CLINICAL PROCEDURE

EMS COVID19 VACCINE ADMINISTRATION

Moderna mRNA cx-024414

Indication	Dose Regimen
FDA Emergency Use Authorization for active immunization of individuals 18 years of age and older to prevent COVID-19 caused by SARS-CoV-2 virus	2 DOSES ONE MONTH APART Must both be Moderna Give second dose day 24 to 32 (or as soon as possible after day 32)

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

Contraindications

- Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of the Moderna COVID-19 vaccine
- Age less than 18 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

Complications

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

Patient Preparation

- Ensure appropriate monitoring equipment and treatment supplies are available to manage any adverse reactions (e.g. anaphylaxis)
- Verify correct patient identification
- Confirm "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

Vaccine – Storage and Handling

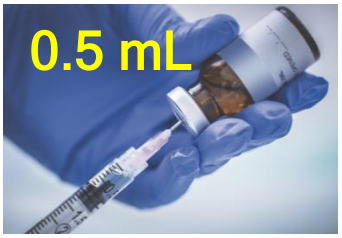
- Multiple-dose vials are stored frozen between -25º to -15ºC (-13º to 5ºF).
- Store in the original carton to protect from light. Do not store on dry ice or below -40ºC (-40ºF).
- May be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. ***DO NOT re-freeze once thawed***.
- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. ***DO NOT refreeze***.

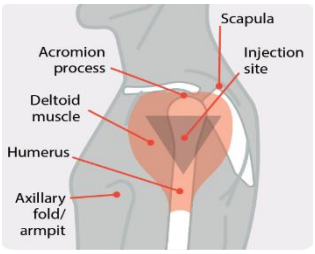
Vaccine – Dose Preparation

1. Each patient dose is 0.5 mL
2. There are 10 doses per vial – ***DO NOT*** **dilute the vaccine**
   *****Note - A vial may contain more than 10 doses due to manufacturing – Utilize all FULL DOSES from a vial but *DO NOT* mix partial doses from multiple vials*****
3. The Moderna COVID 19 vaccine is a white to off-white suspension.
   - It may contain white or translucent product related particulates.
   - Visually inspect the Moderna COVID 19 vaccine vials for other particulate matter and/or discoloration prior to administration.
     - If either of these conditions exists, the vaccine should not be administered.
4. Remove the required number of vials from frozen storage and thaw each vial before use:
   - Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
   - Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
   - After thawing, do not re-freeze.
5. Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) ***for up to 30 days prior to first use***

Vaccine – Administration

1. Withdraw the required 0.5 mL dose of vaccine using a sterile needle and syringe.
2. Check that there are no particulates or discolorations present in the vaccine prior to administration
3. 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)
4. Inject 0.5 mL of the vaccine intramuscularly in the deltoid muscle of the arm
5. Cover injection site with bandage





Vaccine – Ongoing Handling and Storage

1. Swirl vial gently after thawing and between each withdrawal. ***DO NOT*** **shake**. ***DO NOT*** **dilute the vaccine.**
2. After the first dose has been withdrawn:
   - the vial should be held between 2° to 25°C (36° to 77°F)
   - record the date and time for first use on the vial label.
   - discard vial after 6 hours. ***DO NOT*** **re-freeze.**

Vaccine – Adverse Event Monitoring and Management

Monitor for adverse reactions (e.g. anaphylaxis) for a minimum of 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 (1 mg/mL concentration) intramuscular (may use epinephrine auto-injector if available)
  - Perform airway management per local EMS protocols
  - Establish intravenous/intraosseous
  - Initiate cardiac monitoring
  - Diphenhydramine 50 mg intravenous, intramuscular or intraosseous
  - Albuterol 2.5 mg nebulized if wheezing/dyspnea, may repeat x 1
  - Initiate transport per local EMS protocols
  - Consult OLMC for additional epinephrine/push dose pressor as needed
- Report any adverse reactions

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

References
• Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation- FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA • https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html • https://www.modernatx.com/covid19vaccine-eua/