



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)



BARDA Industry Day: Influenza Rapid Diagnostics and Respiratory Devices

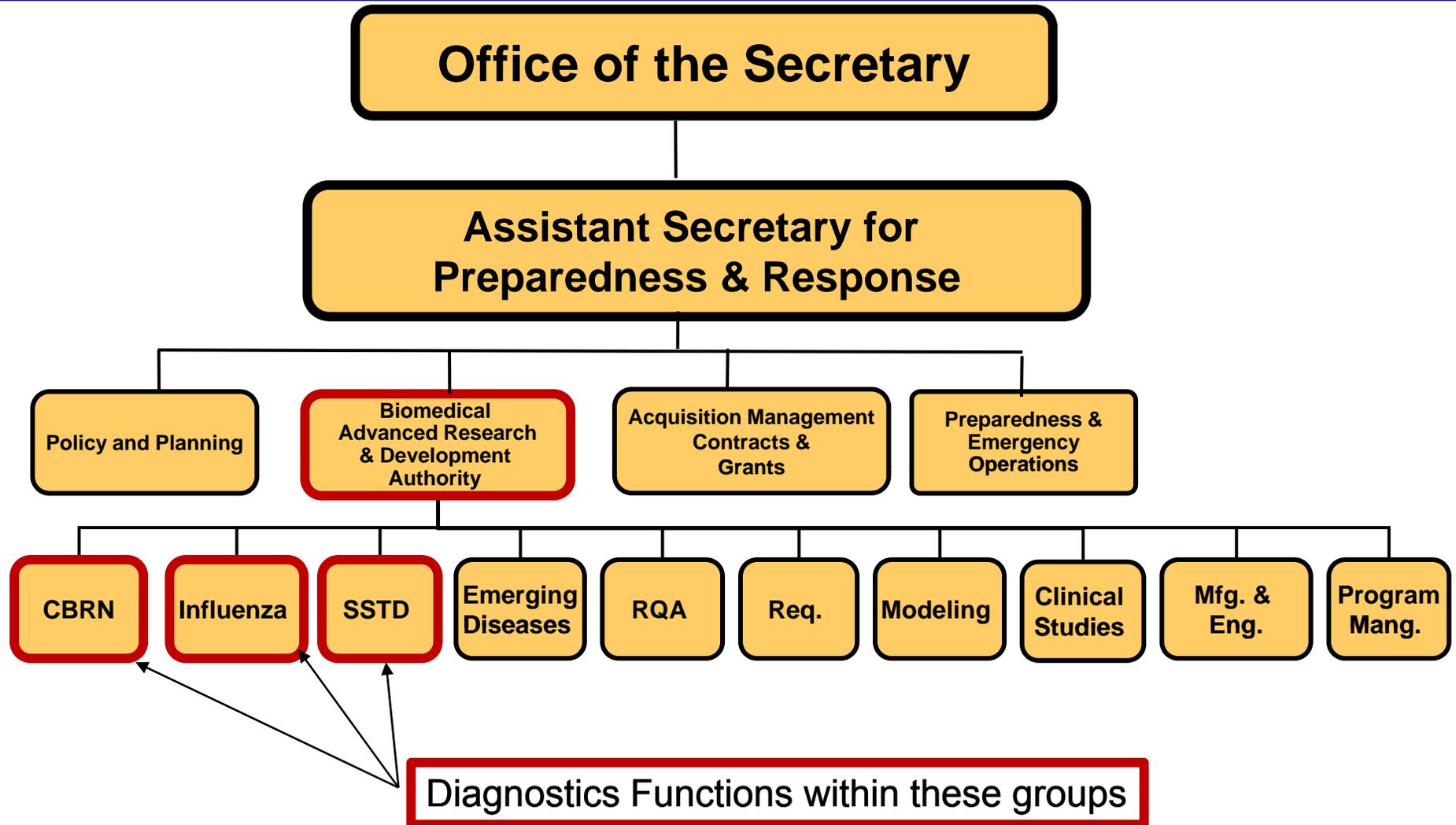
**Roxanne Shively
Influenza Division, BARDA**

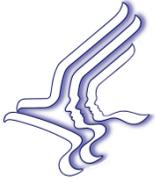
San Diego, CA

June 7, 2011



Diagnostic Programs within BARDA





BARDA Dx Programs



- **BioDosimetry**
 - Initiated in FY 2009; Awards FY 2010
- **BioDiagnostics**
 - Initiated in FY2010; Awards expected FY2011
- **ChemDiagnostics**
 - Initiated in 2011; Awards ?

