Standing Order for Administering Moderna/SPIKEVAX®
COVID-19 Vaccine (Adult ≥ 18 years of age)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals ≥ 18 years of age who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) licensure or Emergency Use Authorization (EUA), and the Department of Defense (DoD).

Policy: Under these standing orders, eligible healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

1. Moderna/SPIKEVAX® COVID-19 vaccine is:
   - FDA-licensed for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥ 18 years of age.
   - FDA-authorized under EUA for a third primary series dose for individuals ≥ 18 years of age who are moderately or severely immunocompromised.
   - FDA-authorized under EUA for a one or two booster doses for individuals ≥ 18 years of age who have completed a primary COVID-19 vaccination series. See Table 1 for all dosing intervals.
2. Individuals vaccinated outside the United States who received all or some of:
   - An FDA-licensed or FDA-authorized COVID-19 vaccine, a World Health Organization emergency use listed (WHO-EUL) COVID-19 vaccine not FDA-licensed or FDA-authorized, or a heterologous (mix and match) series from those two groups: do not restart the series in the U.S. Receive subsequent doses according to Table 1.
   - A non WHO-EUL COVID-19 vaccine primary series: doses do not count towards U.S. vaccination. Start a primary series ≥ 28 days after the last dose, and receive subsequent doses according to Table 1.
3. Moderna/SPIKEVAX® COVID-19 vaccine and other vaccines may be co- administered without regard to timing, including same-day administration, with one exception: per DoD policy, ACAM2000™ smallpox vaccine must be separated from any COVID-19 vaccine by ≥ 28 days.
4. Defer receipt of tixagevimab/cilgavimab (EVUSHELD™) for ≥ 2 weeks after vaccination with Moderna/SPIKEVAX® COVID-19 vaccine. There is no recommended vaccination deferral period after receipt of passive antibody therapy (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma).

***Note**:*
- *The FDA-licensed SPIKEVAX® COVID-19 vaccine and the FDA EUA-authorized Moderna COVID-19 vaccine have the same formulation and can be used interchangeably without presenting any safety or effectiveness concerns.*

5. Using DHA Form 207, screen all individuals for contraindications and precautions to the COVID-19 vaccine:

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component to include polyethylene glycol (see the fact sheets for the red cap and dark blue cap products for complete lists of excipients).

Precautions:

- Moderate or severe acute illness with or without fever.
- History of severe allergic reaction (e.g. anaphylaxis) to any injectable medication.
- Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine: defer additional primary or booster doses.*
- Syncope (fainting) can occur in association with administration of injectable vaccines. Have procedures in place to avoid a falling injury (e.g. observation after administration) and to restore cerebral perfusion following syncope.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Support Center at (877) 438-8222, Option 1 or DSN 761-4245.

Note:

** A subsequent dose or alternative COVID-19 vaccine may be considered using shared clinical decision-making but is not covered under these standing orders: these patients must obtain a written order from a privileged provider.*

Special Populations:

- **Pregnancy:** Pregnant and postpartum individuals may receive any current FDA-licensed or FDA EUA-authorized COVID-19 vaccine, to include additional primary or booster doses. Data on the safety of COVID-19 vaccines in pregnancy is limited, but reassuring. Individuals vaccinated during pregnancy should be encouraged to enroll in the Moderna/SPIKEVAX® COVID-19 Pregnancy Registry by calling 1-866-MODERNA (1-866-663-3762). Routine pregnancy testing before receipt of COVID-19 vaccine is not indicated, and pregnancy need not be delayed after vaccination.
- **Lactation:** COVID-19 vaccination is recommended for all lactating individuals. SARS-CoV-2 antibodies have been found in the breast milk of individuals who have received mRNA COVID-19 vaccines, suggesting a potential protective effect against infection in the infant; the degree of clinical benefit is not yet known.
- **Immunocompromised:** Individuals who are moderately or severely immunocompromised may be at increased risk for severe COVID-19. These individuals should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider. These conditions can include (but are not limited to):
    - Generalized malignancy
    - Solid organ or stem cell transplant
    - Congenital or acquired immunodeficiencies (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome, HIV/AIDS, or lymphocyte or complement deficiencies)
    - Iatrogenic immunosuppression (e.g., treatment with immunosuppressive drugs, including long-term systemic corticosteroids, biologics, or radiation therapy)
- **COVID-19 Vaccine Clinical Trial Participants**: Unless they have received or plan to receive a booster dose through a clinical trial, participants ≥ 18 years of age (including moderately or severely immunocompromised people who received an additional primary dose) who completed a primary series of a WHO-EUL COVID-19 vaccine (not a placebo) can receive a single COVID-19 vaccine booster dose. These individuals should confer with their trial POCs before vaccination.

