The Pandemic Influenza Countermeasures Portfolio

Biomedical Advanced Research and Development Authority (BARDA)

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Today:

• Influenza: Virus(es) and disease(s)
• Consequences of Pandemic Influenza
• US response(s) and evolution of the Pandemic Influenza Portfolio
• BARDA’s Influenza Division
Influenza

Mild URT infections
Severe URT infections
Viral pneumonia
Bacterial pneumonia
Severe Acute Respiratory disease.

Systemic infections
Epidemics, pandemics, sporadic infections
High risk groups
1918-19 Influenza
Measures of Disease Burden
Estimates of morbidity and mortality 2009 pH1N1 Influenza
April 2009 - April 2010

- Deaths: 12,469
- Hospitalized: 274,304
- Cases: 60,837,748

Rate per 100,000 population:
- 0-4
- 5-24
- 25-49
- 50-64
- ≥65

Slide courtesy of Lyn Finelli, CDC
H1N1 hospitalization rates

EIP* Laboratory-Confirmed Cumulative Hospitalization Rates (per 100,000), 2009-10 Season

Age Group
- 0-4
- 5-17
- 18-49
- 50-64
- 65+
- Total

EIP* Laboratory-Confirmed Cumulative Hospitalization Rates (per 100,000), 2010-11 Season

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Case Counts</th>
<th>Rates (per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4 yr</td>
<td>594</td>
<td>36.4</td>
</tr>
<tr>
<td>5-17 yr</td>
<td>104</td>
<td>7.6</td>
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<tr>
<td>18-49 yr</td>
<td>1002</td>
<td>5.9</td>
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<tr>
<td>50-64 yr</td>
<td>879</td>
<td>20.3</td>
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<tr>
<td>65+ yr</td>
<td>1654</td>
<td>62.1</td>
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<tr>
<td>All Ages</td>
<td>4513</td>
<td>15.1</td>
</tr>
</tbody>
</table>

*BP results represent surveillance in the 10 BP states (CA, CO, CT, GA, ID, IN, MA, NY, OR, TN).
OUR MISSION: Using the influenza virus against itself

Advancing science and technology into countermeasures

**Estimated Timeline of H1N1pdm Vaccine Development and Delivery in the U.S.**

- **April**
  - CDC isolates H1N1, April 15
  - WHO H1N1 vaccine virus recommendation, April 27

- **May**
  - Vaccine virus reassortment started at CDC and NYMC, April 25 and 28
  - CDC ships high growth reassortant viruses to mfrs (X-179A and RG-15), May 26 and 27
  - Working seed developed by vaccine manufacturers, June 20-30

- **June**
  - Monovalent concentrate, August

- **July**
  - Test monovalent concentrate
  - Pool monovalent concentrate

- **August**
  - HBER release, Sept 15 & 18, (W/p)
  - Filling, September (at risk)
  - Final September 30
  - September 30: Distribution

- **September**
  - October 5: Start Vaccination

(*) Manufacturers were transiently limited in their ability to develop seed viruses due to lack of facilities to grow virus in large volume at the required BSL3 biocontainment

($) Production of monovalent inactivated vaccine is a continuous process

www.cdc.gov/H1N1flu

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Slide courtesy of Dr. N. Cox CDC
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, October 1, 2006 – January 2, 2010

New Technologies advantage?
HHS Responses to Influenza Pandemics

Effective Vaccines and Programs—More, Better, Faster

Effective Antivirals and Delivery—Avoiding resistance

Sensitive, Specific Diagnostics—Usage and interpretation

Mitigation of Severe Respiratory Impact—Stockpiles, surge, simplicity
Infrastructure Development-cell based production
Global pandemic (H1N1) 2009 vaccine production capacity: June 2009 estimate

Assumptions / Methodology

- Survey sent to 36 potential influenza vaccine manufacturers
  - 100% response rate
  - All 21 current influenza vaccine producers responded
  - 26 manufacturers that intend to produce pandemic vaccines
  - Includes LAIV and one recombinant vaccine capacity

- Survey assumes
  - 1:1 H1N1 to seasonal yields
  - Most dose sparing formulation for each manufacturer
  - Use of full production capacity

Estimated H1N1 Vaccine Capacity
At 1:1 yields, most dose-sparing formulation, full capacity

Max 3B doses (October 2009)

Source: WHO survey (Collin N. et al, Vaccine 2009. 27(38):5194-6)
ID International Program Objectives

1. Protect America by reducing risks of influenza epidemics outside our borders—one world one health.

2. Help to develop and sustain influenza vaccine manufacturing capabilities and capacity and pandemic readiness: promote investment; establish partnerships

3. Help achieve sustainable influenza vaccine production capacity worldwide by leveraging BARDA’s unique resources.
International Capacity Building
Total Financial Commitment through 2009: $52 million

• FY 2005 $1 million ASPR funding to Vabiotech-Vietnam
• FY 2006 $10 million of emergency supplemental funding to WHO; granted to India, Indonesia, Vietnam, Thailand, Mexico & Brazil
• FY 2007 Funding requested in annual budget; not appropriated
• FY 2008 $14.4 million of annual funding to WHO; granted to six original grantees plus Egypt, Serbia and Romania.
• FY 2009 $3.6 million to WHO; granted to Russia’s Institute for Experimental Medicine; plus $7.9 million to PATH; and $3.5 for rapid diagnostics to support clinical trials
• FY 2010 $11M to WHO, Universities: Lausanne, NC State, Utah State. Non-profit: IDRI (Seattle)
• FY 2011 $11: WHO, adjuvants, training, multiproduct manufacturing feasibility
Serum Institute of India, Pune
BARDA Influenza Division (Transitional)

Director: Michael Perdue (until July 19)
Deputy Director: Robert Huebner

Current Staff: 32 (27 FTE, 5 Contractors)

5 Divisional Teams: Antivirals; Vaccines-advanced development; Vaccines-Stockpiles; Diagnostics/Devices; “International”

BARDA Pandemic Influenza Program: > 50 staff including manufacturing, clinical, regulatory, innovation
Interfacing with BARDA

• [www.phe.gov](http://www.phe.gov)  
  — Program description, information, news, announcements

• [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)  
  — Portal to BARDA  
  — Register, request a meeting  
  — Tech Watch

• [www.fedbizopps.gov](http://www.fedbizopps.gov)  
  — Official announcements and detailed information about all government contract solicitations