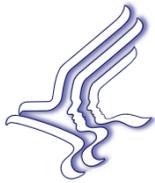
BAAs with Diagnostic Areas of Interest:

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

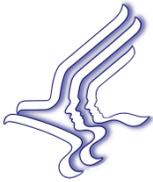
“Science and Technology Platforms applied to MCM Development”
(Division of Strategic Science and Technology)



Integrated Portfolio Approach: Pandemic Influenza



	<i>Vaccines</i>	<i>Antivirals</i>	<i>Diagnostics/ Respiratory Devices</i>
<i>Advanced Development</i>	Cell-based Antigen-sparing Recombinant & Molecular	IV Antivirals	<u>Diagnostics</u> Point of Care; Clinical Lab Next Generation <u>Ventilators</u>
<i>Stockpiling & Acquisitions</i>	H5N1 Pre-Pandemic Vaccine	Federal & State Stockpiles IV Antivirals: EUA	Masks & Respirators
<i>Infrastructure Building</i>	Egg-based Supply Retrofit Mfg Facilities New Mfg Facilities		



Planning Strategies

THE WHITE HOUSE
WASHINGTON
October 18, 2007

PUBLIC LAW 109-417—DEC. 19, 2006 120 STAT. 2861

Subject: Homeland

Purpose: (1) This Preparedness Century the Ame

Definition: (2) In th

January 31, 2007

Subject: Medical Countermeasures

BACKGROU

(1) Weapon (CBRN) – in challenges that compromise damage that

(2) Our Nat for the 21st ability to ma but we must have made mitigate imp and acquist from CBRN

(3) It is not possible the caused by el process. Th to Combat V Nation's me

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(b) Y evol

Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Draft BARDA Strategic Plan
for Medical Countermeasure
Research, Development, and Procurement

July 2007

NATIONAL STRATEGY FOR
PANDEMIC INFLUENZA

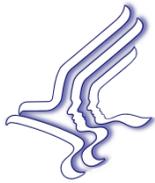
HOMELAND SECURITY
NOVEMBER 2006

HHS Pandemic Influenza Plan

NATIONAL STRATEGY FOR
PANDEMIC INFLUENZA

IMPLEMENTATION PLAN

HOMELAND SECURITY COUNCIL
MAY 2006



Pandemic Diagnostic Preparedness Strategy - 2007



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



BARDA/CDC Influenza Diagnostics Pre- 2009



Projects	Awards	Contractors	Objectives
Point of Care	2006	4	Differentiate novel from seasonal flu in 30 min Accurate results for use in outpatient settings
Laboratory Influenza Test	2008	2	Differentiate novel & seasonal influenza viruses Less than 3 hr test; 150 specimens/8 h
RT-PCR, CDC	2007	Multiple including partnerships, cooperative agreements	FDA-approved PCR test for flu A,B, H1, H3, H5 Distribute test to states and international labs
Rapid Influenza Immunity Test	2008	Multiple (1 POC, 3 HTP)	Improve capability to rapidly test blood samples for flu antibodies: <ul style="list-style-type: none">• Point-of-care field use• High throughput

CURRENT TESTS (2006)