6. Provide all patients (or their parent/legal representative) with a copy of the Moderna/SPIKEVAX® COVID-19 vaccine Fact Sheet for Recipients and Caregivers or the VIS, as applicable. Provide non-English speaking patients with a copy in their native language, if available and preferred.

7. Provide Moderna/SPIKEVAX® COVID-19 vaccine as follows:

Table 1: Dosing intervals

COVID-19 Vaccine Product	Age group	# of primary doses	# of booster doses	Interval: 1st to 2nd primary dose	Interval: 2nd to 3rd primary dose	Interval: primary series to 1st booster dose	Interval: 1st booster dose to 2nd booster dose
Moderna	≥ 18 years						
• **Immunocompetent**		2	1 or 2*‡	4-8 weeks†	NA	≥ 5 months	≥ 4 months
• **Immunocompromised**		3	1 or 2*‡	4 weeks	≥ 4 weeks	≥ 3 months	≥ 4 months

*A 2nd booster dose with an mRNA COVID-19 vaccine is recommended for **immunocompromised** individuals ≥ 12 years of age and **immunocompetent** individuals ≥ 50 years of age ≥ 4 months after receipt of a 1st booster dose of any FDA-licensed or FDA-authorized COVID-19 vaccine.

†An 8-week interval may be optimal for some individuals ≥ 12 years of age, especially for males 12-39 years of age. A shorter interval (4 weeks for Moderna) between the 1st and 2nd doses remains the recommended interval for: **immunocompromised** individuals; adults ≥ 65 years of age; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

‡**Immunocompetent** individuals 18-49 years of age who received Janssen COVID-19 vaccine as both their primary series dose and 1st booster dose may receive a 2nd booster dose with an mRNA COVID-19 vaccine ≥ 4 months after the Janssen booster dose.

- Using a sterile needle and 1mL syringe, administer the appropriate dose intramuscularly in the deltoid muscle. Separate multiple injection sites by 1 inch or more and if possible, administer COVID-19 vaccines and vaccines that may be likely to cause a local reaction in different limbs.

8. Dosing intervals:
   - An 8-week interval may be optimal for some people. While absolute risk remains small, the relative risk for myocarditis is higher for males 12-39 years of age; this risk might be reduced by extending the interval between the 1st and 2nd primary dose.
   - A 4-week interval between the 1st and 2nd primary doses is recommended for: moderately to severely immunocompromised individuals; adults ≥ 65 years of age; individuals needing rapid protection due to increased concern for community transmission or risk of severe disease.
   - DO NOT compress minimum intervals for clinic convenience. However, doses administered ≤ 4 days (the "grace period") before the minimum interval (e.g., prior to imminent travel or immunosuppressive therapies) are considered valid.
   - A primary dose administered earlier than allowed by the grace period (24 days) is invalid and should be repeated. The repeat dose should be given ≥ 28 days after the invalid dose. Invalid doses do not count towards a series or the maximum number of doses.
   - Booster doses administered prior to the minimum interval do not need to be repeated.
   - COVID-19 vaccines are NOT interchangeable for initial vaccination: complete the **primary series** with the same product.

IM Needle Length and Injection Site for Adolescents & Adults		
Use a 22 – 25 gauge needle: choose needle gauge and length appropriate to administration route and the patient's age and body mass.		
Patient sex and weight	**Needle Length**	**Injection Site**
All individuals ≤ 18 years of age	1 inch	Deltoid Muscle of Arm
All individuals ≥ 19 years of age:		
Men and Women (<130 lbs)	1 inch†	
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)		

Women (152-200 lbs)	1-1.5 inches	
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)		

Adapted from General Best Practice Guidelines for Immunization: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
† Some experts recommend a 5/8 inch needle for individuals who weigh <130 lbs: stretch skin tightly (do not bunch subcutaneous tissue)

