Information Sharing and Collaboration: Applications to Integrated Biosurveillance: Workshop Summary

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Deepali M. Patel and Steve Olson, Rapporteurs; Planning Committee on Information-Sharing Models and Guidelines for Collaboration: Applications to an Integrated One Health Biosurveillance Strategyâ€"A Workshop; Institute of Medicine

Information Sharing and Collaboration

APPLICATIONS TO INTEGRATED BIOSURVEILLANCE
WORKSHOP SUMMARY

Deepali M. Patel and Steve Olson, *Rapporteurs*

Planning Committee on Information-Sharing Models and Guidelines for Collaboration: Applications to an Integrated One Health Biosurveillance Strategy

A Workshop

Board on Health Sciences Policy

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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PLANNING COMMITTEE ON INFORMATION-SHARING MODELS AND GUIDELINES FOR COLLABORATION: APPLICATIONS TO AN INTEGRATED ONE HEALTH BIOSURVEILLANCE STRATEGY—A WORKSHOP[1]

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[1]Institute of Medicine planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop summary rests with the workshop rapporteurs and the institution.

Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **Claire V. Broome,** Adjunct Professor, Division of Global Health, Rollins School of Public Health, Emory University. Appointed by the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance

with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors and the institution.

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Acronyms

AFHSC	Armed Forces Health Surveillance Center
APHIS	Animal and Plant Health Inspection Service
BATR	biological assessment threat response
BCU	Biosurveillance Coordination Unit (renamed in 2009 as Biosurveillance Coordination Activity)
CDC	Centers for Disease Control and Prevention
CONOPS	concept of operations
DHS	Department of Homeland Security
DOD	Department of Defense
DSOP	Directorate of Strategic Operational Planning
EOC	emergency operation center
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FSIS	Food Safety Inspection Service
GAO	Government Accountability Office
HHS	Department of Health and Human Services
HSPD	Homeland Security Presidential Directive
IDF	Israeli Defense Forces
IOM	Institute of Medicine

MACFIO	Multiple Agency Coordination Foodborne Illness Outbreak
NBAS	National Biosurveillance Advisory Subcommittee
NBIC	National Biosurveillance Integration Center
NBIS	National Biosurveillance Integration System
NC-DETECT	North Carolina Disease Event Tracking and Epidemiologic Collection Tool
NC DHHS	North Carolina Department of Health and Human Services
NCTC	National Counterterrorism Center
NSS	National Security Staff
OIG	Office of Inspector General
OODA	observe, orient, decide, and act
STEC	Shiga toxin-producing *Escherichia coli*
USDA	Department of Agriculture

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Introduction and Overview[1]

Biosurveillance is a complex concept defined by Homeland Security Presidential Directive 21 (HSPD-21) as "active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health—whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin—in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity" (White House, 2007). The biosurveillance process detects, monitors, and characterizes national security health threats, in human and animal populations, food, water, agriculture, and the environment. It involves the detection of disease outbreaks as well as the responsibility to "provide decision-makers and the public with accurate and timely information about how adverse impacts might be prevented, managed or mitigated" (Nuzzo, 2009). Many federal agencies and all 50 states are involved in biosurveillance activities, in addition to local governments and many public and private organizations. Each year, billions of dollars are spent on biosurveillance, including animal, human, and environmental surveillance, as well as health care management and technology and infrastructure maintenance, activities which have implications for biosurveillance (Wagner et al., 2006). However, despite the recognition of its importance, definitions and boundaries of biosurveillance activities (especially as they coincide with other areas of public health and security) often vary based on perspective.

[1]The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop.

Priority was placed on developing a biosurveillance strategy following the September 11, 2001, terrorist attacks on the United States and the 2001 anthrax attacks. Several activities resulted, some of which were parallel but independent of each other at different agencies, in recognition of this priority. The following describes some of these activities, many of which overlap but do not necessarily align.

In 2004, HSPD-9 (Defense of United States Agriculture and Food) and HSPD-10 (Biodefense for the 21st Century) charged the Secretary of Homeland Security to "integrate all federal agency efforts" and to "create a new biological threat awareness capacity" that would detect biological attacks early. In 2004, the Department of Homeland Security (DHS) created the National Biosurveillance Integration System (NBIS), which was intended to be the nation's "first system capable of providing comprehensive and integrated biosurveillance and situational awareness" (OIG, 2007), and designed to include a role for the pertinent federal agencies in building this integrated system.

In 2007 the Implementing Recommendations of the 9/11 Commission Act created the National Biosurveillance Integration Center (NBIC) within DHS to identify, integrate, and analyze data to detect biothreats and disseminate alerts. NBIC is charged with working with partner agencies to (1) acquire data that can be analyzed, (2) leverage expertise, (3) obtain strategic and operational guidance, and (4) maintain innovative information technologies. NBIC was established to realize the goals of NBIS and to serve as the center for information and personnel contributed by NBIS partners.

