



PANDEMIC INFLUENZA VACCINE STOCKPILE

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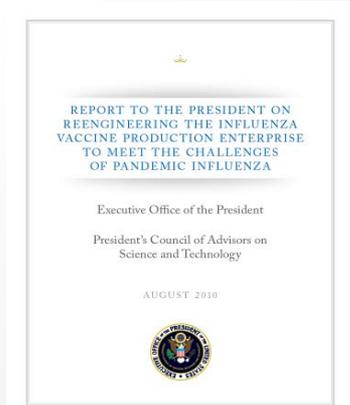
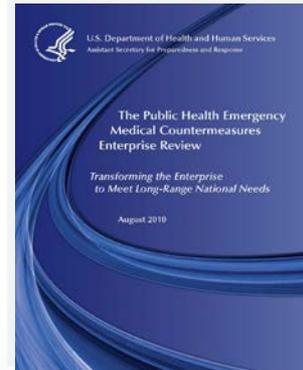
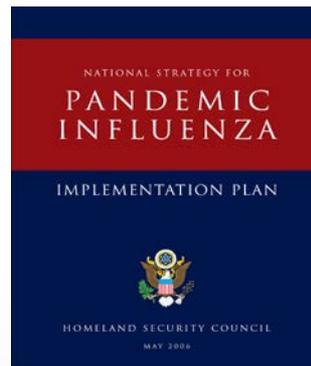
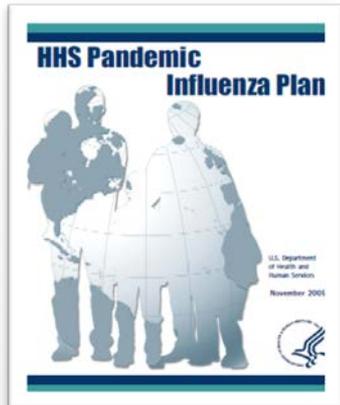
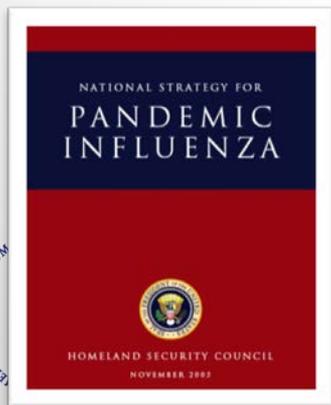
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Pandemic Influenza MCM Strategic Goals

- Expansion of domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration.
- Establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat

The requirements are derived from a number of documents that guide the US Government efforts to prepare for pandemics



U.S. Pre-Pandemic Influenza Vaccine Stockpile: A National Asset

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



Pandemic Vaccine Stockpile Program Preparedness

- Program established in 2004
- National stockpile comprised primarily of bulk antigen and oil-in-water adjuvants
- 2009 - Achieved the goal of 20M doses for the critical work force, with the use of adjuvants stockpile can potentially provide 200-400 M doses
- H5N1 (multiple sub-clades) and H7N9
- Sanofi Pasteur as antigen-alone formulation licensed in 2007
- GSK Q-Pan (H5N1-ASO3) licensed in 2013



Current Stockpile: Vaccine and Adjuvant



Vaccine Stockpile Durability

- Potency measured by SRID
- Vaccine stored in bulk shows 65-90% potency retention which seems to be strain dependent
- Stability protocols include testing of products in different storage containers
- Immunogenicity and safety of long-term stored bulk antigen and adjuvant:
 - One study completed with Indonesia strain stored for 5 years
 - First BARDA-sponsored H5N1 clinical study will be launched in 2016 utilizing the BARDA Clinical Studies Network



Mix-N-Match Studies: H1N1, H5N1, H7N9

- **Objective:**

To determine whether pre-pandemic vaccines and adjuvants produced by different manufacturers and stockpiled by the USG can be combined and used safely and effectively. Collaboration with NIAID

