



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



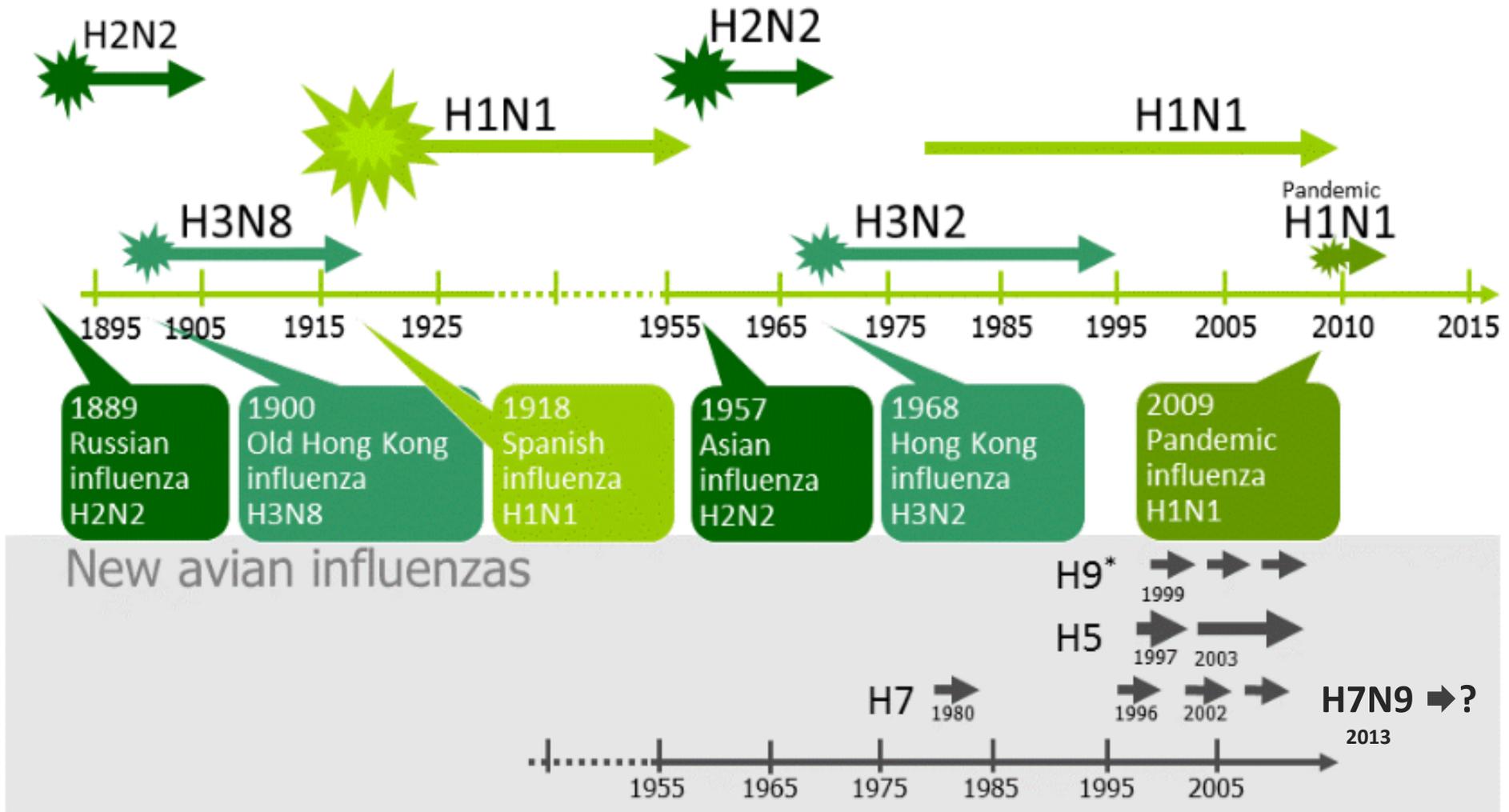
# New Approaches to Stockpiling: Risk Assessment and Management



