

THE STATE OF BIOPREPAREDNESS

Lessons from Leaders, Proposals for Progress

CONFERENCE REPORT

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I would just ask you to think for a minute about the day after a biological attack occurring in Seoul or San Francisco. What is it that we're not doing that we will wish we had been doing that could have prevented that? And what is it that we weren't doing enough of or fast enough or in enough places that could have better prepared us to deal with such an attack? - Andrew Weber

INTRODUCTION

The state of biopreparedness in the U.S. is improving, but many important challenges remain. Since 2001, federal, state, and local governments and their private sector and NGO partners have collaborated across disciplines to cultivate working relationships and

build systems for preparedness, response, and recovery from biological attacks and other public health threats. Experiences with SARS, West Nile virus, hurricanes

Katrina and Rita, H5N1 influenza, the 2010 earthquake in Haiti, and the H1N1 pandemic tested U.S. response plans and systems and provided important lessons that have helped strengthen systems and capabilities.

With regard to biodefense specifically, the U.S. has grown stronger in the past 10 years, but there is work that remains to be done in many realms crucial to biopreparedness—including threat assessment, detection and surveillance, countermeasure development and distribution, public health and medical response, and national recovery—all steps in the chain of resilience described by Senator Bob Graham.

Senator Graham characterized the chain of resilience at the recent Center for Biosecurity conference, “The State of Biopreparedness: Lessons from Leaders, Proposals for Progress” (Washington, DC; September 23, 2010). The Center convened this national meeting to provide a forum for thought leaders from the public and private sectors to discuss ongoing challenges and priorities in biopreparedness and identify opportunities for improvement. Highlights are offered below; full conference proceedings can be found at www.upmc-biosecurity.org/biopreparedness.



Speaker

Senator Robert Graham
Senator Bob Graham,
Chairman, WMD
Commission;
Co-Founder,
The WMD Center

Conference Speakers

Greg Burel, Director, Division of Strategic National Stockpile, CDC

Joseph Donovan, Senior Vice President, Beacon Capital Partners

Richard Falkenrath, Principal, the Chertoff Group; former Deputy Commissioner for Counterterrorism, NYPD; former White House Deputy Homeland Security Advisor

Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer, DHS; former Director of Military Programs, ER One Institute, Washington Hospital Center

Senator Bob Graham, Chairman, WMD Commission; Co-Founder, The WMD Center

Dan Hanfling, Special Advisor on Emergency Management and Disaster Response, Inova Health System; Clinical Professor, Department of Emergency Medicine, George Washington University

Richard Hatchett, Director for Medical Preparedness Policy, White House National Security Staff

James G. Hodge, Jr., Lincoln Professor of Health Law and Ethics, Sandra Day O'Connor College of Law, and Fellow, Center for the Study of Law, Science, and Technology, Arizona State University

Peter Jutro, Deputy Director for Science & Policy, Homeland Security Research Center, EPA

Michelle Larson, SNS State Coordinator, Minnesota DoH

Kathleen Sebelius, Secretary, HHS

David Starr, Director, Countermeasures and Response Unit, Office of Emergency Preparedness and Response, New York City DOHMH

John Tesh, Deputy Director, Capabilities, UK Civil Contingencies Secretariat

Andrew C. Weber, Assistant to the Secretary of Defense for NCB Defense Programs

Center for Biosecurity Speakers & Moderators

Thomas V. Inglesby
Chief Executive Officer
and Director

Anita Cicero
Chief Operating Officer
and Deputy Director

Eric Toner
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TAKING STOCK

Progress and Challenges

Center for Biosecurity Director, Thomas Inglesby, opened the conference by citing a number of gains in biopreparedness made since the 2001 anthrax attacks. Several examples are provided in the table below.