Antigenic Characterization

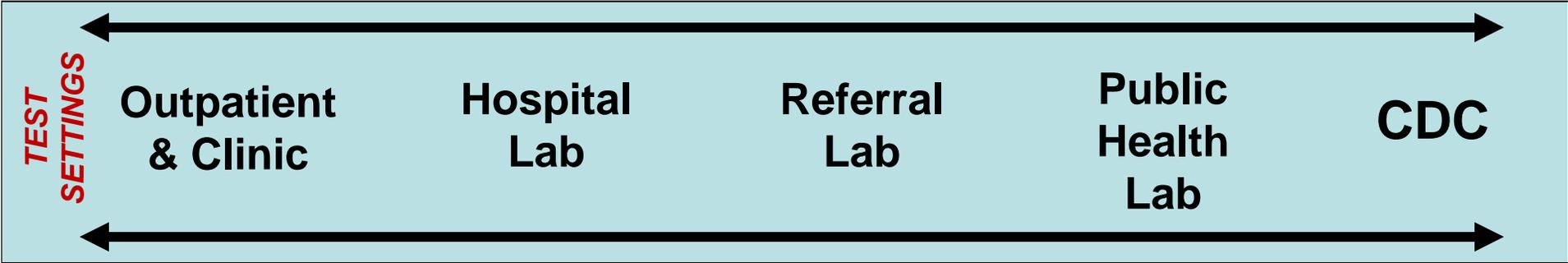
Viral Culture

Immunofluorescence

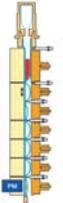
Serology

Immunoassay

LRN H5 PCR



Under Development (2006-2008)

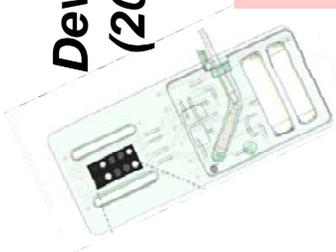


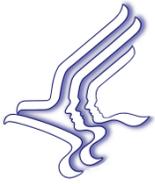
POC Influenza Test (4 contracts)

Laboratory Influenza Test (2 contracts)

