



December 15, 2020

TO: Residents, Family Members and Care Team Members

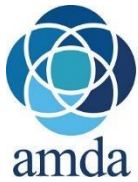
FROM: Loriman Looke, Executive Director and Administrator

As has been widely publicized, the Food and Drug Administration (FDA) has approved a COVID-19 vaccine created by Pfizer and is on the cusp of approving others for distribution to the American people. Already, the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (DHHS) are beginning to dispense the vaccines within the State of Maine.

While at present there is no federal information sheet for these vaccines, the attached packet from The Society for Post-Acute and Long-Term Care Medicine™ (AMDA) serves to address some of the most common questions. The vaccines have been reported as safe and effective (up to 95%) in numerous clinical trials. Vaccination will require two doses 21 or 28 days apart, depending on the vaccine received. Adverse effects that have been noted include fatigue, injection site pain and/or redness, muscle aches and headache.

At Quarry Hill, we are diligently preparing to receive our allotment of vaccine. Soon we will be reaching out to ask if you wish to be vaccinated and will request that you complete a Consent Form. I encourage you to review the enclosed packet and to educate yourself about the COVID-19 vaccines in anticipation of vaccination being offered in the near future.

As more detailed information becomes available, we will be in contact. Please reach out if you have questions.



Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

December 1, 2020

1. How is a vaccine developed and tested?

- Approval of a vaccine for use in people involves multiple phases with different goals for assessing effectiveness and safety in different populations. There are a total of 4 phases and the vaccine must meet very intense safety criteria before completing each phase. Once a vaccine is approved for use after phase 3, it has been tested in tens of thousands of people and if no significant harmful side effects are noted, it is considered safe for use. Phase 4 involves continued monitoring and gathering of safety data. This type of clinical trial has been used for decades to approve medications and vaccines.

2. What are the Food and Drug Administration (FDA) requirements for the safety and efficacy of a COVID-19 vaccine?

- FDA requires 50% efficacy of a COVID-19 vaccine (the COVID-19 vaccines from Pfizer and Moderna are showing 94-95% efficacy in preventing COVID-19 disease during this trial phase). Many other companies are working on a vaccine and we expect that others will be approved by the FDA.
- FDA requires 8 weeks of safety data on the COVID-19 vaccine.

3. How will we know it is safe?

- Safety is the most important requirement for the vaccine and is assessed in trials by independent experts.
- Most adverse side effects occur within 6 weeks of vaccine administration, and the FDA has required 8 weeks of safety monitoring so it can track any side effects.
- FDA advises a minimum of 3,000 participants to assess safety. The current phase 3 trials have 30,000 to 50,000 participants. This really demonstrates how safety is a top priority for the FDA and the medical community.

4. Who else will be evaluating this vaccine to ensure it is safe and effective?

- There are 2 advisory committees: (1) The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA; (2) The Advisory Committee on Immunization Practices (ACIP) that advises the CDC.
- These advisory boards are independent. Their job is to monitor vaccines to ensure safety regardless of money, politics, etc.
- The people on these committees are experts from academic institutions and they are vetted to avoid a conflict of interest. Experts who may have a conflict of interest are not put on these committees.
- The committees will evaluate the vaccine data for safety and efficacy, and also help to determine how it will be distributed.

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5. What are the types of potential vaccines that may be approved?

- Messenger RNA (mRNA) vaccines are a new type of vaccine undergoing clinical trials (see *question #6 below for more information on this*). There are also other types vaccines being studied that are similar to vaccines we have used for other diseases. **None of these can give you COVID-19!** The goal is to give your body the tools it needs to fight COVID-19 effectively and/or prevent you from getting it at all.
- Also, **none of the proposed vaccines contain live or killed viral particles**, even though some other effective vaccines for other diseases have (see *question #6 below for more information on how these new vaccines work*).
- Most of the vaccines that are currently being tested will require 2 doses to be effective, given about 3-4 weeks apart.
- This is to make sure your body has enough antibodies to fight COVID-19. Getting 2 doses within 3-4 weeks has been shown to be safe and there are other vaccines we have been using for years that require multiple doses without causing harm.

6. How does an mRNA vaccine work?

- According to the Centers for Disease Control (CDC) website, mRNA vaccines contain material from the SARS-CoV-2 virus that causes COVID-19. This material gives our cells instructions for how to make a harmless protein that is unique to the virus. This protein cannot build a virus or cause infection. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build antibodies that will remember how to fight the virus that causes COVID-19 if we are infected in the future.
- While mRNA technology is new in vaccine development, this technology is being successfully used in cancer treatments.
- For more information, visit the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/how-they-work.html>

7. What is an Emergency Use Authorization (EUA) and if the vaccine is approved for an EUA, what does that mean?

- An EUA is based on the need to use a vaccine quickly to save lives during an urgent health crisis.
- You may be anxious about the speed with which a vaccine has been approved. While the EUA is a shorter process, no steps are skipped in the safety evaluation process.
- This approval can still take weeks and the FDA will re-evaluate the numbers and data to ensure that the calculations are correct.
- The FDA will assess if the vaccine's known and potential benefits outweigh the known and potential risks.
- Both advisory boards (VRBPAC and ACIP) will also review all the data and information.

8. How long will the vaccine protect us?

- It is likely that we will not know the answer to that question when a vaccine is released. That will take more research.

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- This vaccine may be like the annual flu vaccine, where we may need to have vaccine shots for COVID-19 on a regular basis. More research is needed to know this and it also depends on whether and how much the virus changes over the coming months to years.

