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Moving Lives Forward

December 18, 2020

Dear Friends and Family,

I pray you have all been staying healthy and safe. I have a few updates to share over the past week. We have been working diligently to keep your loved ones and staff safe.

At the writing of this letter both the Assisted Living and the Nursing Home are still in an outbreak status. This being said we have many residents that are starting to come off of quarantine because they are no longer symptomatic. As of today, we have had a facility wide COVID testing by the national guard and are scheduled for another one next Thursday the 24th.

On January 6th and 27th Warde's nursing home residents and staff will have the opportunity to receive the Pfizer COVID-19 vaccine. This will be distributed during a clinic set up by Walgreen's Pharmacy on the Warde Campus. I have attach an informational packet provided by the State of NH.

As a reminder, Warde has a COVID-19 update page with key information specific to our community at <https://wardehealthcenter.org/covid-19-update/>. I would encourage you to review the updated information weekly. Information regarding facility wide testing will also be reported on this site.

We would also like to welcome Diane Brace as our new Director of Nurses for Warde Rehabilitation and Nursing Center. She comes to us with a wealth of nursing experience in both the long-term care and hospital setting. We also want to give a large thank you to Lee McCurley for her dedication to our residents. We wish her best in her future endeavors.

Thank you all for your continued support and prayers. Please do not hesitate to reach out to our director of nurses or myself, if you have any questions. Please keep us in your prayers. Wishing you all a blessed and peaceful week.

Peace,



Bret Pomeroy, NHA
Administrator

COVID-19 Vaccine Frequently Asked Questions (FAQs) for Healthcare Providers and Public Health Partners

Last Updated: December 13, 2020

Please Note: New or updated information appears in orange text

The purpose of this document is to provide public health partners and healthcare providers with frequently asked questions and answers that may be used to assist in responding to inquiries from their communities.

What is an mRNA vaccine?

The Pfizer-BioNTech and Moderna/NIH vaccines are likely to be the first vaccines available **and authorized for use** to protect people from COVID-19. These two vaccines use messenger RNA (mRNA) to create an immune response and protect a person from future infection with SARS-CoV-2 (the coronavirus which causes COVID-19).

mRNA is the genetic recipe that all organisms, including humans, use to make their proteins. These mRNA vaccines are a new approach that modify the SARS-CoV-2's mRNA so that our muscle cells can use the recipe to make a protein called the "spike protein". The spike protein is found on the surface of the SARS-CoV-2 virus and is harmless by itself. The spike protein is then seen by your immune system which in turn makes antibodies against SARS-CoV-2 to protect you from natural infection. After your muscle cells use the mRNA recipe, they **quickly** break it down and get rid of it. The mRNA vaccines do NOT contain live virus, and the mRNA never enters the nucleus of a person's cells where your DNA (genetic material) is kept, so the vaccine cannot cause any changes or damage to your DNA.

More information can be found at the CDC website about [Understanding mRNA Vaccines](#).

Is this new vaccine technology safe?

Yes, the new mRNA vaccines **are safe, and have been subject to** the same rigorous studies and regulatory **review** process as other vaccines to ensure that these vaccines are both safe and effective. Researchers have been studying and working with this type of vaccine for decades.

Haven't the COVID-19 vaccines been rushed into use?

The federal government has funded vaccine manufacturers to produce the vaccines while they were being studied for safety and efficacy (termed "Operation Warp Speed"). The vaccines' safety trials and the **authorization** process, however, is guided by science. The vaccine trials have been held to the same scientific standards as other vaccines that have been licensed for use, and the size of the vaccine studies are similar to other vaccine trials. The U.S. Food and Drug Administration (FDA) has not lowered their standards for reviewing these vaccines. First, a science advisory committee to the FDA (the Vaccine and Related Biological Products

Advisory Committee, or VRBPAC) reviews all the trial data and makes a recommendation to the FDA to **authorize the vaccine for use (i.e., Emergency Use Authorization)**. Then a medical advisory committee to the U.S. Centers for Disease Control and Prevention (the Advisory Committee on Immunization Practices, or ACIP) provides recommendations on how to safely use any **authorized** vaccine. Therefore, while we do not yet have data on the long-term protection, the vaccines have been appropriately studied to ensure they are safe and effective. **Scientists and researchers will continue to actively monitor** the vaccines for any long-term safety concerns and to better understand how long protection lasts.

