



Summary of Key Recommendations Meeting to Solicit Stakeholder Input on Forthcoming 2017 National Biodefense Strategy

June 22, 2017
W Hotel, Washington, DC

Introduction

On June 22, 2017, the Johns Hopkins Center for Health Security (Center for Health Security) convened a meeting in Washington, DC, to solicit stakeholder inputs to the forthcoming National Biodefense Strategy and Implementation Plan (“the Strategy”) called for by the National Defense Authorization Act (Sec. 1086).¹ The aims of the meeting were to consider the United States’ biological threat landscape; discuss existing programs, policies, and mechanisms for mitigating the broad spectrum of naturally occurring, accidental, and deliberate biological threats facing the nation; articulate unmet challenges in global, national, and subnational emergency preparedness and response efforts; and identify priorities for strengthening the United States’ national biodefense enterprise.

The meeting featured participation from members of government, academia, and industry, including subject matter experts from a range of disciplines and sectors: public health, health care, emergency management, defense, the life sciences, veterinary science, agriculture, biotechnology, and the pharmaceutical industry. A list of meeting participants is attached. The meeting provided an opportunity to share frank, open feedback about US biodefense strengths and limitations with federal officials who attended the meeting and who are leading the development of the Strategy. Comments made were not for attribution.

The meeting was supported by the Open Philanthropy Project. The Center for Health Security did not attempt to reach stakeholder consensus on the topics discussed. What follows is the Center’s synthesis of recommendations made by one or more stakeholders during the meeting.

Improving Biosurveillance Capabilities and Laboratory Networks

Strong biosurveillance capabilities and effective early warning systems should be a cornerstone of preparedness efforts. Existing surveillance systems have provided some early notification of new disease outbreaks, and systems intended to provide early detection and notification will remain very important to support. We do not yet have technologies that can predict new outbreaks, but we should continue to invest in research toward that goal. We should also invest in better modeling approaches for epidemic disease, and we should develop closer relationships between government and the nongovernment expert modeling community, as has been done in the UK. Biosurveillance in the United States critically depends on getting surveillance information from the local level, where disease is occurring and getting initially diagnosed and reported. To have strong local biosurveillance systems requires strong public health systems, and those systems require a trained and resourced workforce. That workforce has been shrinking over time in many places, and resources for this work have been decreasing, a trend that should be reversed.

Strong surveillance also requires a robust, technically proficient laboratory network. Our laboratory systems for human diseases, such as those represented by the Association of Public Health Laboratories, have

¹ National Defense Authorization Act for Fiscal Year 2017. <https://www.congress.gov/114/crpt/hrpt840/CRPT-114hrpt840.pdf>

technical and scientific strength; however, in some places they have recently gotten weaker because of reduced support. Other untapped sources of information for human disease surveillance – such as electronic medical records—could be valuable, but they are not yet connected to public health systems in most places. The National Plant Diagnostic Network and state veterinary diagnostic laboratories are fundamental elements of early detection for plant and animal outbreaks, but neither are well funded and both need major strengthening.

Forging stronger links between the distinct systems capturing data on human, animal, and plant health could facilitate data-sharing and could increase understanding of the factors shaping infectious disease emergence and spread. Overall, stronger investment in human, animal, and plant laboratory networks should be made. In the animal and plant worlds, early reporting by farm owners is a highly effective and necessary form of early warning. However, reporting new outbreaks on a farm can result in extraordinary losses. To incentivize reporting of outbreaks, there need to be ways to compensate owners for these losses.

Internationally, laboratory and surveillance systems for early detection of new outbreaks will be most effective when they serve the needs of countries where they are housed. It will not work for the US to create systems to gather and export data that the US needs from countries if those countries do not get the information themselves and find it to be valuable.

