THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D.C.

OCT 15 1999

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE

SUBJECT: Policy for Reporting Adverse Events Associated with the Anthrax Vaccine

This memorandum establishes the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP) policy for reporting requirements on adverse events possibly related to the anthrax vaccine adsorbed (AVA).

Requirements for Generating a Vaccine Adverse Event Reporting System (VAERS) Form VAERS-1

For the purposes of reporting anthrax vaccine adverse events, a Form VAERS-1 must be completed and submitted using Service reporting procedures for those events resulting in a hospital admission or time lost from duty for greater than 24 hours or for 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 appear to be unexpected in nature or severity. In addition, the patient or a health care provider may submit a Form VAERS-1 directly to the Food and Drug Administration (FDA) for any possible adverse event. To obtain Form VAERS-1, contact the FDA at 1-800-822-7967 or visit the FDA web site www.fda.gov/cber/vaers/vaers.htm. Additional VAERS statistics are available from the National Technical Information Services (NTIS) at 1-800-553-6847.

A supplemental form, specifically for use in connection with anthrax vaccine adverse event reporting, will be used by the Services' reportable disease project officers to verify completeness of and to classify each Form VAERS-1. The Services will submit a copy of the Form VAERS-1 and a supplemental form to the Army Medical Surveillance Activity (AMSA), U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). The AMSA will serve as the central repository and monitor all Form VAERS-1 submitted. The AMSA will coordinate the results of these reports directly with the DoD AVIP Agency, Office of the Army Surgeon General (OTSG) and the Services' Surgeon General.

Services Reporting Procedures

Army: All reports of anthrax vaccine adverse events are submitted by the chief of preventive medicine through the Army's automated reportable disease system to AMSA. These reports are consolidated daily into the Defense Medical Surveillance System (DMSS). In addition, a Form VAERS-1 is submitted to the chairman of the supporting medical treatment facility's (MTF) Pharmacy and Therapeutics Committee. Reports are submitted by the chairman, MTF Pharmacy and Therapeutics Committee, to the FDA's Vaccine Adverse Event Reporting System and copies of the Form VAERS-1 is provided to the reportable disease project officer at AMSA,

DSN: 662-0471 or commercial: 202-782-0471.

Navy: All reports of anthrax vaccine adverse events are submitted by the preventive medicine department or the senior medical officer through the Navy Disease Reporting System (NDRS) to the Navy Environmental Health Center (NEHC). These reports are consolidated monthly into the DMSS. In addition, a Form VAERS-1 is submitted by the health care provider to the FDA's Vaccine Adverse Event Reporting System and a copy to the reportable disease project officer at NEHC DSN: 864-5603 or commercial 757-462-5500. NEHC forwards a copy of the Form VAERS-1 and the supplemental form to AMSA.

Air Force : All reports of anthrax vaccine adverse reactions are submitted by the military health care provider to the Force Health Protection and Surveillance Branch, IERA/RSRH, 2513 Kennedy Circle, Brooks AFB, TX 78235-5123, DSN 240-3471 (commercial:210-536-4371), FAX DSN 240-6841 (commercial: 210-536-6841). If the incident is life threatening or a death has occurred, the report will be made by telephone within 24 hours to IERA/RSRH. These reports are consolidated monthly into DMSS. A Form VAERS-1 is submitted to the FDA's Vaccine Adverse Event Reporting System and a copy to the Force Health Protection and Surveillance Branch. A copy of the Form VAERS-1 and supplemental form are sent to AMSA. Copies are also provided to the local Pharmacy and Therapeutic Committee, major command clinical points of contact and the Air Force Medical Operations Agency (AFMOA).

Timeliness of Form VAERS-1 Reporting

A copy of Form VAERS-1 should be submitted to each Services' reportable disease project officer (AMSA, NEHC, IERA/RSRH) within seven days of the occurrence of the adverse event. The reportable disease project officer is responsible for verifying the completeness of the information on each report and completing an anthrax vaccine adverse event supplemental form prior to sending the report to AMSA. The reportable disease project officer has seven days from receipt to submit the copy of Form VAERS-1 and a completed supplemental form to AMSA so that consolidated DoD reporting can be provided to the AVIP Agency, OTSG.

Adverse events that are deemed life-threatening (such as anaphylaxis), result in death, or are suspected to be the result of contaminated lots must be reported telephonically to each Services' reportable disease project officer within 24 hours of the occurrence of the event. Each reportable disease project officer has an additional 24 hours to notify AMSA of the occurrence. Hard copy reports of the event should follow the initial telephonic report.

Classification of the Form VAERS-1

Each Services' reportable disease project officer is responsible for classifying Form VAERS-1 reports based on the information submitted and any other supplemental information necessary to complete a report and make a determination. The following classification system will be used to classify each report on the supplemental form:

Local Reactions:

Mild local reactions involve local erythema and induration of 1-2 cm in diameter that may increase in size to 3-5 cm. Usual onset is within 24 hours and the reaction subsides by 48 hours. Reactions tend to increase in severity by the fifth injection, then decrease in severity with subsequent doses. Mild reactions may occur in up to 30 percent of recipients.

Moderate local reactions involve local erythema, induration, and pruritus involving an area more than 5 cm diameter. Subcutaneous nodules may occur at the injection site and persist for several weeks. Moderate reactions occur in up to 4 percent of recipients.

Large local reactions can consist of extensive edema from the site of injection extending past the elbow to possibly involving the forearm, in addition to local inflammatory reaction, focal rash, itching, and subcutaneous nodules. Large local reactions occur less frequently.

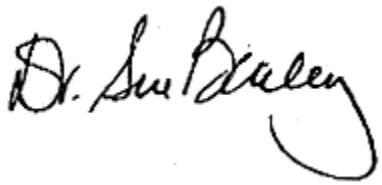
Systemic Reactions:

Systemic reactions usually are characterized by malaise, myalgia, arthralgia, and fatigue. The individual may have generalized rash and pruritis, dyspnea, and fever. Focal swelling and itching may appear at areas other than injection site. A simple headache may last a short duration and is treatable. Chills and fever are rare. Immediate reactions are suggestive of anaphylaxis. Systemic reactions rarely occur (greater than 0.2% injections).

Report to the Executive Agent of AVIP

AMSA is responsible for forwarding to the DoD AVIP Agency a weekly summary of the reported anthrax vaccine adverse events. This summary will compile the reports of anthrax vaccine adverse events submitted by each Service. The classification system maintains consistency of anthrax vaccine adverse event reporting within the DoD.

This policy provides guidance to support the Department's AVIP through improving vaccine adverse event reporting procedures of the Services' instruction "Immunization and Chemoprophylaxis" (AFJI48-110; AR 40-562; BUMEDINST 6230.15; CG COMDTINST M6230.4E) of November 1, 1995. This policy is effective immediately and shall be included in all Service and Joint Staff plans and policies for the AVIP and for joint medical surveillance and force health protection.



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