



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041

REPLY TO
ATTENTION OF

Military Vaccine Agency

16 December 2008

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Implementation Instructions for Change in Route and Change in Dosing Schedule for the Anthrax Vaccine Adsorbed (AVA) in the Department of Defense Anthrax Vaccine Immunization Program (AVIP)

1. References:

a. Department of Defense Directive (DODD) 6205.02E, *Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries*, 19 September 2006. Available at:

<http://www.vaccines.mil/documents/973Policy620502p.pdf>.

b. Under Secretary of Defense for Personnel and Readiness, *Implementation of the Anthrax Vaccine Immunization Program (AVIP)*, 6 December 2006. Available at:

<http://www.vaccines.mil/documents/979AVIP%20Implementation%20Guidance%206%20Dec%202006.pdf>.

c. Assistant Secretary of Defense for Health Affairs, *Policy on Clinical Issues Related to Anthrax Vaccination*, 6 August 2002. Available at:

<http://www.anthrax.mil/documents/141ClinicalIssues.pdf>.

d. Department of Defense Joint Regulation (Army Regulation 40–562, BUMEDINST 6230.15A, AFJI 48–110, CG COMDTINST M6230.4F), *Immunizations and Chemoprophylaxis*, 29 September 2006. Available at:

http://www.vaccines.mil/documents/969r40_562.pdf.

e. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), *Anthrax Vaccine Adsorbed- Product Approval Letter*, 15 December 2008. Available at: <http://www.fda.gov/cber/approvltr/biothrax121108L.htm>.

f. Emergent BioSolutions, BioThrax® (Anthrax Vaccine Adsorbed) Package Insert. Available at: <http://www.fda.gov/cber/label/biothraxLB.pdf>.

h. Department of Defense, *Communication Plan – Anthrax Vaccine Adsorbed – Route Change and Dose Reduction*, 15 December 2008.

Military Vaccine Agency

SUBJECT: Implementation Instructions for Change in Route and Change in Dosing Schedule for the Anthrax Vaccine Adsorbed (AVA) in the Department of Defense Anthrax Vaccine Immunization Program (AVIP)

i. Department of Defense educational brochure, *What You Need To Know About Anthrax Vaccine*, pending update. Available at: <http://www.anthrax.mil/AVIP2008>.

2. Purpose: To provide instructions to Service representatives on the change in the route of administration and the change in the dosing schedule of Anthrax Vaccine Adsorbed (AVA) as part of the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP).

3. Summary: 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.

4. Timeline:

a. Effective 11 December 2008: DoD healthcare providers will begin administering AVA via the intramuscular (IM) route per the FDA approved manufacturer's recommendation.

b. Effective 11 December 2008: DoD healthcare providers will begin adhering to the new FDA approved manufacturer recommended 5 dose vaccination series as described in the vaccine prescribing information.

5. Anthrax Vaccine Immunization Program (AVIP) Policy: The DoD policy for AVIP remains the same. This new route and schedule is a clinical change and does not alter the population being vaccinated or the previous requirements of AVIP.

6. Clinical Requirements: Anthrax vaccination will be given as a series of five 0.5-ml intramuscular doses at 0, 4 weeks, 6 months, 12 months, and 18 months, with boosters given annually to maintain immunity. Injections are given in the deltoid region of the upper arm. The significant changes are:

a. As stated in prior policies, doses of the vaccine should not be administered on a compressed or accelerated schedule. The doses will be administered intramuscularly at 0, 4 weeks, 6 months, 12 months, and 18 months for the primary series and yearly boosters thereafter. For an individual who is late or has missed a dose in the standard immunization schedule, the following procedures shall be followed:

Military Vaccine Agency

SUBJECT: Implementation Instructions for Change in Route and Change in Dosing Schedule for the Anthrax Vaccine Adsorbed (AVA) in the Department of Defense Anthrax Vaccine Immunization Program (AVIP)

1) 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.

2) Per the Advisory Committee on Immunization Practices (ACIP) recommendations, the primary AVA series does not need to be restarted regardless of time elapsed since last dose. Once the primary series of five doses is complete, the primary series is never repeated. 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 entire 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.

7. Vaccine Safety:

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

b. Results demonstrated that 4 subcutaneous (SC), 4 intramuscular (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.

c. Our scientific understanding of the safety profile for anthrax vaccination is shaped by over 30 human safety studies conducted by both military and independent civilian expert panels, including a comprehensive evaluation by the National Academy of Sciences and its Institute of Medicine (IOM). After a two-year review, the IOM concluded that scientific evidence for the vaccine's safety and effectiveness is sound.

8. 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

Military Vaccine Agency

SUBJECT: Implementation Instructions for Change in Route and Change in Dosing Schedule for the Anthrax Vaccine Adsorbed (AVA) in the Department of Defense Anthrax Vaccine Immunization Program (AVIP)

through MILVAX by phone at 877-GET-VACC or email at vaccines@amedd.army.mil. These products are also available on-line for downloading at: <http://www.anthrax.mil/AVIP2008> or <http://www.vaccines.mil/anthrax>.

9. Vaccine Ordering, Storage, and Handling Procedures:

a. The ordering process will remain the same. Customers will order from the USAMMA-DOC.

b. The AVA vaccine will be distributed and stored at 2-8° C (36-46°F).

c. DoD uses the same FDA approved vaccine that is maintained in the Strategic National Stockpile. This vaccine is approved for use in the DoD.

10. 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.

11. POC for this message is LTC Patrick Garman, COM: 703-681-5101 or DSN: 761-5101.



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