



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



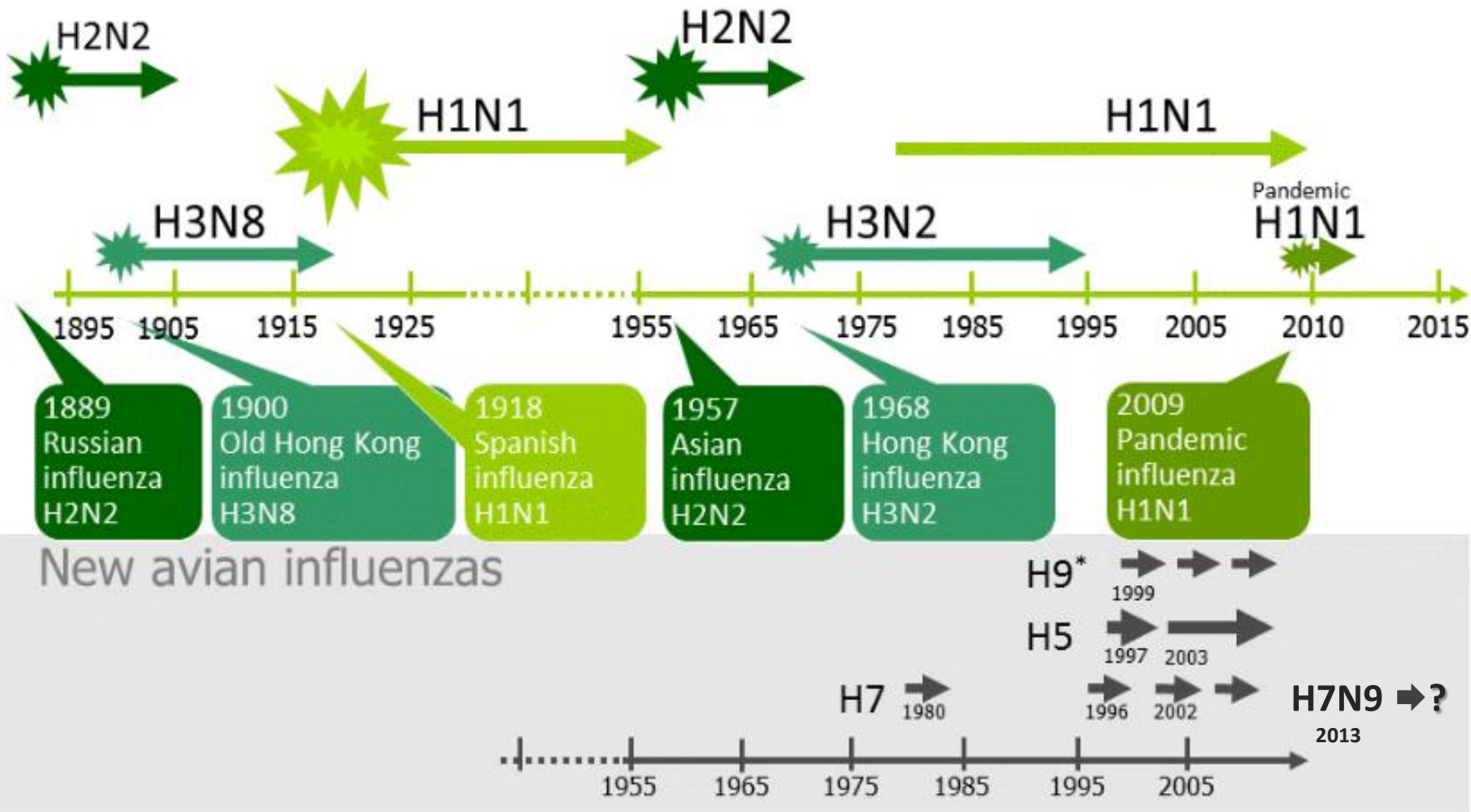
Approaches to Pandemic Influenza Vaccine Preparedness

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Development Authority (BARDA)**

