Vaccine Safety and Effectiveness Working Group Report

Gregory A. Poland, MD
Vice-President, Defense Health Board
Chair, Infectious Diseases Control Subcommittee
Purpose

- DoD request to form a Work Group with the following objectives:
  - Discuss DoD post-licensure vaccine safety, effectiveness, and surveillance studies
  - Review and discussion of published and unpublished data from DoD research of vaccines in use by DoD
  - Discuss future vaccine safety, effectiveness, and surveillance studies within DoD
  - Focus on FDA-approved vaccines
  - Work group to provide guidance and advice on what studies should be done, priorities, identify research gaps, and areas of research which should be developed
Background

- DHB attendees:
  - G. Poland
  - E. Kaplan
  - J. Silva
  - M. Miller
  - D. Walker
- Location: USUHS
- Date: 2 June 2008
Background

• Briefings
  – Col. Randy Anderson (MILVAX)
  – Dr. Tyler Smith (DHRC)
  – Col. Phil Pitman (Vaccine Clinical Research Center – USAMRIID)
  – Dr. Angelia Eick (AFHSC)
  – CDR. Kevin Russell (NHRC)
  – Col. Renata Engler (VHC)
Format

- ✔ Significant progress
- ✔ Some progress
- ✔ Little/no progress
Specific Issues

• Enhanced interactions, coordination, and collaborative efforts across DoD with respect to vaccine surveillance

• External validation of vaccine research initiatives

• Anthrax, smallpox, influenza vaccines
  – Recipient concern re: long-term safety, reproduction, hospitalization, etc.
  – Reproductive health (need for cross-specialty, interdisciplinary research)
  – ACAM 2000
  – Adenovirus vaccine
AFEB 1999

• DoD-Wide Review of Vaccine Policy and Procedures
  – Multiple meetings
  – Outside contractor
  – Published monograph
  – Resulted in a series of 12 major recommendations
Recommendation 1

• Urgently recommend that policies and practices that insure the ready supply to the military of vaccines essential to the mission be developed
  – Assign “watchdog” organizations within DoD
  – Provide funding for collaborative projects and development of strategically important vaccines that have limited markets
  – ? DoD-owned manufacturing facility

✓ Some progress

✓ Military Vaccine (MILVAX) Agency and OASD(HA) monitor supply situation, engage other DoD entities as needed. Adenovirus vaccine project funded and well underway

✓ New vaccine development inadequately funded and slow. DoD-owned manufacturing facility not implemented beyond WRAIR pilot plant.
Recommendation 2

- DoD further develop and expand efforts towards standardized computerized record-keeping and tracking of all administered vaccines to all persons (AD, reserve, beneficiaries, etc.)
  - Include ability to rapidly access information
  - Standardized across services and facilities

- Substantial progress
  - Work remaining:
    - Upgrade USN shipboard system for consistent synchronization with shore-based systems
    - Enhance ability to track family members and retiree
    - Enhance ability to exchange electronic immunization records
    - Enhance ability to give retirees and separated personnel access to their immunization records
Recommendation 3

• Each service measure and report up-to-date immunization rates as key indicators of medical care delivery and force readiness
  
• Some progress
  ✓ Immunization rates as indicators of troop readiness available and tracked
  ✓ Work remaining: Immunization rates of communities based on age or underlying risk factors insufficiently developed or implemented
Recommendation 4

• Consider the concept of a “Vaccine and Immunobiologics Oversight Board”
  – Increase involvement of Reserves and National Guard in the planning and implementation of immunization programs

✓ Achieved.
✓ MILVAX Agency (previously the AVIP Agency from 1998 to 2002) performing admirable job in synchronizing and coordinating programs among the Armed Services (including Active, Reserve, and Guard).
Recommendation 5

- DoD should develop and disseminate, as soon as practical, a new Joint Instruction
  - Address policy for use of IND vaccines
  - Policy for introducing new vaccines
  - Obtaining informed consent
  - Revise record-keeping requirements
  - Reduce differences between services
  - Address issue of screening for immunity


✓ Great success with USAF and US Army screening of basic trainees for pre-existing immunities. USN should emulate. Status for USMC, USCG?
Recommendation 6

• Address whether current procedures and resources are sufficient to insure appropriate personnel are aware of current official policy
  – Develop a web page or other communication devices


✓ Work remaining: Ongoing effort to educate providers, medics, troops, families.
Recommendation 7

- DoD commit to full informing every service member of the health risks, personal and military benefits, and proper use of all vaccines and other medical countermeasures
  - Develop risk communication materials
  - Provide VIS
  - Off-label use policies
  - Risk communication research

✓ Substantial progress. Extensive information at www.vaccines.mil and other sources.

✓ Work remaining: Availability of VIS, perhaps as posters?
Recommendation 8

- DoD should address issues of standardized training and proficiency of immunization delivery practice
  - Training and licensure requirements
  - Ongoing proficiency standards and continuing medical education
  - Address credentialing and licensing
  - Better define the above issues in the Joint Instruction

✓ Substantial progress. Immunization University represents a novel and creative effort to disseminate training across continents and time zones. The CQIP quality-improvement tool sets precedent and raises the bar for civilian settings.

✓ Work remaining: DoD should expand the training effort to reach 100% of immunizers and adopt/enforce explicit criteria for training. Consolidation of enlisted medic training offers another opportunity for increased standardization.
Recommendation 9

• DoD develop a vaccine policy and practice statement for the use of vaccines and immunobiologics in humanitarian missions

X Little/no progress
Recommendation 10

- Recommend maintaining the current centralized DSCP procurement system, while providing flexibility at the local level with the many other adjunct procurement systems

- Centralized procurement of influenza, anthrax, and smallpox vaccines.
- Decentralized procurement of other vaccines along commercial “prime vendor” model.
Recommendation 11

• Recommend DoD continue to participate in the development of a comprehensive Pandemic Influenza Planning document and devise, disseminate and test a DoD-wide plan

✓ Substantial progress. DoD has been an active and energetic partner in the national influenza pandemic planning process.
Recommendation 12

• Review of vaccine policy, practice and use recommendations every 2-3 years

✓ Now is a good time to begin a systematic review of the 2006 Joint Regulation/Instruction, training requirements, and other needs identified by the present discussion.
Overall Assessment Since 1999

• Overall letter grade A
• DoD has made *substantial* progress in virtually ALL areas identified in the 1999 DoD-wide review

• Opportunities:
  – Enhance DoD electronic immunization tracking
  – Develop a humanitarian vaccine policy
  – Insure availability of all vaccines (adenovirus example)
  – Vaccinator certification
Other Findings

- Continued delays in adenovirus vaccine deployment
- Lack of vaccine immunogenetics research within DoD
- Guard and Reserve components generally excluded from safety studies
- No established post-marketing entity within DoD for vaccine safety research
- MILVAX an outstanding asset!
Specific Recommendations

• Prioritization of research given limited time, personnel and other resources
• Cross-disciplinary approaches and teams needed for vaccine safety research
• A central office should manage phase IV research
• Portfolio of AVA research should be limited in view of new anthrax vaccines
Specific Recommendations

• Immunogenetic research architecture should be developed within DoD

• MILVAX role should be considered for expansion
  – Phase IV research coordinating office
  – Vaccine safety coordinating office
  – Guard and Reserve studies
Next Steps

• Further Meetings Likely to be Productive
  – First meeting was introductory and provided background material
  – Next Steps involve:
    • Agendas specific to particular vaccines (anthrax, smallpox in particular)
    • Overall coordination and management of vaccine surveillance efforts
DISCUSSION