Standing Order for Administering COVID-19 Vaccine (Adult)

Purpose: To reduce morbidity and mortality from COVID-19 disease by vaccinating all individuals 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) product labeling, and the Department of Defense (DoD).

Policy: Under this standing order, eligible health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

1. Identify individuals ≥ 18 years of age who do not have documented receipt of an updated (2023 - 2024 Formula) mRNA COVID-19 vaccine.
2. Using DHA Form 207, screen all patients for contraindications and precautions to 2023-2024 Formula:

   Contraindications:

   - History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine is a contraindication to the same type of COVID-19 vaccine (e.g., mRNA [Moderna, Pfizer] or protein subunit [Novavax]).
   - For information on vaccine components, refer to the package inserts/FDA Fact Sheets for Spikevax / Moderna, Comirnaty / Pfizer-BioNTech, Novavax, or the CDC Interim Clinical Guidance.

   Precautions:

   - History of a diagnosed non-severe allergy to a COVID-19 vaccine component or a non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type. These individuals may receive the alternative vaccine type (e.g., mRNA or protein subunit).
   - Moderate or severe acute illness, with or without fever.
   - History of Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A).
   - History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.
   - For questions or concerns, consider consulting the DHA Immunization Healthcare Support Center at (877) 438-8222, Option 1 or DSN 312-761-4245.

   Special Populations:

   - **Pregnancy and Lactation:** COVID-19 vaccination is recommended for individuals who are pregnant, trying to get pregnant, might become pregnant in the future, and those who are breastfeeding. Routine pregnancy testing before receipt of COVID-19 vaccine is not required, and pregnancy need not be delayed after vaccination.
   - **Immunocompromised**: Individuals who are or become moderately or severely immunocompromised should receive the COVID-19 vaccine and dosage appropriate for their age and immune status on the day of vaccination. COVID-19 vaccination should not be delayed in patients taking immunosuppressive therapies, but whenever possible:
     - Administer ≥ 2 weeks before initiation or resumption of immunosuppressive therapies
     - For those receiving B-cell-depleting therapies on a continuing basis: administer approximately 4 weeks before the next scheduled therapy
   - **Received COVID-19 vaccine outside the U.S.:** Everyone ≥ 6 months of age vaccinated outside the U.S. with any previous formulation should receive at least 1 age-appropriate dose of 2023-2024 Formula.

3. Prior to vaccine administration, provide all patients (or their parent/legal representative) with a copy of one of the following (a VIS-equivalent)
   - Patient Package Insert (ages 12 years and older) (Spikevax, or Comirnaty)
   - Provide non-English speaking patients with a copy in their native language, if available and preferred by the patient.

4. Provide COVID-19 vaccine as follows:
   - Administer the appropriate 2023-2024 Formula dose intramuscularly (IM) according to tables 1-3
   - Interchangeability:
     - Moderna and Pfizer-BioNTech vaccines are interchangeable in healthy persons ≥ 18 years of age; the same product is recommended, but not required.
     - Individuals ≥ 18 years of age who are moderately or severely immunocompromised should receive a 3-dose initial series from the same manufacturer. A different age-appropriate vaccine may be given when:
       - Same vaccine not available
       - Previous dose unknown
       - Person would otherwise not complete the series
       - Person now has a contraindication to the previous product
   - Moderately or severely immunocompromised individuals may receive 1 additional dose of 2023-2024 Formula ≥ 2 months following the last recommended 2023-2024 Formula dose.
   - Current ACIP recommendations do not include use of Novavax COVID-19 vaccine: this standing order will be updated if new information is released.
   - Janssen COVID-19 vaccine is no longer authorized for use in the US.
   - COVID-19 vaccine and other vaccines may be co-administered without regard to timing, including same-day administration, with one exception:
     - Per DOD policy, smallpox/mpox vaccines (ACAM2000 or JYNNEOS) should be separated from any mRNA COVID-19 vaccine by ≥ 28 days. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.
   - Certain situations are not covered under this standing order. These patients must obtain a written order from a privileged provider:
     - History of MIS-C or MIS-A, myocarditis, or pericarditis
     - Vaccination of patients taking immunosuppressive therapies outside the dosing intervals described in "Special Populations".
     - Revaccination of certain immunocompromised patients who received COVID-19 vaccine during treatment (e.g., recipients of HCT, CAR-T-cell, or limited B-cell-depleting therapy).
     - > 4 doses of 2023-2024 Formula for moderately or severely immunocompromised individuals.

