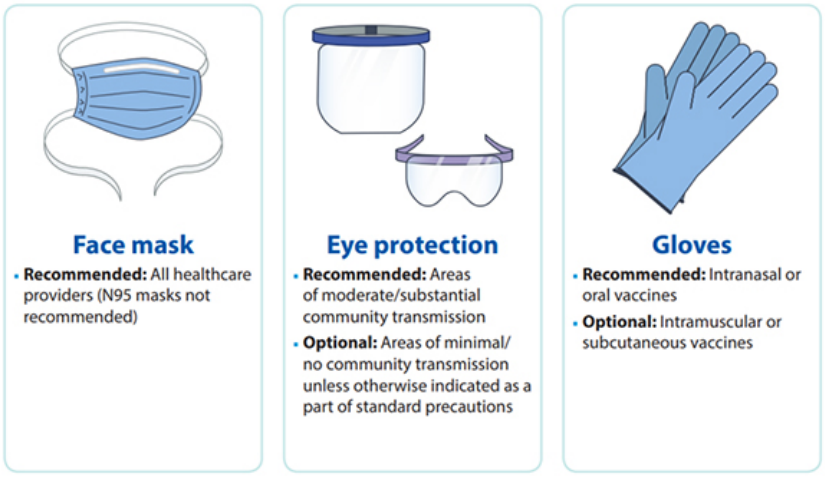
CHECKLIST for Nurses and EMS Personnel
Administering Pfizer-BioNTech COVID-19 VACCINE
GMVEMSC JITSO for Paramedics and Adv. EMTs
9/29/2021 (Updated material highlighted)

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection for use in individuals **12** years of age and older, administered as a series of two doses (0.3 mL each) 3 weeks apart.
Additionally, Pfizer-BioNTech COVID-19 Vaccine, is authorized for use as:

- a third primary series dose (0.3 mL) at least 28 days following the second dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose (0.3 mL) may be administered at least 6 months after the primary series:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of severe COVID-19 or serious complications

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and **can be used interchangeably**.

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:

The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume sufficient for up to 6 doses, 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 (35ºF to 46ºF) or at room temperature (up to 77ºF). See Storage and Handling in EUA Fact Sheet for Providers for full process.

Dilution and Preparation

- Undiluted vials may be stored at room temperature for no more than 2 hours.
- After dilution, store vials between 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 contains particulate matter.
- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (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).
- 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 and diluent 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 6 doses of 0.3 mL.
- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Discard any unused vaccine 6 hours after dilution.

Preparation of individual 0.3 ml doses of Pfizer-BioNTech covid-19 vaccine:

- Use a new, sterile needle and syringe for each injection. Use low dead-volume syringes/ needles to extract 6 doses from a single vial. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes per vial (e.g., 4 low dead-volume syringes and 2 non-low dead-volume syringes).
- Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe. Regardless of the type of syringe used, **ensure the amount of vaccine in the syringe equals 0.3 mL**. If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
- Do NOT combine vaccine from multiple vials to obtain a dose.
- Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch.
- 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.

- For use in individuals 12 years of age and older.
- Provide "Fact Sheet for Recipients and Caregivers" prior to giving the Vaccine.
- 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.
- 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.
- 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.

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**

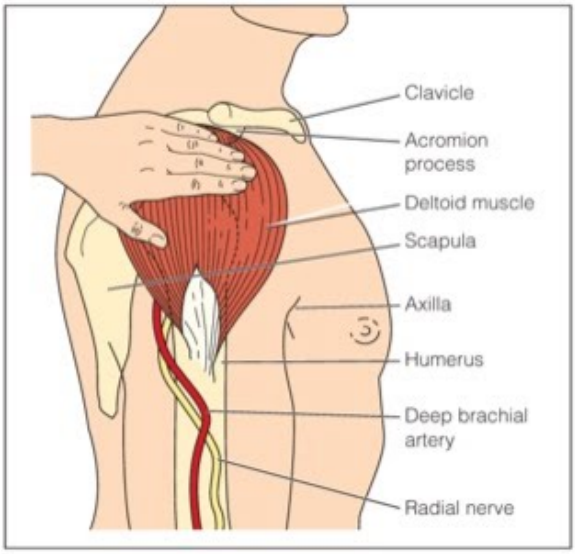
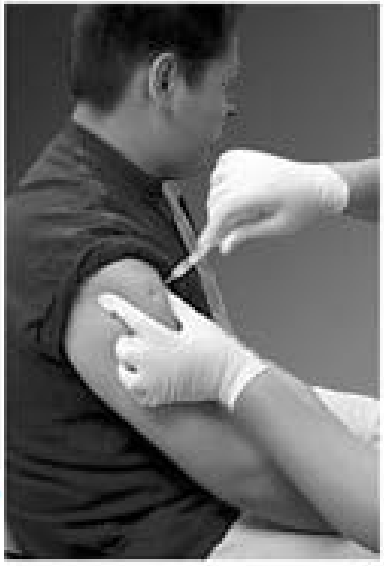
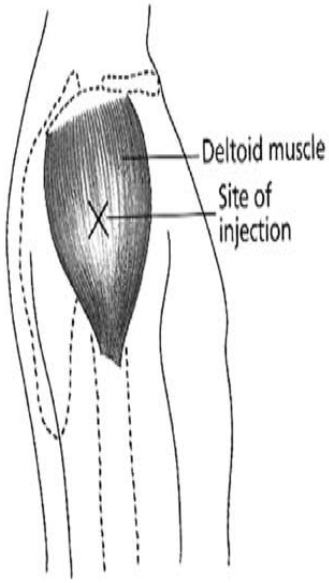


FIGURE 31.38 A method of establishing the deltoid muscle site for an intramuscular injection





Monitoring and Reporting Requirements

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

1. For use in individuals **12** 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:**
Observe recipients after vaccination for an immediate adverse reaction:

- 30 minutes: Persons with a:
    - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
    - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech vaccine
    - History of anaphylaxis due to any cause
- 15 minutes: All other persons
- Manage syncopal episodes 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. Those include syncope and decreased appetite. There have been rare reports of myocarditis and pericarditis following administration of the Pfizer COVID-19 Vaccine