Risk Management:
Pre-pandemic Influenza Vaccines

Rick Bright, PhD
Director, Influenza Division
Biomedical Advanced Research and Development Authority (BARDA)
Influenza Risk Assessment & Management

Attributes of the virus
- Receptor Binding Properties
- Transmission in Animal Models
- Genomic Variation
- Antiviral Susceptibility

Attributes of the population
- Population Immunity
- Disease Severity
- Antigenic Relationship to Vaccines

Ecology and epidemiology
- Human Infections
- Infections in Animals
- Global Distribution

IRAT

Monitor and Assess
Pandemic Risk and Severity

Risk Management
Preparedness Response

Observational and Experimental Studies

Disease Surveillance
Virologic Surveillance

Making Decisions about Pre-pandemic Influenza Vaccines

- HHS uses the Pandemic and Seasonal Influenza Risk Management Meeting (FRMM) to make decisions about influenza strains for inclusion in the pre-pandemic vaccine stockpile
  - Senior-level forum for decision-makers from stakeholder agencies to identify and address risk management issues related to the development, acquisition, deployment and utilization of medical and public health countermeasures for influenza
  - Decisions are evidence-based and use a metered approach to response, ranging from monitoring novel strain emergence to a full pandemic vaccine production response
Pre-Pandemic Influenza Vaccine Availability by Risk Management Option

Two pandemic scenarios represented here: 
- HPAI = high pathogenicity avian influenza
- HPI = high pathogenicity influenza

Arrows estimate when vaccine would be available following implementation of each risk management option:

- Full-Scale Bulk Lots
- Clinical lot and Trial
- Seed lot
- Do Nothing
U.S. Pre-Pandemic Influenza Vaccine Stockpile: Risk Based, Metered Approach

- 2005 H5N1 outbreak in SE Asia
  - Established stockpile and met stockpile goals
  - Implemented innovative Mix and Match program
- 2009 H1N1 Pandemic
  - 186 M doses of H1N1 vaccine were filled by the manufacturers
  - 120 M doses of bulk adjuvants (AS03 & MF59) purchased as a contingency
- 2012 H3N2v outbreak in the US
  - Clinical lots were made and clinical trials conducted
- 2013 H7N9 outbreak in China
  - Clinical lots were made and clinical trials conducted
  - Stockpiled bulk antigen
Expands the scientific knowledge base of diverse influenza viruses and antigens

— Physical properties
  • Production experience for a variety of influenza viruses
  • Antigen / adjuvant stability
  • Storage conditions

— Immunological properties
  • Mix and Match antigen / adjuvant combinations
  • Heterologous prime / boost strategies
  • Contributes to research agenda for systems biology and development of more effective, next generation influenza vaccines