Vaccine Safety and Effectiveness Working Group Update

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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  - Review published and unpublished DoD vaccine research data for vaccine safety and effectiveness for vaccines currently in use by DoD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® Phase IV enhanced safety surveillance study
  - ACAM2000® 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® 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