BARDA Industry Day:
Influenza Rapid Diagnostics
and
Respiratory Devices

Roxanne Shively
Influenza Division, BARDA

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Diagnostic Programs within BARDA

Office of the Secretary

Assistant Secretary for Preparedness & Response

Policy and Planning

Biomedical Advanced Research & Development Authority

Acquisition Management Contracts & Grants

Preparedness & Emergency Operations

CBRN

Influenza

SSTD

Emerging Diseases

RQA

Req.

Modeling

Clinical Studies

Mfg. & Eng.

Program Mang.

Diagnostics Functions within these groups
BARDA Dx Programs

• BioDosimetry
  — Initiated in FY 2009; Awards FY 2010

• BioDiagnostics
  — Initiated in FY 2010; Awards expected FY 2011

• ChemDiagnostics
  — Initiated in 2011; Awards ?

BAAs with Diagnostic Areas of Interest:

BARDA-CBRN-BAA-10-100-SOL-00012
“Advanced research, development and acquisition of medical countermeasures”
(Division of Chemical, Biological, and Nuclear Threats)

BARDA BAA 11-100-SOL-00001
“Science and Technology Platforms applied to MCM Development”
(Division of Strategic Science and Technology)
# Integrated Portfolio Approach: Pandemic Influenza

<table>
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<th></th>
<th>Vaccines</th>
<th>Antivirals</th>
<th>Diagnostics/Respiratory Devices</th>
</tr>
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<tbody>
<tr>
<td><strong>Advanced Development</strong></td>
<td>Cell-based Antigen-sparing Recombinant &amp; Molecular</td>
<td>IV Antivirals</td>
<td>Diagnostics Point of Care; Clinical Lab Next Generation Ventilators</td>
</tr>
<tr>
<td><strong>Stockpiling &amp; Acquisitions</strong></td>
<td>H5N1 Pre-Pandemic Vaccine</td>
<td>Federal &amp; State Stockpiles IV Antivirals: EUA</td>
<td>Masks &amp; Respirators</td>
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<tr>
<td><strong>Infrastructure Building</strong></td>
<td>Egg-based Supply Retrofit Mfg Facilities New Mfg Facilities</td>
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Planning Strategies
An Interagency Coordination Team collaboratively developed a strategy with 7 broad objectives for focus:

- Develop New Diagnostic Tests and Improved Diagnostic Capabilities
- Improve Surge Capacity
- Implement Proficiency Testing
- Develop Regulatory Preparedness
- Improve Access to Viruses and Reagents
- Provide Guidance for Clinicians
- Improve Virologic Surveillance
<table>
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<tr>
<th>Projects</th>
<th>Awards</th>
<th>Contractors</th>
<th>Objectives</th>
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<tbody>
<tr>
<td>Point of Care</td>
<td>2006</td>
<td>4</td>
<td>Differentiate novel from seasonal flu in 30 min Accurate results for use in outpatient settings</td>
</tr>
<tr>
<td>Laboratory Influenza Test</td>
<td>2008</td>
<td>2</td>
<td>Differentiate novel &amp; seasonal influenza viruses Less than 3 hr test; 150 specimens/8 h</td>
</tr>
<tr>
<td>RT-PCR, CDC</td>
<td>2007</td>
<td>Multiple including partnerships, cooperative agreements</td>
<td>FDA-approved PCR test for flu A,B, H1, H3, H5 Distribute test to states and international labs</td>
</tr>
</tbody>
</table>
| Rapid Influenza Immunity Test    | 2008   | Multiple (1 POC, 3 HTP) | Improve capability to rapidly test blood samples for flu antibodies:  
  • Point-of-care field use  
  • High throughput                                                              |
CURRENT TESTS (2006)

- Antigenic Characterization
- Viral Culture
- Immunofluorescence
- Serology
- LRN H5 PCR
- Immunodassay

TEST SETTINGS
- Outpatient & Clinic
- Hospital Lab
- Referral Lab
- Public Health Lab
- CDC

Under Development (2006-2008)
- POC Influenza Test (4 contracts)
- Laboratory Influenza Test (2 contracts)
- Validated CDC 5 Target PCR
- Rapid Influenza Immunity Test
Emergence and Spread of Pandemic Influenza A (H1N1v): Case Reports

Rapid Assessment of 2009H1N1 spread in the U.S.
(Respiratory specimen testing from ~150 laboratories participating in
CDC’s virus surveillance system)

