

## Standing Order for Administering Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine BNT162b2)

**Purpose:** To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) Emergency Use Authorization, and the Department of Defense (DoD).

**Policy:** Under these standing orders, eligible nurses and other healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

**Procedure:**

1. For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older
2. Screen all patients for contraindications and precautions to the COVID-19 vaccine:

**Contraindications:**

- A history of a serious reaction (e.g., anaphylaxis) after vaccination or to a vaccine component (see product fact sheet for complete list of excipients)

**Precautions:**

- Moderate or severe acute illness with or without fever
  - Pregnancy: There are no or limited amount of data from the use of Pfizer-BioNTech COVID-19 vaccine in pregnant women. Animal reproductive toxicity studies have not been completed. Pregnant women desiring the Pfizer-BioNTech COVID-19 vaccine should consider discussing the risks and benefits of such vaccination with their obstetrics provider to include participation in a pregnancy registry should the patient choose to receive the vaccine.
  - Breastfeeding: Patients should be counseled that these vaccines have not been evaluated in breastfeeding women. Counseling may include noting that CDC/ACIP does not require breastfeeding-specific data to consider other vaccines safe in breastfeeding. In general, the benefits of vaccinating nursing women usually outweigh potential risks. However, a risk to the newborns/infants cannot be excluded.
  - Allergies: Persons with a history of severe allergic reaction (e.g. anaphylaxis) to an injectable medication should use caution when receiving the vaccine and follow a 30-minute observation period if vaccinated with the Pfizer-BioNTech COVID-19 vaccine.
  - COVID-19 Vaccine Clinical Trial Participants: anyone who reports they are in a clinical trial for a COVID-19 vaccine candidate needs to confer with their trial POCs before proceeding with vaccination with Pfizer-BioNTech COVID-19 vaccine.
  - Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g. 15 minute observation after administration) and to restore cerebral perfusion following syncope
  - For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245
3. Provide all patients (or their parent/legal representative) with a copy of the Emergency Use Authorization (EUA) fact sheet for recipients and caregivers. Provide non-English speaking patients with a copy in their native language, if available and preferred.

4. Provide vaccine as follows:

- The Pfizer-BioNTech COVID-19 vaccine is a 2-dose series spaced at least 21 days apart
- Administer 0.3mL of appropriately diluted vaccine intramuscularly in the deltoid muscle.
- The multidose vial may be stored frozen at -80°C and must thaw prior to dilution
- Frozen vials should be transferred to 2°C-8°C to thaw; alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 25 °C for immediate use.
- Once thawed, the undiluted vaccine can be stored for up to 5 days at 2°C-8°C and up to 2 hours at 25°C.
- Diluted vaccine must be used within 6 hours from the time of dilution and stored between 2°C and 25°C.
- Dilute the multidose vials according to the following directions:
  - Allow the thawed vial to come to room temperature and gently invert 10 times prior to dilution; do not shake.
  - The thawed vaccine must be diluted in its original vial with 1.8 mL of preservative-free sodium chloride (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic technique.
  - Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
  - Gently invert the diluted solution 10 times; do not shake.
  - The diluted vials should be marked with the dilution date and time and stored between 2°C to 25°C.
- After dilution, the vial contains 5 doses of 0.3 mL. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle and a 1mL syringe and discard any unused vaccine within 6 hours after dilution.

<b>Needle Length and Injection Site of IM Injections for Adults</b>		
Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient’s age and body mass.		
<b>Age Group</b>	<b>Needle Length</b>	<b>Injection Site</b>
Men and Women (<130 lbs)	1 inch <sup>†</sup>	Deltoid Muscle of Arm
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)	1-1.5 inches	
Women (152-200 lbs)		
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)		

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration

<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>

<sup>†</sup> Some experts recommend a 5/8 inch needle for men and women who weigh <130 lbs, skin must be stretched tightly (do not bunch subcutaneous tissue)

5. Provide all patients with the one-page enrollment sheet for V-safe at the time of vaccination and strongly encourage the patient to enroll in this program. V-Safe is a smart-phone based tool that uses text messaging and web surveys to provide personalized health check-ins after a patient receives a COVID-19 vaccination. It also reminds the patient of the second dose timing.

