



EMERGING INFECTIOUS DISEASE PREPAREDNESS

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Resilient People. Healthy Communities. A Nation Prepared.

Institute of Medicine Workshop

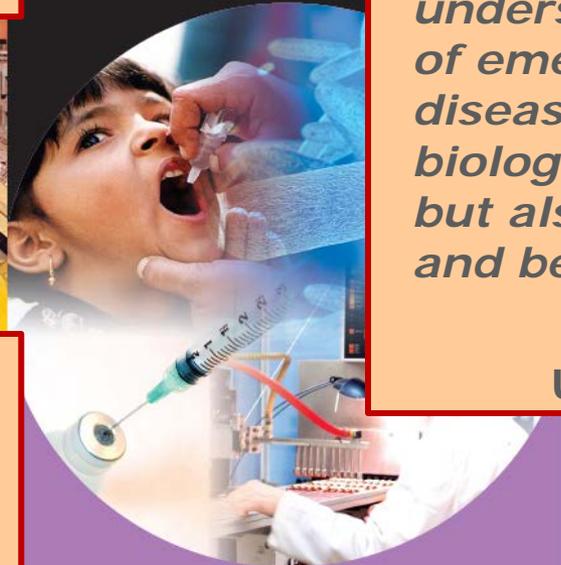
"Companies need to see business models that work along with commercial potential . . . providing an opportunity for a return on investment."

Rajeev Venkayya
Takeda Pharmaceuticals

Rapid Medical Countermeasure Response to Infectious Diseases

Enabling Sustainable Capabilities Through Ongoing Public- and Private-Sector Partnerships

Workshop Summary



"The public needs to understand real-world risk of emerging infectious diseases, not just the biological assessment of risk but also the social, economic and behavioral risks."

Michael Osterholm
University of Minnesota

"We will continue to be reactionary unless better efforts are made during inter-epidemic periods to advance preparedness."

Gerald Parker
Texas A&M University

The National Academies of
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Background

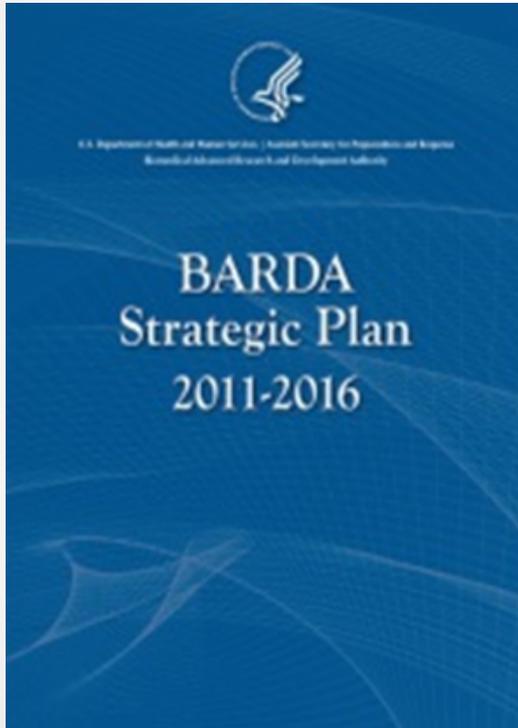
- BARDA has made major investments in developing response capabilities
- BARDA increasingly responds in real time to infectious disease events
 - 2009-H1N1
 - H7N9
 - Ebola
 - MERS-CoV.....
- Threat-focused funding for EID countermeasures is problematic
 - Episodic, reactive, unsustainable
 - SARS, Ebola, even Flu.....
- Threat tempo is varied
 - Perpetual (Flu)
 - Evanescent (SARS)
 - Endemic (MERS)
 - Dual (Ebola)
 - Gathering (AMR)



BARDA Strategic Plan 2011-2016

GOALS

- An advanced development pipeline replete with MCMs and platforms to address unmet public health needs, emphasizing innovation, flexibility, multipurpose and broad spectrum application and long-term sustainability
- A capability base to provide enabling core services to MCM innovators
- Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats
- Responsive and nimble programs and capabilities to address novel and emerging threats
- A ready capability to develop, manufacture, and facilitate distribution of MCMs during public health emergencies.