What is in the new Pfizer-BioNTech vaccine?

The Pfizer-BioNTech vaccine contains the mRNA recipe for **our cells to make** the SARS-CoV-2 spike protein. The vaccine also includes the following ingredients:

- 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 dehydrate
- Sucrose

The vaccine does NOT have any chemicals used as preservatives, like thimerosal.

How is the Pfizer-BioNTech vaccine prepared and administered?

The Pfizer-BioNTech vaccine is supplied frozen between -80°C to -60°C in a multi-dose vial. **Undiluted vials can be stored in the refrigerator (2°C to 8°C) for up to 5 days (120 hours); undiluted vials may be stored at room temperature for no more than 2 hours.**

To use the vaccine, first the vaccine is thawed **from the ultra-low storage temperatures to room temperature. The vial must first reach room temperature and then be diluted within 2 hours**. Then it is diluted in its original vial with 1.8 mL of sterile **0.9% Sodium Chloride Injection, USP (use ONLY this formulation of Sodium Chloride as a diluent)**. After dilution, the vial contains 5 doses of vaccine (0.3 mL per dose) and must be stored between 2°C to 25°C and administered within 6 hours **from the time of dilution. Unused vaccine must be discarded after 6 hours and cannot be refrozen.**

The Pfizer-BioNTech vaccine is administered intramuscularly (IM) as a series of two 30 µg doses (0.3 mL each after dilution) given 21 days apart. **Both doses are necessary for full protection. If the second dose of the vaccine is given 17-21 days after the first dose, it is still considered valid (i.e., there is a 4-day “grace period”). If more than 21 days has gone by since the first dose, then the second should be given as soon as possible, but no doses need to be repeated.**

Vaccines may not be interchanged. So a person who gets their first vaccination with the Pfizer-BioNTech vaccine must get their second dose with the Pfizer-BioNTech vaccine to complete the series. Providers should refer to the FDA's [Fact Sheet for Healthcare Providers Administering Vaccine](#) for detailed guidance and information BEFORE administering any vaccine.

Can the Pfizer-BioNTech vaccine be given with other vaccines?

No. The Pfizer-BioNTech COVID-19 vaccine should be administered alone with at least 14 days of separation before or after any other vaccine is given. This is because there is no information on the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine when administered at the same time with other vaccines. However, if the Pfizer-BioNTech COVID-19 vaccine is accidentally administered within 14 days of another vaccine, there is no need for either vaccine to be repeated.

How effective is the new Pfizer-BioNTech vaccine?

7 days or longer after the second dose of vaccine, people were 95% protected against symptomatic confirmed COVID-19. Only 8 people who received the vaccine developed COVID-19 compared to 162 people who received the placebo (no vaccine) in the Phase 2/3 vaccine trial. The high vaccine efficacy was observed independent of race/ethnicity and chronic medical conditions (including obesity, diabetes, hypertension, and chronic cardiopulmonary disease). The vaccine efficacy was also high even for people older than 65 years, but the number of children younger than 16 years of age was inadequate to evaluate efficacy in the younger pediatric age population. The number of people studied who were immunocompromised (e.g., those with HIV/AIDS) was also too small to evaluate efficacy in this population.

The vaccine may also protect against developing severe COVID-19. But the number of people that got the vaccine and were subsequently infected and develop severe COVID-19 was a very small number, so it is hard to know for sure.

Is this vaccine effective in older adults?

Yes. About 21% of vaccine study participants were 65 years of age or older. Vaccine efficacy at preventing COVID-19 was estimated to be **95% in adults 65 years of age and older**, with only a single infection identified in this age group in vaccine recipients compared to **19** individuals who received the placebo.