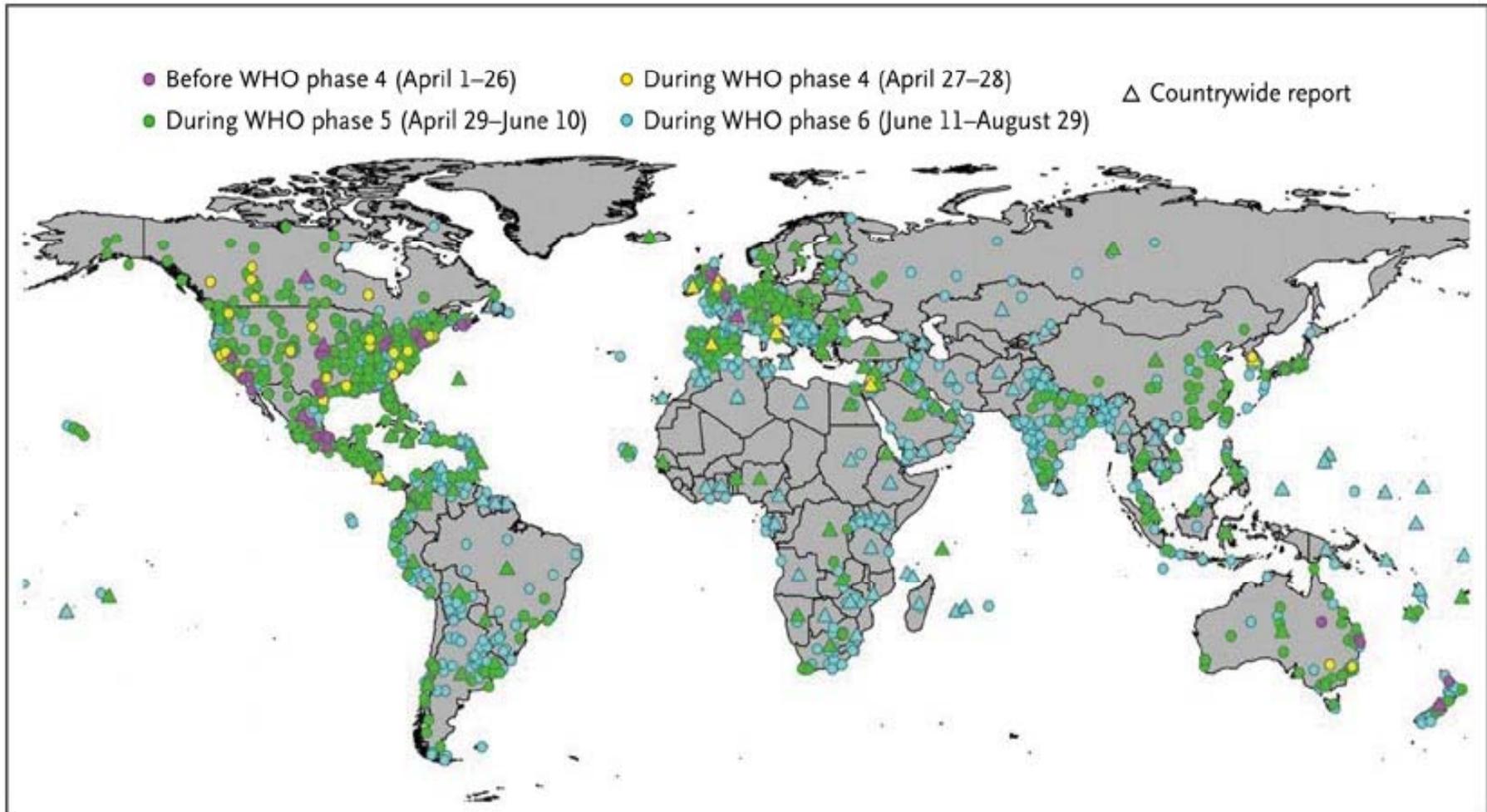
Validated CDC 5 Target PCR

Rapid Influenza Immunity Test





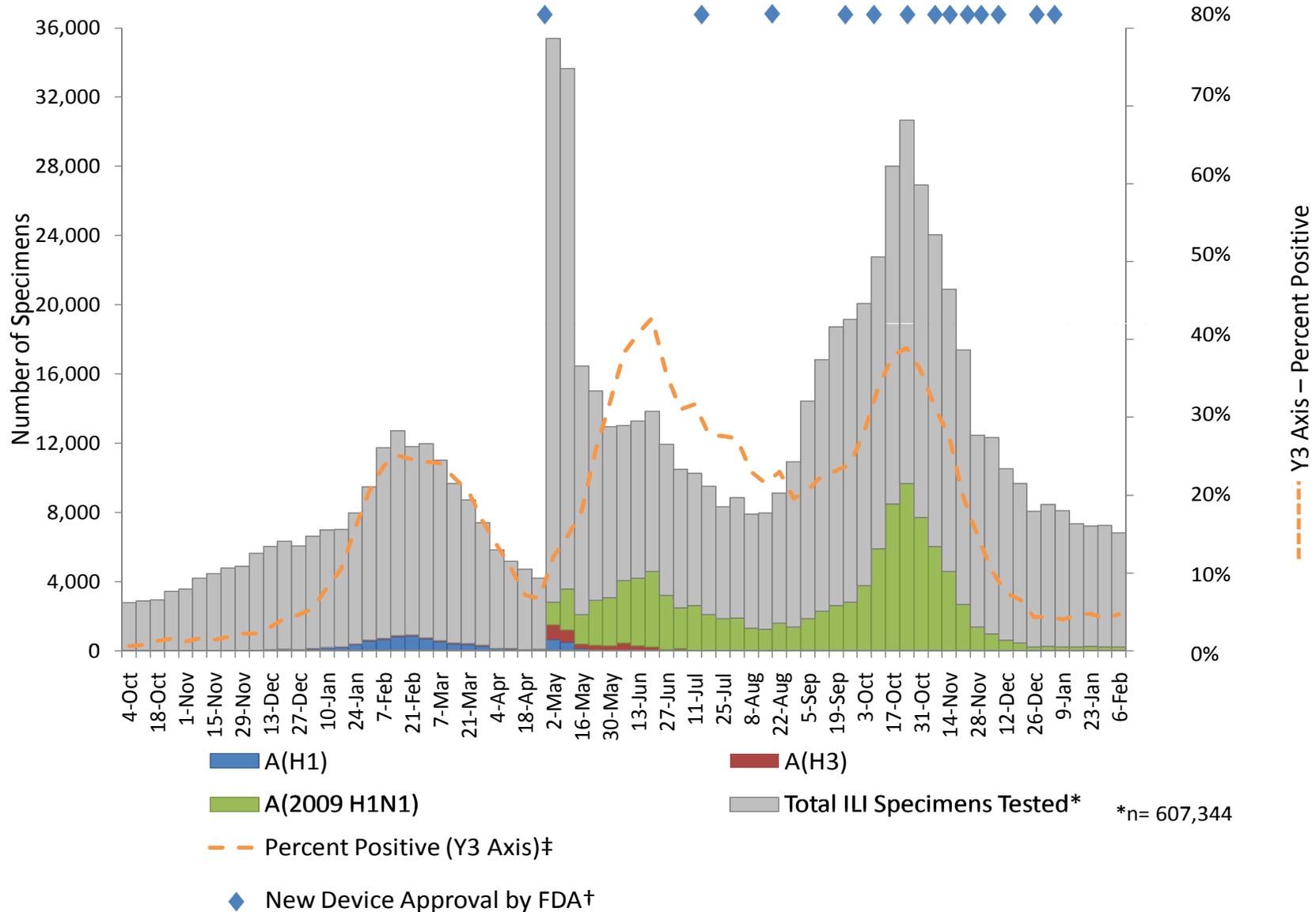
Emergence and Spread of Pandemic Influenza A (H1N1v): Case Reports



