



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D.C.

MAR 10 2000

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE**SUBJECT:** Policy on Adherence to the Anthrax Vaccine Immunization Schedule and Medical Exemptions to Anthrax Vaccination

This memorandum is intended to provide policy guidance on the following medical issues: compliance with FDA-approved vaccine guidelines on the scheduling and administration of anthrax vaccine; the medical exemptions to anthrax vaccination; and the reporting of adverse events associated with the anthrax vaccine.

Dosage Schedule.

The Commissioner of the Food and Drug Administration (FDA) recently expressed concern over reports that some members of the Armed Forces in both Active and Reserve components are receiving their anthrax vaccine doses substantially later than called for by the schedule approved by the Food and Drug Administration (FDA), as described in the vaccine manufacturer's package insert. As stated clearly in all Anthrax Vaccine Immunization Program (AVIP) policies, full immunization requires six doses administered at 0, 2, and 4 weeks, and at 6, 12, and 18 months, to complete the primary series. This schedule is the only schedule approved by the FDA at this time.

All reasonable steps should be taken to ensure that shots are given on or as close as possible to the recommended schedule. As stated in my memorandum of September 11, 1998 (HA Policy No. 98-045), doses of the vaccine should not be administered on a compressed or accelerated schedule (for example, shorter intervals between doses or more doses than required).

Continued senior leadership attention is necessary to assure proper implementation of the program. Administration of the vaccination schedule at the unit command level requires, at a minimum, notification to the recipient of the date, time, and location for the next scheduled shot, the availability of the next shot at the proper time, and implementation of a procedure to recall the patient if he or she does not appear as scheduled. Higher command levels should monitor and provide appropriate follow-up to ensure compliance. Accurate documentation in both individual medical records and Service-specific automated immunization tracking systems will greatly aid this effort. Attention should be directed to those units having a significant percentage of the second and third doses being administered more than seven days late, and the fourth, fifth, or sixth doses being given more than 30 days late.

To ensure uniformity of practice, in cases in which a dose is received beyond the scheduled date, administration of the next shot in the series should be based on the interval of time between doses, as indicated on the FDA-approved schedule. 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 six weeks after dose 2 (rather than the normally scheduled two weeks), dose 4 should be given five months after dose 3. There are no data to support reduced immune effectiveness of the vaccine if doses are given later than the scheduled time but doses given too early may result in reduce immune responses.

Medical Exemptions.

The granting of medical exemptions is a medical function that can only be performed by a privileged health care provider. Such individual exemptions should be applied only when medically warranted, with the overall health and welfare of the patient clearly in mind. The granting of medical exemptions should be based on potential benefits versus risks and should always take into consideration the immediate threat assessment.

Temporary medical exemptions are warranted in the five situations 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 of potential suppression of the immune response, these individuals should be deferred from receiving the anthrax vaccine until immune function returns, as determined by the attending physician.
2. **Acute Illnesses.** Serious acute diseases or acute injuries may be potentially aggravated by anthrax vaccination or can lead to more severe side effects with immunization. This includes any acute febrile illnesses. Vaccinations may resume, as determined by the attending physician.
3. **Post-surgery.** Post-surgical situations may warrant temporary vaccination deferment in order to ensure full recovery through convalescence. The timeframe when vaccinations may resume following a surgical procedure will be again be determined by the patient's attending physician.
4. **Pregnancy.** Anthrax vaccine should be deferred until after pregnancy. Because anthrax immunization is largely based on occupational risk, vaccination should resume with full assumption of duties following pregnancy, unless a longer post-partum interval is medically indicated, and be in accordance with current DoD and Service policies.
5. **Other Conditions.** In situations where a medical condition is in the process of being evaluated or treated, a temporary deferral of anthrax vaccination may be warranted. This would include significant vaccine-associated reactions that are being evaluated. The timeframe for deferral will be determined by the attending physician, and in accordance with current DoD and Service policies.

Situations warranting a permanent medical exemption include: severe reaction to a previous anthrax vaccination, where it has been determined that further vaccination will seriously endanger the health status of the patient; and Human Immunodeficiency Virus (HIV) infection and other chronic immunodeficiencies, where the immune response may be unpredictable and such individuals would not be deployed to a high threat area.

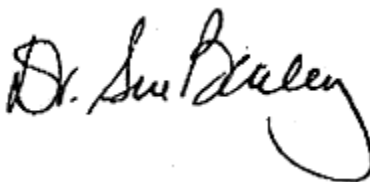
If an individual's case is complex or not readily definable, an allergist/immunologist, or other appropriate medical specialist, should be consulted before any exemption is granted. If a permanent deferment from further immunizations is indicated, appropriate DoD and Service policies will be pursued for the granting of such exemptions. Medical records will be accurately and appropriately annotated pertaining to any temporary or permanent exemptions. Health care providers will periodically review exemptions, to assure that they continue to be valid.

Adverse Events.

As provided in HA Policy No. 99-031, Policy for Reporting Adverse Events Associated with the Anthrax Vaccine, 15 October 1999, any serious adverse reaction temporally associated with receipt of a dose of anthrax vaccine should be immediately evaluated by a privileged health care provider and any specialists, if indicated. The clinical practice guidelines available on the AVIP web site (www.anthrax.osd.mil). can also be consulted.

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 greater than 24 hours or from those events suspected to have resulted from contamination of a vaccine lot. Further, health care providers are encouraged to report other adverse events that in the provider's professional judgment appears to be unexpected in nature or severity. In other situations in which the patient wishes to submit a Form VAERS-1 report, the health care provider will assist the patient in completion of the reporting form. VAERS-1 form reports may be obtained by accessing the AVIP web site or by calling the FDA at 1-800-822-7967.

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

A handwritten signature in black ink, appearing to read "Dr. Sue Bailey". The signature is written in a cursive style with a large, sweeping flourish at the end.

Dr. Sue Bailey

cc:

Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director of the Joint Staff