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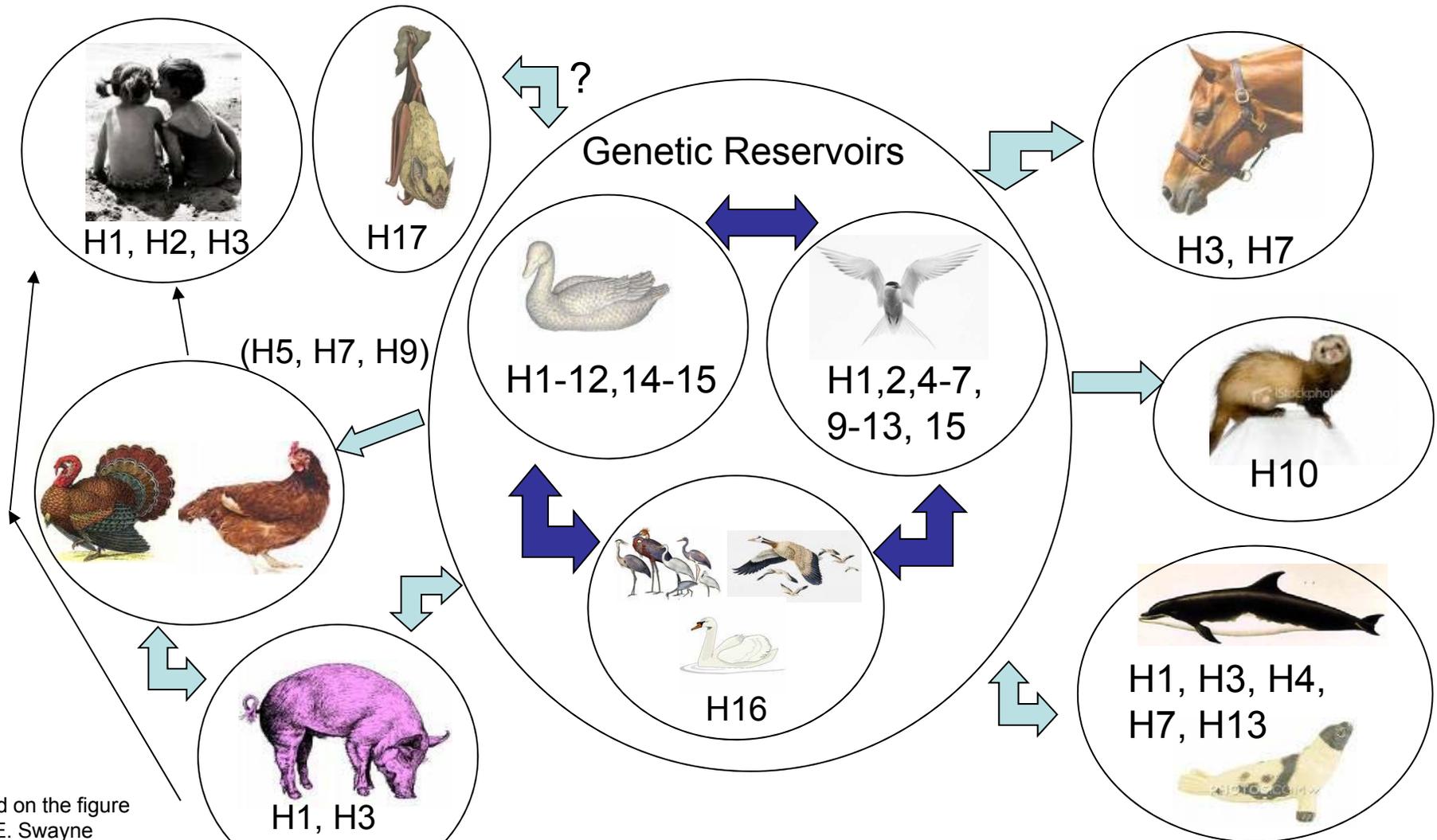


# Perpetual Challenge of Responding to Influenza



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

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



Based on the figure of D.E. Swayne Emerging Infectious Diseases of Animals. pp101-130, ASM press, 2000