Examples of Biopreparedness Gains Since 2001	
Surveillance	
2001 Very little effort to develop early detection, surveillance, or attribution capabilities	2010 BioWatch Generation 3 (in development); BioSense and other biosurveillance systems at state and federal levels
Threat assessment and strategic plans	
2001 No biological threat assessment processes in place; no strategic planning	2010 DHS material threat assessments; National Planning Scenarios; HHS playbooks for bio threats; National Health Security Strategy
Preparedness	
2001 Limited state or local programs for public health or hospital preparedness	2010 CDC Public Health Emergency Preparedness Cooperative Agreement Program; HHS National Healthcare Preparedness Grant Program
Countermeasure development	
2001 No wide-scale systematic efforts to develop or distribute medical countermeasures	2010 BARDA and BioShield; Cities Readiness Initiative (CRI)
Volunteer response	
2001 Limited coordination and effective engagement of volunteers for emergency response	2010 Medical Reserve Corps; Emergency System for Advance Registration of Volunteer Health Professionals

Dr. Inglesby also described a number of priorities and challenges for the future. For instance, there is a new HHS Medical Countermeasure strategy, but to be successful, it will need skilled execution and commensurate resources. New approaches to domestic and international disease surveillance and detection are being considered that will have to be tested and put into practice. Coordination and interactions between federal and local partners on preparedness programs must continue to be strengthened. And the U.S. should place a priority on working with and learning from our international partners to improve prevention and response efforts.



Speaker
Thomas V. Inglesby
Opening Remarks

RECENT GAINS

Better Understanding of Threat and Response

Most speakers agreed that the risk of bioterrorism has increased and continues to grow as rapid advances in the biological sciences provide greater access to knowledge, technologies, and pathogens. Senator Bob Graham asserted as well that terrorists will continue to look for ways to inflict the greatest amount of harm:

The [intelligence community's] consensus judgment is that if a terrorist group were to come into possession of a biological weapon, they would ask themselves the question: Where can we use this weapon to inflict the greatest degree of damage and terror?

Fortunately, with a greater understanding of the threat posed by biological agents, leaders in the U.S. government and in the private sector are working to build national response capacity and resilience.



Speaker
Secretary
Kathleen Sebelius
HHS Perspectives
on Biopreparedness

Focus on Improving the Systems of Response

The U.S. approach to countering biological threats has evolved along with the understanding of the threat. Secretary Kathleen Sebelius described the U.S. government response to the H1N1 pandemic:

The H1N1 flu tested our entire public health system. How well we were able to respond depended on the strength and numbers of our healthcare workforce. It

depended on whether we had enough hospital beds and working emergency rooms. It depended on our ability to coordinate across government agencies and how well we could execute a national response strategy on the local level. It depended on how well informed and engaged the public was. It even depended on the international community's response. With so many factors in play at once, coordination was key. . . . [T]o be ready for the next public health crisis, we need to focus on our entire end-to-end response.

Plans and systems for rapid dispensing of medical countermeasures have continued to evolve. The Cities Readiness Initiative (CRI) has been effective in building capacity for rapid mass dispensing of countermeasures. This CDC program focuses on facilitating and strengthening health departments' abilities to dispense antibiotics to 100% of an affected population within 48 hours of the decision to do so following an anthrax attack. Other mass dispensing efforts utilizing the private sector and other elements of the public sector have also been established.

New Technologies and Platforms

Secretary Sebelius outlined a number of initiatives undertaken by HHS, including new and innovative approaches to development and production of medical countermeasures. She noted that HHS recently released a full review of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which, if implemented, would make the U.S. "better able to produce medical countermeasures quickly in the face of an attack or threat." The Secretary said this is especially important given the limitations of, for instance, current vaccine production technologies:

As quickly as we acted on H1N1, there was one fundamental problem we couldn't overcome: we were fighting the 2009 H1N1 flu with vaccine technology from the 1950s. We could race to begin vaccine production, but there was nothing we could do if the virus grew slowly in eggs. We could make deals with foreign vaccine producers ahead of time, but we still wouldn't have as much control over the vaccine as we have with companies based in the U.S. . . . We were working to squeeze every last bit of efficiency out of a safe, but outdated technology.