From: Brownstein J et al. N Engl J Med 2010;362:1731-173

Rapid Assessment of 2009H1N1 spread in the U.S.

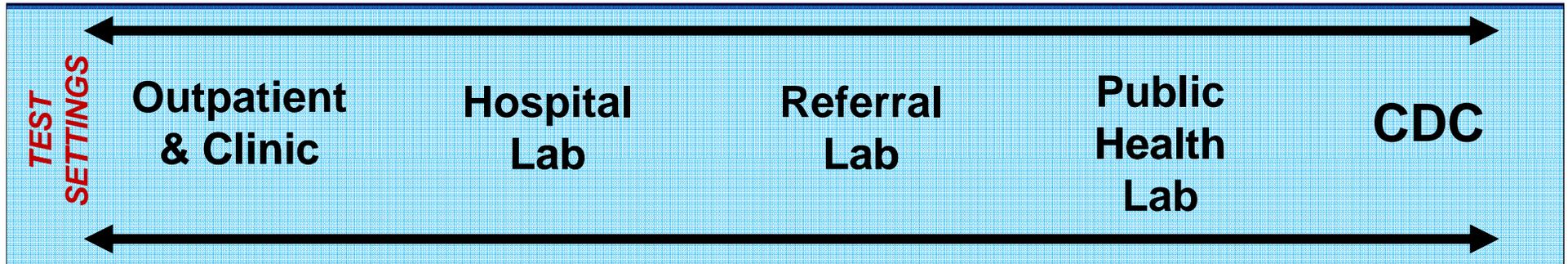
(Respiratory specimen testing from ~150 laboratories participating in CDC's virus surveillance system)



From: Jernigan et al. Clin Infect Dis. 2011 Jan 1;52 Suppl 1:S36-43



Influenza Diagnostic Dilemma



Clinical assessment – preliminary clinical diagnosis



RIDTs
(CLIA-waived)

RIDTs

DFA

PCR

Viral Culture

Diagnosis Lab-Confirmed at Public Health Lab, or CDC



Time to Results

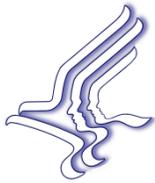


Refining the Diagnostic Strategy



The 2009-H1N1 pandemic highlighted the following needs:

