



# **Defense Health Board**

## **Infectious Diseases Control Subcommittee Update**

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

**Defense Health Board Meeting**  
**18 August 2010**



## 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

## 9 June 2010 Meeting: Agenda Topics

- **Department of Defense (DoD) Novel 2009 H1N1 Summary**
  - COL Wayne Hachey (OSD(HA))
- **Question to the Board: Inclusion of Measles/Mumps/Rubella (MMR) Vaccine in Navy Accessions Screening and Immunization Program (ASIP)**
  - Dr. Robert Morrow, on behalf of CAPT Neal Naito (BUMED)
- **DoD Immunization Programs for Smallpox, Anthrax, and Influenza and Military Vaccine Agency Operations (MILVAX)**
  - COL Michael Krukar (MILVAX)



# Recent Activities (Continued)

## 14 July 2010 Meeting: Agenda Topics

- **Blood Look Back Program Information Brief**
  - LTC Kenneth Davis (ABPO)
  - COL Frank Rentas (ASBP)
- **Smallpox Vaccine (ACAM2000) and Anthrax Vaccine (AVA) Safety and Effectiveness: Follow-Up**
  - COL Michael Krukar (MILVAX)
- **Inclusion of MMR Vaccine in Navy ASIP: Follow-Up**
  - CAPT Neal Naito (BUMED)
- **U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) Special Immunizations Program (SIP): Follow-Up**
  - Dr. Ellen Boudreau and Dr. Judy Pace-Templeton, on behalf of COL John Svorak (USAMRIID)



## DoD Novel 2009 H1N1: Summary

- **DoD outbreak response elements, including surveillance, detection, communication, and prevention efforts were handled in an exemplary manner**
  - Evidenced by DoD's involvement in state allocation programs, vaccine distribution and immunization rates, safety monitoring activities
    - 90% of Active Duty vaccinated for H1N1
    - 96% of Active Duty vaccinated for seasonal influenza
  - Success of DoD communication initiatives
    - DoD Pandemic Influenza Watchboard
    - MILVAX Flash Info system



## DoD Novel 2009 H1N1: Summary (Continued)

- **Lessons learned regarding DoD's H1N1 efforts:**
  - Risk communication is a top priority
  - More accurate definition of Service member prioritization is necessary
  - Greater emphasis should be placed on preventive medicine and preparedness exercises
  - Need for a universal, standardized immunization tracking system



# Review of DoD Smallpox and Anthrax Immunization Policies

- **Examined issues pertaining to:**
  - Adverse events
  - Early detection
  - Current prophylaxis policies
  - Availability of alternative countermeasures
  - Threat evaluation
  - Continued need



## Proposed Recommendations: DoD Smallpox Immunization Policy

- **Suspend current DoD smallpox routine immunization program absent an immediate or credible threat**
  - Burdens associated with unnecessary vaccination
    - Avert unnecessary costs in administering unwarranted vaccines
    - Minimizes need for multiple vaccines administered on routine basis
    - No clear benefit to date: no cases prevented; many AE's induced
  - Availability of alternative treatments: vaccinia immune globulin (VIG) and two antivirals, cidofovir and an investigational drug
- **However, special circumstances might exist where smallpox vaccine would be necessary and should continue (DoD to decide, i.e. SpecOp, etc.)**





## **Proposed Recommendations: DoD Smallpox Immunization Policy (Continued)**

- **Recommend configuration of antiviral and vaccine stockpiles to “ready level”**
- **Extend surveillance window beyond current FDA requirement of 5 years for follow-up of ACAM2000 recipients who incurred specific vaccine-related adverse events**
  - Capture late-onset cases (ex. propensity for congestive heart failure following resolved myopericarditis)



## **Proposed Recommendations: DoD Anthrax Immunization Policy**

- **Current anthrax immunization policy should not be changed**
  - Anthrax is a continuing and credible threat
  - Ease of agent acquisition and engineering for biowarfare capability
  - CDC has not reported any linkage of AVA to increased risk of life-threatening or permanently disabling adverse events in the short- or long-term
  - Effectiveness of AVA against anthrax
- **Continue current safety monitoring and reporting of AVA-associated adverse events (VAERS, others)**