Surveillance

Dr. Alexander Garza discussed plans to improve biological detection and surveillance, including efforts to integrate multiple federal, state, and local surveillance systems through the National Biosurveillance Integration Center (NBIC). He also described new BioWatch detection technologies and protocols aimed at detecting pathogens more quickly, as well as the need for networking and coordination:



Speaker
Alexander Garza
 DHS Biodefense
 Programs and
 Priorities: Now and in
 the Years Ahead

Our nation has extensive biosurveillance capabilities. Unfortunately, they're not networked. What we really have now is a system of systems in biosurveillance. And so it's one of my priorities to continue to work with our partners to build a very truly robust biosurveillance capability for the nation

Senator Graham indicated that he is encouraged by BioWatch Generation 3: ". . . if this functions as it is presented, it will provide an automated real-time detection of more pathogens and also provide the opportunity for this detection to work in an indoor setting."

The Department of Defense has also made a new commitment to improving international disease surveillance and collaboration, as was made clear by Andrew Weber:

. . . imagine how much better equipped we would be to prevent epidemics if we had a system of real-time valid data . . . a global laboratory response network that used the same protocols, the same reagents, and the same reporting formats , and then we shared that data like we share weather data. . . . [We could get] away from this archaic notion that infectious disease information is part of national sovereignty, because countries have a right to know what's going on on the border, what's coming their way, just like they do with hurricanes and other weather events.

MAJOR CHALLENGES

Understanding Has Improved, But Not Enough.

Although significant progress has been made since 2001, meeting participants agreed that more work is needed. Senator Graham argued that major disasters, including the recent financial crisis and the oil spill in the Gulf of Mexico, share significant similarities:

1. Defense was outpaced by the force causing the disaster.
2. Threat severity was downplayed by leaders inside and outside of government.
3. Warning signals were systematically dismissed.

He emphasized that, while we have already experienced a calamitous financial crisis and an oil spill that caused enormous environmental damage, we have not yet experienced an attack with a weapon of mass destruction. Thus, the nation still has the opportunity to avoid the mistakes noted above. "The good news is that . . . we still have a chance to avoid what I think would be the ultimate catastrophe . . . a weapon of mass destruction."



Speaker
Richard Falkenrath, PhD
Contrasting Federal and
Local Biodefense Views

Dr. Richard Falkenrath asserted that the biological weapons threat and the need to enhance biopreparedness are still not receiving appropriate attention in the national security community:

But the truth is, biodefense . . . is not a tier 1 issue in U.S. national security policy. I tell you this as someone who has dealt with truly tier 1 issues, matters of going to war and major arms control negotiations. . . . It is unfortunate that, even after the events of October 2001 and all the long-term threat assessments and risk assessments and stud [ies] of what's happening in the world of biology, that biodefense remains, I would say, a third-tier issue in U.S. national security strategy. I am worried because if the 20th century [was] the era of the nuclear threat, this is the era, I think, of the biology threat.

Secretary Sebelius underscored the need to strengthen the nation's public health infrastructure, which undergirds U.S. response to disasters. She made reference to a recent CDC report on performance of the Public Health Emergency Preparedness cooperative agreement program, which demonstrated that the economic downturn and reductions in preparedness funding may be hindering gains in preparedness at the state and local levels.



Better Plans for Dispensing Medical Countermeasures Are Needed

In a catastrophic health emergency, such as a large-scale bioterrorism attack or a severe pandemic, it is necessary, but not sufficient, to have stockpiles of medicines and vaccines. We must also have the ability to dispense those countermeasures to the public in time to be effective. Federal, state, and local public health officials have been working to plan for a mass dispensing scenario, but it remains a difficult challenge, and there are policy, legal, and logistical issues that must be resolved. CDC and state health departments play a key role in distributing countermeasures, but local health departments are responsible for actually dispensing them, or getting them directly to the population.