- Storage and use of vials:
  - During storage, minimize exposure to room light, and avoid exposure to direct sunlight and UV light.
  - Thawed vials can be handled in room light.
  - Vials must reach room temperature before use.
  - Mark vials with the date and time of first puncture.
  - Once thawed, **do not refreeze**.
  - Do not pool excess vaccine from multiple vials.
  - Punctured vials must be stored at 2° to 25°C and discarded after 12 hours.
  - Information in the "Fact Sheet for Healthcare Providers" supersedes information on vial and carton labels (see graphic on last page).
- The Moderna/SPIKEVAX® COVID-19 vaccine is supplied in two presentations which contain the same ingredients but have different concentrations:
  - A multiple dose vial with a **red cap** and a label with a **light blue border** which **can be used for primary series and booster doses**, and is available in two volumes (5.5 mL and 7.5 mL):
    - Primary series doses: **0.5 mL** each
    - Booster doses: **0.25 mL** each
  - A multiple dose vial with a **dark blue cap** and a label with a **purple border** which **can only be used for booster doses,** and is available in one volume (2.5 mL):
    - Booster doses: **administer 0.5 mL each**
  - When extracting only booster doses or a combination of primary series and booster doses from vials with **red caps** and labels with a **light blue border**, the maximum number of doses that may be extracted from either vial size should not exceed 20: **do not puncture the vial stopper more than 20 times.**

9. Provide all individuals (or their parent/legal representative) with information on the v-safe program and strongly encourage them to enroll. V-safe is an app that provides personalized health check-ins and dose reminders after receipt of a COVID-19 vaccine.
10. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, VIS date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.

- The CVX code for Moderna/SPIKEVAX® COVID-19 vaccine with **red caps** and labels with a **light blue border** is **207**.
- The CVX code for Moderna/SPIKEVAX® COVID-19 vaccine with **dark blue caps** and labels with a **purple border** is **221**.

11. **Mandatory observation.** All individuals who receive any COVID-19 vaccine must be monitored as follows:

- **30 minutes** - individuals with:
  - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy.
  - History of anaphylaxis due to any cause.

- **15 minutes**: all other individuals.

12. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

13. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome in adults (MIS-A) or children (MIS-C), and hospitalized or fatal cases of COVID-19 following vaccination with any COVID-19 Vaccine**.** Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at https://vaers.hhs.gov.

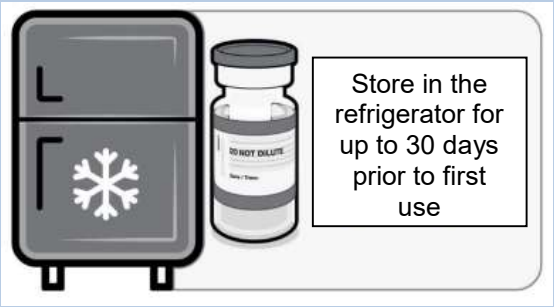
14. This policy and procedure shall remain in effect for all patients of the _____ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

_____ _____

Medical Director's Signature Date

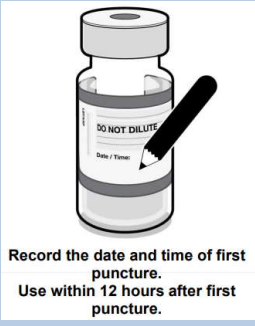
Moderna/SPIKEVAX® COVID-19 vaccine

Storage / Thawing



- Do not store on dry ice or below -50°C
- Store frozen between -50°C to -15°C (-58°F to 5°F):
  - May be stored until expiry date
- Store in the refrigerator at 2°C to 8°C (36°F to 46°F):
  - May be stored for up to 30 days prior to first use
- Store in the refrigerator at 8°C to 25°C (46°F to 77°F):
  - May be stored for a total of 24 hours prior to first use
- Thaw in the refrigerator at 2°C to 8°C (36°F to 46°F):
  - 2.5mL vial: 1 hour
  - 5.5mL vial: 2 hours and 30 minutes
  - 7.5mL vial: 3 hours
- Thaw at room temperature at 15°C to 25°C (59°F to 77°F):
  - 2.5mL vial: 30 minutes
  - 5.5mL vial: 1 hour
  - 7.5mL vial: 1 hours and 30 minutes

Preparation



- Swirl vial gently after thawing and between each withdrawal
- **Do not shake**
- **Do not dilute**
- The vaccine should appear as a white to off-white suspension, and may contain white or translucent product-related particulates
- Do not administer if vaccine is discolored or contains other particulate matter