Does the vaccine prevent asymptomatic infection transmission of COVID-19 from one person to another?

We don't yet know if the vaccine prevents asymptomatic infection or prevents transmission of SARS-CoV-2 from individuals who were vaccinated but develop infection anyway. It is possible that people who have been vaccinated can still get asymptomatic infection and spread COVID-19, but that may occur less than for people who have not been vaccinated. We need more studies about whether the vaccine prevents viral shedding and transmission, especially in people who develop asymptomatic infection.

Does the vaccine provide long-term protection and immunity?

We don't know yet how long a person's protection lasts after vaccination. The Pfizer-BioNTech vaccine study is following participants for up to 2 years after the second dose of the vaccine, **which is one way we may learn more.**

Given the limited supply of the vaccine, should we only be giving one dose to people to maximize the number of people with at least some level of protection?

No. People should get 2 doses of the Pfizer-BioNTech vaccine. The Pfizer-BioNTech vaccine study showed that after a single dose of vaccine (but before the second dose was given) the vaccine reduced the number of infections by about 52% – far less than the 95% after two doses. So there is some protection with one dose; but it is less than two doses and may not last as long. The vaccine study did not study just one dose to know for sure how effective a single dose may be.

What are the most common symptoms I might experience after receiving the vaccine?

The new Pfizer-BioNTech vaccine was studied in more than 43,000 people (including more than 21,000 people who got the vaccine and more than 21,000 people who got a placebo). At the time the vaccine study data was submitted to the FDA for consideration of an Emergency Use Authorization (EUA), about 92% of the people in the study had been followed for at least 1 month, and 51% had been followed for at least 2 months after the second dose of the vaccine to assess for adverse reactions to the vaccine.

The most common adverse reactions were:

- Localized injection site reactions (84.1%) including pain, redness, and swelling
- Systemic reactions including fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%)

Both localized and systemic reactions were more common in participants 18-55 years of age compared to people over the age of 55. Localized and systemic reactions were mostly mild-to-moderate in severity and occurred within 1 to 2 days after vaccination.

Other symptoms reported more in the vaccine group when compared to the placebo group included lymph node swelling (lymphadenopathy; reported in 64 vaccine recipients vs. 6 individuals in the placebo group), and Bell's Palsy (reported in 4 vaccine recipients vs none in the placebo group), although the rate of Bell's palsy in the vaccine group was similar to the expected background rate in the general population.

There were no specific safety concerns identified in subgroup analysis of the vaccine study data when analyzed by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. There is currently insufficient data to make conclusions about the safety of the vaccine in certain groups, such as children less than 16 years of age, pregnant and lactating women, and immunocompromised individuals.

Did people who got the vaccine have serious adverse reactions?

The frequency of serious adverse events overall was low (~0.5%) without significant differences between people who did and didn't get the vaccine. People who got the vaccine were NOT more likely to die compared to those who didn't get the vaccine (2 people died who got the vaccine compared to 4 people who did not receive the vaccine) – the 2 people who died in the vaccine group were both adults over the age of 55 who died from cardiac arrest and arteriosclerosis, and the 4 people who died in the placebo group died from myocardial infarction, hemorrhagic stroke, and unknown causes. No deaths were considered by study investigators to be related to the vaccine or placebo.

Does the Pfizer-BioNTech vaccine cause serious allergic reactions?

Any medicine or vaccine can cause an allergic reaction, including serious reactions like anaphylaxis. The rate of allergic reactions in the vaccine study was low for people that got the vaccine, although slightly higher than compared to the group that didn't receive the vaccine (0.63% of people who got the vaccine had an allergic reaction compared to 0.51% in the placebo group). Anybody who has had a serious allergic reaction, like anaphylaxis, to the vaccine or any component of the vaccine (see list of ingredients above) should NOT be vaccinated with the Pfizer-BioNTech vaccine.

