



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

January 12, 2021

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 have shown 94-95% efficacy in preventing COVID-19 disease). Many other companies are working on vaccines 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 do we know the vaccine 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 phase 3 trials for the Pfizer and Moderna vaccines had 30,000 to 44,000 participants. This really demonstrates how safety is a top priority for the FDA and the medical community.

4. Who else evaluated 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 conflicts of interest are not put on these committees.
- The committees evaluate the vaccine data for safety and efficacy, and also help to determine how it will be distributed.

5. What are the types of vaccines that have been or may still be approved?

- Messenger RNA (mRNA) vaccines are a new type of vaccine. Both the Pfizer and Moderna vaccines that have been approved are mRNA vaccines (*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

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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.

- The vaccines that are currently being distributed 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 some of the genetic material from the SARS-CoV-2 virus that 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?

- EUA is based on the need to use a vaccine quickly to save lives during an urgent health crisis.
- EUA is a shorter process **but no steps are skipped in the safety evaluation process.**
- This approval can still take weeks and the FDA re-evaluates the numbers and data to ensure that the calculations are correct.
- The FDA assesses if the vaccine's known and potential benefits outweigh the known and potential risks.
- Both advisory boards (VRBPAC and ACIP) also review all the data and information.

8. How long will the vaccine protect us?

- We do not yet know the answer to that question. This will take more research.
- 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 how much the virus changes over time.

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

- Even when people receive the vaccine they are not immediately protected and will need to continue wearing masks, social distancing and practicing frequent hand hygiene.
- Current vaccines require 2 shots, with a few weeks between each shot, and protection usually occurs about 2 weeks after the second shot.
- While no vaccine is 100% effective, the current vaccines 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.

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- 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 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 and others who have received the vaccine report that the discomfort went away after 1-2 days, 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.

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

- 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 I wait for my turn to get the vaccine?

- It is important to know about the process of how a vaccine is approved so you can ask questions.
- If you still have questions about the approval process for the vaccines, 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 made their decision to get the COVID-19 vaccine.

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- It is vital 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 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?

- Residents and staff in nursing homes are among the first to get the vaccine. It is important that long-term care staff vaccinated to decrease the risk of spreading COVID-19 to their coworkers and residents. Long-term care staff 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.

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>