# Recent H5N1 Activity



**Table 1. Recent influenza A(H5N1) activity reported to international agencies**

Country, area or territory	Host/source	Genetic clade
Bangladesh	Poultry/environment	2.3.2.1
Cambodia	Poultry	1.1
	Human (10)#	1.1
China	Poultry/environment	2.3.2.1, 2.3.4.2, 7.2
Democratic People's Republic of Korea	Poultry	2.3.2.1
Egypt	Poultry	2.2.1
	Human (3)	2.2.1
India	Poultry/wild birds	2.3.2.1
Indonesia	Poultry/wild birds	2.3.2.1*
	Human (1)	2.1.3.2
Nepal	Poultry/wild birds	2.3.2.1
Viet Nam	Poultry/wild birds	1.1/2.3.2.1/7.2
	Human (2)	1.1

# denotes number of human cases with illness onset dates falling within reporting period

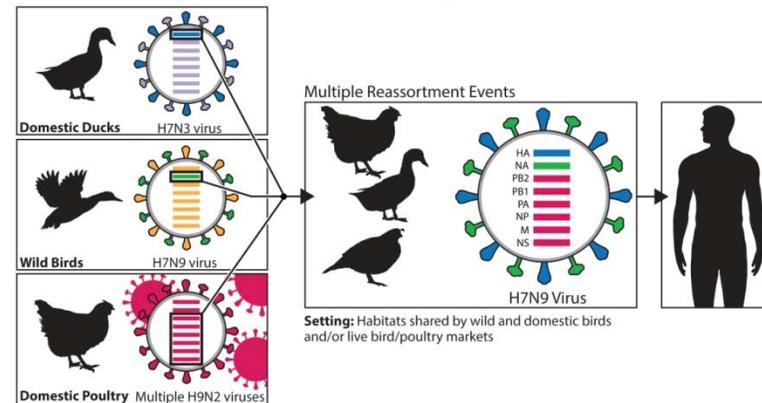
\* wild birds illegally imported into Europe from Indonesia were positive for A(H5N1) clade 2.3.2.1 virus

- H3N2v



- The novel H7N9 influenza

Genetic Evolution of H7N9 Virus in China, 2013



The eight genes of the H7N9 virus are closely related to avian influenza viruses found in domestic ducks, wild birds and domestic poultry in Asia. The virus likely emerged from "reassortment," a process in which two or more influenza viruses co-infect a single host and exchange genes. This can result in the creation of a new influenza virus. Experts think multiple reassortment events led to the creation of the H7N9 virus. These events may have occurred in habitats shared by wild and domestic birds and/or in live bird/poultry markets, where different species of birds are bought and sold for food. As the above diagram shows, the H7N9 virus likely obtained its HA (hemagglutinin) gene from domestic ducks, its NA (neuraminidase) gene from wild birds, and its six remaining genes from multiple related H9N2 influenza viruses in domestic poultry.