Perpetual Challenge of Responding to Influenza Threats



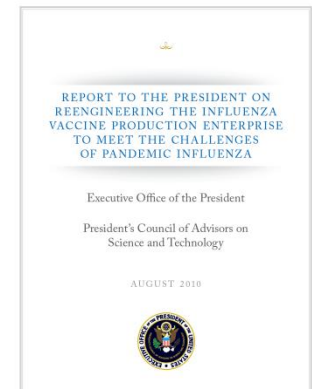
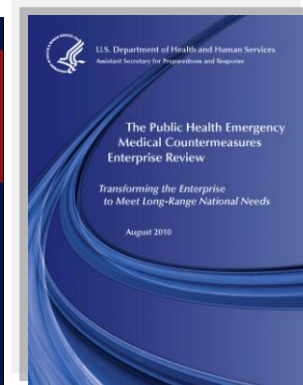
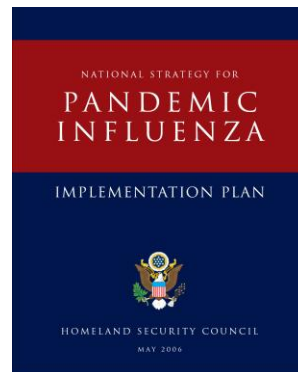
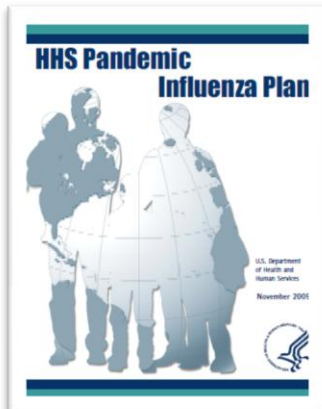
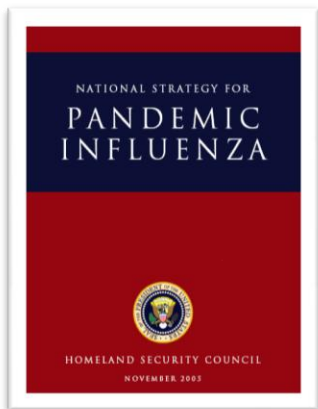
Centre for Influenza Virus Research, National Institute of Infectious Diseases (NIID), Japan (2009)



U.S. Pandemic Influenza Strategic Goals: Vaccine



- 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
- Development of new, better influenza vaccines
- The requirements are derived from a number of documents that guide the US Government efforts to prepare for influenza pandemics