HSPD-21, which was released a few months after passage of the act that created NBIC, charged the U.S. Department of Health and Human Services (HHS) with establishing "an operational national epidemiologic surveillance system for human health, with international connectivity where appropriate, that is predicated on state, regional, and community-level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers." In response to this directive, the Centers for Disease Control and Prevention (CDC) established the Biosurveillance Coordination Unit (BCU) in 2008. BCU supports the National Biosurveillance Advisory Subcommittee (NBAS), established in 2008 by CDC per a mandate in HSPD-21 to create an advisory body to HHS on biosurveillance matters. In 2008, BCU released the *National Biosurveillance Strategy for Human Health*, and it subsequently revised the strategy and released an expanded version

in 2010 (CDC, 2010). This strategy defined the scope and function of biosurveillance for human health to include

- all hazards, including biological, chemical, radiological, nuclear, and explosives, both intentional and natural;
- definitions established by urgency and the potential for multi-jurisdictional interest;
- urgent notifiable conditions and nonspecific and novel health events;
- ad hoc data gathering, analysis, and application of information;
- functions including case detection, event detection, signal validation, event characterization, notification and communication, and quality control and improvement; and
- support for rapid and efficient discharge of responsibilities for the International Health Regulations.

The strategy also named six priorities for national biosurveillance: electronic health information exchange, electronic laboratory information exchange, unstructured data, integrated biosurveillance information, global disease detection and collaboration, and the future biosurveillance workforce.

STATUS OF NATIONAL BIOSURVEILLANCE INTEGRATION

In the past several years, recognition has been made of the gaps and challenges in biosurveillance efforts and the integration of biosurveillance activities, and several steps to address these challenges have been taken. In 2007, DHS released a report following its auditing of the NBIS program (OIG, 2007). DHS determined that NBIS was falling short of its objectives, partly due to a lack of leadership and staff provided by DHS. Documents to guide information technology were not complete, and management communication and coordination with stakeholders and contractors were ineffective.

In 2009, the NBAS recommended (1) the establishment of an interagency coordination committee (led by the Executive Office of the President) to define goals and establish responsibility for a biosurveillance strategy, (2) the scope of biosurveillance to be global, (3) adequate fund-

ing and assignment of personnel, (4) the leveraging of electronic data, and (5) investment in new technologies (NBAS, 2009).

In 2011, NBAS made further recommendations to build on its 2009 recommendations in the following areas:

1. **Governance:** Establish federal biosurveillance oversight (reiterating the 2009 recommendation).
2. **Information Exchange:** Support the implementation of the International Health Regulations; integrate human, animal, food, vector, and environmental surveillance systems; expand biosurveillance to include environmental aspects.
3. **Workforce:** Promote a sustainable interdisciplinary workforce with investments in expertise (especially in public health informatics; social and behavioral epidemiology; environmental, human, and animal health; vector biology; and disaster response).
4. **Research and Development:** Invest in research to develop and build on innovative technologies that will enhance the efficiency and sensitivity of biosurveillance; select the best approaches and scale them (NBAS, 2011).

In 2009, the Government Accountability Office (GAO) recommended that NBIC define and communicate a common mission and purpose, define common procedures and strategies to align multiple agency cultures, and establish performance measures to monitor and evaluate the effectiveness of collaboration (GAO, 2009). The report stressed coordination and integration among agencies and biosurveillance efforts. The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (2010) subsequently issued a report determining that the U.S. government was "failing" at protecting the United States from threats. Also in 2010, GAO made further recommendations to establish a leadership mechanism with authority and accountability and to develop a national biosurveillance strategy that

1. defines the scope and purpose of a national capability;
2. provides goals, objectives and activities, priorities, milestones, and performance measures;
3. assesses the costs and benefits associated with supporting and building a national capability and identifies the resource and investment needs;

4. clarifies the roles and responsibilities of leading, partnering, and supporting a national capability; and
5. articulates how the strategy is integrated with and supports other related strategies' goals, objectives, and activities (GAO, 2010).

OVERVIEW OF THE WORKSHOP

On September 8-9, 2011, the Institute of Medicine (IOM), held a workshop to explore the information-sharing and collaboration processes needed for the nation's integrated biosurveillance strategy. As William Raub, co-chair of the planning committee for the workshop and former science advisor to the Secretary of HHS, said in his introductory remarks, integration and communication of information "is a formidable and technical challenge. The collaboration, the sharing, and the integration are difficult in the context of multiple agencies with multiple missions and a rich variety of data sets, including areas where the data sets are nonexistent. . . . If it were easy, it would be done."

The goals of the workshop were to

- examine the strengths and limitations of different models of information analysis, control, and distribution, with a focus on identifying best practices and incentives for information sharing and exploring the options for when and what information is shared and how it is attributed and acknowledged;
- consider examples and lessons learned from other similar information sharing collaborations;
- explore approaches to developing an effective and sustainable concept of operations that includes joint rules, procedures, and performance measures; and
- illustrate the value added in collaboration through scenarios and real-life examples.

