CHECKLIST for Nurses and EMS Personnel
Administering Moderna COVID-19 Vaccine Under EUA
GMVEMSC JITSO for Paramedics and Adv. EMTs 9/29/2021 (Updated material highlighted)

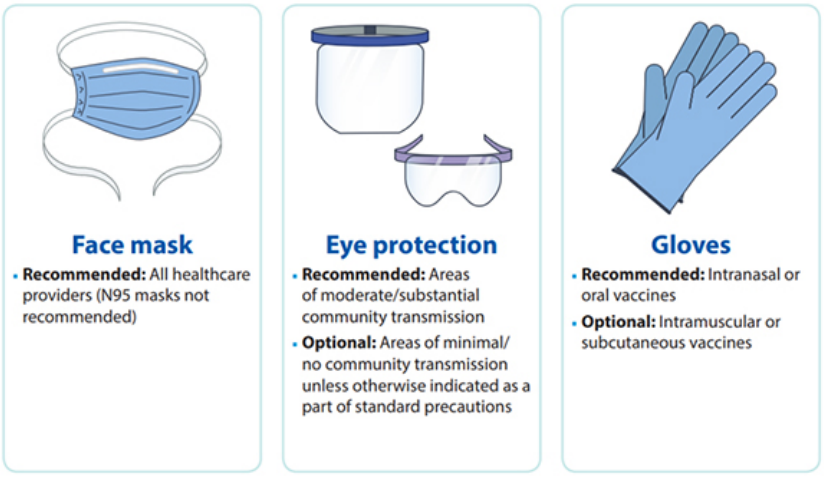
Moderna COVID Vaccine is a suspension for intramuscular (IM) injection, authorized under an Emergency Use Authorization for active immunization to prevent COVID infection in those aged 18 and older. It is administered as a series of two doses (0.5mL each) one month apart.
A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For Storage and other handling information, see the full "EUA Fact Sheet for Providers". The storage and handling information in the EUA Fact Sheet supersede storage and handling information on the vial and carton labels.

The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
- A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).

Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial.



Storage and Dose Preparation

The Moderna COVID-19 Vaccine multiple-dose vial (11 or 15 doses per vial) contains a frozen suspension, stored at -58° to 5°F, Vials may be stored refrigerated between 36° to 46°F for up to 30 days prior to first use. Vials may be stored between 46° to 77°F for a total of 24 hours. After the first dose has been withdrawn, the vial should be held between 35° to 77°F. Vials should be discarded 12 hours after the first puncture. Thawed vials can be handled in room light conditions. Do not refreeze once thawed.

- The vaccine can be thawed in a refrigerator or at room temperature.
- Thaw in refrigerated conditions between 36° to 46°F for 2 hours and 30 minutes, or 3 hours for the 15 dose vial. After thawing, let vial stand at room temperature for 15 minutes before administering.

- Alternatively, thaw at room temperature between 59° to 77°F for 1 hour for the 11 dose vial, or 1 hour and 30 minutes for the 15 dose vial.
- After thawing, do not refreeze.
- **Swirl vial gently** after thawing and between each withdrawal. **DO NOT SHAKE**. Do not dilute the vaccine.
- Visually inspect Moderna COVID Vaccine. It is a white to off-white suspension. It may contain white or translucent product-related particulates. If there is other particulate matter and/or discoloration, the vaccine should not be administered.
- Each dose is 0.5 mL administered intramuscularly.
- After the first dose has been withdrawn, the vial should be held between 36° to 77°F. Record the date and time for first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Dosing and Schedule

- Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a **second dose of the <u>Moderna</u>** COVID- 19 **Vaccine** to complete the vaccination series, one month apart.

Vaccine Administration

Administered intramuscularly as a series of two doses (0.5 mL each), 1 month apart.

Visually inspect each dose (as above):

- Verify the dosing volume of 0.5 mL.
- Confirm no other particulates and no discoloration is observed.
- Do not administer if vaccine is discolored or contains other particulate matter.

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.

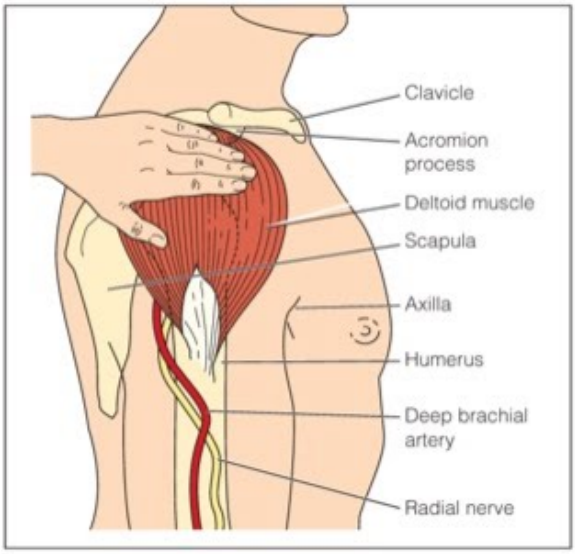
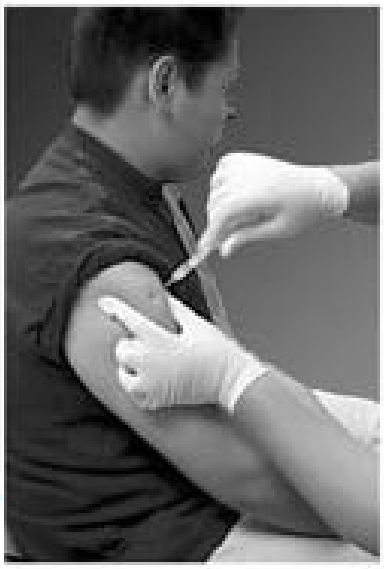
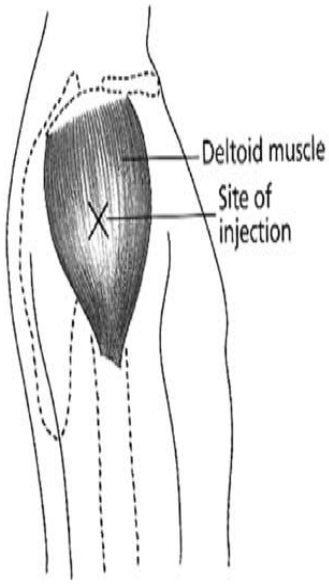


FIGURE 31.38 A method of establishing the deltoid muscle site for an intramuscular injection





Monitoring and Reporting Requirements

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

- For use in individuals 18 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.

Contraindications

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

Warnings and Precautions

Appropriate treatment to manage immediate allergic reactions must be immediately available.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions:

Observe recipients after vaccination for an immediate adverse reaction:

- 30 minutes: Persons who:
  - Have a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy.
  - Received Moderna COVID-19 vaccine because of a contraindication to a different COVID-19 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 reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.
- Severe adverse reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials. There have been rare reports of myocarditis and pericarditis following administration of the Moderna COVID-19 Vaccine.