There have been rare anecdotal reports of severe allergic reactions in people receiving the Pfizer-BioNTech vaccine during mass vaccination events outside of clinical trials in persons with a previous history of severe allergic reactions to injectable medications. Therefore, the CDC recommends that everybody be monitored for at least 15 minutes after vaccination, but people with a history of a severe allergic reactions (e.g., anaphylaxis) to any vaccine or injectable medicines (intramuscular, intravenous, or sub-cutaneous) should be observed for 30 minutes after being vaccinated.

Is it possible that people who get the vaccine can get more severe COVID-19 if infected later after vaccination (“vaccine-enhanced disease”)?

Available data do NOT indicate a risk of vaccine-enhanced disease. Rather, data suggests the vaccine is effective at preventing severe disease.

If I have symptoms that I think might be a vaccine reaction, do I need COVID-19 testing?

If you develop symptoms consistent with COVID-19 after receiving a COVID-19 vaccine, you should contact your healthcare provider for further evaluation and report those symptoms through CDC's “v-safe” program. V-safe is a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination.

It is certainly possible for a person to be vaccinated and then develop COVID-19 from natural infection (from an exposure either before or soon after receiving the vaccine, before it has had a chance to work). The only way to tell the difference between symptoms from a vaccine reaction from symptoms of COVID-19 is to be tested. Any localized injection site reactions (redness, pain, swelling at the site of vaccination) that resolve on their own does not need further medical evaluation nor testing for COVID-19 because such localized symptoms are not

consistent with COVID-19. However, if you develop systemic symptoms after vaccination (e.g., fatigue, headache, muscle pains, fever, chills), you should seek medical attention for evaluation and consideration for testing for COVID-19.

If a person's symptoms are the typical ones associated with the vaccine, occur within 1-2 days after vaccination, quickly resolve without medical intervention, and the person doesn't have any identified high-risk COVID-19 exposures **in the previous 14 days**, then the person may not need further testing for COVID-19 (**note: respiratory symptoms or loss of taste and smell are NOT related to a vaccine reaction**). But that person should not return to work until they are fever-free for at least 24 hours (off any fever reducing medications) and other symptoms are improving. If, however, a person's symptoms are severe, persist, or progress, then the symptomatic person should be tested for COVID-19. **Any person who has had an identified exposure to somebody with COVID-19 in the previous 14 days but still receives the vaccine and then develops symptoms of COVID-19 should be excluded from work, isolate at home, and be tested for COVID-19.**

If it is unclear whether symptoms might be related to a vaccine reaction vs. COVID-19, then providers and employers should err on the side of caution and test the symptomatic person, especially if that person works with vulnerable patients/populations or works in a congregate living setting. Antigen testing can be used in these situations to provide rapid turn-around of results and minimize duration a person is out of work. Even with a negative test, however, a person should not return to work until they are fever free for at least 24 hours (off any fever reducing medications) and other symptoms are improving.

Will the COVID-19 vaccine cause me to test positive for SARS-CoV-2 infection (by PCR or antigen testing) even if I'm not really infected?

No, the COVID-19 vaccines will not cause a person to test positive for active SARS-CoV-2 infection by either PCR or antigen tests.

If I recently received an antibody therapy as treatment for COVID-19, when can I be vaccinated?

CDC recommends that the COVID-19 vaccine should not be given for at least 90 days after a person receives antibody therapy to avoid the possibility that the antibody therapy interferes with the body's immune response to the vaccine; this recommendation is based on the half-life of antibody therapies and evidence suggesting that re-infection is uncommon within 90 days after an initial infection.

If I have previously been diagnosed with COVID-19, should I still get the vaccine?

Yes. We know that people who have been previously infected with the SARS-CoV-2 coronavirus can be infected again. Previously infected individuals may receive additional protection from receiving the vaccine. **Vaccination should not be given until a person recovers from COVID-19 (i.e., meets criteria for discontinuing isolation), but otherwise there is no minimum interval recommended between infection and vaccination.** Healthcare organizations, however, can consider prioritizing those critical front-line health workers for vaccination who have NOT had a previous infection in the prior 90 days.

