THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

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MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
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SUBJECT: Policy on Clinical Issues Related to Anthrax Vaccination

This memorandum establishes policy on medical issues involving anthrax vaccination: dosing schedule; education materials; medical screening before immunization; pregnancy screening; injection-site selection; medical exemptions; and adverse events management.

Dosage Schedule

As stated in all previous Anthrax Vaccine Immunization Program (AVIP) policies, full immunization requires six doses administered at proper intervals: 0, 2, and 4 weeks, and 6, 12, and 18 months. Annual boosters are given to sustain immunity. This is the only dosage schedule approved by the Food & Drug Administration (FDA) at this time. Do not administer anthrax vaccine on a compressed or accelerated schedule.

Take reasonable steps to ensure that shots are given on or as soon after recommended dates as possible. Encourage commanders to remind personnel about upcoming shots and recall people who do not appear as scheduled. Accurate documentation in both individual medical records and automated immunization tracking systems is required. Encourage commanders to pay special attention to units with a significant fraction of personnel more than 30 days late for vaccination.

Whenever a vaccine dose is received after a scheduled date, base the date for the next shot on the interval between doses. For anthrax vaccine, the approved dosing intervals are: two weeks between doses 1 and 2; two weeks between doses 2 and 3; five months between doses 3 and 4; six months between doses 4 and 5; and six months between doses 5 and 6. For example, if dose 3 is received three weeks after dose 2 (rather than the normally scheduled two weeks), dose 4 should still be given five months after dose 3. Any dose administered one or more days earlier than the date of the prescribed minimal interval will not be considered valid.

Personnel whose vaccination series was interrupted during the previous AVIP slowdown will not need to repeat any doses already received in the vaccine series or receive extra doses. Rather, they will resume the vaccination schedule from the point of deferment (subject to any applicable medical or administrative exemption). This guidance is consistent with the best practice of medicine, guidance of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and consultation with the FDA. This DoD policy

supercedes the DoD Policy for Deviation from Anthrax Vaccine Immunization Schedule, dated 11 September 1998.

Educational Materials

Educational materials provided to all personnel before anthrax vaccination shall address the benefits, side effects, and other medical information concerning the vaccine. For personnel for whom the dosing schedule was interrupted, the educational materials shall include information on the interruption and the deferred dosing schedule.

Medical Screening Before Immunization

The national standard of practice for all immunizations, including the anthrax vaccine, shall be adhered to when immunizing personnel. This includes medical screening prior to immunization. Education and screening shall be conducted for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated. A sample screening questionnaire is provided at Example 1.

Pregnancy Screening

DoD policy is to defer routine anthrax vaccinations until after pregnancy. In accordance with FDA and ACIP recommendations, all efforts will be taken to avoid unintended vaccination during pregnancy. All immunization clinics and providers will display in a prominent place written warning against unintentionally vaccinating pregnant women. This warning shall be visible during the screening process. Women of childbearing age are to be questioned/screened for pregnancy prior to receiving immunizations. Women who are uncertain about pregnancy status shall be medically evaluated for pregnancy prior to immunization IAW service policies.

Injection-Site Selection

The Anthrax Vaccine Expert Committee (AVEC), an independent civilian review panel, evaluates all reports submitted to the Vaccine Adverse Event Reporting System (VAERS) involving anthrax vaccine. This committee identified several reports related to ulnar nerve irritation that may be prevented through a choice of site injection. The committee concluded that subcutaneous (SC) injections given over the triceps muscle may result in localized inflammation, that could compress the nearby ulnar nerve and produce temporary paresthesia (i.e., numbness, tingling).

The preferred injection site is the subcutaneous tissue over the deltoid muscle. This minimizes the chance of temporary paresthesias. Most people have sufficient SC tissue over the deltoid for proper SC deposition of the vaccine. Unusually lean people might avoid injection-site reactions by vaccination in the anterolateral thigh. Additionally, providers should rotate injection sites. As always, appropriate clinical judgement is warranted.