9. When will we be protected after we get the vaccine?

- Even when people receive the vaccine they will not be immediately protected and will need to continue wearing masks, social distancing and practicing frequent hand hygiene.
- Some vaccines will require 2 shots, with a few weeks between each shot, and protection will usually occur about 2 weeks after the second shot.
- While no vaccine is 100% effective, some of the vaccines proposed are anticipated to be more than 90% effective. This will greatly reduce your risk of getting sick with COVID-19 and spreading COVID-19 to your loved ones.

10. After I have had the second dose of the vaccine and it is 2 weeks after my second shot, do I still have to wear a mask?

- Yes. Even though you have received your vaccine, most of the people around you have not. We know the vaccine prevents disease in the vaccinated person, but it still may be possible to transmit the disease to others, until the vaccine is in widespread use.
- Wearing a mask, social distancing, and practicing hand hygiene protects those who have not been vaccinated, especially our residents in long-term care.

11. What if I had COVID-19 or I took a test that showed I have antibodies? Should I get the vaccine?

- Yes, even if you have had COVID-19, it is safe to get the vaccine and this can add additional protection without causing any harm.
- If you have had a test that shows you have COVID-19 antibodies, you should still get the vaccine. It is safe and can increase your protection from future COVID-19 infections.

12. What are some of the possible side effects of the COVID-19 vaccine? Will the vaccine make me sick?

- The vaccines currently being tested in clinical trials can cause short-term discomfort (such as headache, muscle pains, fatigue, chills, fever, and pain at injection site) in a percentage of the people who receive them. This is the effect of your body developing immunity. Clinical trial participants reported that the discomfort went away after a day, sometimes sooner. When you receive the second dose of the vaccine, the discomfort can be more pronounced. This is a normal reaction, so be prepared.
- If you experience discomfort after the first dose of the vaccine, it is very important that you still receive the second dose a few weeks later for the vaccine to be effective.
- **This does not mean that the vaccine has given you COVID-19.** Rather, this means that the vaccine is causing your body's immune system to react and create antibodies to fight off the virus. **In other words, if you feel some discomfort, then the vaccine is doing its job!**
- In some cases, a person may **already** be infected with COVID-19 when they get the vaccine but are asymptomatic or pre-symptomatic. If they later have symptoms of COVID-19 or test positive for it, it **does not** mean they got COVID-19 from the vaccine.

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13. We should expect that vaccine recommendations will change as additional vaccines are approved.

- At first, we may have one vaccine, then hopefully two or three. As different vaccines become available, some may be found to be better for different populations and different circumstances.
- Just like our knowledge about the virus itself changes over time, so will the recommendations about vaccines.

14. What can I be doing now while we wait for a vaccine to be approved and distributed?

- It is important to know about the process of how a vaccine is approved so you can ask questions.
- Listen to the VRBPAC and ACIP committees' discussions as they are all public. Check the websites for updates:
 - VRBPAC meetings: <https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2020-meeting-materials-vaccines-and-related-biological-products-advisory-committee>
 - Here's a link to the recorded meeting from October 22, 2020: <https://www.youtube.com/watch?v=iXTiLgrUpkg>
 - ACIP meetings: <https://www.cdc.gov/vaccines/acip/meetings/index.html>
- **Ask your medical director or provider about the vaccine** and have them share information and answer questions. You can talk to them about how they are planning to make their decision to get the COVID-19 vaccine.
- It will be important to get your information from reliable sources, such as the CDC (www.cdc.gov), the Immunization Action Coalition (<https://www.immunize.org>), your facility's medical director, and other providers so you can get accurate information. **Social media is full of misinformation and opinions based on that misinformation, so be careful to look to reputable sources (such as those affiliated with academic institutions or non-profit professional organizations like AMDA) for information.**
- Look for specific data on potential COVID-19 vaccines and listen to/read the scientists' evaluations of the data.

15. Is the flu vaccine also safe and effective?

- **Yes!** The flu vaccine is a good example of how vaccines can help prevent disease and be safe.
- It is more important this year than ever to get your flu shot so you can decrease your risk of getting the flu (you can get both the flu and COVID-19 at the same time), and reduce the spread of flu to others. This will also decrease the burden on healthcare staff who are caring for those with COVID-19.

16. Who will be able to get the vaccine in a nursing home?

- CDC is recommending that nursing home residents and staff be among the first to get the vaccine. Long-term care staff will often be able to get vaccinated before the residents to decrease the risk of exposing the residents to COVID-19. Long-term care staff will include anyone who works in a nursing home, such as those who work in environmental services, not just those who perform direct patient care. This also includes staff who visit the nursing home, including doctors, physician assistants, nurse practitioners, medical directors, lab technicians and consultants.

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Now is the time to understand the process, ask questions and get accurate information!

Additional Resources from the CDC:

CDC: About COVID-19 vaccines. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines.html>

CDC: Provider Resources for COVID-19 Vaccine Conversations with Patients and Answering Patients' Questions. <https://www.cdc.gov/vaccines/hcp/covid-conversations/>
<https://www.cdc.gov/vaccines/hcp/covid-conversations/answering-questions.html>

CDC: Understanding the Pharmacy Partnership for Long-Term Care Program and Frequently Asked Questions. <https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html>
<https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-faqs.html>

CDPH: COVID-19 Vaccine Planning Questions and Answers.

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-19-Vaccine-Planning-Questions-and-Answers.aspx>



Approved by the AMDA Executive Committee
December 1, 2020