



HEALTH AFFAIRS

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

JUL 31 2009

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Clinical Policy for the Administration of the Anthrax Vaccine Adsorbed

- References:
- (a) Deputy Secretary of Defense Memorandum, "Anthrax Vaccine Immunization Program," October 12, 2006
 - (b) Undersecretary of Defense (Personnel and Readiness) Memorandum, "Implementation of the Anthrax Vaccine Immunization Program (AVIP)," December 6, 2006
 - (c) Assistant Secretary of Defense (Health Affairs) Memorandum, "Policy for Reporting Adverse Events Associated with the Anthrax Vaccine," October 15, 1999, hereby rescinded
 - (d) Assistant Secretary of Defense (Health Affairs) Memorandum, "Reactions to the Anthrax Vaccine," October 6, 2000, hereby rescinded
 - (e) Assistant Secretary of Defense (Health Affairs) Memorandum, "Immunizing Females of Childbearing Age," January 15, 2002, hereby rescinded
 - (f) Assistant Secretary of Defense (Health Affairs) Memorandum, "Policy on Clinical Issues Related to Anthrax Vaccination," August 6, 2002, hereby rescinded
 - (g) Assistant Secretary of Defense (Health Affairs) Memorandum, "Resumption of Anthrax Vaccinations for Personnel Previously Deferred," July 28, 2004, hereby rescinded
 - (h) Assistant Secretary of Defense (Health Affairs) Memorandum, "Continuation of the Anthrax Vaccine Immunization Program (AVIP)," December 22, 2005, hereby rescinded
 - (i) Joint Publication (AR 40-562, BUMEDINST 6230.15A, AFJI 48-110, CG COMDTINST M6230.4F), "Immunizations and Chemoprophylaxis," September 29, 2006
 - (j) Undersecretary of Defense (Personnel and Readiness) Memorandum, "Change in Policy for Pre-Deployment Administration of Anthrax and Smallpox Vaccines," September 10, 2007

Under the authority of references (a) and (b), this memorandum updates and consolidates policy on the administration of anthrax vaccine adsorbed (AVA). AVA is administered per the U.S. Food and Drug Administration (FDA)-approved dosing

HA POLICY: 09-016

schedule and route. Immunizations are administered in accordance with standard clinical practices, Centers for Disease Control and Prevention (CDC) recommendations, and the Joint Publication (Reference (i)). This policy consolidates and replaces guidance in References (c) through (h).

Medical issues covered in this policy include dosing schedule, injection site selection, medical screening before immunization and education materials, pregnancy screening, medical exemptions, and adverse event management.

Applicability

As provided in Reference (a), AVA is mandatory for uniformed personnel, emergency-essential and equivalent civilian personnel or contractors deployed to U.S. Central Command (USCENTCOM) or Korean areas of responsibility for 15 or more consecutive days. AVA is also mandatory for certain uniformed personnel assigned to special units and units with bio-defense related missions. Uniformed Active Duty, selected Reserves, and U.S. government civilian personnel who previously received at least one dose of AVA and are no longer deployed to areas within USCENTCOM or Korea may continue the series on a voluntary basis. Vaccinations also are voluntary for U.S. citizen adult family members who are 18 to 65 years of age and are accompanying Department of Defense (DoD) military civilian or contractor personnel for 15 or more consecutive days to areas within USCENTCOM or Korea. Reference (j) authorizes vaccinations to begin 120 days before deployment.

Dosage Schedule

DoD shall adhere to the FDA-approved five dose primary vaccination series schedule. Administer AVA via 0.5 ml intramuscular (IM) doses at day 0, 4 weeks, 6 months, 12 months, and 18 months, with a requirement for annual boosters. Do not compress or accelerate this dosing schedule.