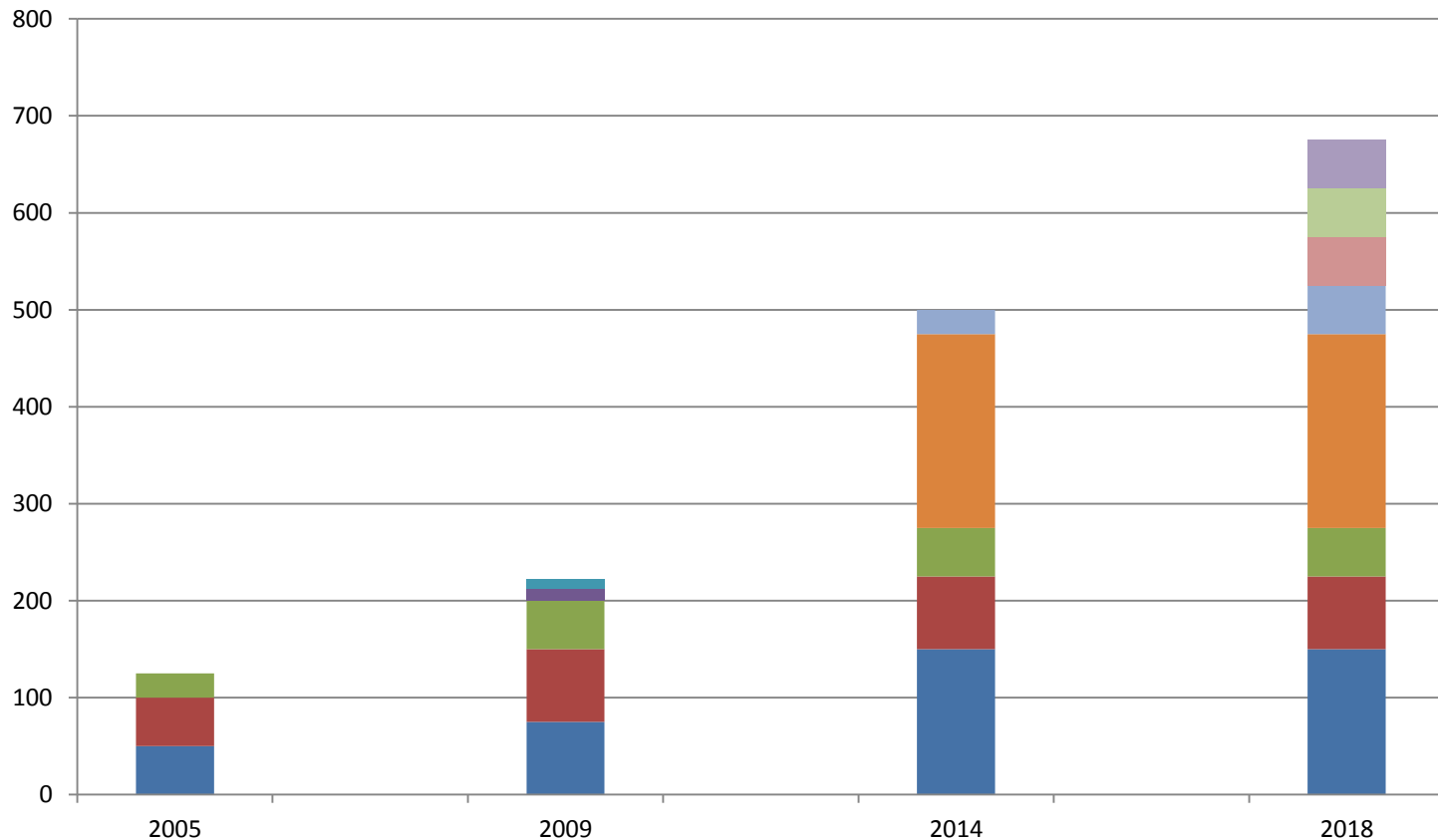




Increased Domestic Influenza Vaccine Manufacturing Capacity: A Cornerstone of Pandemic Preparedness



U.S. pandemic influenza vaccine target is two doses for everyone (~ 600 M doses) within 4-6 months of pandemic onset





Increased Global Vaccine Manufacturing Capacity: BARDA International Influenza Vaccine Manufacturing Capacity Building Program



GOAL: Enhance sustainable influenza vaccine production capacity in developing/under-resourced countries

