CLINICAL PROCEDURE
EMS COVID19 VACCINE ADMINISTRATION
PFIZER mRNA BNT162b2

Indication	Dose Regimen
FDA Emergency Use Authorization for active immunization of individuals 16 years of age and older to prevent COVID-19 caused by SARS-CoV-2 virus	2 DOSES ONE MONTH APART Must both be Pfizer Give second dose day 17 to 25 (or as soon as possible after day 25)

Contraindications – Mission Specific

- Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of the Pfizer COVID-19 vaccine
- Age less than 16 years old
- Current Illness (infection)
- Received any type of vaccination in the last 14 days
- Any of the following symptoms in the last 10 days:
  - Fever (>100.4F)
  - Chills
  - Cough
  - Shortness of Breath
  - Difficulty Breathing
  - Fatigue
  - Muscle or Body Aches
  - Headache
  - Diarrhea
  - Sort Throat
  - Congestion or Runny Nose
  - Nausea
  - Vomiting
  - New Altered Sense of Taste or Smell

Cautions

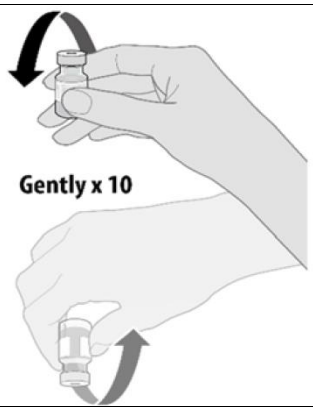
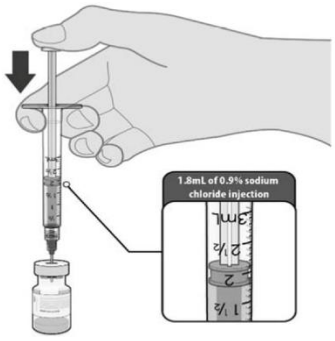
- History of severe allergies or reactions to any medications, foods, vaccines, or latex → Monitor closely after administration (minimum 30 minutes)
- Immunocompromised or on a medication that affects the immune system → Inform patient vaccine might not provide as strong an immune protection
- Bleeding disorder or taking blood thinners → Risk of hematoma at injection site
- Currently pregnant, breastfeeding or chance of becoming pregnant → Advise patient that there is limited safety data in this population but give vaccine if patient desires
- Received first dose of another COVID-19 Vaccine → Ensure same manufacturer as previous dose
- Had any COVID-19 Antibody therapy within the last 90 days (e.g. Regeneron, Bamlanivimab, COVID Convalescent Plasma, etc.) → Delay vaccine till 90 days have passed

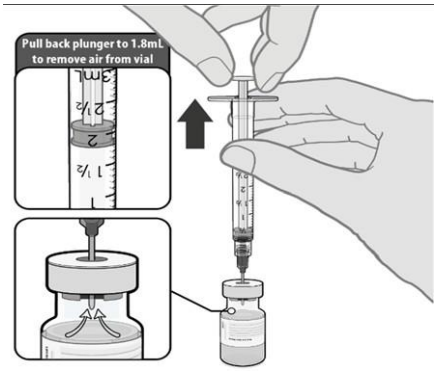
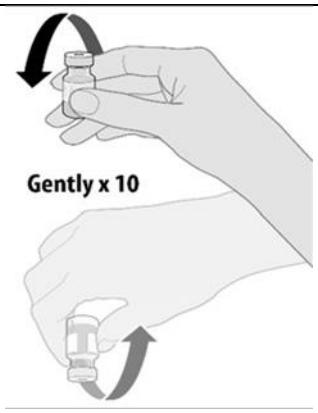
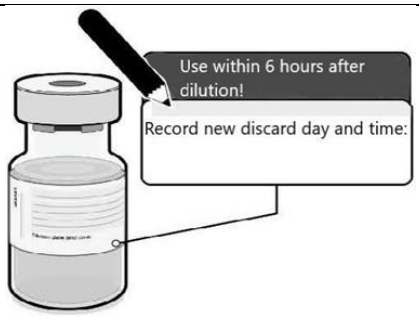
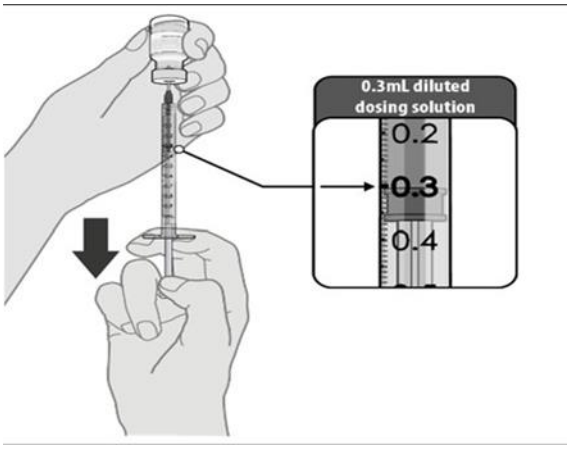
Procedure