Why can't I get the vaccine if I'm having symptoms of COVID-19?

Anybody who is having any new or unexplained symptoms of COVID-19, even mild upper respiratory symptoms of a cold, needs to isolate themselves at home, and seek testing for COVID-19 (and only go out for testing or necessary medical care). It is not appropriate for a person who might have COVID-19 to go into public locations and potentially expose other people to the virus, such as the COVID-19 vaccination clinic staff.

Additionally, people who are sick are typically recommended to defer any vaccination until they feel better in case the person has an adverse reaction to the vaccine, and so that symptoms can be clearly attributed to infection vs. vaccination.

Why shouldn't I get the vaccine if I don't have symptoms of COVID-19, but I'm supposed to be quarantining (from travel or exposure to another person with COVID-19)?

About 40-50% of people infected with the SARS-CoV-2 virus will be asymptomatic (infected but not showing symptoms of COVID-19), but they are still able to spread their infection to others. In order to protect the public and the vaccination clinic staff, people with a risk factor for COVID-19 who are supposed to be staying home and out of public places should not put others at risk by breaking quarantine to receive the COVID-19 vaccine (unless allowed to work under public health critical infrastructure worker guidance).

Additionally, if someone does develop symptoms of COVID-19, that person will need to be tested for COVID-19, and it is important to not confuse symptoms of COVID-19 with a potential vaccine reaction. A person, for example, with COVID-19 who thinks their symptoms are because of a vaccine reaction may go on to spread infection to others, and reduce public confidence in the vaccine.

In contrast, residents of long-term care facilities (LTCFs) or other congregate living settings experiencing outbreaks may be vaccinated. This is because the vaccine will offer protection to this vulnerable population, and the vaccination campaign can be done in a controlled way that is unlikely to result in additional exposures, as long as vaccination staff use appropriate infection prevention and control measures, including PPE recommended in outbreak settings.

Who is this vaccine recommended for?

The FDA EUA allows the Pfizer-BioNTech vaccine to be used in people 16 years of age and older who have no contraindication to vaccination.

Who is NOT able to get the vaccine?

People with a history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the Pfizer-BioNTech vaccine, or who have had a severe allergic reaction to any ingredient in the vaccine (see list of ingredients above), should NOT get the Pfizer-BioNTech vaccine.

People with severe allergies to other medicines, foods, chemicals, environmental exposures, etc. can still receive the vaccine, but, because there have been rare anecdotal reports of severe allergic reactions during mass

vaccination clinics, CDC recommends that people with a history of a severe allergic reaction to ANY vaccine or injectable medical therapy (intramuscular, intravenous, or sub-cutaneous medicines) should be observed for at least 30 minutes after vaccination (instead of the usual 15 minutes of observation).

Can pregnant or breastfeeding women be vaccinated?

Yes. Vaccine can be administered to women who are pregnant or breastfeeding as long as the woman does not have another reason that they cannot be vaccinated (see above), and they are included in the populations prioritized for vaccination. Pregnant and breastfeeding women, however, are encouraged to first discuss the risks and benefits of vaccination with their primary pregnancy provider (for pregnant women) or their infant's pediatrician.

There is no data on the safety of COVID-19 vaccines in pregnant and lactating women because the vaccines were not studied in these women. However, the mRNA vaccines are NOT live virus vaccines, and the modified viral mRNA quickly breaks down after use, so there is not a clear biological reason why a developing fetus or breastfed baby would be harmed by the vaccine. We do know, however, that pregnant women are at increased risk of severe COVID-19, and infection might increase risk of adverse pregnancy outcomes due to COVID-19. So benefits of vaccination might outweigh any hypothetical risks from the vaccine. For this reason, pregnant and lactating women should discuss with their provider and their baby's pediatrician before vaccination.

Pregnant women who are vaccinated and experience a fever after vaccination should be counseled to take acetaminophen because fever can contribute to poor pregnancy outcomes.

Routine testing for pregnancy prior to COVID-19 vaccination is not recommended.