Performing Risk Assessments and Characterizing Threats

Formulating a new US biodefense strategy creates an opportunity to revisit the risk assessment process for biological threats. A new approach could be implemented at the White House level – one that allows for risk comparison among naturally occurring, accidental, and deliberate biological threats, as well as with other threats to national health security. This national risk assessment could be modeled after approaches used in the United Kingdom and Canada, where subject matter expert judgment is combined with quantitative data to inform strategies around national-level potential threats and hazards. Such a national risk assessment could be complementary to and informed by the Department of Homeland Security’s ongoing Terrorism Risk Assessments, and it could help inform resource allocation decisions across government. Existing risk assessment and threat characterization programs should devote further resources to considering ways in which intentionally enhanced biological agents or novel pathogens of synthetic origin might change biological threats facing the US.

There should be better information sharing among federal, state, and local levels of government and enhanced communication at fusion centers. Given that fusion centers are currently law enforcement–centric, public health officials should be fusion center representatives and incorporate relevant health, medical, and scientific information flows into fusion center operations.

Strengthening Emergency Response Capabilities, Including Decontamination Efforts

Federal biodefense efforts need to account for a broad range of preparedness needs at subnational levels, noting that many state and local jurisdictions are shifting investments from infectious disease preparedness toward other high-probability public health threats, such as active shooters and opioid addiction. The same state and local workforce is responsible for this whole range of issues.

A few particular emergency response challenges were noted. Robust emergency response efforts depend on an understanding of resource availability (e.g., number of available beds, workforce size, supply chain vulnerabilities, etc.); we don’t have that kind of situational awareness in many places. To some, the BioWatch program appears to be diverging from the efforts of the national Laboratory Response Network; for that program to function, there needs to be alignment and close collaboration with local public health and emergency management. There was a recommendation that the Strategy not only consider challenges associated with detection, preparedness, and response, but also that it should focus on recovery from biological events.

Environmental decontamination presents another critical challenge; many of the policies and protocols governing decontamination efforts require strengthening, particularly for persistent threat agents such as anthrax. Some cities, such as NYC, have roles and responsibilities clearly assigned for how to pursue decontamination; other cities have done little or no planning for this. Many of the most complicated policy and technical problems that existed in 2001 remain unaddressed.

Building Global Capacities for Bio-threat Preparedness and Response

Engagement with international partners will help build global capacity for bio-threat preparedness and response. Continued support of the Global Health Security Agenda (GHS) and the World Organization for Animal Health (OIE) will reduce the risk of transnational disease spread to the US. These efforts not only build epidemic preparedness, they also strengthen US diplomatic efforts. They are low-cost, high-impact strategies compared to the alternatives; if the US works alone, without a multilateral approach, on these issues, it often ends up providing large-scale assistance on its own in the aftermath of epidemics, which is a more expensive proposition.

Efforts like GHS and the One Health Initiative recognize how connected animal and human health are and how emerging and re-emerging infectious diseases often arise overseas and can easily be imported by trade or travel. Much of the work of GHS is centered at CDC and USAID. But there are also important roles for DOD, including the cooperative threat reduction efforts that aim to detect and contain infectious disease threats overseas. For all of these programs, the US should send its best scientists and health experts for international work; our international partners know when they are interacting with scientific leaders and experienced public health experts versus those with too little expertise.

Prevention-Related Efforts

The Biological Weapons Convention (BWC) has established international norms to help prevent development, production, and stockpiling of dangerous biological weapons. Yet, the US has invested comparatively few resources in implementing this treaty or helping it to evolve to meet novel biological threats not envisioned at the time of the treaty's original establishment. The BWC has not received the kind of attention that the nuclear nonproliferation regime or the CWC has garnered. Given growing concerns around these issues in the life sciences, the forthcoming Strategy should deepen investment and commitment to the BWC. The US could also consider being more deliberate in calling out those who are in violation of the BWC.

In January, a White House document was released titled “Potential Pandemic Pathogen Care and Oversight.” The guidance makes useful proposals on how to evaluate and decide on the risks and benefits of potential pandemic pathogen–related research and whether the US government should support it. However, this guidance is not binding on federal agencies, and the extent to which it will be implemented is unclear. The new Strategy should consider these potential pandemic pathogen issues carefully and develop a White House and agency approach to managing these and other novel high-end biological risks that may emerge.