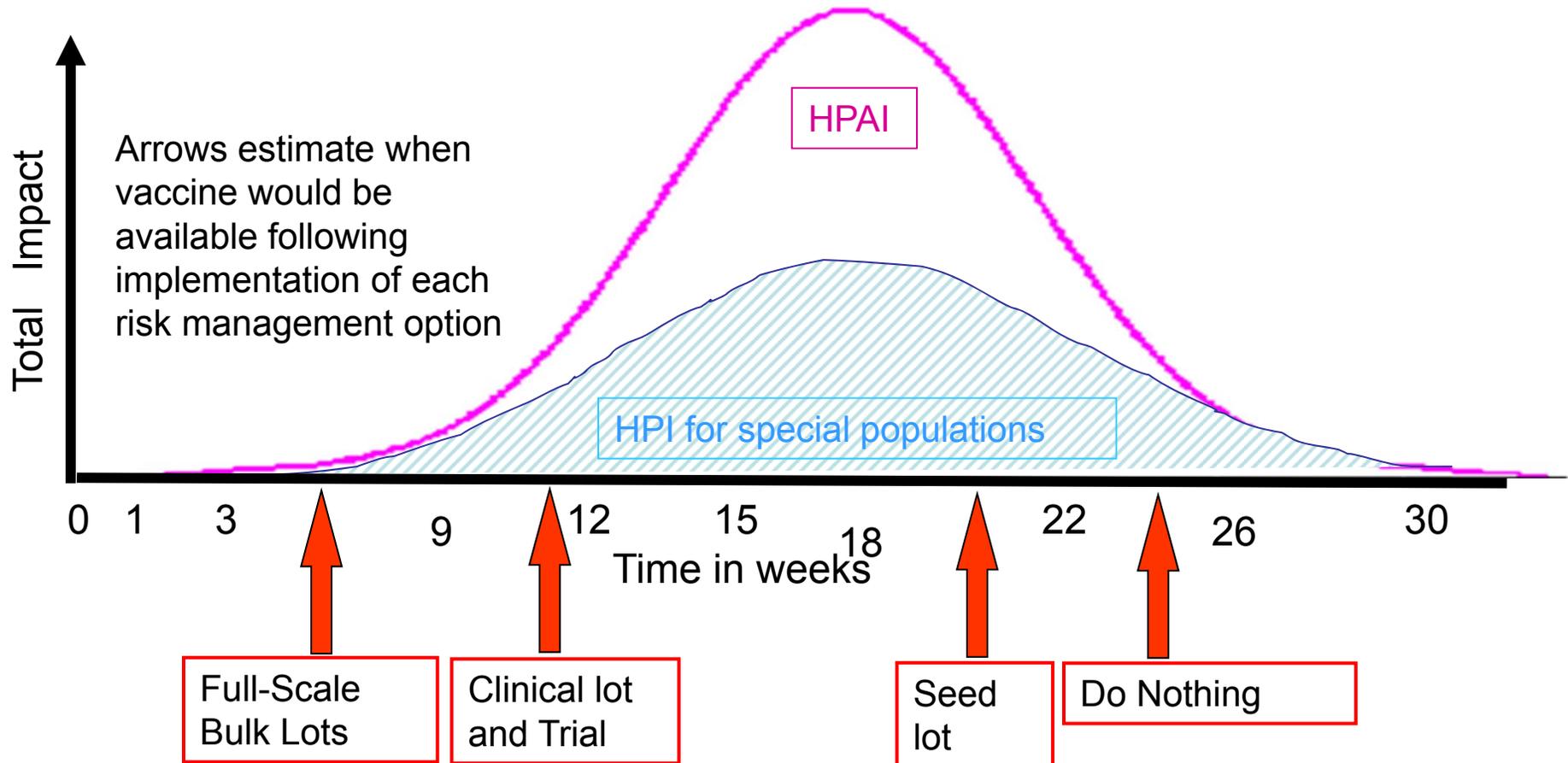
- Not all threats are equal



# Pre-Pandemic Influenza Vaccine Availability by Risk Management Option



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





# Risk Assessment



- Influenza Risk Assessment Tool (IRAT)
  - Evaluation tool being developed by the CDC and external experts
  - 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