- Prepare patient and supplies:
  - Ensure appropriate monitoring equipment and treatment supplies are available to manage any adverse reactions (e.g. Anaphylaxis)

- Ensure correct patient identification
- Verify "Covid-19 Screening and Consent Form" has been completed
- Ensure "Notice of Privacy Practices" and "EUA Fact Sheet for Recipients and Caregivers" have been provided
- Re-confirm patient meets indications and has no contraindications

- <u>Thaw and prepare dose (if not already done):</u>

Frozen vials should be transferred to 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours 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 to 8 °C, and up to 2 hours at temperatures up to 25 °C.	
Allow the thawed vial to come to room temperature and gently invert 10 times prior to dilution. DO NOT SHAKE Prior to dilution the vaccine should present as an off-white solution with no particulates visible Discard the vaccine if particulates or discoloration are present	
The thawed vaccine must be diluted in its original vial with 1.8 mL 0.9% sodium chloride for injection, using **aseptic** techniques. **Warning:** Unpreserved 0.9% sodium chloride for injection is the **only** diluent that should be used. This diluent is not provided in the vaccine carton	

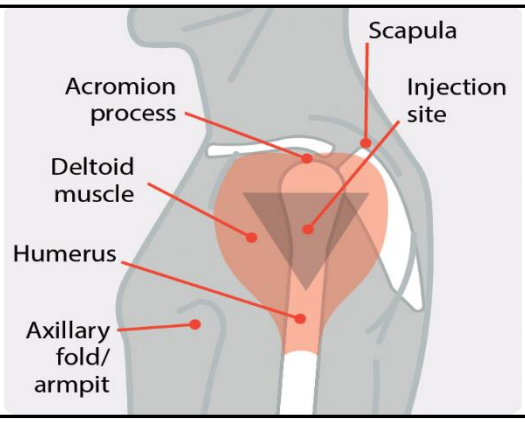
Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.	
Gently invert the diluted solution 10 times. DO NOT SHAKE. The diluted vaccine should present as an off- white solution with no particulates visible. Discard the diluted vaccine if particulates or discoloration are present.	
The diluted vials should be marked with the new discard date and time and stored between 2 °C to 25 °C. Use immediately, and within 6 hours after dilution.	
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 syringe and discard any unused vaccine within 6 hours after dilution.	

- Administer Vaccine Dose:

Choose correct needle length (1" or 1.5") to reach muscle, prep skin with alcohol swab, and stabilize/stretch skin if excess soft tissue (do not bunch skin)

Inject 0.3 mL of the Pfizer COVID-19 mRNA Vaccine BNT162b2 vaccine intramuscularly in the deltoid muscle of the arm

Cover injection site with bandage



Monitor for adverse reactions (e.g. anaphylaxis) for minimum 15 minutes and initiate immediate treatment (below) as needed

- If mild injection site reaction or allergic reaction consult ordering physician/On-Line Medical Control (OLMC) for management
- If signs of severe allergic reaction/anaphylaxis (dyspnea, stridor, severe urticaria, tachycardia, hypotension, or Altered Mental Status) activate emergency response system and initiate treatment if available:
    - Epinephrine 0.3 mg (1mg/mL concentration) intramuscular (may use epinephrine auto-injector if available)
    - Perform Airway Management as required per local EMS protocols
    - Establish IV/IO access and initiate cardiac monitoring
    - Diphenhydramine 50 mg IV/IO or intramuscular
    - Methylprednisolone sodium succinate 125 mg IV/IO
    - Albuterol 2.5 mg nebulized if wheezing/dyspnea, may repeat x 1
    - Obtain 12-lead ECG after any epinephrine administration
    - Initiate transport per local EMS protocols
    - Consult OLMC for additional epinephrine/epinephrine drip as needed
    - Report any adverse reactions

Documentation: Use provided forms to document vaccine manufacturer, injection site, lot number and expiration date.

Complications

- Allergic/anaphylactic Reaction
- Bleeding, local site pain, infection
- Common side effects (fever, headache, chills, muscle aches, fatigue)

References

- PFIZER-BIONTECH COVID-19 VACCINE (BNT162, PF-07302048) VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE BRIEFING DOCUMENT MEETING DATE: 10 December 2020
- https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html
- https://www.cdc.gov/vaccines/hcp/vis/index.html
- CDC Vaccine Storage and Handling Toolkit - November 2020