## Review of MMR Vaccine Inclusion under Navy ASIP

- **Examined issues pertaining to:**
  - Incidence of mumps among DoD Active Duty Service Members between 2000 and 2009
  - Serological data indicating immunity to measles and rubella among Armed Forces recruits
    - Percent Navy accessions receiving MMR vaccine
  - Cost estimates for MMR screening program and MMR vaccination program
  - Projected cost-savings if only MMR screening were to be conducted
  - Cost per dose of MMR vaccine
  - MMR vaccine side-effects and adverse events



## Review of MMR Vaccine Inclusion under Navy ASIP (Continued)

- **Three potential courses of action proposed for consideration:**
  - Continue current Navy ASIP
  - Drop MMR vaccine from ASIP and resume mandatory universal MMR vaccination upon accession
  - Continue Navy ASIP at recruit training centers
    - Monitor mumps case incidence within the Services and broader community
    - Reinstigate mandatory universal MMR vaccination for recruits if mumps outbreaks occur either in recruit training sites or mumps cases incidence increases



## **Proposed Recommendations: Inclusion of MMR Vaccine in Navy ASIP**

- **Navy should continue current practice followed under ASIP of administering MMR vaccine to eligible recruits following serological screening**
  - Vaccine recipients are recruits who are non-immune to measles and rubella (present immunization rate is 15%-20% of estimated 40,000 Navy accessions per year)
  - Unwarranted vaccinations would be averted
  - Significant resource and cost-savings
    - Cost per screening assay is \$5.00
    - Cost of MMR vaccine is between \$45 and \$60
- **Close surveillance should be maintained**
  - Any increase in mumps case incidence, or changes in the epidemiology, should be reported



## USAMRIID SIP: Summary

- **SIP was established to confer added protection to laboratory personnel engaged in research on countermeasures for select agents**
  - Over 600 volunteers:
    - 60% from USAMRIID
    - 40% from other DoD, federal and non-government institutions
  - **Licensed vaccines** (Food and Drug Administration [FDA]-approved) required under SIP
  - **Investigational new drug (IND) vaccines** used for both research and immunizing laboratory personnel:
    - Legacy vaccines developed by the Salk Institute from the 1960s to the 1990s; recommended under SIP
- **Major issues affecting the sustainment of the SIP include policy, availability, and ethical use considerations**



## **SIP: Terms of Reference for DHB Examination**

- **Determine whether the SIP still serves an important role in the context of USAMRIID's overall biosafety and occupational health program**
  - Advent of modern personal protective equipment (PPE) and other engineering controls
- **Define the appropriate role of vaccination in protecting against laboratory-acquired infections**
  - Determination regarding who should be vaccinated, if vaccinations still play an important role
- **Determine the ethical issues associated with the SIP, if any, and how to address them**
- **Assess the value of the legacy IND vaccines for DoD and determine whether they should be maintained**
  - Assuring future availability of any legacy vaccine found to be valuable for laboratory-acquired exposures and/or force health protection



## **USAMRIID SIP: Main Issues Reviewed by Subcommittee to Date**

- **List of licensed and IND vaccines administered**
- **Benefits and risks of IND vaccines, and to whom they are administered**
- **Program funding source and costs for sustainment**
- **Appropriateness of and compliance with existing biosafety precautions and practices, particularly for personnel who refuse (required) licensed vaccines or (voluntary) IND vaccines**
- **Personal Protective Equipment (PPE) and availability of alternative safety measures**





## **USAMRIID SIP: Main Issues Reviewed by Subcommittee to Date (Continued)**

- **Vaccine immunological potency evaluations, manufacture and lot release dates, and remaining supply (at present rate of use)**
- **Vaccine storage, vial labeling, and integrity of vials and vial stoppers**
- **Safety and immunogenicity data**
- **Data on vaccine local and systemic side effects**
- **Number of possible organism exposures addressed in SIP**
- **Continuation and need of the SIP in the context of USAMRIID's overall biosafety and occupational health program**



## **SIP: Subcommittee Current Plan of Action**

- **National Academies of Science (NAS) committee initiated a study of issues pertaining to the USAMRIID SIP on March 2010**
  - Identify pathogens for which the availability of vaccines would be highly desirable
  - Examine technical issues related to expanding the USAMRIID SIP
  - Inform U.S. Government high level policy discussion regarding the role of vaccines in the context of Select Agent research
- **A report expected within 9-12 months of start date**
- **DHB will delay comment; may address any residual, highly focused questions relating to the specific areas of its members' expertise following the release of the NAS report**



# DISCUSSION