efforts. We are waiting to hear as the plans are in

development at this time. Whether all employees or only direct client serving employees will be included is also yet to be determined however we have requested that all employees of the agency be considered for the first tier of vaccine administration due to the nature of our work and exposures. More information will be forwarded by your supervisors when it is available.

Further questions and concerns:

We as an agency have continued to provide the highest service to our patients and families and acted with great strength and dedication in a most daunting and fearful time. The care that has continued to emanate from this agency is remarkable. We will continue to attempt to be transparent and forthcoming with any information available to help you continue your efforts for our patients and families and keep yourself and your loved ones safe. If you have any questions concerning COVID19, work requirements or your personal health/work situation please seek guidance from your supervisor or the COVID19 team. Remember to not work if you have any symptoms of fever, cough congestion, or loss of taste or smell, do your daily temperature and email check in and wear appropriate PPE in all setting. Knowing and understanding the specifics of the virus and its threat gives us the greatest power over the fear and sickness it is creating, and working together keeps us all safe. WE ARE BETTER TOGETHER! BE SAFE!