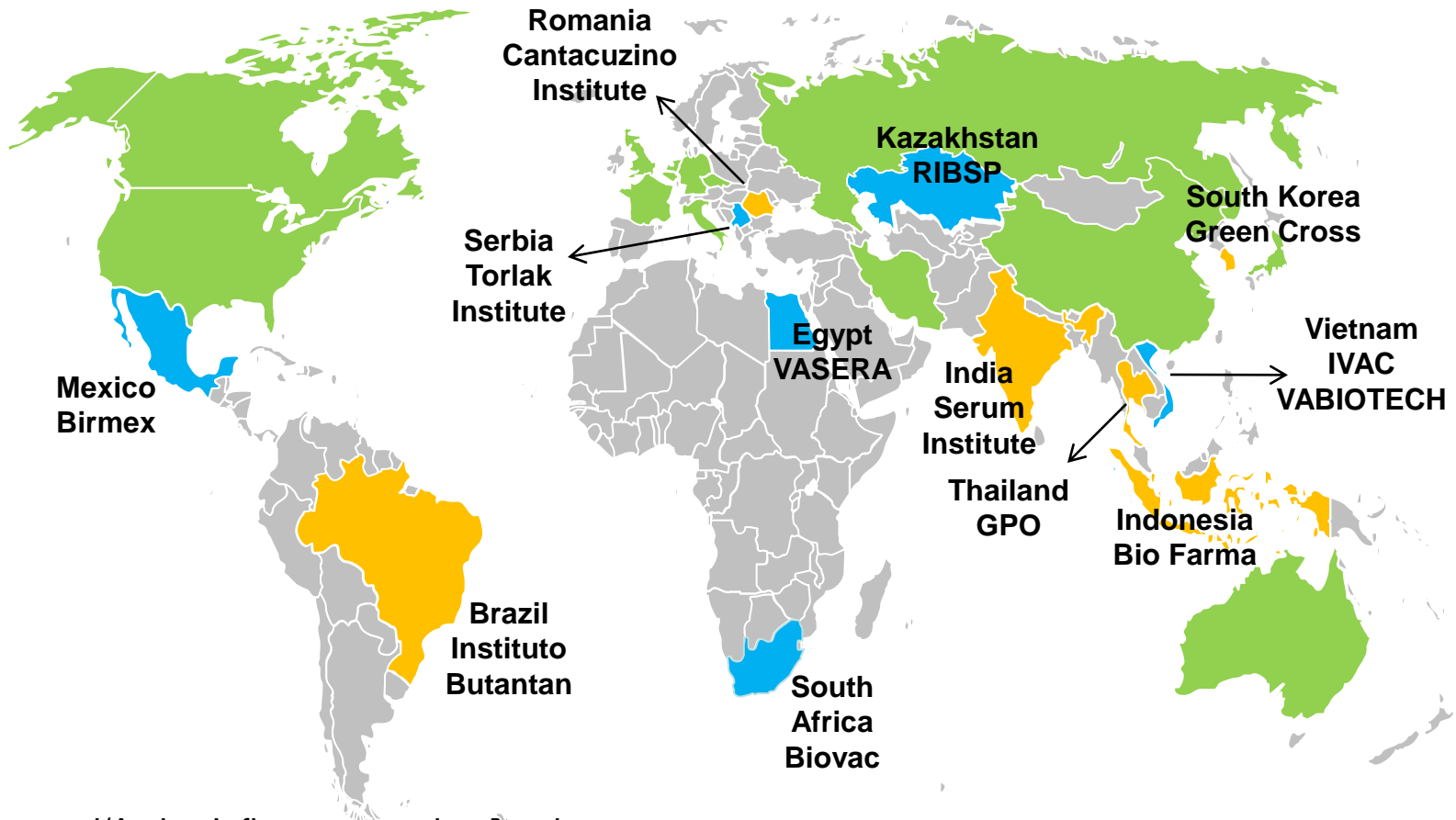
Objectives

- Protect people by reducing the global risk of influenza
- Develop and sustain influenza vaccine manufacturing capabilities and capacity for pandemic readiness
- Promote international investment, diplomacy and partnerships
- Achieve sustainable influenza vaccine production capacity worldwide by leveraging BARDA's unique resources

Approach

- Expanding global vaccine manufacturing capacity through technical support of manufacturers in developing countries
- Ensuring a skilled workforce to make cGMP quality vaccine through training
- Providing in-country technical implementation assistance
- Making available technology for scalable manufacturing capacity

Goal: Wider Geographical Distribution of Influenza Vaccine Production



- Licensed/Active Influenza vaccine Producers
- BARDA/WHO Cooperative Agreement Grantees
- BARDA/WHO Grantees with Licensed Vaccine for Human Use (as of 2/2014)



U.S. Pandemic Vaccine Stockpile Preparedness Program



- Program established in 2005
- National stockpile comprised primarily of egg-derived bulk H5N1 antigen and oil-in-water adjuvants
- Achieved the goal vaccine for the 20 M critical work force
 - With the use of adjuvants, 125 M doses (potentially 200-400 M doses)
 - Multiple sub-clades of H5N1 viruses represented



US Pre-Pandemic Influenza Vaccine Stockpile: Evolution



- Past risk management actions focused on acquisition of bulk vaccine antigen and adjuvant. Now, metered response options that address relative costs and benefits are systematically considered for implementation.
- The new approaches to risk assessment and management are the pillars of a newly flexible and dynamic pre-pandemic stockpiling program capable of meeting our strategic vaccine MCM goals and the perpetual challenge of responding to pre-pandemic influenza