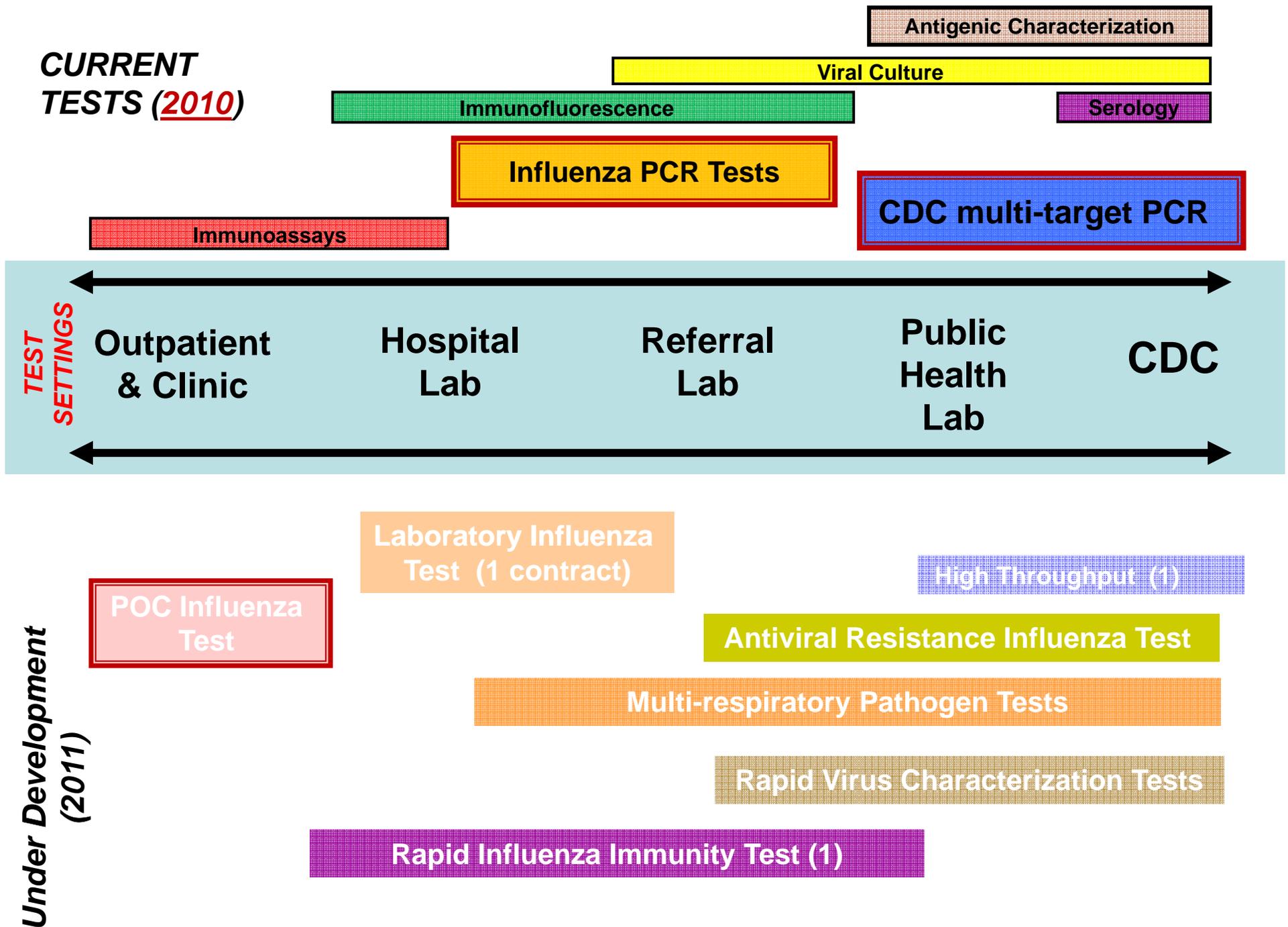
- Reliable, accurate point-of-care tests in outpatient settings
- Timely, accurate influenza tests in hospital settings
- Capability to identify multiple respiratory pathogens; rapid differential diagnostics
- Guidance and resources for clinicians
(Clinical algorithms and tools for maximizing testing 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



Projects	Awards	Contracts / Mechanisms	Objectives
Innovative Flu Testing Platform	2010	1	Multi-use, flexible format
High Throughput Multiplex Testing	2010	1	<ul style="list-style-type: none">• Multiple respiratory pathogens, dual effort with CBRN targets• Field deployable
Manufacturer Support for Flu Test Development	2010	5 contract labs	Studies, validations, reagents for development, and evaluations of influenza tests





Planning: Next Steps post 2009



PUBLIC LAW 109-417—DEC 19, 2006 120 STAT. 2681

THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

Federal Register / Vol. 72, No. 63 / Tuesday, March 29, 2007 / Notices

Homeland

January 31, 2007

Subject: Medical countermeasures to protect the American people. This 2005 Public Health Emergency Act...

BACKGROUN

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Draft BARDA for Medical Research, Develop