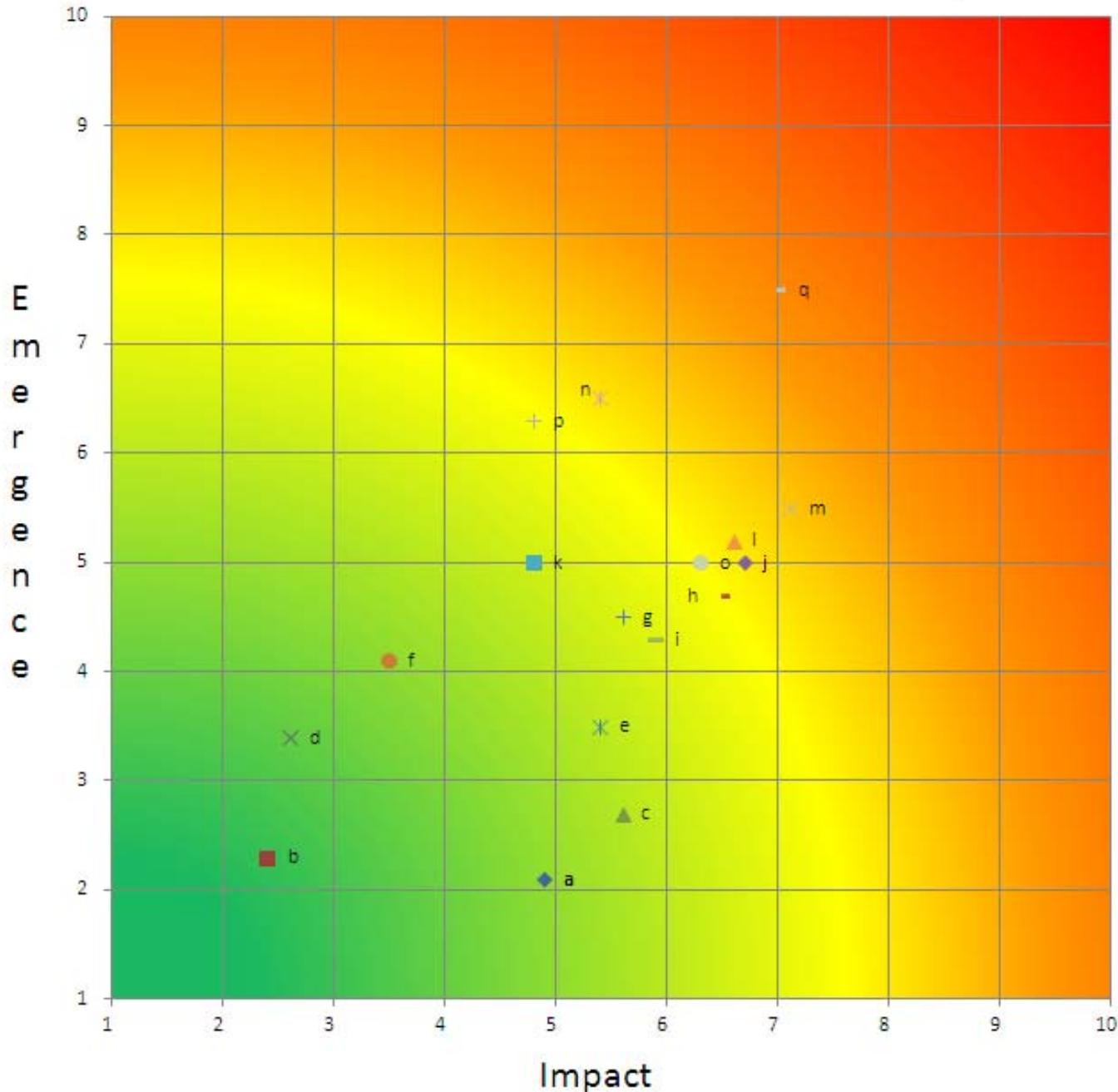


# Risk Assessment Analysis Steps



- Ten factors that encompass properties of the virus, attributes of the population and environmental and epidemiological factors are evaluated
  - Human infections
  - Transmission in lab animals
  - Receptor binding
  - Existing population immunity
  - Infection in animal species
  - Genomic variation
  - Antigenic relationship to vaccine candidates
  - Global distribution in animals
  - Disease severity and pathogenesis
  - Antiviral treatment susceptibility/resistance

## Notional Influenza Risk Assessment Heatmap



Each criterion is weighted and scored based on their significance in each scenario (emergence and impact)



Aggregate scores for each emerging influenza virus can be plotted to visualize relative risk



# Updating the US Pre-Pandemic Stockpile



- 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



# New Stockpile Approaches



- Vaccines

- Vendor managed stockpile

- Contracting and stockpiling approach more fine tuned for preparedness and response

- Greater use of risk assessment tools

- Antiviral drugs, ventilator, respiratory protection devices and ancillary supplies

- Strategic National Stockpile (SNS)

- Approach/requirements are being reassessed





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**Thank You**