There is a need for further development and promulgation of norms for members of the life science community regarding the prevention of the potential misuse of biology, whether intentional or accidental. It should continue to promote education in the life sciences community on these issues and ethical codes of conduct. There is a need for systems of reporting in biosafety that are “no fault” in the sense that scientists are not punished for reporting.

Another prevention priority that was raised was the need to invest in building international biosafety expertise. Currently, expertise resides primarily in high-income countries but not in more vulnerable, lower-income countries. In addition, biosafety itself has not yet been recognized as an area of legitimate scientific inquiry and academic research in and of itself.

Organization of the US Government for Biodefense

The Strategy should recognize interdependence among and shared vulnerabilities across plant, animal, and human health domains. Those communities have typically not worked closely on biodefense-related issues, but this strategy development process has necessitated the collaboration of DHS, HHS, DOD, and the USDA in a new way. Hopefully this interaction can continue beyond the strategy development process. Given that biodefense responsibilities are distributed across the US government, continued White House NSC leadership remains crucial for organizing and leading interagency actions and policy development. There have been earlier calls to have a leader such as the vice president run biodefense for the US government, in order to raise visibility and drive the process. At this meeting, this suggestion was made again, but there was also vocal opposition to the proposal, with opponents reasoning that it would create risks to move it outside of the normal White House policy development process.

Leveraging Private-Sector Capabilities to Counter Biological Threats

The US government should work to better engage private-sector capabilities to counter biological threats, especially given that much of the critical infrastructure in the US is owned by private-sector stakeholders. Private-sector organizations could function as important partners in local capacity-building, with examples including in-kind contributions and subject-matter expertise in critical fields such as medical countermeasure development, production, and distribution; clinical trial coordination; and support for “last mile” operations. Soliciting more private-sector participation in federal, state, and local exercises could help further engage and orient the private sector in national biodefense efforts. Perspectives from the private sector can also help inform and stimulate thinking in the federal government. A private-sector coordinating council for biodefense modeled on the Combating Antibiotic-Resistant Bacteria Accelerator (CARB-X) public-private partnership should be pursued.

Catalyzing Innovation in Medical Countermeasure Research, Development, Trials, and Delivery

The US needs to continue to strengthen basic research, advanced development, regulatory science, and manufacturing for MCMs. High-level goals set forth in the 2016 PCAST report on biodefense are on target, especially related to national goals for accelerating the process of MCM development following emergence of a novel epidemic pathogen. The Biomedical Advanced Research and Development Authority and the Gates Foundation are currently the only entities making investments in advanced-stage MCM development in the world, and so US government support for BARDA needs to continue. Without BARDA support for advanced development, basic science investments will not continue into product development for biodefense. To the extent that it is possible, continued research should be pursued for platforms that could help accelerate the development process. Some have suggested that the US government should pursue an approach of getting things developed through Phase 1 and then put in reserve, to be pulled out in a crisis; others have noted that industry will not be incentivized to work with the US government if this approach is pursued.

BARDA should continue to push further into the rapid development and manufacturing of MCMs against emerging and re-emerging infectious diseases (e.g., Zika virus) as it now does for deliberate biological threats and pandemic flu. It was also suggested that development efforts such as those of BARDA should be considered for plant and animal diseases in some way.

The Strategy should help strengthen protocols for studying investigational products in the midst of a response; some areas of medicine, such as oncology, might offer insights into adaptive clinical trial design that could prove useful for assessing MCM efficacy during a crisis. The infrastructure for emergency clinical trials should be built in the US before the next epidemic crisis. This infrastructure does not now exist, and it won't happen just with the normal industry approach to clinical trials.

Clinical trials should also be planned and readied for international response. The experiences with peramivir use during H1N1 and the Ebola experience in West Africa showed us what can happen if we are not better prepared for clinical trials: We end up with too little meaningful information to understand the safety and efficacy of products at the end of the epidemic.

