

INFORMATION PAPER

Military Vaccine Agency
23 December 2008

SUBJECT: Anthrax Vaccine Route Change and Dose Reduction

1. Purpose. To describe the anthrax vaccine route change and dose reduction.

2. Facts.

a. Dose reduction and route change of anthrax vaccine. The FDA has approved a change in route of administration for the anthrax vaccine adsorbed (AVA) from a subcutaneous (SC) injection to intramuscular (IM). The FDA has also approved a change in the vaccination series by removing the 2 week dose post-vaccination and asserting the safety and effectiveness of the new 5 dose regimen. This is a change from the originally licensed 6 dose regimen.

(1) Researchers at the Centers for Disease Control and Prevention (CDC) conducted a randomized double-blinded study and found that dose reduction from 6 doses to 5 doses, over an 18 month period to include annual boosters, receive the same benefit of protection from anthrax vaccine.

(2) Results demonstrated that 4 SC, 4 IM, and 3 IM regimens provide equivalent immunological priming by the 7th month. The IM administration significantly reduced the occurrence of local adverse events at the injection site for both men and women.

b. Vaccination. Anthrax vaccinations will be given as a series of five 0.5-ml intramuscular doses, optimally at 0, 4 weeks, 6 months, 12 months, and 18 months, with annual boosters given to maintain immunity. Injections are given in the deltoid region of the upper arm. Doses of the vaccine should not be administered on a compressed or accelerated schedule. For an individual who is late for or has missed a dose in the primary 5 dose immunization schedule the following procedures should be followed:

(1) Resume the primary series with administration of the next scheduled dose. Administer subsequent doses of the vaccine at intervals based on the date the last dose was given, not when it was originally scheduled.

(2) Available AVA specific data suggests that significantly increasing the interval between doses does not adversely affect immunogenicity or safety. Therefore, as with other vaccines, interruption of the vaccination schedule does not require restarting the primary series or the addition of extra doses.

(3) 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.

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(4) For those individuals who received their second dose at 2 weeks, the primary 6 dose schedule of 0, 2 weeks, 4 weeks, 6 months, 12 months, and 18 months will still be used. The route of administration will be IM.

c. Department of Defense (DoD) policy. The DoD policy for AVA remains the same. AVA is mandatory for uniformed personnel, emergency essential and equivalent civilian personnel or contractors deployed (or deploying within 120 days) to U.S. Central Command (CENTCOM) or Korea 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 and are no longer deployed to U.S. CENTCOM or Korea may continue the series on a voluntary basis. Vaccinations are also voluntary for U.S. citizen adult family members, 18-65 years of age, accompanying DoD military, civilian personnel, or contractor personnel for 15 or more consecutive days to the U.S. CENTCOM area of responsibility and Korean peninsula.

d. Education requirements. Prior to vaccination with AVA, all vaccinees must receive a copy of the Vaccine Information Statement (VIS) and the DoD Anthrax Individual Information Trifold Brochure. These are shipped to clinics at no cost in the same quantity as the ordered vaccine. Additionally, clinics may request additional copies through MILVAX by phone, at 877-GET-VACC or email at vaccines@amedd.army.mil. These products are also available on-line at: www.anthrax.mil/avip2008.

e. The ordering process will remain the same. Customers will order from the USAMMA-DOC www.usamma.army.mil/vaccines/anthrax/antxhome.cfm.

f. Immunization record keeping procedures. There is no change to the immunization record keeping requirements. Every vaccination must be entered into a DoD approved electronic immunization tracking system.

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