Standing Order for Administering Pre-Exposure Prophylaxis (PrEP) Rabies Vaccine (Adult and Pediatric)

Purpose: To reduce morbidity and mortality from disease caused by Rhabdoviridae lyssavirus 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 these standing orders, eligible healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

1. Identify individuals of any age (birth to adult) in need of vaccination with pre- exposure prophylaxis (PrEP) rabies vaccine based on one or more risk categories below (see Table 1 for expanded guidance):
    - **Risk category 1 (highest):** People who work with live or concentrated rabies virus in laboratories.
    - **Risk category 2:** People who frequently handle or have contact with bats, enter high-density bat environments like caves, or perform animal necropsies.
    - **Risk category 3:** People who interact (or are at risk to interact) with mammals other than bats that could be rabid, for a period longer than three years after they receive PrEP. This can include:
        - Veterinarians, veterinary technicians, and animal control officers (and their students/trainees); wildlife biologists, rehabilitators, trappers; and spelunkers (cave explorers).
        - Travelers to regions outside the United States where canine rabies virus variant (CRVV) or wildlife rabies virus variants (RVV) are endemic.
    - **Risk category 4:** Same as risk category 3, but for ≤ 3 years after receiving PrEP.
    - **Risk category 5 (lowest):** General U.S. population.

Note: This standing order does not cover post-exposure cases, which are a medical urgency. Rabies is associated with the highest case fatality rate of any infectious disease. All patients with a suspected rabid bite or non- bite exposure should seek immediate medical care at their local Emergency Department to begin post-exposure treatment and Public Health surveillance.

2. Using DD Form 3111 (Adult) or DD Form 3110 (Pediatric), screen all individuals for contraindications and precautions to PrEP rabies vaccine:

    Contraindications:

    - A history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component, to include neomycin.
    - For information on vaccine components, refer to the manufacturer's package insert or The CDC Pink Book Appendix B.

    Precautions:

    - Moderate or severe acute illness with or without fever.
    - 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.

Special Populations: These individuals should discuss vaccine receipt timing and medication management with their primary or specialty healthcare provider(s).

- **Pregnancy:** There is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids, and a growing body of data demonstrate the safety of such use.
- **Lactation:** Inactivated vaccines have not been shown to affect the safety of breastfeeding for women or their infants.
- **Immunocompromised:** In persons with primary or secondary immunodeficiencies, delay PrEP vaccination (when possible) until a temporary immunocompromising condition has resolved or immunosuppressive medications can be withheld.

3. Provide all patients (or their parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred.

4. Provide vaccine as follows (see Table 1 and Table 2):
   - Rabies vaccine (Imovax®, RabAvert®) for pre-exposure prophylaxis consists of a 2-dose primary series given intramuscularly (IM) at 0 and 7 days. Both vaccines are supplied by the manufacturer in a pre-packaged single-dose (1mL) kit.
   - Administer booster doses based on risk category and titer level. For Risk Category 3, patients may elect to receive a booster dose between 21 days and 3 years after the primary series in lieu of a one-time titer check.
   - Do not start PrEP if series cannot be completed before travel.

TABLE 1. ACIP Rabies Pre-Exposure Prophylaxis (PrEP) Recommendations

Risk Category	Typical population*	Primary Series (2 doses)	Titer / Booster (1 dose)
1. Elevated risk for unrecognized† or recognized†† exposures, including unusual or high- risk exposures	Work with live rabies virus in research or vaccine production facilities; perform rabies testing in diagnostic laboratories	Vaccine on days 0 and 7	Titer: every 6 months Booster: if titer < 0.5 IU/mL§‖
2. Elevated risk for unrecognized† or recognized†† exposures	Frequently handle or have contact with bats; enter high- density bat environments; perform animal necropsies (e.g., biologists who frequently enter bat roosts or who collect suspected rabies samples)	Vaccine on days 0 and 7	Titer: every 2 years Booster: if titer < 0.5 IU/mL§‖

3. Elevated risk for recognized†† exposures, sustained risk¶	Interact with animals that could be rabid# (e.g., veterinarians, vet techs, animal control officers; wildlife biologists, rehabilitators, and trappers); spelunkers	Vaccine on days 0 and 7	Titer: once, 1–3 years after PrEP Booster: if titer < 0.5 IU/mL§‖ **OR** These patients may elect to receive a booster dose 3 weeks-3 years after PrEP in lieu of a one- time titer check.‖
	Travelers with increased risk for exposure to potentially rabid animals (particularly dogs) who might not have prompt access to safe PEP (e.g., rural area, far from closest PEP clinic)		
4. Elevated risk for recognized†† exposures, risk not sustained¶	Same as Risk Category 3, but risk duration ≤ 3 years (e.g., short-term animal care, no expected high-risk travel > 3 years after PrEP)	Vaccine on days 0 and 7	None
5. Low risk for exposure	Typical person living in the United States	None	None

Adapted from CDC MMWR 71, 619-627 (06 May 2022): https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a2.htm

Abbreviations: IU = international units; PEP = post-exposure prophylaxis

* Nature of exposure is the most important variable to consider when determining risk category. Examples provided are only a guide; categorizations should be done on a case-by-case basis. If an individual falls into more than one category, follow guidance for the highest-risk category. Risk categories may change over an individual's lifetime.

† Example: a small scratch during an inconspicuous personal protective equipment breach while testing neural tissue from a rabid animal or conducting studies on bats in the field, etc.

†† Noticed because the exposure is unusual (e.g., contact with a bat, splash with contaminated fluids) or painful (e.g., bite or scratch from a raccoon).

§ Give a booster when rabies antibody titers are < 0.5 IU/mL. For immunocompetent patients, titers to verify booster response are not needed. For immunocompromised patients, verify response with a titer ≥ 1 week (ideally, 2–4 weeks) after every booster dose.

¶ Elevated risk for rabies > 3 years after the completion of the primary rabies PrEP series.

Rabies virus is unlikely to persist outside a deceased animal's body for an extended time. Risk of transmission to persons handling animal products (e.g., hunters or taxidermists) is unknown but presumed to be low (risk category 5); direct skin contact with saliva or neural tissue of mammals should be avoided regardless of profession or activity.

‖ Titer after recommended booster dose(s) not indicated unless patient has altered immunity.

TABLE 2. IM Needle Length and Injection Site Guide

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

Patient Age	Needle Length	Injection Site
Children & Adolescents (birth-18 years)		
Neonates*	5/8 inch (16 mm)†	Anterolateral thigh
Infants (1-12 months)	1 inch (25 mm)	Anterolateral thigh
Toddlers (1-2 years)	1-1.25 inch (25-32 mm)	Anterolateral thigh‡
	5/8†-1 inch (16-25 mm)	Deltoid muscle of arm

Children (3-10 years)	5/8†-1 inch (16-25 mm)	Deltoid muscle of arm‡
	1-1.25 inches (25-32 mm)	Anterolateral thigh
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)	1 inch (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	1.5 inches (38 mm)¶	Anterolateral thigh

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

* First 28 days of life.

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

‡ Preferred site: the alternate site may be used if the muscle mass at the preferred site is inadequate. Do not administer vaccine into the gluteal muscle.

§ Some experts recommend a 5/8-inch needle for men and women who weigh <60 kg. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

¶ Some experts recommend a 1-inch needle if the skin is stretched tightly and subcutaneous tissues are not bunched.

6. 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, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.

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. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov. Additional information about VAERS is also available by telephone (800-822-7967).

9. This standing order 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