6. Observe a minimum interval of 21 days between the 1<sup>st</sup> and 2<sup>nd</sup> dose. DO NOT compress the minimum interval between doses. Do not restart the primary series for any reason; resume the series with administration of the next dose. COVID-19 vaccines are NOT interchangeable. Complete the series with the same product.
7. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt. The CVX code for Pfizer-BioNTech COVID-19 vaccine is 208.
8. Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine as required by the FDA EUA Fact Sheet for Healthcare Providers.
9. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.
10. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at <https://vaers.hhs.gov>
11. This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

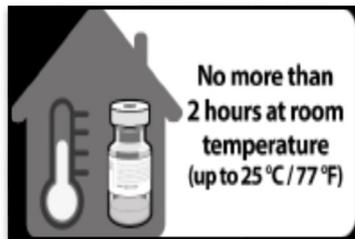
\_\_\_\_\_  
Medical Director's Signature

\_\_\_\_\_  
Date

# Pfizer - BioNTech COVID-19 Vaccine Preparation and Administration

## THAWING PRIOR TO DILUTION

- Thaw vial(s) of Pfizer-BioNTech COVID-19 vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator 2° C - 8° C
  - A carton of vials may take up to 3 hours to thaw and thawed vials can be stored in refrigerator for up to **5 days (120 hours)**
  - Allowing vial(s) to sit at room temperature (up to 25° C (77°F) for **30 minutes**
  - Using either thawed method, vials must reach room temperature before dilution within **2 hours**



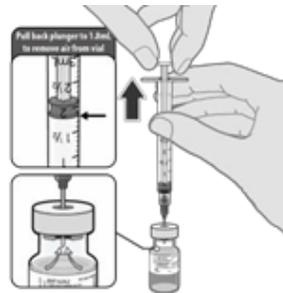
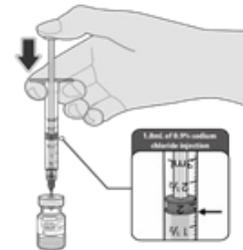
- Before dilution invert vaccine vial gently **10 times**
- **Do not shake**
- Inspect liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles
- Do not use if liquid is discolored or if other particles are observed



## DILUTING THE VACCINE



- Obtain sterile 0.9% Sodium Chloride Injection, USP; Use only this as the diluent
- Using aseptic technique, withdraw **1.8 mL** of diluent into the transfer syringe (21G or narrower needle)
- Cleanse vaccine vial stopper with the single use antiseptic swab
- Add **1.8 mL** of 0.9% Sodium Chloride Injection, USP into the vaccine vial



- Equalize vial pressure before removing the needle from the vial by withdrawing **1.8 mL** air into the empty diluent syringe



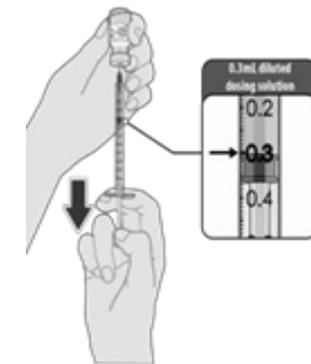
- Gently invert the vial containing the vaccine **10 times** to mix
- **Do not shake**
- Inspect vaccine in the vial
- The vaccine will be an off-white suspension.
- Do not use if vaccine is discolored or contains particulate matter

## PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER BioNTech COVID-19 VACCINE

- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label
- Store between 2° to 25° C (35° F-77° F)
- Discard any unused vaccine **6 hours** after dilution



- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab, and withdraw **0.3 mL** of the Pfizer-BioNTech COVID-19 Vaccine
- Administer immediately



- A single **30 mcg/0.3 mL** dose followed by a second dose **21 days** later