Internal Factors

- Maturation of flagship anthrax, smallpox, and botulinum antitoxin programs and recalibration of CRN program
- Tremendous expansion of filovirus program
- New flu initiatives (universal vaccine, immunotherapeutics)
- Growth of diagnostics portfolio, CARB, CMI
- Build-out of core services and livefire testing during responses
- Expanded menu of partnership options (OTA, non-contractual)
- Improved administrative processes (Tech Watch, BAAs, IPRs, Portfolio Review, BARDA Industry Day)



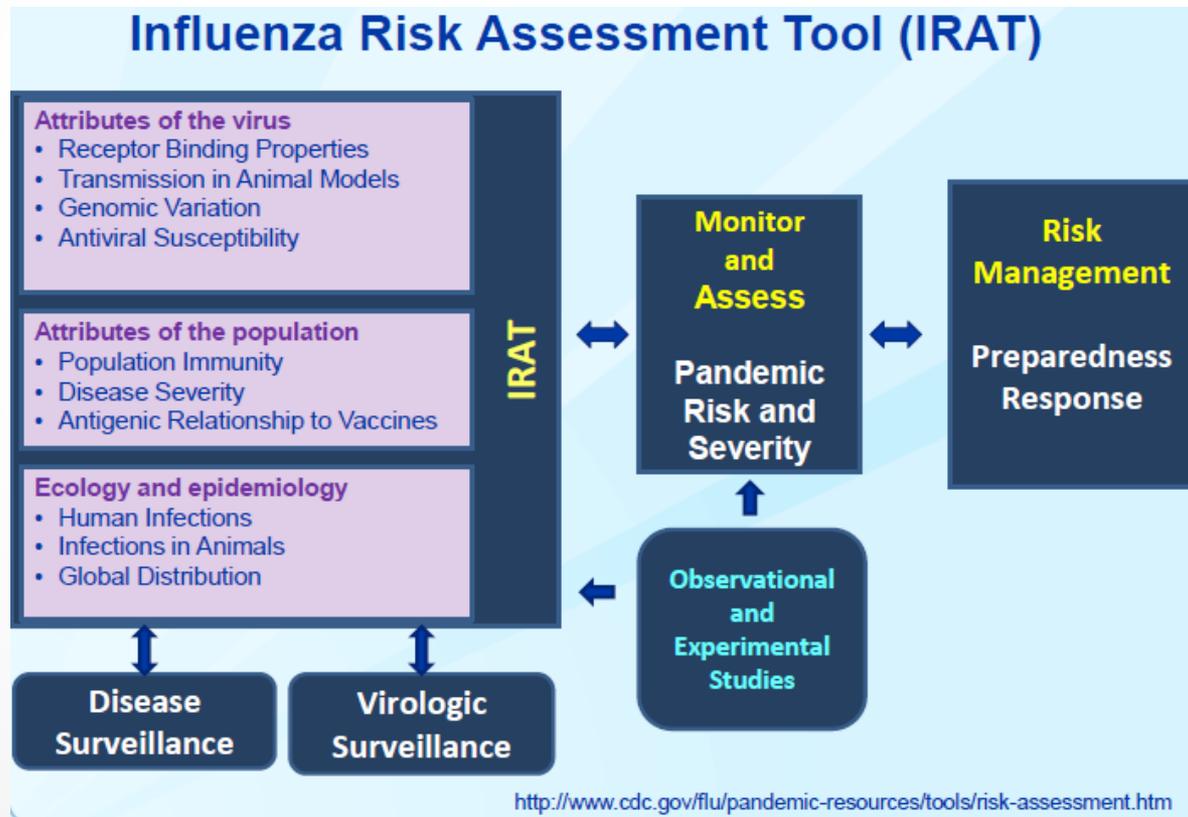
External Considerations

- Threat landscape
 - Convergence of NGS, GOF, Synthetic and DIY Biology
 - Persistent threat of transnational terrorism
 - Steady tempo of new flu viruses and emerging infectious diseases
- Increased engagement with Pharma on CBRN and EID
- New international partnerships (IMI, KSA, STRIVE)
- New interest in emerging threats from international partners and NGOs
 - BMGF, Allen Foundation, Wellcome Trust, World Bank
- Substantial budget constraints in near to mid-term

