In Summary...

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Review of the CDC Anthrax Vaccine Safety and Efficacy Research Program: Interim Report

Background

Inhalational anthrax is a rare but often deadly disease caused by the spore-forming bacterium *Bacillus anthracis*, and is considered to be the foremost threat of biological warfare. The Department of Defense established the Anthrax Vaccine Immunization Program (AVIP) to protect service members in the armed forces from the disease; however, some parties have raised questions about both the safety and efficacy of the vaccine. The Congress has responded to these concerns by mandating further study of the vaccine by the Department of Defense (DoD), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), both individually and collaboratively.

In response, the CDC designed a research program to further study the vaccine's safety and efficacy, as well as to evaluate alternative routes and schedules of administration in order to reduce adverse effects while maintaining vaccine effectiveness. The CDC also contracted with the Institute of Medicine (IOM) to establish an expert panel to review the completeness and appropriateness of their research plan; this report summarizes the interim findings of the committee.

Purpose of this Interim Report

The IOM study will last 24 months, while the CDC research program continues to be developed. The CDC requested this interim report after eight months, so as to be able to make prompt use of the committee's initial findings. Accordingly, the committee offered critical advice and as much specific comment as possible. Both the IOM committee's review and the CDC's research program are ongoing and further development is expected.

Final Reports to Come in the Future

The Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program is due to release its final report in August 2002. The related DoD-sponsored IOM committee to assess the safety and efficacy of the anthrax vaccine will release its report in June 2002.

Committee to Review CDC's Anthrax Vaccine Safety and Efficacy Research Program: Charge to the Committee

The charge to the committee, which reflects closely the congressional mandate to the CDC, is to advise the CDC on the completeness and appropriateness of the CDC plan to respond to the Congressional mandate to study the safety and efficacy of anthrax vaccine, addressing (1) risk factors for adverse reactions, including gender differences; (2) determining immunologic correlates of protection and documenting vaccine efficacy; (3) optimizing the vaccination schedule and routes of administration to assure efficacy while minimizing the number of doses required and the occurrence of adverse events. The CDC, NIH, and the DoD are directed by Congress to collaborate and cooperate fully in this effort.

Findings and Recommendations

The Committee found that the CDC's research program as described to date includes appropriate and well-conceived projects that are responsive to the congressional mandate. The committee found that many of the projects were still in relatively early, or in some cases very early, stages of development. As the projected plans have potential to produce projects of good research value, the committee recommends continuing their development. In some cases, the CDC's scientific projects would benefit from immediate and direct consultation on specific technical matters of study design and execution, a type of advice better supplied by protocol design consultants than by an IOM committee, and the committee recommended that the CDC consider engaging such consultants. The committee also found that the comprehensive, integrated plan for the CDC's over-all program was to date not clear or not yet clearly communicated, and recommended that the CDC clarify its overall plans for research including integration between centers within the CDC, and strengthen and articulate its collaborations with agencies outside the CDC.

Full report online at:
http://www.nap.edu/catalog/10157.html

COMMITTEE TO REVIEW THE CDC ANTHRAX VACCINE SAFETY AND EFFICACY RESEARCH PROGRAM

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