# What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine

***Notes from Clinical Partner Call, Sunday, December 13th, 2020 for LeadingAge members***

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**Of note to LeadingAge members:**

1. Clinical guidance is coming shortly.
2. Communications toolkit for long-term care facilities can be found here.
3. What about informed consent? There is no informed consent required under the EUA. We strongly recommend everyone document receipt of vaccine fact sheet in each patient's records. There will be informed consent like materials in LTC facility toolkit that we anticipate will be available in the coming week, that providers can use and adapt, and to document that residents did consent to receiving the vaccine.
4. Infection prevention and control recommendations for persons with post vaccination symptoms are now available here.
5. FDA is developing an algorithm for the triage of persons presenting for the vaccine. This will be posted shortly. Contraindications do not include people with allergies to environmental allergens, oral medications, or family history or anaphylaxis. Those people can proceed with vaccination. Additional details are summarized below.

**Basics of the Vaccine: Pfizer COVID-19 Vaccine received EUA on December 13th for those 16 and older.**

1. What is an mRNA vaccine? mRNA takes advantage of the process that cells use to make proteins to trigger an immune response. More at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html
2. Rigorously tested, phases 1, 2 and 3.
3. First vaccine to use this technology, but technology has been studied for over a decade.
4. The vaccine does not contain a live virus, making it safer to produce and administer.
5. mRNA from the vaccine does not enter the cell.

**Overview of ACIP Recommendations -** ACIP Recommends that when a vaccine is authorized by FDA and recommended by ACIP, health care personnel, residents of long term care facilities be offered vaccination in the initial phase of the COVID-19 vaccine.

**Administration**

1. 2-doses administered three weeks apart
2. 4-day grace period, 17-21 days, considered valid
3. If more than 21 days, should be given as soon as possible.
4. Efficacy of a single dose has not been evaluated
5. Not interchangeable with other vaccine products. Safety of a mixed product series has not been evaluated.
6. If two doses of different vaccine are administered inadvertently, no additional doses of either product are recommended at this time.
7. Vaccine should be administered alone with a minimum interval of 14 days before or after the administration of other vaccines

**Vaccination of special populations:**

1. **Persons with underlying medical conditions:** Vaccine may be administered to those with underlying medical conditions who have no contraindications to vaccination, including those with increased risk of COVID-19.
2. **Persons with HIV infection, or other immunosuppression medications** might be at increased risk for COVID-19. They may still receive COVID vaccine, but should be counseled about the unknown risk profile of the vaccine.
3. **Pregnant women*** – No data on safety. Animal studies underway. Studies in human are ongoing and planned. mRNA do not enter the nucleus of the cell. If a women is part of a group who is recommended to be vaccinated, she can choose to be vaccinated. Pregnant women and providers should consider the level of community transmission, the risks to her and potential risks to the fetus, the efficacy of the vaccine, the known side effects of the vaccine, the lack of data about the vaccine during pregnancy. Routine pregnancy testing is not recommended prior to administering the vaccine.
4. **Breastfeeding women*** - No data on the safety of COVID Vaccines in lactating women or the effects on the breastfed infant. If a woman is breastfeeding and in a group recommended to be vaccinated, she may choose to be vaccinated.
   **Current guidance for pregnant and breastfeeding women agreed on in partnership with American College of OB and American Academy of Pediatrics. Theoretically there is not a risk, and so we recommend that pregnant women be given the option.*

**Patient Vaccine Counseling**

1. Before, providers should counsel on local and systemic post vaccination symptoms.
2. Unless a person develops a contraindication, they should be encouraged to complete the vaccine series
3. Antipyretic or analgesic medications may be taken for post vaccine symptoms.
4. Two doses are required to receive high efficacy.
5. Public Health recommendations for vaccinated persons. 1-2 weeks following the second dose before the person is considered vaccinated.
6. No vaccine is 100% effective

7. Given current limited data, vaccinated persons should continue to follow all COVID-19 guidance

**Precautions -** Severe allergic reaction to any component of the vaccine is a contraindication to the vaccine. Appropriate medical treatment used to manage allergic reactions must be immediately available in the event.