Building a Pre-pandemic Vaccine Stockpile: Influenza Virus Risk Assessment



- Influenza Risk Assessment Tool (IRAT)
 - Evaluation tool developed by the USG, led by CDC
 - Measures the potential pandemic risk posed by influenza A viruses that currently circulate in animals but not in people
 - Pandemic risk is based on two risk scenarios
 - **Emergence** – acquiring the ability to spread easily and efficiently in people
 - **Public health impact** – potential severity of human disease caused by the virus and the burden on society after emergence



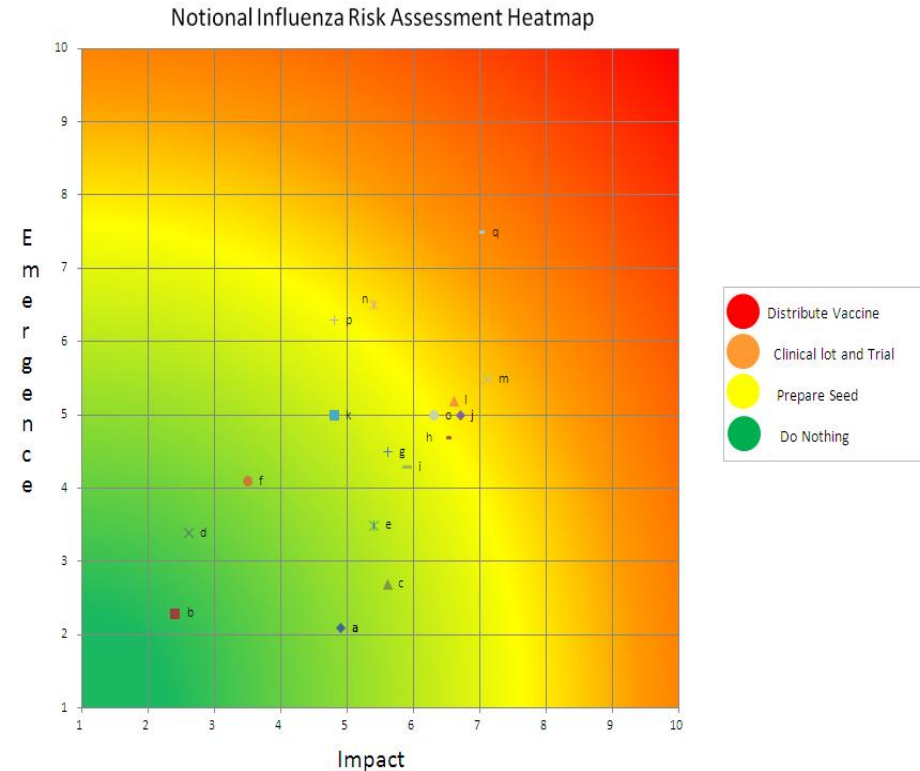
IRAT: Evaluation Criteria



Ten factors that encompass properties of the virus, attributes of the population and environmental and epidemiological factors are evaluated

1. Genomic variation
2. Transmission in lab animals
3. Receptor binding
4. Antiviral treatment susceptibility/resistance
5. Disease severity and pathogenesis
6. Existing population immunity
7. Antigenic relationship to existing vaccine candidates
8. Infection in animal species
9. Genomic variation
10. Global distribution in animals