Influenza Diagnostic Dilemma

TEST SETTINGS

Outpatient & Clinic  Hospital Lab  Referral Lab  Public Health Lab  CDC

Clinical assessment – preliminary clinical diagnosis

Definitive Results

RIDTs (CLIA-waived)  RIDTs  DFA  PCR  Viral Culture

Time to Results

Diagnosis Lab-Confirmed at Public Health Lab, or CDC
Refining the Diagnostic Strategy

The 2009-H1N1 pandemic highlighted the following needs:

- Reliable, accurate point-of-care tests in outpatient settings
- Timely, accurate influenza tests in hospital settings
- Capability to identify multiple respiratory pathogens; rapid differential diagnostics
- Guidance and resources for clinicians
  (Clinical algorithms and tools for maximizing testing practice and test performance, better specimen collection, improved reporting and electronic data management)
- Resource support for manufacturers
  (reagents, specimens, and standards)
- Field assessments in practice settings
- Point-of-care and high throughput testing for immunity/exposure assessments
- Rapid characterization of reassortant influenza viruses and antiviral resistance
## Current Projects

<table>
<thead>
<tr>
<th>Projects</th>
<th>Awards</th>
<th>Contracts / Mechanisms</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative Flu Testing Platform</td>
<td>2010</td>
<td>1</td>
<td>Multi-use, flexible format</td>
</tr>
<tr>
<td>High Throughput Multiplex Testing</td>
<td>2010</td>
<td>1</td>
<td>• Multiple respiratory pathogens, dual effort with CBRN targets&lt;br&gt;• Field deployable</td>
</tr>
<tr>
<td>Manufacturer Support for Flu Test Development</td>
<td>2010</td>
<td>5 contract labs</td>
<td>Studies, validations, reagents for development, and evaluations of influenza tests</td>
</tr>
</tbody>
</table>
CURRENT TESTS (2010)

Viral Culture

Antigenic Characterization

Immunofluorescence

Serology

Influenza PCR Tests

CDC multi-target PCR

Immunoassays

TEST SETTINGS

Outpatient & Clinic

Hospital Lab

Referral Lab

Public Health Lab

CDC

Laboratory Influenza Test (1 contract)

High Throughput (1)

POC Influenza Test

Antiviral Resistance Influenza Test

Multi-respiratory Pathogen Tests

Rapid Virus Characterization Tests

Rapid Influenza Immunity Test (1)

Under Development (2011)
Planning: Next Steps post 2009

http://www.phe.gov/Preparedness/mcm/enterprisereview/
Findings/Recommendations influencing next steps:

- Shift from focusing on developing and stockpiling highly pathogen/threat-specific countermeasures toward a multiuse platform approach.
- New tools, standards and approaches to more efficiently develop products and to facilitate the evaluation of product safety, efficacy (effectiveness), and quality.
- Enhanced ability and capacity to collect data during emergencies.
- A focused solicitation program for more targeted research, using flexible transaction tools, such as rolling Broad Agency Announcements, to capitalize on emerging concepts and recognized gaps in downstream development programs.
On-going Planning

Alert Event(s)

CDC

Notification of a potential PHEIC to the WHO

Identification of activities at each interval of a pandemic curve
Devices Part II:

Next Generation Ventilators
Masks & Respirators
Advanced Development of Next Generation Portable Ventilators

2007: HHS pandemic influenza medical countermeasures gap analysis revealed a national need for large numbers of portable ventilators for emergencies

2009: a survey of U.S. inventory prompted an estimated need for 50,000 more portable ventilators in the U.S. for widespread ARF


Overall objectives for next generation portable ventilators:

- Domestic manufacture
- Fully-kitted and enables standard of care for adults, children, neonates
- Can be easily used by untrained care givers
- Unit cost goal of <$3000 per unit.
- Surge production goal of 10,000 units within 6 months
- Minimal maintenance; suitable for stockpiling

2010: BARDA awarded an advanced development contract for a next generation portable ventilator
- Little to no research available to guide use recommendations or decisions

- **March 2010**: BARDA awarded an IAA to
  - Determine the filtration efficiency and
  - Characterize total inward leakage of FDA-cleared N-95s using an H1N1 influenza challenge.

- Results should be published on completion.
Thank You for your Attention!

Time for Questions/Comments
(also at the end of today’s session)
Interfacing with BARDA

• **www.phe.gov**
  — Program description, information, news, announcements

• **www.medicalcountermeasures.gov**
  — Portal to BARDA
  — Register, request a meeting
  — Tech Watch

• **www.fedbizopps.gov**
  — Official announcements and detailed information about all government contract solicitations

[Image of www.fbo.gov]