Medical Exemptions

The vast majority of individuals will complete the vaccine series though some may experience minor side effects. Some individuals will have either acute or chronic pre-existing

conditions that may warrant medical exemption from anthrax vaccination. Furthermore, a small proportion of individuals will develop a more serious reaction during the vaccination series that may warrant medical exemptions, temporary and permanent, from anthrax vaccination.

Granting medical exemptions is a medical function performed by a privileged health-care provider. The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat assessment.

The two most common medical exemptions utilized are medical temporary (MT) and medical permanent (MP).

Temporary medical exemptions are warranted when a provider has a concern about the safety of continued immunizations. Examples of situations that warrant a temporary medical exemption are listed below:

1. Immunosuppressive Therapy. Individuals receiving systemic corticosteroid therapy, other immunosuppressive drug therapies, or radiation therapy may be in a state of temporary immunodeficiency. Because they may not respond fully to vaccination, defer these individuals from receiving the anthrax vaccine until immune function returns, as clinically appropriate.

2. Acute Situations. Serious acute diseases, post-surgical situations, or acute injuries potentially may warrant temporary vaccination deferment, if immune response to vaccination might be impaired or adverse events affected. This includes acute febrile illnesses. Vaccinations may resume when clinically appropriate.

3. Pregnancy. Under normal circumstances, defer anthrax vaccine until after pregnancy. Anthrax immunization is largely based on occupational risk, therefore vaccination should resume with full assumption of duties following pregnancy, unless a longer postpartum interval is clinically indicated. Breast-feeding is not a contraindication to any immunization.

4. Other Conditions. In situations where a medical condition is being evaluated or treated, a temporary deferral of anthrax vaccination may be warranted, up to 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending physician will determine the deferral interval, based on individual clinical circumstances.

Medical permanent exemptions are generally warranted if the medical condition or adverse reaction is so severe that the risk of continued immunization is not justified. Examples of situations, which warrant a permanent medical exemption, are listed below:

1. Severe reaction after a previous anthrax vaccination, such that additional doses would pose an undue risk to the vaccine recipient.

2. Human immunodeficiency virus (HIV) infection or other chronic immune deficiencies.

3. Evidence of immunity based on serologic antibody tests or documented previous anthrax infection.

If the situation changes, a permanent medical exemption can be removed by a provider experienced in vaccine safety assessment.

If an individual's clinical case is complex or not readily definable, consult an appropriate medical specialist with vaccine safety assessment expertise, before a permanent medical exemption is granted. In addition, the original health care provider may consult with physicians located at the Vaccine Healthcare Center Network, DoD's vaccine centers of excellence. If a permanent medical exemption is indicated, appropriate DoD and Service policies will be pursued for granting such exemptions. Service members who disagree with a given provider or consultant's recommendations regarding an exemption may be referred for a second opinion to a provider experienced in vaccine adverse-event management. Medical records will be accurately and appropriately annotated pertaining to any temporary or permanent medical exemptions. When no longer clinically warranted, medical exemptions will be revoked.

If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion at the next higher medical treatment facility. If the second opinion is one with which the patient again disagrees, he or she may be referred directly to the Vaccine Healthcare Center Network.

Each military treatment facility will assist Service members in obtaining appropriate specialty consultations expeditiously and assist in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of the patient to his or her primary-care provider is not required if the referring specialist deems a permanent medical exemption is warranted. The following medical exemption codes relate to all vaccines. A Vaccine Adverse Event Reporting System (VAERS) report should be filed for any permanent medical exemption due to a vaccine related adverse event.