- **Products:**

Vaccines: H1N1, H5N1, H7N9

Adjuvants: ASO3 and MF59

- **Studies:**

Physical-chemical compatibility of vaccine-adjuvant

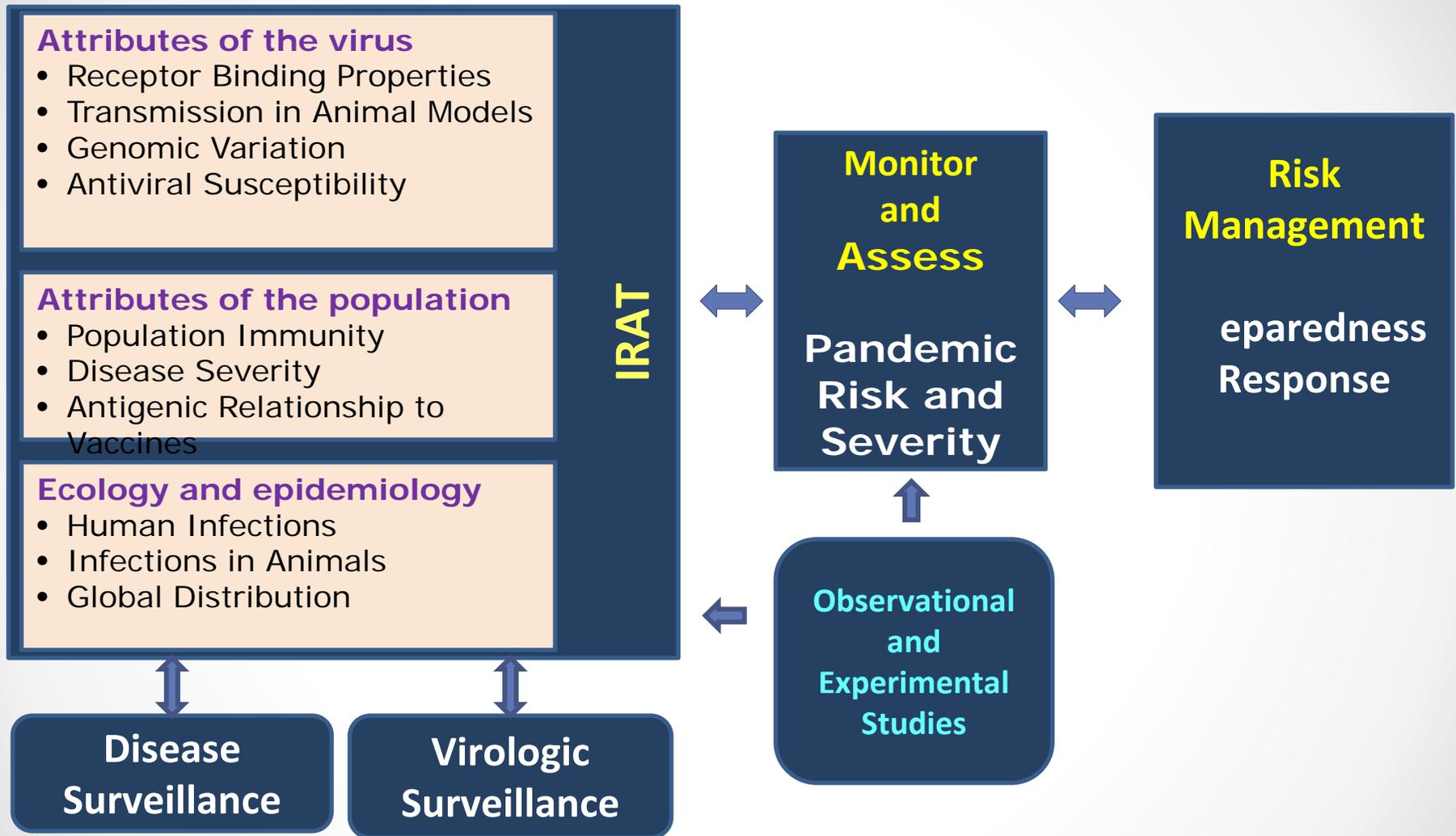
Animal and Clinical Studies

- **Publications:**

Clinical studies results have been published



Influenza Risk Assessment & Management



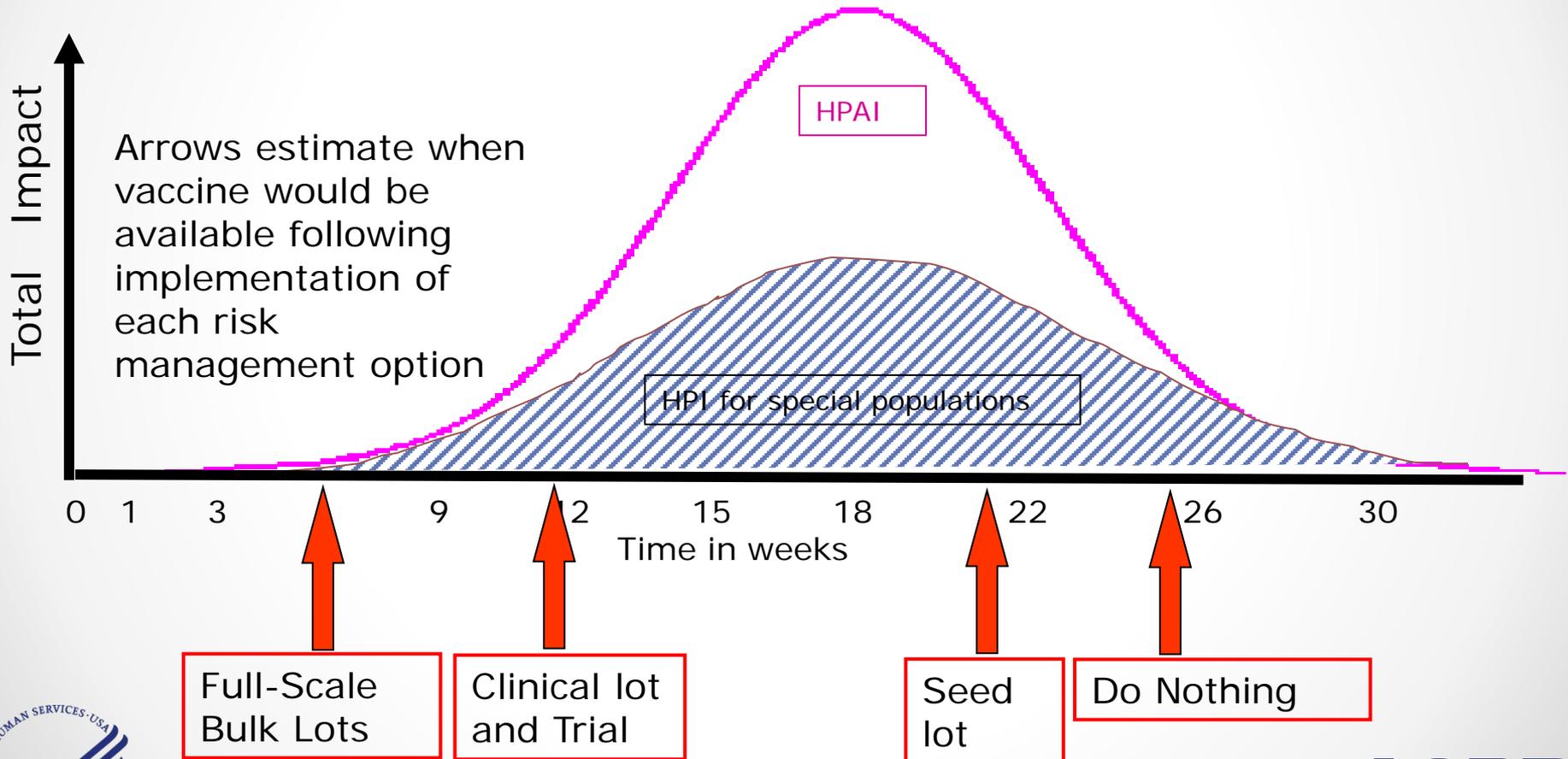
Making Decisions about Pre-pandemic Influenza Vaccines

- 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



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
- 2015 H5N8 poultry outbreak in the US
 - Clinical lots in production and clinical trial in preparation



Acquisition of MCM for Pandemic Influenza Preparedness and Response – Strategies

- Work with manufacturers of US-licensed seasonal influenza vaccines (inactivated, LAIV, recombinant, cell-based)
- Manufacturing of pre-pandemic vaccines using processes, facilities, systems and trained personnel for US-licensed influenza vaccines



Acquisition of MCM for Pandemic Influenza Preparedness and Response - Contracts

- Indefinite Delivery/ Indefinite Quantity (ID/IQ) type of contracts are awarded
- Depending on the requirements from the FRMM a Request for Task Order Response (RTOR) is sent to manufactures to compete on specific objectives:
 - Optimized Master and working seeds
 - Pilot lots, clinical lots and commercial scale bulk lots
 - Adjuvants
 - Formulation, fill and finish
 - Storage and stability of bulk lots and final containers (vaccine and adjuvants)
 - Animal testing
 - Clinical studies
- RFP published in 2015



THANK YOU