The Center's Brooke Courtney led a panel discussion of approaches to countermeasure dispensing that have been taken around the country. David Starr explained that the New York City DOHMH plans to open nonmedical points of dispensing (PODs) in predetermined, convenient locations from which members of an affected population can pick up emergency medications. Michelle Larson described the Minnesota Department of Health's model, which entails having USPS mail carriers deliver an initial course of antibiotics to affected households in select zip codes. Greg Burel of CDC outlined other approaches, including private sector and drive-through PODs and preplacement of countermeasures

in the homes of first responders through MedKits. Clearly, the variety of approaches represents efforts to meet local needs, realities, and capacities; however, the wide range in plans also contributes to challenges in coordinating responses across and within states.

Crisis Standards of Care Are Needed

Most medical providers recognize an ethical duty to provide care in an emergency. In daily practice, clinicians are expected to do what is in the best interest of their patients, and failure to do so may result in allegations of malpractice. But there are no clear guidelines for determining what constitutes the best interest of a patient. Instead, decisions are based on an overarching medical and legal concept of a “standard of care,” and a clinician is expected to do what other reasonable and similarly trained clinicians would do in a similar situation.

The need for a different concept of care for disasters, now referred to as “crisis standards of care,” has become apparent. The Agency for Healthcare Research and Quality (AHRQ) and, more recently, a work group convened by the Institute of Medicine (IOM) have been working to establish a framework for crisis standards of care. However, challenges remain; among them are those discussed by panelists Eric Toner, Dan Hanfling, and James Hodge.



Dr. Eric Toner emphasized the need to develop protocols and standards in advance of a disaster to help assure uniformity and equity in distribution of assets and implementation of crisis standards. Dan Hanfling discussed the role of regional healthcare partners and communities in planning and decision making, explaining that, because implementation of crisis standards of care will have implications that extend well beyond individual healthcare institutions, all stakeholders should be engaged in those processes.

James Hodge stressed the necessity of legal protections for healthcare practitioners who must make difficult and time-

sensitive decisions during a crisis: “What you don’t want is medical practitioners debating what they can do because of their fear of liability.” He discussed the legal challenges that pose a significant barrier to implementation of crisis standards of care. Still to be resolved are issues related to liability protections, interstate medical licensure, legal standards of care, and temporary expansion of scopes of medical practice in an emergency.

Decontamination Research and Policy Are Needed

The anthrax attacks of 2001 contaminated both public and private buildings: USPS facilities, media buildings in New York City and Florida, and congressional offices in Washington, DC. Unquestionably, the 2001 attacks were a significant event for the victims, their families, and the country. However, the amount of contamination was small compared to what could be expected following a large-scale anthrax attack.

Crystal Franco, who led the panel discussion on decontamination, recently authored a paper that made the case for more research to improve the nation’s decontamination capacity before the next event. Although scientific and technological advancement has occurred since 2001, policy is not keeping pace—a point made vividly by Senator Graham:

We have not made the effort to understand and prepare for environmental cleanup that’s required. In fact . . . the United States Marine Corps will spend twice as much [in 2011] on its marching bands as the EPA will spend on research for cleaning up an American city after a WMD attack.

No federal standard currently defines “how clean is safe” with regard to reoccupation of a contaminated area after a biological attack. In the past, the CDC has required decontamination of a building until zero viable spores could be found. However, this standard would likely be impossible to achieve after a large-scale attack that contaminated indoor and outdoor areas of a city.

Peter Jutro argued for more scientific research that sheds light on: (1) the movement and behavior of biological contaminants; (2) assessment of contamination; (3) effective decontamination methods for indoor versus outdoor areas and a variety of surfaces; and (4) management and disposal of waste generated by remediation. He stressed that policy to guide decontamination must be based on science.