If dosing intervals exceed the recommended intervals, resume the regimen with administration of the next dose in the series. Administer subsequent doses of vaccine at intervals based on the date the last dose was given, not when it was originally scheduled. Do not restart the series. This prevailing medical practice is consistent with recommendations of the Advisory Committee on Immunization Practice and implicit in the FDA-approved dosing schedule. All doses are given via the IM route.

If an annual booster has not been administered on time, administer the booster dose at the earliest possible date and adjust the subsequent booster schedule accordingly. Once the five dose primary regimen is complete, the primary series is never repeated.

Injection Site Selection

AVA is administered via the IM route and the preferred injection site is the deltoid muscle region of the upper arm. The CDC conducted a large human clinical trial investigating the safety and efficacy of a dose reduction and route change for AVA. Study results showed that AVA administered by IM injection over the deltoid muscle region of the upper arm affords the same protection against anthrax with significantly less local edema and discomfort at the injection site. IM administration significantly reduced the occurrence of local adverse events at the injection site for both men and women.

Unusually lean personnel may further reduce the risk of injection site reactions by vaccination in the anterolateral thigh. Immunization providers should rotate injections sites and, as always, exercise appropriate clinical judgment.

Medical Screening and Educational Materials

DoD healthcare personnel will provide education and screening before the administration of the anthrax vaccine to identify medical conditions that could warrant a deferral or initiate further medical evaluation.

Military treatment facilities will distribute the anthrax vaccine brochure to vaccinees (www.anthrax.mil/education) and use it for education sessions. Brochures are shipped with vaccine orders through the United States Medical Materiel Agency or they can be ordered by email message at vaccines@amedd.army.mil. Other educational materials are posted on the Military Vaccine (MILVAX) Agency website: www.anthrax.mil, or www.vaccines.mil/anthrax.

Pregnancy Screening

DoD policy (Reference (i)) is to screen females of childbearing age for pregnancy and defer routine anthrax vaccination until after pregnancy. At a minimum, women of childbearing age are to be questioned/screened for pregnancy before receiving immunizations. Women who are uncertain about pregnancy status shall be medically evaluated for pregnancy before immunization in accordance with Service policies.

Medical Exemptions

Some acute or chronic pre-existing medical conditions may require temporary or permanent medical exemptions from anthrax immunization. Granting medical exemptions is a medical function performed by a privileged healthcare provider. Healthcare providers should be familiar with the package insert prescribing information and grant appropriate exemptions when medically warranted while balancing potential benefits with the risks and considering the threat assessment. Medical exemptions and codes are described in Reference (i).

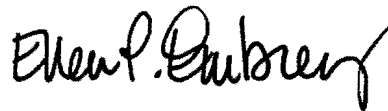
Managing Adverse Events

As with any vaccine, some individuals receiving AVA will experience side effects or adverse events. DoD experience, along with published peer reviewed research studies, has shown that serious adverse events are no more likely with AVA than with other commonly administered vaccines. Manage potential AVA-related adverse events per the Joint Publication "Immunizations and Chemoprophylaxis" (Reference (i)) and per Service-specific policy.

Vaccine Adverse Event Reporting System (VAERS) reports shall be filed using Service reporting procedures for those events resulting in hospital admission, lost duty time or work of 24 hours or more, or from those events suspected to have resulted from contamination of a vaccine vial. Healthcare providers are encouraged to report other potential AVA-related adverse events that in the provider's professional judgment appear to be unexpected in the nature of the severity. VAERS report forms may be accessed at the MILVAX website: www.anthrax.mil, or www.vaccines.mil/anthrax, or at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in DoD's Anthrax Vaccine Immunization Program.

The point of contact for this policy is COL Keith Vesely, who may be reached at 703-845-3310 or Keith.Vesely@ha.osd.mil.



Ellen P. Embrey
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

cc:

Chief of Staff of the U.S. Army
Chief of U.S. Naval Operations
Chief of Staff of the U.S. Air Force
Commandant of the U.S. Marine Corps
Commandant of the U.S. Coast Guard
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force