ASPR in 2016: Poised to reach the next horizon

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ASPR brings together policy, science, and emergency operations
The countermeasure enterprise has learned from other responses, and vice versa.
An impressive track record of success through Public-Private Partnerships

- 2007: Influenza MCM, Biothreat MCM, Radiation MCM, Other
- 2008: H5N1 Vaccine, Antigen Alone Formulation
- 2009: Adult H1N1 Influenza Virus Vaccine (Fluzone®), Adult H1N1 Influenza Virus Vaccine (Afluria®), H1N1 Influenza Virus Vaccine (Fluvirin®)
- 2010: Influenza Virus A/B Rapid Diagnostic (Xpert FLU®)
- 2011: Influenza Virus A/B Rapid Diagnostic (Ventor®)
- 2012: Influenza Virus A/B Rapid Diagnostic (Sophia®), Influenza Virus POC Diagnostic (FluChek®), H7N9 Pandemic Influenza Virus Vaccine w/ Adjuvant
- 2013: H5N1 Influenza Virus Vaccine (Flublok®), Influenza Antiviral Intravenous Drug
- 2014: Influenza Virus POC Diagnostic (Cobas® Liat), H5N1 AS93-Adjuvanted Pandemic Influenza Virus Vaccine for Pediatrics (Q-Pan®)
- 2015: Influenza Virus Vaccine, incactivated w/ Adjuvant, for Seniors (Flued®)
- 2016: * MCMs that are stockpiled but not yet FDA licensed

Excelente registro de éxito a través de Partenariados Público-Privados
CBRN: The B

- Supported 21 MCMs under Project BioShield
  - 14 BARDA-supported MCMs added to SNS
- Focused attention to products for pediatric and elderly populations

- Botulinum Antitoxin
- Anthrax Antitoxins
- Anthrax Vaccine
- Smallpox
- Cell-based Influenza Vaccine
- Influenza IV Antiviral Drug
- H1N1 & H5N1 Vaccines w/ Adjuvant
- Influenza/RSV POC Diagnostic
Focus on products with both CBRN and ‘peacetime’ uses

- Pathogen reduction technologies for blood
- Silver-impregnated dressing for thermal (and other) burns
- Artificial skin substitutes and debridement technologies for thermal burns (and diabetic ulcers)
- Antibiotics for resistant organisms
- Next generation portable ventilators
- Leveraging pandemic investments for seasonal flu
A spirit of innovation crosses all of ASPR
Innovation in technology needed to be matched with innovation in organization

- PHEMCE organization evolving to address impediments to response
  - Inability to move money quickly
  - One-bug, one-drug approach not suited for new diseases
  - Manufacturing processes not fast enough; goals not sufficiently ambitious
  - Limited innovation in business models

- Other organizational changes have enabled continuous improvement, stewardship
Key Inputs Help build MCM response on back of day-to-day systems

2010 Secretary’s MCM Review

• New PHEMCE structure with end-to-end and capabilities focus
  • FDA involved from the beginning
• Shift from one bug, one drug to platform technologies
• New contracting approaches and innovative public private partnerships
• 80 percent goal
• Regulatory science

Authorities

• Other Transaction Authorities
• Emergency Use Authorization in advance of PHE
• Authority to preposition countermeasures
• Temporary redeployment authority

Stakeholder Feedback
Now, BARDA leverages other ASPR capabilities, and vice versa

**BARDA**

- Decision making: Disaster Leadership Group
- Requirement setting
- Surge staffing approaches

**Emergency Management**

- Situational Awareness, Fusion
- Response framework and organization
- Collaboration with end users in healthcare system
- NDMS and personnel surge

**Policy and Planning**

- Modeling
- Delivering on requirements
- Milestone driven approaches
- Public/private partnerships
BARDA is evolving as a response organization
Emerging infectious diseases continue to surface gaps and opportunities

- Highlighted need for better-organized MCM response
- Need faster vaccine development timelines/goals
- Surfaced need for stronger science response infrastructure
- Built fill-finish network (FFN), clinical studies network (CSN)
- Led to platform investments

- Sample sharing challenges inhibited diagnostic test and MCM development
- Clinical research infrastructure needed in areas most at risk

- Platform investments, FFN and CSN put to use
- Challenged global science response infrastructure, including clinical research response
- For USG, no clear responsibility for sample collection to support diagnostic developers
- Ongoing global sample sharing challenges
- Funding challenges highlight need for response fund
- Supported development of 4 vaccine candidates; rapid, point of care diagnostic; 3 therapeutics

- No candidates in pipeline
- Sample sharing and acquisition improved, but important gaps persist
- Assay development/validation; strain selection need harmonization
- Funding delays slow development; highlight need for response fund, again
- Platform investments, FFN, and CSN again put to use
- Supporting development of 2 pathogen reduction technologies; 2 blood screening technologies; 4 serologic diagnostic assays (incl. 1st commercial assay under EUA); 5 vaccine candidates
Core Services Are Building Response Capabilities; More Are Needed

- Clinical Trials Network
- Clinical Studies Network
- Fill Finish Mfg. Network
- Regulatory & Technical Expertise
- Modeling Hub
- Centers for Innovation in Advanced Development & Manufacturing
- Animal Studies Network
- TBD
- Specimen collection network
- Other non-vaccine platforms

Years:
- 2012
- 2013
- 2010
- 2009
- 2006
- TBD
Better research preparedness is essential to doing better next time

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Research as a Part of Public Health Emergency Response
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Francis Collins, M.D., Ph.D., and Thomas Frieden, M.D., M.P.H.

Disasters and public health emergencies provides a finite window of opportunity to identify, collect and analyze critical and time-sensitive data and information needed to protect the health and safety of responders, communities and our Nation.
Better research preparedness is essential to doing better next time

<table>
<thead>
<tr>
<th>WHAT WE NEED TO DO</th>
<th>WHAT WE’VE DONE SO FAR</th>
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<tbody>
<tr>
<td>“Science response” is part of core response plans</td>
<td>Partial roster of SMEs; table-top exercises of research as part of response</td>
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<tr>
<td>Identification of knowledge gaps and research questions</td>
<td>Developed mechanism for IOM to rapidly develop prioritized research agenda; used for Sandy and Ebola</td>
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<td>Generic and scenario-specific templates and protocols</td>
<td>Developed a common master therapeutics trial protocol for Ebola and MERS; templates now available for environmental disasters</td>
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<td>Rapid IRB review mechanisms</td>
<td>Established Public Health Emergency Research Review Board; NIH Common Rule proposes a single IRB for multicenter studies</td>
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<td>Rapid funding</td>
<td>NSF has mechanism; others needed</td>
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<td>Registries and networks for studies</td>
<td>NIOSH ‘registry in a box’; established Zika pregnancy registries early; networks in progress</td>
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<td>Involvement of affected communities</td>
<td>Established collaborative relationships with local, national, and international stakeholders and local philanthropy</td>
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What does the new horizon look like?

- Community and health system resilience
- Population health focus
- Fast, nimble response
- Includes behavioral health
- Continuous leveraging of new technologies

- Rapid research response to all hazards
- Response fund and clear ARD support for EIDs
- End-to-end MCM response coordination
- Improving strong day-to-day development rooted in core mission
- Innovative funding and partnership models
- Ensuring program integrity
Strengthening the Global Environment for MCM Development

• Continue to advance global MCM development and response efforts
  • Encouraged by more funders and partnerships
  • Need approaches that balance partner goals/needs with speed
  • PHEMCE/BARDA has taught us about the complexity of MCM development; global efforts can build on lessons learned
• Continue to meet both National Health Security and Global Health Security needs
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