Defense Health Board

Infectious Diseases Control Subcommittee Update

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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, cidovir 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
    - Reinstitute 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 the1990s; 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