Medical Exemption Codes:

Code	Meaning	Explanation or Example	Duration
MI	Medical, Immune	Evidence of immunity (e.g., serologic antibody test); documented previous anthrax infection	Indefinite
MR	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis). Code can be reversed if an alternate form of prophylaxis is available. Probably warrants VAERS report	Indefinite
MT	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, any temporary contraindication to immunization	Specified period
MP	Medical, Permanent	HIV infection, pre-existing allergy, permanent immune suppression. Can be reversed if the condition changes.	Indefinite
MD	Medical, Declined	Declination of optional vaccines (not applicable to anthrax vaccine), religious waivers	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply	Indefinite

Adverse Events Management

As with any vaccine, some individuals receiving anthrax vaccine will experience side effects or adverse events. Experience has shown that serious adverse events are no more likely with anthrax vaccine than with other commonly administered vaccines.

The attached clinical guidelines offer advice for managing adverse events that may occur after vaccination with any vaccine. These clinical guidelines are also available on the DoD AVIP web site at www.anthrax.osd.mil.

Adverse reactions from DoD directed immunizations are line of duty conditions.

Immunizations are provided as part of the Department's Total Force Protection program. At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, general information on expected adverse events, location of the nearest military treatment facilities (MTFs), a toll free 24-hour medical provider assistance line, and the toll free telephone number of the Military Medical Support Office, in the event medical treatment is required from non-military treatment facilities. Emergency essential DoD U.S. civilian employees and contractor personnel carrying out mission essential services are entitled to the same treatment and necessary medical care as given to the Service members. This includes follow-up and/or emergency medical treatment from the MTF or treatment from their personal healthcare providers or non-military treatment facilities for emergency medical care as a result of immunizations required by their DoD employment.

Whenever a Service member presents at an MTF, expressing a belief that the condition for which treatment is sought is related to an immunization received during a period of duty, the member must be examined and provided necessary medical care. Once treatment has been rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility will be determined as soon as possible. Reserve Component members, who seek medical attention from their personal healthcare providers, or any non-military treatment facility, must ensure that the Military Medical Support Office is notified as soon as possible.

In the case of Emergency-Essential civilian employees presenting to a military treatment facility or occupational health clinic, the initial assessment and any needed emergency care should be provided consistent with applicable occupational health program procedures. In the case of contractor personnel covered by the anthrax vaccination policy presenting to a military medical treatment facility or occupational health clinic, Secretarial designee authority shall be used, consistent with applicable Military Department policy, to allow an initial assessment and any needed emergency care. This policy will facilitate awareness by our medical professionals of adverse events and provide to the patient medical expertise regarding anthrax vaccine events not necessarily available in the civilian medical community. This use of Secretarial designee authority does not change the overall responsibility of the contractor under workers' compensation program for all work-related illnesses, injuries, or disabilities.

As provided in HA Policy No. 99-031, Policy for Reporting Adverse Events Associated with the Anthrax Vaccine, 15 October 1999, any serious adverse event temporally associated

with receipt of a dose of anthrax vaccine should be immediately evaluated by a privileged health-care provider and any specialists, as indicated.

Vaccine Adverse Event Reporting System (VAERS) reports shall be filed using Service reporting procedures for those events resulting in hospital admission or lost duty time or work of 24 hours or more or from those events suspected to have resulted from contamination of a vaccine vial. Further, health-care providers are encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature or severity. In other situations in which the patient wishes a VAERS report to be submitted, the health-care provider will work with the patient to submit one. VAERS report forms may be obtained by accessing either the AVIP web site or www.vaers.org or by calling the VAERS at 1-800-822-7967.

Adverse-event management should be thoroughly documented in medical records. A copy of the VAERS report will be filed in an individual's medical record after submitting the original form through DoD reporting channels, as discussed above. Providers are encouraged to provide a copy of the VAERS report to the patient.

These policies are effective immediately and should be communicated to appropriate commanders, health-care providers, and others involved in the implementation of the AVIP.

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
Chief of Staff of the Army
Chief of Naval Operations
Commandant of the Marine Corps
Chief of Staff of the Air Force
Surgeon General of the Army
Surgeon General of the Navy
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