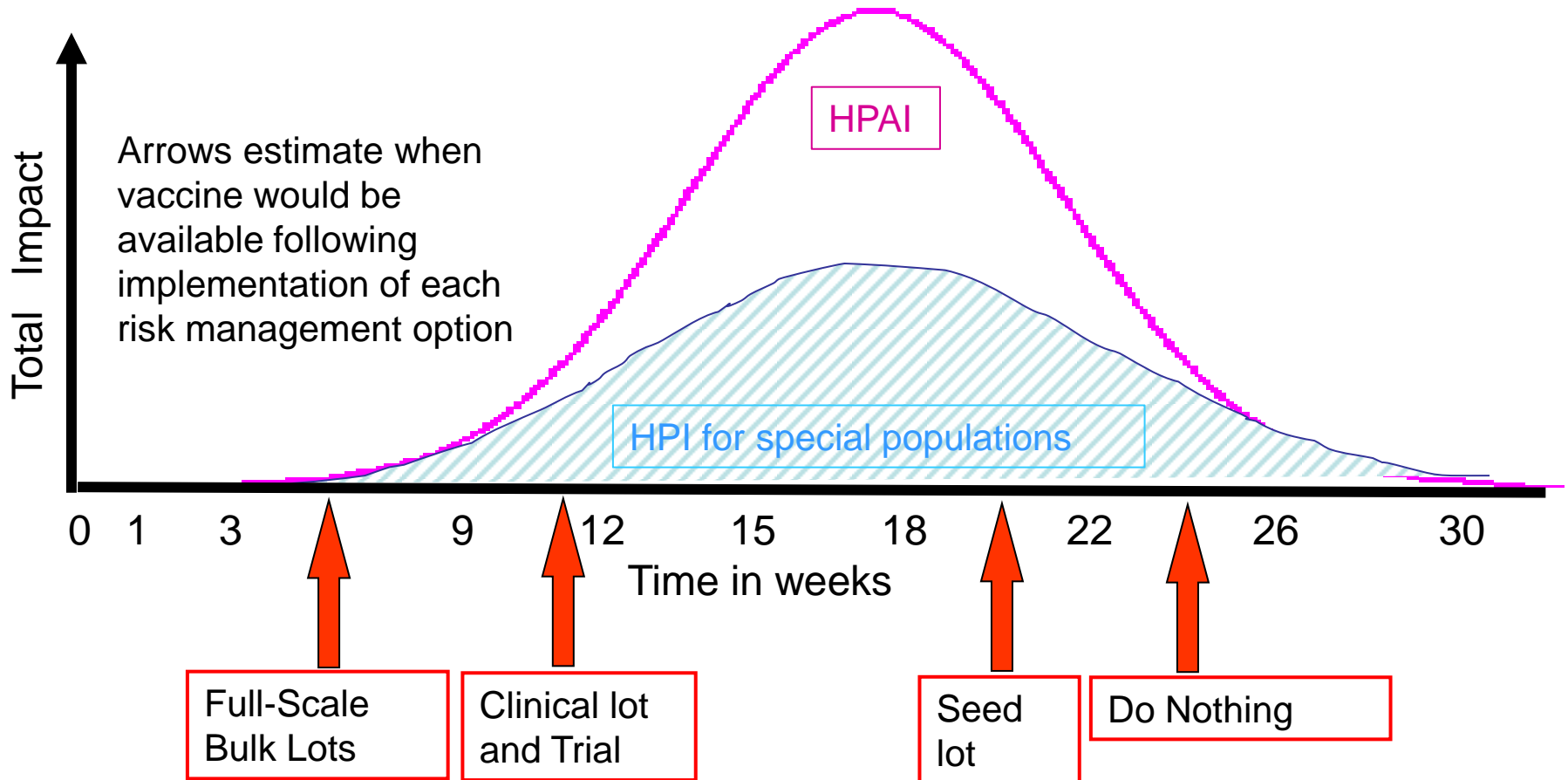
(CDC: <http://www.cdc.gov/flu/pandemic-resources/tools/risk-assessment.htm>)



- Each criterion is weighted and scored based on their significance in each scenario
- Aggregate scores for each emerging influenza virus can be plotted to visualize relative risk

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. Pandemic 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



Sustainable Pandemic Preparedness: **ASPR** Multifaceted and Scalable

ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

- Influenza represents a constant, yet unpredictable pandemic risk
- Vaccines are critical to an effective influenza pandemic response
- The U.S. has used a multi-pronged approach to vaccine pandemic preparedness
 - Dramatic increase domestic and global vaccine manufacturing
 - Investments in new vaccine technologies
 - Risk-based, metered pre-pandemic vaccine stockpiling program



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Capacity Building Program

HHS/ASPR/BARDA

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<http://www.phe.gov/about/barda/>