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| <b>DATE:</b>           | 1/6/2021   |
| <b>TO:</b>             | Health Alert Network                                       |
| <b>FROM:</b>           | Rachel Levine, MD, Secretary of Health                     |
| <b>SUBJECT:</b>        | <b>COVID Vaccination Indications and Contraindications</b> |
| <b>DISTRIBUTION:</b>   | Statewide  |
| <b>LOCATION:</b>       | n/a  |
| <b>STREET ADDRESS:</b> | n/a  |
| <b>COUNTY:</b>         | n/a  |
| <b>MUNICIPALITY:</b>   | n/a  |
| <b>ZIP CODE:</b>       | n/a  |

**This transmission is a Health Advisory: Provides important information for a specific incident or situation; may require immediate action.**

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING, PATIENT SAFETY OFFICER, AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health is providing guidance for providers on COVID-19 vaccination. The information in this HAN should be used to supplement other relevant guidance documents and guide the implementation of public health expectations for vaccine providers.

Key messages included in the guidance:

- There are two mRNA vaccines with 90-95% efficacy in preventing clinical COVID-19 currently available through an Emergency Use Authorization (EUA) by the FDA in the United States.
- The only absolute contraindication to COVID-19 vaccination is history of an immediate allergic reaction to either COVID-19 vaccine or any of their components.
- Severe adverse reactions are uncommon, but vaccine providers should be prepared for this rare event.
- Vaccine providers should report all adverse events following vaccination to [Vaccine Adverse Event Recording System \(VAERS\)](#).
- All COVID-19 mitigation measures should continue to be followed after vaccination.

## 1. The COVID-19 Vaccine:

The goal of the COVID-19 vaccine program is to have every willing, eligible individual in the United States vaccinated against COVID-19 as safely and quickly as possible. There are currently two COVID-19 vaccines approved by the FDA through Emergency Use Authorization (EUA) and recommended by the federal Advisory Committee on Immunization Practices (ACIP). Both vaccines went through thorough safety and efficacy trials. They are both mRNA vaccines administered

intramuscularly in a 2-dose series and have been proven to have a 90-95% efficacy in preventing clinical disease 2 weeks after the 2<sup>nd</sup> dose is given.

**Pfizer-BioNTech vaccine:**

- Indicated for individuals 16 years old and older
- Given as a 0.3mL intramuscular injection
- Minimum of 21 days in between doses

**Moderna vaccine:**

- Indicated for individuals 18 years old and older
- Given as a 0.5ml intramuscular injection
- Minimum of 28 days in between doses

More information about the COVID-19 vaccines can be found at [www.cdc.gov](http://www.cdc.gov) under [COVID-19 vaccines](#)

Due to the initial limited supply of the vaccine, ACIP has recommended that available vaccine be allocated through a [tiered system](#).

**2. Special populations and administration of the COVID-19 Vaccine:**

The COVID-19 vaccine is a safe and efficacious vaccine. There are a few [special circumstances](#) in which the provider should discuss vaccination with the patient prior to proceeding with vaccination. In most of these situations it is safe to proceed with vaccination but there may be a delay in vaccination or a longer observation period post vaccination as outlined in the table below. If an individual has received any other vaccine within 14 days, delay COVID-19 vaccination until at least 14 days have passed since the other vaccine was administered. **The only absolute contraindication to COVID-19 vaccine is a prior immediate allergic reaction to either of the 2 COVID-19 vaccines or their components.** The table below addresses medical conditions and whether those patients should proceed with vaccination.

|            | MAY PROCEED WITH VACCINATION  | PRECAUTION TO VACCINATION  | CONTRAINDICATION TO VACCINATION  |
|------------|---|--|--|
| CONDITIONS | <p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>Immunocompromising conditions</li> <li>Pregnancy</li> <li>Lactation</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Additional information provided*</li> <li>15 minute observation period</li> </ul>   | <p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>Moderate/severe acute illness</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Potential deferral of vaccination</li> <li>15-minute observation period if vaccinated</li> </ul>  | <p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>None</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>  |
| ALLERGIES  | <p><b>ALLERGIES</b></p> <p>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine<sup>†</sup>, other vaccines, injectable therapies, or polysorbate, such as:</p> <ul style="list-style-type: none"> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>30-minute observation period: Persons with a history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: All other persons</li> </ul> | <p><b>ALLERGIES</b></p> <ul style="list-style-type: none"> <li>History of any immediate allergic reaction<sup>‡</sup> to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines<sup>†</sup> or polysorbate, as these are contraindicated)</li> </ul> <p><b>ACTIONS:</b></p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Consider deferral of vaccination and/or referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul> | <p><b>ALLERGIES</b></p> <p>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines<sup>‡</sup>:</p> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components</li> <li>Immediate allergic reaction<sup>‡</sup> of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components<sup>^</sup> (including polyethylene glycol)<sup>#</sup></li> <li>Immediate allergic reaction of any severity to polysorbate<sup>^#</sup></li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Do not vaccinate<sup>#</sup></li> <li>Consider referral to allergist-immunologist</li> </ul> |

