



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



Pandemic Influenza MCM: Current vaccine and adjuvant stockpiles



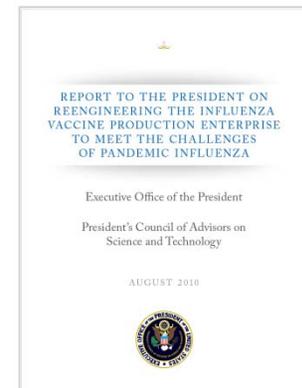
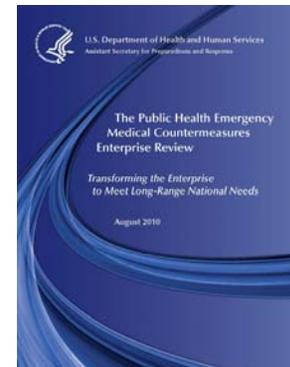
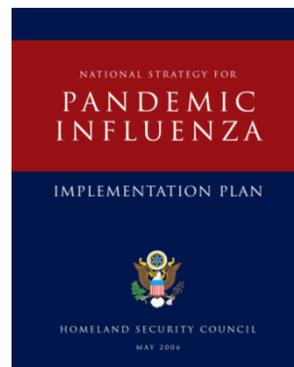
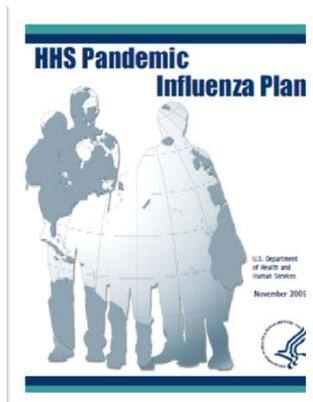
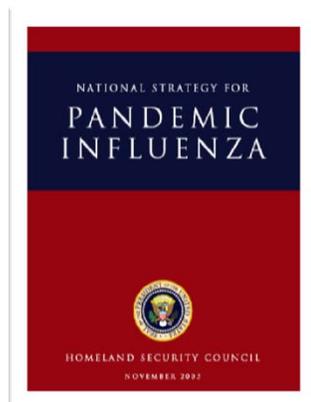
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Pandemic Influenza MCM Strategic Goals



- Establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat
 - 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.
- The requirements are derived from a number of documents that guide the US Government efforts to prepare for pandemics.





Pandemic Vaccine Stockpile Program

Preparedness



- Program established in 2005
- National stockpile comprised primarily of egg-derived bulk H5N1 antigen and oil-in-water adjuvants
- 2009 - Achieved the goal of 20M doses for the critical work force
 - With the use of adjuvants, 125M doses (potentially 200-400 M doses)
 - Multiple sub-clades of H5N1 viruses represented
 - Stockpiled vaccine licensed in U.S. by sanofi pasteur as antigen-alone formulation (90 µg/dose) in 2007



Current Stockpile: Vaccine and Adjuvant



ASPR: Resilient People. Healthy Communities. A Nation Prepared.



Vaccine Stockpile Stability



- Potency measured by SRID
- Prior to the stockpile program in 2005, no stability data existed for flu vaccines stored more than 2 years
- Now, 84 months stability data are available for Vietnam and Indonesia strains
- H5N1 vaccine stored in bulk shows unanticipated long stability over seven years
 - range of 65-90% potency retention
- Stability of the bulk antigen seems to be strain dependent; reasons are unclear
- Immunogenicity and safety of long-term stored bulk antigen is under evaluation (one study completed with Indonesia strain stored for 5 years)
- More clinical trials are planned



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



- **Goal:**

In response to a pandemic, expand the coverage of the influenza vaccine stockpile using the antigen sparing properties of adjuvants. Collaboration between industry partners and other federal agencies (NIAID, VTEU's).

- **Objective:**

To determine whether adjuvants under advanced development by BARDA and pre-pandemic vaccines stockpiled by the USG can be used safely and effectively during an influenza pandemic under EUA.

- **Products:**

Vaccines: H1N1 A/Cal/07/09, H5N1 A/Indonesia/05/05, **H7N9**
Adjuvants: ASO3 and MF59

- **Studies:**

Physical-chemical compatibility of vaccine-adjuvant
Animal studies: immunogenicity and toxicity
Clinical studies: safety and dose ranging



Pandemic Vaccine Stockpile Program **ASPR** Response

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

2009-H1N1 pandemic response: 186 million doses of H1N1 vaccine were filled by the manufacturers (149 provided to CDC for distribution to public, 16 million doses donated internationally, 2.7 million doses supplied to the US military) 120 Million doses of bulk adjuvants (ASO3 and MF59) were also purchased as a contingency.

2012- program more flexible: incremental response, new technologies, 3-year contracts

- 2012- H3N2v outbreak in the US. MVS-WVS, clinical lots were made and clinical trials are in progress
- 2013- H7N9 outbreak in China. Preparedness activities on-going: MVS-WVS, clinical lots, clinical trials, bulk antigen procurement



Acquisition of MCM for Pandemic Influenza Preparedness and Response – Strategies



- Work with manufacturers of US-licensed seasonal inactivated influenza vaccines and (recently added) manufacturers who have developed an Influenza vaccine and completed Phase III clinical studies.
- Support commercial scale manufacturing of pre-pandemic vaccines using manufacturing process, facilities, systems and trained personnel for US-licensed seasonal inactivated influenza vaccines
- Support manufacturing during off-season for US-licensed seasonal inactivated influenza vaccines
- Maintain vaccine as bulk product at manufacturers or storage facilities for fill finish when clinical data and circumstances support final container formulations



Acquisition of MCM for Pandemic Influenza Preparedness and Response – Strategies (2)



Indefinite Delivery/ Indefinite Quantity (ID/IQ) type of contracts are awarded and the manufacturers are requested (RTOR) to work 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
- Domestic, International shipping



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Thank You