



# Defense Health Board

## Vaccine Safety and Effectiveness Working Group Update

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**Co-Vice-President, Defense Health Board**

**Chair, Vaccine Safety and Effectiveness Working Board**

**Defense Health Board Meeting**

**12 November 2009**



# Purpose

- **DoD request to form a Working Group with the following objectives:**
  - Focus on FDA-approved vaccines
  - Examine DoD post-licensure vaccine safety, effectiveness, and surveillance studies
  - Review published and unpublished DoD vaccine research data for vaccine safety and effectiveness for vaccines currently in use by DoD
  - Discuss future DoD vaccine safety, effectiveness, and surveillance studies
  - Identify research priorities as well as existing gaps
  - Provide guidance regarding studies that should be conducted



# Membership

**Dr. Gregory Poland** (Mayo Clinic)

**Dr. Francis Ennis** (University of Massachusetts Medical School)

**Dr. Joseph Silva** (University of California, Davis)

**Dr. Michael Oxman** (University of California, San Diego)

**Dr. Edward Kaplan** (University of Minnesota)

**Dr. Mark Miller** (Fogarty Center, NIH)

**Dr. Walter Dowdle** (Emory University)

**Dr. Pierce Gardner** (Fogarty Center, NIH)

**Dr. Clifford Lane** (NIH)

**Dr. John Clements** (Tulane University)

**Dr. David Walker** (UTMB)



# Recent Activities

## 17 September 2009 Meeting: Agenda Topics

- **Vaccine Analytic Unit Update**
  - Dr. Michael McNeil (CDC)
- **Smallpox Vaccine Shedding Study**
  - COL Phillip Pittman (USAMRIID)
- **Smallpox Vaccine Safety Project**
  - CDR Dennis Faix (NHRC)
  - LTC Patrick Garman (MILVAX)
  - Dr. Ava Marie Conlin, on behalf of Dr. Tyler Smith (NHRC)



# Recent Activities

## 17 September 2009 Meeting: Agenda Topics (Cont'd)

- **Seasonal Influenza Vaccine Effectiveness**
  - Dr. Angela Eick (AFHSC)
  
- **H1N1 Vaccine Safety Study in Pregnant Females**
  - Dr. Ava Marie Conlin, on behalf of Dr. Tyler Smith (NHRC)
  
- **H1N1 Vaccine Safety Surveillance in DoD**
  - Dr. Hector Irizuta (FDA/CBER)
  - LTC Patrick Garman (MILVAX)



# Specific Issues

- **Enhanced interaction, coordination, and collaborative efforts are being pursued within DoD (MILVAX, AFHSC, NHRC) and between DoD and FDA with respect to vaccine safety and adverse event surveillance**
  - ACAM2000<sup>®</sup> Phase IV enhanced safety surveillance study
  - ACAM2000<sup>®</sup> myopericarditis/myocarditis registry
  - Anthrax vaccine adsorbed (AVA) studies



# Specific Issues

- **Quality and reliability of data capture**
  - DoD universal tracking system under consideration to address differences across Services and mitigate “stovepiping”
  - Assessment planned to evaluate DoD adverse event screening accuracy during ACAM2000<sup>®</sup> post-marketing Phase IV surveillance
  - Evaluate completeness and accuracy of DMSS immunization data
- **MILVAX MIDRP: priority research topics**
  - Working Group requested to comment and provide feedback on proposed studies of priority to the DoD



# Specific Issues

- **Seasonal vaccine effectiveness: comparison of LAIV and TIV**
- **External validation of vaccine research initiatives**
- **H1N1 Vaccine Safety Surveillance**
  - Planned analyses examining reproductive health outcomes
  - Identification of all Active Duty recipients
  - Importance of national (interagency) and international collaborations to detect significant adverse events





# Findings: Short- and Long-Term Considerations

- **Develop and formalize “closure mechanism” to facilitate DHB reviews and to inform the DHB in a timely manner regarding:**
  - DoD actions pursued or progress in response to DHB recommendations
  - Availability of new data or research progress
  - Changing “situation on the ground”
  - Shifts in DoD’s priorities



# Findings: Short- and Long-Term Considerations (Cont'd)

- **Improve communication between the DHB and the DoD (proactive vs. reactive role of DHB)**
  - Include DHB in discussions and decision-making process
  - Provide guidance for DoD briefers highlighting interest areas of the Working Group for future meetings
- **Develop process for evaluating whether a threat agent poses or continues to pose a real threat**



# Findings: Short- and Long-Term Considerations (Cont'd)

- **Encourage implementation of consistent risk analyses to inform decisions pertaining to vaccine administration**
- **Commend MILVAX initiative to unify research and funding priorities within DoD and stimulate needed collaborations and endeavors to advance scientific understanding**



# Next Steps

- **Next Biowarfare Countermeasures Workgroup meeting:**
  - Request smallpox and anthrax threat updates
  - Determine whether any change to current post-exposure countermeasures should occur
- **Include adenovirus topics for the next Vaccine Safety and Effectiveness Workgroup meeting**



# DISCUSSION