New Approaches to Stockpiling: Risk Assessment and Management

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Perpetual Challenge of Responding to Influenza

New avian influenzas

1889 Russian influenza H2N2
1900 Old Hong Kong influenza H3N8
1918 Spanish influenza H1N1
1957 Asian influenza H2N2
1968 Hong Kong influenza H3N2
2009 Pandemic influenza H1N1

H9* 1999
H5 1997 2003
H7 1980 1996 2002
H7N9 2013

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

Genetic Reservoirs

H1, H2, H3

H17

(H5, H7, H9)

H1-12, 14-15

H1,2,4-7, 9-13, 15

H16

H10

H1, H3, H4, H7, H13

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

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

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

# 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

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WHO Antigenic and genetic characteristics of zoonotic influenza viruses and development of candidate vaccine viruses for pandemic preparedness. September 2013

**ASPR: Resilient People. Healthy Communities. A Nation Prepared.**
Other Recent Influenza Concerns

• H3N2v

• The novel H7N9 influenza

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

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.
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
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
Thank You