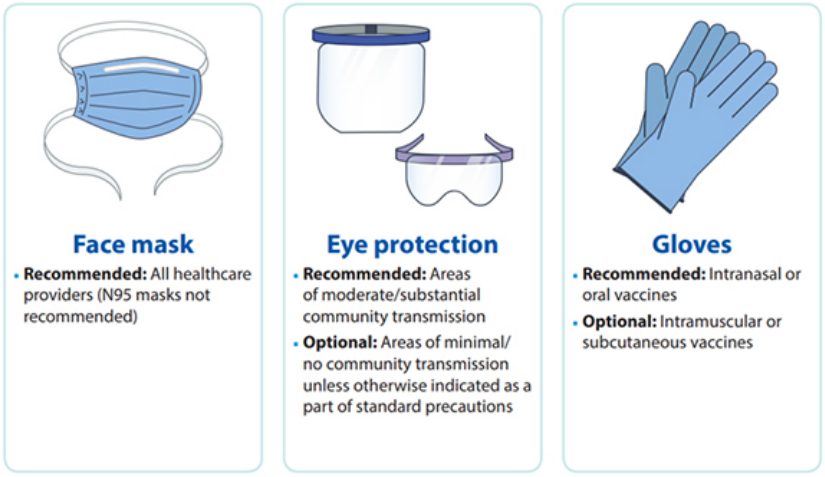
CHECKLIST for Nurses and EMS Personnel
Administering Pfizer-BioNTech COVID-19 VACCINE Under EUA
GMVEMSC JITSO for Paramedics and Adv. EMTs 1/14/2021

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection for use in individuals **16** years of age and older, administered as a series of two doses (0.3 mL each) 3 weeks apart.

For Storage and other handling information, see the full "EUA Fact Sheet for Providers." For the most recent Fact Sheet, please see www.cvdvaccine.com.



Dose Preparation:

1. The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
   - Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)]. **See Storage and Handling in EUA Fact Sheet for Providers for full process.**
2. Dilution and Preparation
   - Undiluted vials may be stored at room temperature for no more than 2 hours.
   - After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
   - During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
   - Any vaccine remaining in vials must be discarded after 6 hours.
   - Do not refreeze.
   - Vials must reach room temperature before dilution.
   - Before dilution invert vaccine vial ***gently*** 10 times.
   - **Do not shake.**
   - Inspect the 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.
   - Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. **ONLY** use 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. **Do not add more than 1.8 mL of diluent.**
   - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
   - Cleanse the vaccine vial stopper with a 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 Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- **Do not shake.**
- Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
- After dilution, one vial contains up to 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Discard any unused vaccine 6 hours after dilution.

3. Preparation of individual 0.3 ml doses of Pfizer-BioNTech covid-19 vaccine:
    - 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 preferentially using a low dead-volume syringe and/or needle.
    - Administer immediately.

Dosing and Schedule

- Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a **second dose of Pfizer-BioNTech COVID-19 Vaccine** to complete the vaccination series. Vaccine brands are NOT interchangeable.

Vaccine Administration

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,
    - verify the final dosing volume of 0.3 mL.
    - confirm there are no particulates and that no discoloration is observed.
    - do not administer if vaccine is discolored or contains particulate matter.
- Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.
- After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain up to six doses of 0.3mL. Low dead-volume syringes and/or needles can be used to extract up to six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.3 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
    - Do not pool excess vaccine from multiple vials.

Provide a vaccination card to recipient or caregiver with date to return for the second dose.

IM Injections in Deltoid Muscle

- **Use proper landmarks and technique to identify the injection site**
- **Use proper needle length for age and size of patient**
- **Aspiration is not recommended when administering vaccines**

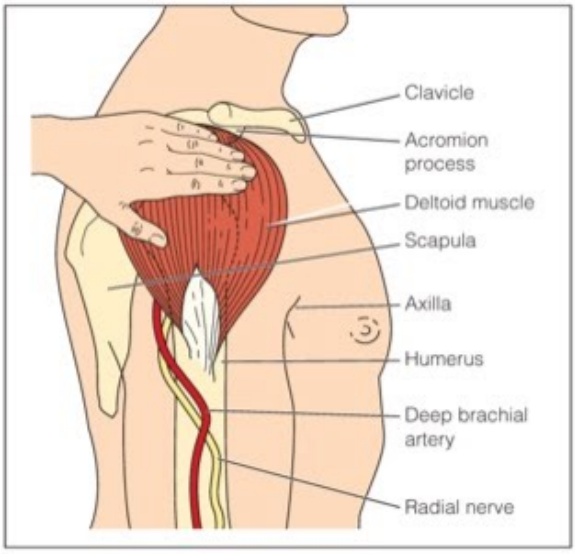
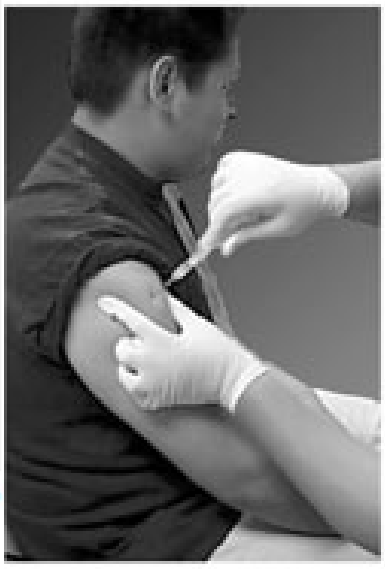
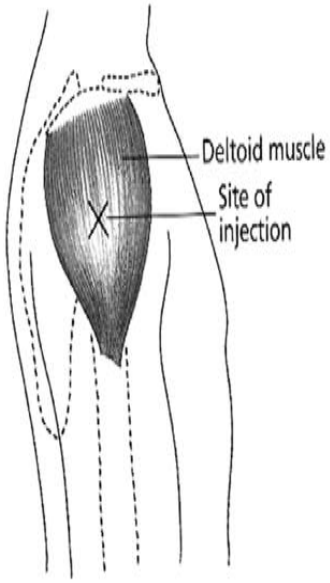


FIGURE 31.38 A method of establishing the deltoid muscle site for an intramuscular injection





Monitoring and Reporting Requirements

Pfizer-BioNTech COVID-19 Vaccine is limited to the following (all requirements **must** be met):

1. For use in individuals **16** years of age and older.
2. Provide "Fact Sheet for Recipients and Caregivers" **prior** to giving the Vaccine.
3. Document in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS) vaccine administration errors whether or not associated with an adverse event, serious adverse events* (irrespective of attribution to vaccination), cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death.
   - Submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.

Warnings and Precautions

Appropriate treatment to manage immediate allergic reactions must be immediately available

Monitor Pfizer-BioNTech **COVID-19 vaccine recipients for the occurrence of immediate adverse reactions:**

- **At least 15 minutes for all recipients**
- **At least 30 minutes for recipients with a prior history of allergic reactions**
- Media reports indicate there have been some syncopal episodes after the injection. These are likely vasovagal reactions to the injection; no indication of anything to do with the vaccine. Manage with positioning and supportive care.

Adverse Reactions

- Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy (see Full EUA Prescribing Information).
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID- 19 vaccination. For more information, visit: www.cdc.gov/vsafe.