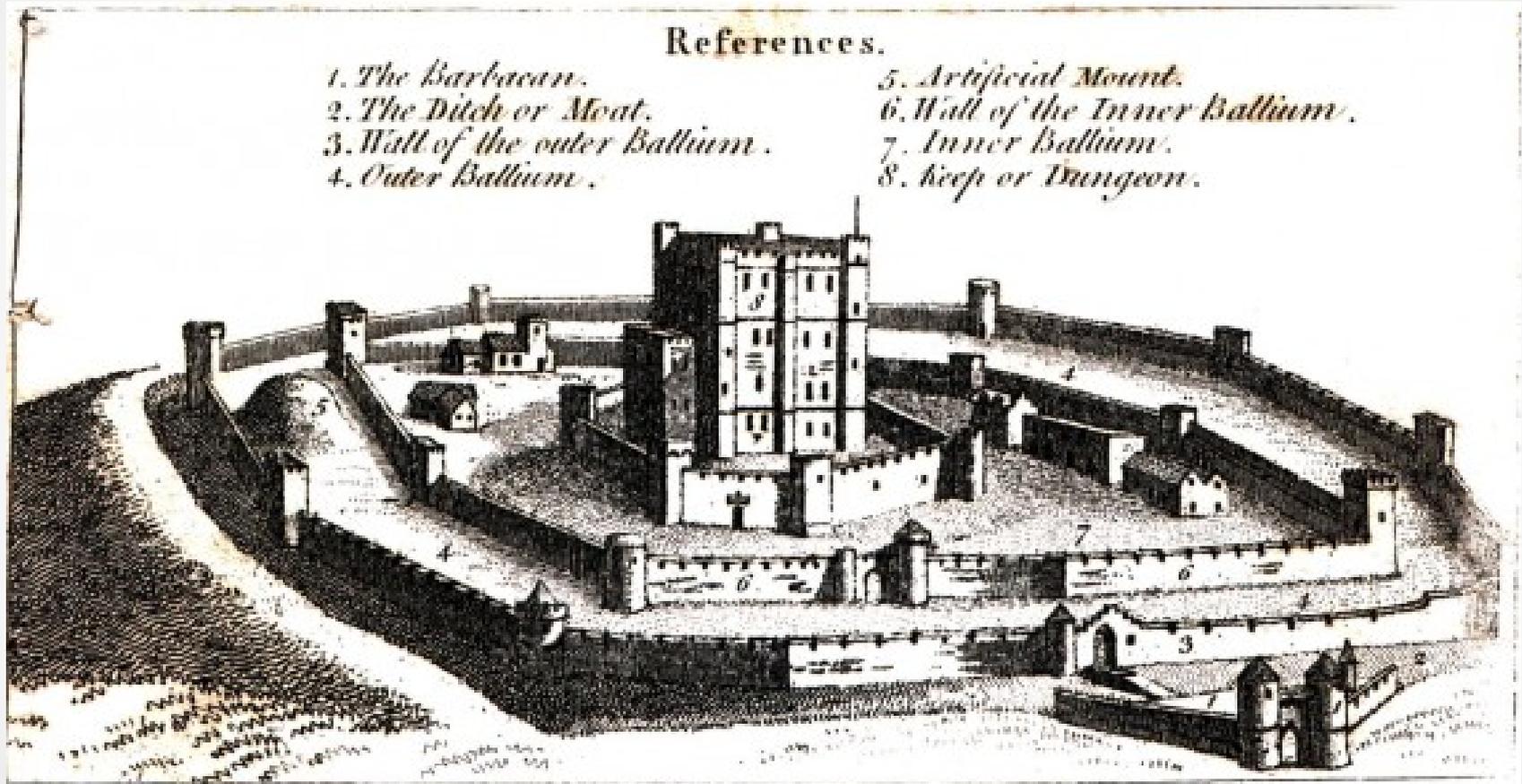


Threat Assessment

- Assessment of novel emerging threats and definition of requirements for established EIDs should fall within the remit of an interagency EID Working Group that functions as an analogue of the Flu Risk Management Meeting



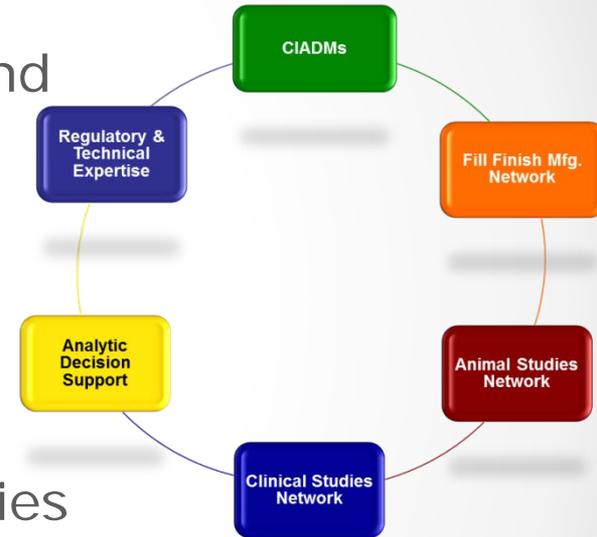
Layered Defense



“TEOTWAWKI”

Where We Are Now

- National Medical Countermeasures Response Infrastructure in place
- Investments in host-based therapeutics and broad-spectrum antivirals
 - AB103
 - Nitazoxanide
 - BCX4430
- Expanded menu of partnership opportunities
- EID programs diffused across different program areas and funding to address new threats is reactive



Outstanding Issues

- Achieving clear line of funding
- Internal organization
- Recruitment of SMEs, thought leaders
- Efficiency of contracting during a response
- Status of international efforts and partnerships
- Questions of policy
 - Should BARDA own IP or write/compile/submit NDA/BLAs?
 - How far do we take individual products?



An Inquiry into the Peculiarities of Human Memory

"The health problems of our giant cities are especially daunting. Consider Mexico City, with a population of 19 million officially and several million more than that in reality, that is to say, a population considerably greater than those of Norway, Sweden, and Denmark added together. Such megalopoli are sprouting rankly across the world, most spectacularly in the regions where the facilities and income are insufficient to take the most effective measures to control disease."

Preface to the New Edition (2003)