TABLE 1. IM Needle Length and Injection Site Guide

- Use a 22 – 25-gauge needle
- Choose needle gauge and length appropriate to the patient's age, sex, and weight

Patient age	Needle Length	Injection Site
Children & Adolescents, 11-18 years	5/8* - 1 inch (16-25 mm)	Deltoid muscle of arm†
	1 - 1.5 inches (25-38 mm)	Anterolateral thigh
Adults (≥ 19 years)		
Men and women, <60 kg (130 lbs)	5/8* - 1 inch (16-25 mm)	Deltoid muscle of arm
Men and women, 60-70 kg (130-152 lbs)	1 inch (25 mm)	
Men, 70-118 kg (152-260 lbs)	1-1.5 inches (25-38 mm)	
Women, 70-90 kg (152-200 lbs)		
Men, >118 kg (260 lbs)	1.5 inches (38 mm)	
Women, >90 kg (200 lbs)		
Men and women, any weight	1 inch* - 1.5 inches (25-38 mm)	Anterolateral thigh

Adapted from the CDC General Best Practice Guidelines: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

* If skin is stretched tightly and subcutaneous tissues are not bunched.

† Preferred site.

TABLE 2. COVID-19 Vaccine Product Summary, ≥ 18 years of age

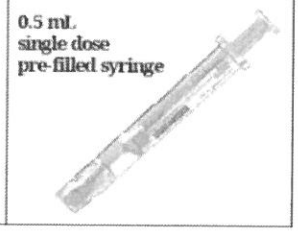
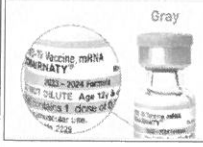
Moderna	Pfizer-BioNTech
SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula) 12 Years of Age and Older  0.5 mL single dose vial  0.5 mL single dose pre-filled syringe	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula DO NOT DILUTE Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5). 12 years and older  COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PREFILLED SYRINGE Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5). 12 years and older 

TABLE 3. COVID-19 Vaccine Schedule by Age and History, ≥ 18 years of age

COVID-19 vaccination history prior to updated (2023 - 2024 Formula) mRNA COVID-19 vaccine	Updated (2023 - 2024 Formula) mRNA COVID-19 vaccine*	# of doses	Dosage (mL/mcg)	Vial cap and label colors	Interval
Individuals who are NOT immunocompromised					
Unvaccinated	Moderna	1	0.5 mL/50 mcg	Dark blue cap; blue label	NA
	Pfizer-BioNTech	1	0.3 mL/30 mcg	Gray cap; gray label	
≥ 1 dose any mRNA **-OR-** ≥ 1 dose Novavax or Janssen (including in combination with any mRNA dose)	Moderna	1	0.5 mL/50 mcg	Dark blue cap; blue label	≥ 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 mcg	Gray cap; gray label	
Individuals who ARE moderately or severely immunocompromised†					
Unvaccinated	Moderna	3	0.5 mL/50 mcg	Dark blue cap; blue label	Dose 1 to 2: 4 weeks Dose 2 to 3: ≥ 4 weeks
	Pfizer-BioNTech	3	0.3 mL/30 mcg	Gray cap; gray label	Dose 1 to 2: 3 weeks Dose 2 to 3: ≥ 4 weeks
1 dose any Moderna or Pfizer	Moderna	2	0.5 mL/50 mcg	Dark blue cap; blue label	Dose 1: 4 weeks after last dose Dose 1 to 2: ≥ 4 weeks
	Pfizer-BioNTech	2	0.3 mL/30 mcg	Gray cap; gray label	Dose 1: 3 weeks after last dose Dose 1 to 2: ≥ 4 weeks
2 doses any Moderna or Pfizer	Moderna	1	0.5 mL/50 mcg	Dark blue cap; blue label	≥ 4 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 mcg	Gray cap; gray label	
≥ 3 doses any mRNA **-OR-** ≥ 1 dose Novavax or Janssen (including in combination with any mRNA dose)	Moderna	1	0.5 mL/50 mcg	Dark blue cap; blue label	≥ 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 mcg	Gray cap; gray label	

* 2023—2024 Formula Moderna COVID-19 Vaccine and 2023—2024 Formula Pfizer-BioNTech COVID-19 Vaccine are available in vials or prefilled, single-dose syringes for individuals ≥ 12 years of age.

† Moderately or severely immunocompromised individuals may receive 1 additional dose of 2023-2024 Formula ≥ 2 months following the last recommended 2023-2024 Formula dose. Further additional dose(s) may be administered but are not covered under this standing order.

5. 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, FDA Fact Sheet / patient package insert / Vaccine Information Sheet (VIS) date (if one has been published), and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.
6. **Mandatory observation:** All individuals who receive any COVID-19 vaccine must be monitored as follows:
   - **30 minutes** - individuals with:
     - Contraindication to a different type of COVID-19 vaccine
     - Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
     - Anaphylaxis after non-COVID-19 vaccines or injectable therapies
   - **15 minutes**: all other individuals
7. 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.
8. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors, serious adverse events, cases of MIS-A or MIS-C, cases of myopericarditis or pericarditis, and hospitalized or fatal cases of COVID-19 following vaccination with any COVID-19 vaccine. Reports can be submitted to VAERS online at https://vaers.hhs.gov. Additional VAERS information is available by telephone at (800) 822-7967.
9. This standing order shall remain in effect for all patients of the Hart Medical Consulting until rescinded and/or upon a change in the Medical Director, whichever is earlier.

Medical Director's Signature

August 15, 2023
Date