

## ANTHRAX VACCINE

### WHAT IS THE PUBLIC HEALTH ISSUE?

The purpose of the Anthrax Vaccine Research Program (AVRP) is to conduct studies to determine factors associated with side effects from the vaccine. The goal is to discover whether the vaccine route can be changed and the number of doses reduced, while still providing protection against anthrax disease. The studies are also expected to provide more information on when a person becomes protected and how long the protection lasts. The current anthrax vaccine is injected in a series of 6 doses over 18 months, followed by a booster dose given each year. One of the most common side effects of the vaccine is redness and swelling in the arm because the shot is given just under the skin instead of into the muscle. Some recent studies have shown that if the shot is given in the muscle, there may be less pain and swelling. It may also be possible to protect people with fewer than 6 shots. By doing this research, CDC hopes to reduce the number of side effects seen with the vaccine, while maintaining its effectiveness and increasing its acceptability.

### WHAT HAS CDC ACCOMPLISHED?

CDC designed and initiated a human clinical trial to assess route change and dose reduction. To date, the five study sites have enrolled 1470/1560 (94%) of volunteers; full accrual is expected by March 2004. The interim analysis will be presented to the Food and Drug Administration in September of 2004. The goals are to reduce the number of doses administered by dropping the 2 week dose in the priming series (currently recommended 0, 2, and 4 weeks in the primary series) while not diminishing the peak anti-protective antibody levels following the 4 week dose and to change injection site to the intramuscular way of administration. The final analysis will be presented to FDA in 2007.

CDC also designed and implemented non-human primate (NHP) studies to determine correlates of protection against inhalation anthrax and to support research on dose reduction in the human clinical trial. Animals are vaccinated by similar regimens as in human study and are challenged at 12, 30 and 42 months post-vaccination with lethal doses of *B. anthracis* spores. The NHP experiments began in 2002 and final data are expected by 2005. Data from these studies will determine whether a person is protected by anthrax vaccine, when protection is achieved, and what the duration of protection is. CDC has developed laboratory assays to measure the human and animal vaccine study primary endpoints. These assays will be used to assess human immune response to second generation anthrax vaccines now in development. The anthrax vaccine studies were endorsed by the Institute of Medicine Committee for CDC Anthrax Vaccine Safety and Efficacy Plan.

### WHAT ARE THE NEXT STEPS?

For bioterrorism preparedness, CDC has undertaken studies to test efficacy of an anthrax immune globulin product as treatment for persons who are ill with anthrax, but failing traditional antibiotic therapy. The benefits of this research extend to both the military and civilian communities. The AVRP studies will help optimize the use of the current vaccine, increase its acceptability, and provide greater understanding about correlates of protection that will extend to next generation anthrax vaccines.