Healthcare System Response and Strengthening the Workforce

The US healthcare system response to infectious diseases needs to be stronger. Even after the investments made during Ebola to strengthen US healthcare system response, there are still only about 120 beds across the country to care for highly contagious diseases. Investments were made to build containment units, but there is little support now for training and exercises or technical workforce development. Meanwhile, the support for Hospital Preparedness Program grants have diminished over time. It remains a big challenge to communicate effectively with clinicians around the country in an emergency, so more work needs to be done to improve that. There is also a need for initiatives like the National Ebola Training Education Center (NETEC), which was developed to increase the ability of frontline clinicians to manage potential Ebola patients by developing and implementing clinical protocols and disseminating knowledge relating to infection control practices.

National and international preparedness for biological threats requires a strong workforce, including public health experts and animal and plant disease scientists. To some degree, success at controlling infectious diseases in the US may have inadvertently resulted in workforce attrition in these fields. Federal support for developing the workforce in these fields is important.

Internationally, “train-the-trainer” systems are important, particularly in countries that lack expertise in biosafety, clinical care, waste management, and other aspects of health security. The Global Health Security Agenda has begun to address some of these issues, but more remains to be done.

Conclusion

The development of a new 2017 National Biodefense Strategy is a chance to gauge past successes, major challenges, and new and emerging needs. Stakeholders outside the government are a critical source of expertise and judgment regarding these issues. These ideas presented above represent a range of practical recommendations for consideration by US government officials as they develop the Strategy in coming months.

The following members of the Johns Hopkins Center for Health Security contributed to this report: Diane Meyer, Erica Neibaur, Sanjana Ravi, Crystal Watson, Matthew Watson, Matthew Shearer, Anita Cicero, and Tom Inglesby.



Consideration of the National Biodefense Strategy

June 22, 2017

Meeting Participants

Nick Alexopoulos
Communications Director
Johns Hopkins Center for Health Security

Jennifer Alton
Vice President
Public Policy & Government Affairs
Bavarian Nordic

Gerrit Bakker
Senior Director, Public Health Preparedness
ASTHO

Tom Bates
Director, Biodefense Knowledge Center
Lawrence Livermore National Laboratory

Kenneth Bayles
Associate Vice Chancellor for Basic Science
Research
University of Nebraska

Tammy Beckham
Dean
Veterinary Medicine
Kansas State University

Laura Biesiadecki
Senior Director, Preparedness, Recovery and
Response
NACCHO

James Blumenstock
Chief, Health Security
ASTHO

Elizabeth Cameron
Senior Director for Global Biological Policy and
Programs
NTI

Ellen Carlin
Co-Director
Blue Ribbon Study Panel on Biodefense

Rocco Casagrande
Founder and Managing Director
Gryphon Scientific

Lindsey Childers
Policy Analyst, National Security Policy Staff
USDA/OHSEC/NSPS

Anita Cicero
Deputy Director
Johns Hopkins Center for Health Security
acicero@jhu.edu

Alison Criss
Director
UVA Global Infectious Diseases Institute

Jere Dick
Acting Director, APHIS
USDA

Bradley Dickerson
Chief Science Officer, Office of Health Affairs
US Department of Homeland Security

Katie Dwyer
Director, Public Health Preparedness
NACCHO

Jerry Epstein
Assistant Director for Biosecurity and Emerging
Technologies
OSTP

John Fischer
Director, Chemical Biological Defense Division
US Department of Homeland Security

Jacqueline Fletcher
Regents Professor Emerita
National Institute for Microbial Forensics &
Food and Agricultural Biosecurity
Oklahoma State University

David Franz
SBD Global

Chris Frech
Vice President, Government Affairs
Emergent BioSolutions

Dylan George
Associate Director, B.Next
In-Q-Tel

Julia Gunn
Director, Communicable Disease Control
Division
Boston Public Health Commission

Dan Hanfling
Special Advisor, Hospital Preparedness Program
US Department of Health and Human Services

Chris Hassell
Deputy Assistant Secretary of Defense for
Chemical and Biological Defense
US Department of Defense

