



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D.C.

SEP 11 1998

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Policy for Deviation from Anthrax Vaccine Immunization Schedule

Full immunization with Anthrax Vaccine Adsorbed requires six doses administered over 18 months to complete the primary series. Doses are to be administered at 0, 2, and 4 weeks, 6 months, 12 months, and 18 months (where the first dose is given at "week 0"). Yearly boosters are administered thereafter to maintain immunity. This schedule is the only regimen shown to protect humans against anthrax and is the schedule approved by the Food and Drug Administration.

At its April 15, 1998 meeting, the Infectious Diseases Control Subcommittee of the Armed Forces Epidemiological Board (AFEB) reviewed the data available on this issue and made recommendations based on this data. This DoD policy is based upon the AFEB recommendations. In addition, the Advisory Committee on Immunization Practices (ACIP), U.S. Public Health Service (*MMWR* Vol. 43, No. RR-1, Jan. 28, 1994) does not generally recommend reinstatement of the entire series of a vaccine because of an interruption in the immunization schedule. For the anthrax vaccine, this approach is supported by unpublished data in humans that shows a robust antibody response to the anthrax vaccine one to two years after a partially completed primary series. However, because the consequences of inhalation anthrax are severe and the correlation between serum anthrax antibody titers and protection in humans is uncertain, the policy outlined in this memorandum reflects a more conservative approach to dealing with an interruption of the anthrax vaccine immunization schedule than the ACIP recommendation (i.e., restart the primary immunization series with the first dose if only one dose in the primary series has been administered and more than two years have elapsed).

Based on the findings cited above, the Department of Defense policy shall be to adhere to the published immunization schedule. Deviation from this schedule should be the exception rather than the rule and be documented by bonafide reasons such as pregnancy, active infection, etc. Although the effect of specific deviations from this schedule on the efficacy of the vaccine is unknown, in general, the greater the deviation the less certain the protective effect in humans.

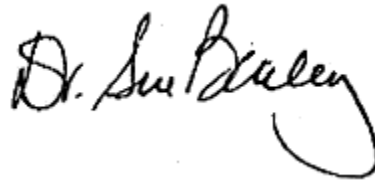
Doses of the vaccine should not be administered on a compressed or accelerated schedule (for example, shorter intervals between doses or more doses than required). For an individual who is late for or has missed a dose in the standard immunization schedule, the following procedures shall be followed:

- If only one dose in the primary series has been administered and more than two years have elapsed, restart the primary immunization series with the first dose.
- If one dose in the primary series has been administered but less than two years have

elapsed or two or more doses have been administered, the primary series does not need to be restarted. Resume the primary series 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.

- If an annual booster has not been administered on time, administer the booster dose at the earliest possible date, adjusting the subsequent booster schedule accordingly. Once the primary series of six doses is complete, the primary series is never repeated.

This policy is effective immediately and should be included in Service and Joint Staff plans and policies for the Department's Anthrax Vaccine Immunization Program.

A handwritten signature in black ink that reads "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

HA Policy 98-045
