



Defense Health Board

Vaccine Safety and Effectiveness Working Group Report

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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 - Review and discussion of published and unpublished data from DoD research of vaccines in use by DoD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
- ✓ Achieved. **US Army Regulation 40-562; Navy Bureau of Medicine & Surgery Instruction 6230.15A; Air Force Joint Instruction 48-110; Coast Guard Commandant Instruction M6230.4F. Immunizations and Chemoprophylaxis. 2006(Sep 29):1-31.**
www.apd.army.mil/pdf/files/r40_562.pdf
- ✓ 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
- ✓ **Substantial progress. Extensive data and resources available at www.vaccines.mil, www.anthrax.mil, www.smallpox.mil, 877-GET-VACC, email, and other communications media.**
- ✓ **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