Because both public and private buildings may be contaminated in a large-scale attack, building owners and managers, along with government officials, will be called on to make difficult decisions regarding protection of people and property. Joe Donovan of the Business Owners and Managers Association strongly emphasized the need to involve private industry in planning for and responding to a biological event to limit economic disruption and aid in recovery; this is especially true when decontamination is required.

NEXT STEPS TOWARD IMPROVING BIOPREPAREDNESS

Prevention and Deterrence

Senator Graham called for hardening the U.S. against a biological attack with “[a] commitment to remove bioterrorism from the category of a weapon of mass destruction” through programs in prevention, preparedness, response, resilience, and recovery. If the damage that can be inflicted is minimized, then it stands to reason that the appeal of bioweapons for terrorists will be diminished.

Andrew Weber was optimistic about the nation’s ability to prevent and deter bioterrorism through preparedness:

... our actions can actually strengthen preparedness: by investing in medical countermeasures and better detection capability and response capability, we can actually deter a bioterror attack from ever happening. And I believe we can make the whole class of biological weaponry obsolete.

Preparedness and Response

As indicated by Secretary Sebelius, HHS recently completed its review of the Medical Countermeasures Enterprise, which outlines major initiatives that will improve biopreparedness,

including 5 efforts to improve U.S. countermeasure development:

1. Upgrading regulatory science at the FDA to modernize countermeasure development and evaluation
2. Establishing U.S. facilities for development and manufacturing of countermeasures
3. Guiding and facilitating the work of scientists—from discovery through drug development
4. Ensuring faster influenza vaccine development with new, faster-growing vaccine seed strains and modernization of methods to test potency and sterility
5. Launching a nonprofit strategic investment organization to provide financial and business planning support for companies that would like to contribute to public health preparedness.



What is absolutely critical now is that the new HHS initiative is implemented with the resources and commitment necessary to meet Secretary Sebelius’s policy vision on these issues.

Andrew Weber stressed other areas in need of work, including diagnostics and the need to “integrate better our environmental detection capabilities and our medical and clinical infectious disease monitoring capabilities.”

I believe that with . . . biotechnologies, molecular diagnostics, as well as IT, its within our reach to have a real-time global disease monitoring architecture that would allow us to prevent epidemics from ever happening, and perhaps even predict epidemics before they happen.

Emerging Threats

Advances in the biological sciences and technological development provide great benefit; however, if misused, they could pose a serious threat. Among several speakers who highlighted the importance of ensuring that the nation's defense keeps pace with rapid advancements in biology and technology and the potential threats ahead was Alexander Garza: "What was worthy of a Nobel Prize a couple of decades ago, a high school student does now in his lab. So, we need to be thinking about the future and what its implications are for national security, especially in biodefense."



Speaker
Richard Hatchett
White House Views
on Biopreparedness



Moderator
Anita Cicero

***Panelists, from left, photos on pages 4, 5, and 6:**

Panel 1: Brooke Courtney, Greg Burel, Michelle Larson, David Starr

Panel 2: Eric Toner, Dan Hanfling, James Hodge

Panel 3: Joseph Donovan, Crystal Franco, Peter Jutro



Speaker
John Tesh
The United Kingdom
Strategy for
Biodefense

International Biopreparedness

John Tesh echoed the urgency felt in the U.S. with regard to biopreparedness. He explained several priorities of the United Kingdom, where the coalition government is now reevaluating and updating its national security strategy, with a focus on strong risk assessment processes and an emphasis on societal resilience and community engagement. The strategy will also take an end-to-end approach to assessing emerging threats—from acquisition of raw materials to motivational factors for a WMD attack.

Andrew Weber also conveyed the need to engage global partners in efforts to counter biological threats:

For the first time we have a prevention strategy in place. . . . What's also important about this strategy is [that] it recognizes that this is a global problem that we can only deal with on a global basis working very closely with international partners.