Noreen Hynes
Director, Geographic Medicine Center of the
Division of Infectious Diseases
Johns Hopkins Medicine

Tom Inglesby
Director
Johns Hopkins Center for Health Security
tinglesby@jhu.edu

Patrick Iverson
Founder
LS Pharma

George Korch
Acting Assistant Secretary for Preparedness
and Response
US Department of Health and Human Services

Nina Lamba
Business Development Manager
Office of BioHealth and Life Sciences
Maryland Department of Commerce

James Lawler
ACESO Director and Chief, Clinical Research
Department, Biodefense Research Directorate
US Navy

Theresa Lawrence
Director, Division of Biosafety, Biosecurity, and
Countering Biological Threats
US Department of Health and Human Services

Marci Layton
Assistant Commissioner for the Bureau of
Communicable Disease
NYC Department of Health

Kimberly LeButt
Director, Medical Programs
Office of the Deputy Assistant Secretary of
Defense for Chemical and Biological Defense
US Department of Defense

Julia Limage
Director, Public Affairs & Policy Coordination
DHS Office of Health Affairs

Scott Linsky
Chief, National Security Policy Staff
USDA

Dan Lucey
Senior Scholar, O'Neill Institute for National and
Global Health Law
Georgetown University

Michael Mair
Director of Strategic Operations, Office of
Counterterrorism
FDA

Beth Maldin Morgenthau
Assistant Commissioner
NYC Department of Health

Lisa Maragakis
Senior Director of Healthcare Epidemiology and
Infection Prevention
Johns Hopkins Medicine

Scott Marshall
Vice President
National Assembly of State Animal Health
Officials

Mac McClendon
Director, Office of Public Health Preparedness &
Response/EMC
Harris County Public Health

Stacy McGuigan
Nuclear, Chemical, and Biological Defense
Programs
US Department of Defense

Chris Millard
Program Manager & Research Associate, Global
Health Policy Center
Center for Strategic and International Studies
(CSIS)

Susan Monarez
Deputy Assistant Secretary
US Department of Homeland Security
Steve Morrison
Senior Vice President
CSIS

Erica Neibaur
Intern Analyst
Johns Hopkins Center for Health Security

Philip Newton
Advisor for Biological Preparedness
OUSD Policy/HD&GS/HDI&DSCA

Jennifer Nuzzo
Senior Associate
Johns Hopkins Center for Health Security

Kristin Omberg
Technical Group Manager, National Security
Directorate
Pacific Northwest National Lab

Gerald Parker
Associate Dean for Global One Health, College
of Veterinary Medicine and Biomedical Sciences
Texas A&M University

Michael Pentella
Chair, Biosafety and Biosecurity Committee
APHL

Ellen Raber
Associate Program Manager, Global Security
Directorate
Lawrence Livermore National Laboratory

Terry Rauch
Acting Deputy Assistant Secretary of Defense
(Health Affairs) Health Readiness Policy and
Oversight
US Department of Defense

Sanjana Ravi
Senior Analyst
Johns Hopkins Center for Health Security

James Roth
Director, Center for Food Security and Public
Health
Iowa State University

Lewis Rubinson
Assistant Chief Medical Officer for
Critical Care
University of Maryland Medicine

Robert Salesses
Homeland Defense and Global Security
US Department of Defense

Roslyne Schulman
Director, Policy Development
American Hospital Association

Matt Shearer
Senior Analyst
Johns Hopkins Center for Health Security

Jim Stack
Director, Great Plains Diagnostic Network
Kansas State University

Jim Stalzman
Director, Domestic CBRN Response and
Preparedness Policy
US Department of Defense

David Stiefel
Policy Analyst, National Security Policy Staff
USDA

Eric van Gieson
University of Nebraska Medical Center

Craig Vanderwagen
Senior Partner
Martin, Blanck & Associates

Rajeev Venkayya
President, Global Vaccine Unit
Takeda Pharmaceuticals

Crystal Watson
Senior Associate
Johns Hopkins Center for Health Security

Matt Watson
Senior Analyst
Johns Hopkins Center for Health Security