

ANTHRAX VACCINE IMMUNIZATION PROGRAM
INFORMATION PAPER

SUBJECT: Route of Administration for Anthrax Vaccine

16 September 2004

1. PURPOSE. To describe an alternate route for administering anthrax vaccine.

2. FACTS.

a. The US government license (approved by the Food and Drug Administration (FDA)) for anthrax vaccine is based on injecting the vaccine subcutaneously, about ½-inch under the skin. Subcutaneous (SC) injections place the vaccine in fatty tissue between the skin and underlying muscle. The anthrax vaccine was 92.5% effective in preventing anthrax infection when injected subcutaneously in a key study (Brachman, 1962; FDA, 1985; FDA, 2004).

b. In a small study, people given anthrax vaccine SC or IM were compared for antibody levels and side effects. The two groups developed roughly the same amount of antibodies. But people vaccinated by the SC route were more likely to develop tenderness, redness, warmth, swelling, or lumps at the injection site, compared to people vaccinated by the IM route. Other information shows that anthrax-fighting antibody levels are somewhat higher when the intervals between anthrax vaccinations are prolonged a few weeks longer than usual. These data come from the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD (ACIP, 2000).

c. Although it is DoD policy to follow the FDA-approved method of SC injections, this policy does not prevent a physician or other privileged health-care provider from making a clinical decision to use an IM injection in a special case. A special case could be to alleviate future discomfort for a patient who developed a large or persistent injection-site reaction or experienced a significant systemic event after an earlier dose of anthrax vaccine given by SC injection. In such a case, IM administration is not prohibited if the health-care provider believes IM injection will provide appropriate protection and reduce side effects, and informs the patient of the special circumstances.

d. The independent civilian panel known as the Advisory Committee on Immunization Practices reported that available data “do support some flexibility in the route and timing of anthrax vaccination under special circumstances. As with other licensed vaccines, no data indicate that increasing the interval between doses adversely affects immunogenicity or safety.”

3. REFERENCES.

a. Brachman PS, Gold H, Plotkin SA, Fekety FR, Werrin M, Ingraham NR. Field evaluation of a human anthrax vaccine. *American Journal of Public Health* 1962;52:432-45.
www.anthrax.mil/media/pdf/field_eval.pdf.

b. Food & Drug Administration. Biological products; Bacterial vaccines and toxoids; Implementation of efficacy review. *Federal Register* 1985;50(Dec 13):51002-117.
www.anthrax.mil/media/pdf/fed_reg.pdf.

c. Food & Drug Administration. Biological products; Bacterial vaccines and toxoids; Implementation of efficacy review. *Fed Reg* 2004;69(Jan 5):255-67; errata 2004;69(Feb 13):7114-5.
www.access.gpo.gov/su_docs/fedreg/a040105c.html

d. Advisory Committee on Immunization Practices. Use of anthrax vaccine in the United States. *Morbidity & Mortality Weekly Report* 2000;49(RR-15):1-20. www.cdc.gov/mmwr/PDF/rr/rr4915.pdf.

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