**Required observation times:**

- 30 minutes - those with a history of an allergic reaction to a vaccine or injectable
- 15 minutes – all others

**Questions and Answers:**

1. **Will receiving the vaccine change someone's PCR or POC test results?** Prior receipt of the vaccine will not affect results of the PCR or POC tests. Antibody tests could be affected, positive test could indicate either vaccination or prior infection.
2. **Should someone who previously had COVID infection be vaccinated?** Yes. Vaccine should be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19. Data from phase 2-3 clinical trials suggest it is still efficacious
3. **Should someone who has a current COVID infection be vaccinated?** Vaccination should be deferred until recovery from acute illness. No minimal interval between infection and vaccination. Persons with documented acute infection in the preceding 90 days may defer vaccination until the end of the 90-day period if desired.
4. **Should someone who received plasma or monoclonal antibody treatment receive the vaccine?** There is no data on safety or efficacy in combo with other treatments. Vaccination should be deferred to at least 90 days after the treatment to avoid potential interference.
5. **Should those with a known exposure to COVID-19 be vaccinated?** People in the general community who have a known COVID-19 exposure should not seek vaccine until quarantine has ended to protect healthcare personnel. For LTC and other healthcare personnel, and residents of LTC with a known COVID exposure, vaccine may be given before quarantine period is up. Employ appropriate safety protocols. Those in other congregate settings – correctional or homeless, vaccine can be administered to those who have been exposed.
6. **Should those with a history of extreme anaphylaxis to non-medications be vaccinated?** Yes, we do not have any contraindications or precautions that are not related to a vaccine or an injectable. Latex, pollen, animals, a food, etc. Where we have cautions is those who have had anaphylaxis to any vaccine or injectable. This means that we want those people to have a discussion with the provider, and to understand what may have happened, and understand what the reaction was really caused by, was it a severe allergic reaction, etc. They can still get the vaccine but should be counseled on the unknown risks of the vaccine. Recommend 30 minutes observation period for those with a previous reaction to a vaccine or injectable.

7. **What if someone had a previous anaphylaxis to an ingredient of the COVID-19 vaccine? Can they get the vaccine?** They should NOT be given the vaccine. A potential source of allergic reaction is the ingredient poly ethaline glycol (PEG). This ingredient is in some other injectable medications. We are being abundantly cautious about this question. We do not want people who have mild allergic reactions to be concerned about being vaccinated. The two individuals who experienced anaphylaxis after the COVID-19 vaccine had both experienced severe anaphylaxis to a vaccine in the past. There were no cases of anaphylaxis in the clinical trial.
8. **Does this vaccine protect against transmission?** This vaccine was evaluated to see if it protected individuals from the virus itself. It does not provide information about transmission of the virus to others. This is the reason we will continue to have guidance, washing hands, social distancing, even after vaccination. We will also continue with some guidance for quarantine even for those who are vaccinated. We do know this vaccine is very good at keeping you from getting the virus. Over the next several weeks we will evaluate transmission. The company has said during the FDA advisory board meeting that they would be doing this type of study. This involves taking vaccinated persons and doing nasal swabs regularly. We expect to know more in the coming weeks and months. Guidance will change as needed when we have more information.
9. **How do you recommend increasing vaccine confidence in healthcare workers?** We appreciate this question. We know that there is a lot of hesitancy around this vaccine. That is part of the reason we are here today, to explain how these vaccines work, and how we are monitoring safety. Healthcare providers are one of the key ways we can increase vaccine confidence. If we can get all staff vaccinated, we will have people who can talk about it with confidence and increase confidence for the entire population.
10. **What about informed consent?** We strongly recommend everyone document receipt of vaccine fact sheet in their patient records. We will have informed consent like materials in LTC facility toolkit that we anticipate will be available next week, that providers can use and adapt, and to document that residents do consent to the vaccine.

**After getting vaccinated or giving the vaccine are there any requirements for follow up?**
The requirements under the EUA:

1. All patients receive the patient FAQ sheet that Pfizer has available online
2. All patients are provided a vaccine shot card
3. All vaccinations given are reported to the vaccine registry. Knowing which product someone received is critical so we can ensure they get the same product in their second dose.
4. If a patient has an adverse event it is required to report to the vaccine adverse event reporting system.