

## Anthrax Vaccine Safety Profile

In one landmark study<sup>1</sup> regarding the safety profile of the anthrax vaccine, the U.S. Anthrax Vaccine Expert Committee (AVEC) reviewed complete data on 1,349,327 doses that were administered to over 400,000 subjects. Adverse events were collected by the U.S. Vaccine Adverse Event Surveillance System (a.k.a. VAERS)

and then investigated by AVEC via the Defense Medical Surveillance System (DMSS). By all accounts, this is a most impressively large and comprehensive review.

**Project EQUIPP**

### Anthrax Vaccine Safety Overview

- The anthrax vaccine has been safely used for over 40 years.
- To date, more than 20 human studies have assessed the safety of anthrax vaccination.
  - No unusual or unexpected patterns of adverse events have been identified.
  - No deaths or serious/long term adverse events have been determined to have been caused by the vaccine.
- The vaccine is safe for its intended use per:
  - Institute of Medicine
  - Anthrax Expert Vaccine Committee
  - CDC Advisory Committee on Immunization Practices
  - Armed Forces Epidemiology Board
  - FDA

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To understand the results it is necessary to first define terms. An Adverse Event is a self-limited, transient event such as injection site reactions, irritability, prolonged crying and fever or headache, nausea, fatigue, etc. An Adverse Event is considered to be a Serious Adverse Event if it is a condition that is fatal, life-threatening, or resulting in hospitalization or permanent disability. In public health surveillance, high sensitivity is the aim; that is, more input or data is better than less to avoid missing a “signal” of an important trend (good

or bad). Consequently, in the U.S. Vaccine Adverse Event Reporting System (VAERS) construct, any symptom can be reported as an adverse event, by anyone, anytime after vaccination.

In the AVEC review of data in VAERS and DMSS, only 602 adverse events were reported out of 1,349,327 injections. That equals **1 adverse event in 25,000 injections** or 40 adverse events in 1 million doses. Of these 602 adverse events, 34 met the definition of a Serious Adverse Event and upon close scrutiny by the Anthrax Vaccine Expert Committee, 7 Serious Adverse Events (out of 1.35 million injections) were considered to be Very Likely/Certain/Probably caused by the vaccination. None were fatal, life-threatening or caused permanent disability. This computes to a **1 in 200,000 chance of a serious adverse event**.

For perspective, the odds of being struck by lightning are 1 in 10,000.<sup>2</sup> And more specific to immunization practices, more than 2.5 million people have received over 10 million doses of the anthrax vaccine to date and not one death, life-threatening illness, or permanent disability has occurred as a result.

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24 June 2011

1 Sever et al. Safety of anthrax vaccine: a review by the Anthrax Vaccine Expert Committee (AVEC) of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). *Pharmacoepidemiology and Drug Safety* 2002; 11: 189–202.

2 National Oceanic and Atmospheric Administration (NOAA). National Weather Service. Office of Climate, Water, and Weather Services. Internet Citation: <http://www.lightningsafety.noaa.gov/medical.htm>. Last accessed June 2011.