\* See Special Populations section for information on patient counseling in these groups

<sup>†</sup> Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

<sup>‡</sup> Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

<sup>^</sup> See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

<sup>#</sup> These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

Table above and additional information on COVID-19 vaccination and testing including Tuberculosis testing can be found at the following link: COVID-19 [Vaccine Information](#)

### **Vaccinating patients who have been exposed to or have had COVID-19.**

COVID-19 vaccination is recommended for people who have been exposed to or who have had COVID-19, especially those that have underlying medical conditions and/or those living or working in congregate care settings. However, vaccination may be delayed due to maintaining quarantine/isolation and/or vaccine availability.

- *Current or Previous COVID-19 infection:* No serologic screening is recommended prior to vaccination. In cases where previous COVID-19 is documented, it is reasonable but not required, to delay vaccination until 90 days have passed since the initial infection. This is based on the low risk of re-infection to these individuals during this 90-day time frame. In addition, during vaccine shortages, delaying vaccination in these individuals would allow earlier administration of vaccine to nonimmune individuals. While individual who were positive in the last 90 days can defer vaccination, those with underlying medical conditions or who reside in a congregate care facility are encouraged to get vaccine when offered/available.
- *Previous COVID-19 treatment with monoclonal antibodies or convalescent plasma therapy:* Vaccination should be deferred for at least 90 days post treatment as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune response.
- *Known exposure to COVID-19:* These individuals are encouraged to wait until after completion of their quarantine period in order to minimize exposures to health care personnel.
- *Strongly suspected COVID-19 or pending COVID-19 testing results:* These individuals are encouraged to wait until after completion of their isolation/quarantine period in order to minimize exposures to health care personnel. If positive for COVID-19, consideration for 90-day delay before vaccination also applies to this group.

### **3. Vaccine adverse events and monitoring:**

Mild to moderate reactions post vaccination occur within 3 days of vaccination and will typically resolve within 1-3 days of onset. Severe reaction such as anaphylaxis are rare but providers should be prepared for post vaccination anaphylactic reactions.

- Common adverse reactions of both vaccines:
  - Local reactions: pain, erythema, swelling at the injection site
  - Systemic reactions: fatigue, headache, arthralgia, myalgia, chills, fever, diarrhea, nausea, lymphadenopathy
- When medically appropriate, antipyretics or analgesic medications, such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), may be taken for post-vaccination local or systemic symptoms. However, these medications are not recommended for routine prophylactic use.
- Anaphylaxis after vaccination is rare but it is recommended that all vaccination providers have supplies immediately available to address acute anaphylactic reactions. In order to appropriately monitor and attend to any allergic reaction to the vaccine, all vaccine providers should have the following supplies available to assess and treat anaphylaxis: epinephrine, H1 antihistamine, blood pressure cuff, stethoscope, and a timing device to assess pulse.
- Reporting of adverse events:
  - All vaccine providers must report adverse reactions through the [VAERS reporting system](#)
  - All vaccine recipients are encouraged to download and report on the [V-safe app](#) which was developed by the CDC to monitor COVID-19 vaccine adverse events.

### **4. Post-vaccination guidance:**

Early COVID-19 vaccine studies analysis have shown up to 90–95% efficacy in preventing symptomatic COVID-19. Thus far, we still do not yet have sufficient efficacy data to support prevention of all COVID infections. At this time, it is recommended that mitigation measures, isolation, quarantine, and contact tracing continue until further data is available

- **All COVID-19 mitigation measures should continue:**
  - Always wear a mask over the nose and mouth when in public
  - Stay at least 6 ft from others when in public
  - Wash and sanitize hands frequently
  - Avoid large crowds/gatherings
- **All isolation, quarantine and contact tracing recommendations should continue for all individuals even after vaccination.**

**If you have questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1- 877-724-3258) or your local health department.**

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of January 6, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.