July

DEPARTMENT OF HEALTH & HUMAN SERVICES

NATIONAL STRATEGY FOR
PANDEMIC INFLUENZA

HHS Pandemic Influenza Plan

U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response

The Public Health Emergency Medical Countermeasures Enterprise Review

Transforming the Enterprise to Meet Long-Range National Needs

August 2010

NATIONAL STRATEGY FOR
PANDEMIC INFLUENZA

IMPLEMENTATION PLAN

HOMELAND SECURITY COUNCIL
MAY 2006



PHEMCE Review, August 2010

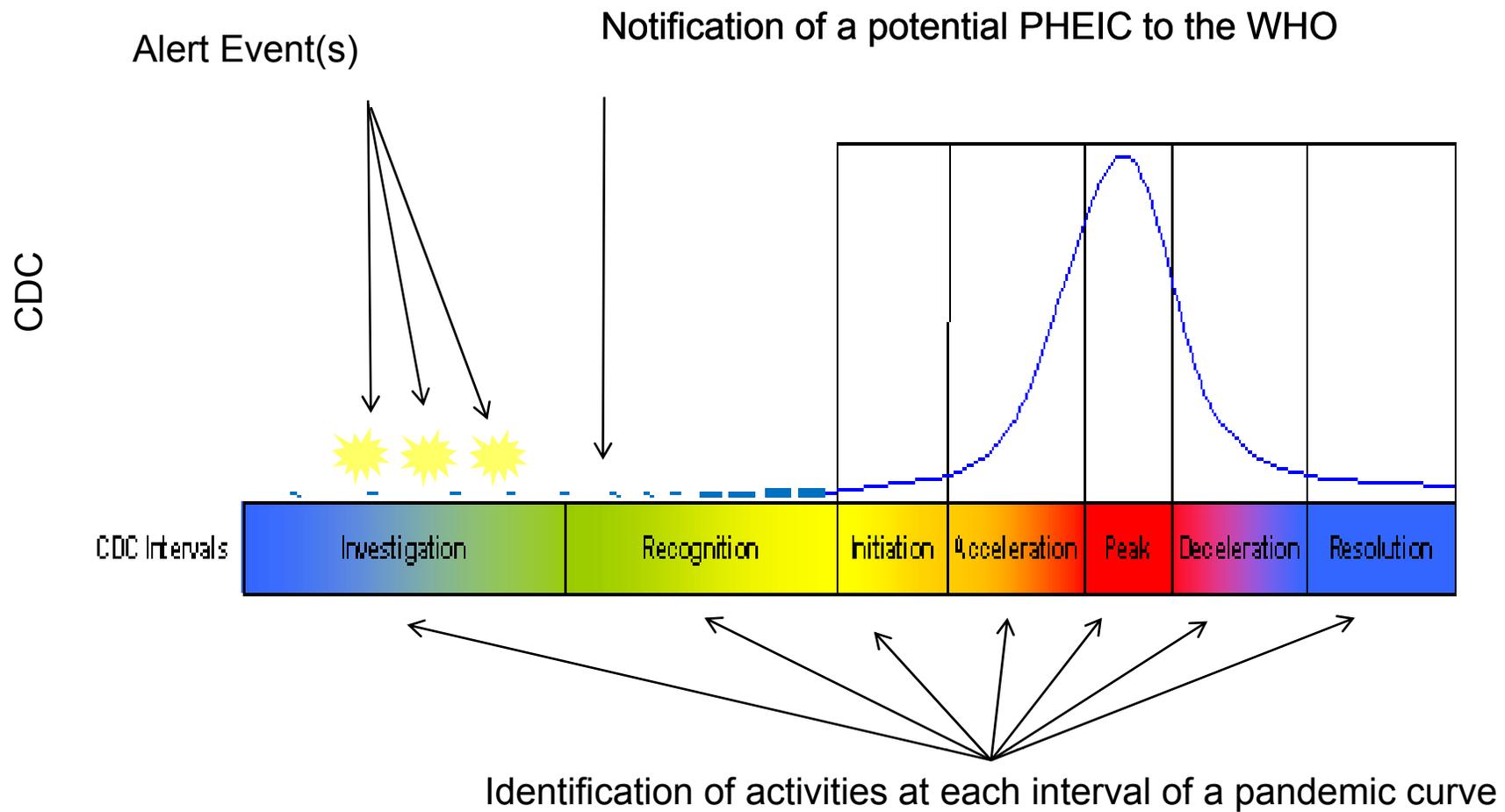


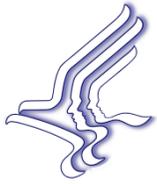
Findings/Recommendations influencing next steps:

- *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



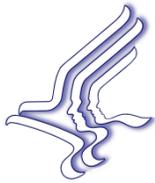


Devices Part II:



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

(Rubinson et al, Disaster Med Public Health Prep. 2010 Oct;4(3):199-206)

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



Filtration efficiency of N-95 respirators with influenza virus



- 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