The planning committee designed the workshop to be pragmatic. Its goal was to explore concrete, near-term steps which could set the community in the right direction. Raub recalled advice he once received from the renowned computer designer Wesley A. Clark, who said that planning requires three things: a rough sense of where you want to be eventually, precise knowledge of what you need to do next, and the willingness to iterate as you go forward so that you can get where you want

to go. "Much of what motivated our design is to figure out precisely what to do next," said Raub.

ORGANIZATION OF THIS SUMMARY

This summary provides a factual account of the presentations given at the workshop. Opinions expressed within this summary are not those of the Institute of Medicine, the Standing Committee, or its agents, but rather of the presenters themselves. Statements are the views of the speakers and do not reflect conclusions or recommendations of a formally appointed committee. This summary was authored by a designated rapporteur based on the workshop presentations and discussions and does not represent the views of the institution, nor does it constitute a full or exhaustive overview of the field.

Chapters 2, 3, and 4 of this report summarize the remarks of eight invited presenters who spoke at the workshop. Chapter 2 presents perspectives from three government agencies: CDC, the Department of Agriculture, and the Department of Defense. Chapter 3 describes the presentations of three state and local public health officials from New York City, North Carolina, and Marion County, Indiana. Chapter 4 offers views from two outside observers: one a Federal Reserve official, the other a top medical official from Israel.

Chapter 5 summarizes an extended panel discussion that occupied the central portion of the workshop. The discussion was organized around a fictional scenario based on a foodborne pathogen, with several moves of the scenario meant to illustrate the issues involved in coordinating surveillance and response. Participation by representatives from a range of federal agencies provided a rich variety of insights into both the potential and difficulties of biosurveillance.

Finally, Chapter 6 describes the talks of four speakers who collectively proposed elements of a concept of operations (CONOPS) for biosurveillance, using NBIC as an example, as a way of moving toward a more secure nation and world. The chapter also summarizes the discussion at the end of the workshop.

ACKNOWLEDGMENTS

The production of this summary would not be possible without the hard work and dedication of several people, and the sponsorship of the DHS's Office of Health Affairs. The workshop was held under the auspices of the Standing Committee on Health Threats Resilience, whose expertise shaped the agenda, goals, and objectives. It was planned by a dedicated committee who provided hard work and effort toward executing the agenda. The reviewers' thoughtful comments added further insight. Finally, IOM staff involvement and support throughout the process ensured a smooth and swift process from start to finish.

2

Experiences of Federal Agencies

Many federal agencies are involved in biosurveillance, but several have lead roles. All federal agencies have complex needs for coordination and communications within their agencies and with other agencies. In the fast-changing context of biohazard response, systems for coordination and communication can be sorely tested. This chapter summarizes presentations from representatives of three agencies: the Centers for Disease Control and Prevention (CDC), the Department of Agriculture (USDA), and the Department of Defense (DOD), to showcase examples of lessons learned.

In addition, Matthew Hepburn of the White House National Security Staff (NSS) shared some remarks regarding the importance of biosurveillance, the need for integration, and the desire to find a way to move forward.

RESPONDING TO EPIDEMICS AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION[1]

The response to the 2009 H1N1 pandemic offers many valuable lessons for biosurveillance, said Stephen Redd, Influenza Coordination Unit, CDC. Comprehensive and targeted response relies on the most accurate and timely information provided by successful biosurveillance processes. Most important, the systems and relationships developed before the pandemic were critical in making correct decisions. Technology

[1]This section is based on the presentation by Stephen Redd, Influenza Coordination Unit, CDC.

also played a role, and technological systems can be improved, said Redd, but understanding the information generated during an epidemic requires "relationships and trust."

Response to a pandemic flu is based on the systems set up to identify and respond to seasonal influenza, Redd observed. Also, state and local health departments are essential components of these systems, because they both gather information and implement interventions. Finally, laboratory findings often constitute the lead information for pandemic preparedness, which is not necessarily the case for other kinds of emergencies.

Redd also emphasized several aspects of situational awareness. Determining what has happened and what could happen requires detection, characterization, assessment of the burden, and determination of what has changed. Situational awareness also requires knowledge of the tools that can be used to mitigate impacts, including antivirals, vaccines, and nonpharmaceutical interventions, along with knowledge of the effectiveness of those tools.

Detection and Early Response

Within a few days of detection of the 2009 H1N1 signal cases, the CDC director was receiving a daily briefing on the situation. Preparing the briefing brought people together at CDC and resulted in the preparation of slides that could be distributed within the agency and to other federal agencies. Daily calls were held with the White House, and the Domestic Readiness Group was regularly briefed, said Redd. State health officials, epidemiologists, and laboratory directors also received daily updates, which provided these officials with a common picture of what was happening.

As pandemic response progressed, daily teleconferences convened by the Department of Health and Human Services chief of staff included representatives from several federal agencies. Weekly videoconferences involved a wider range of agencies, and weekly calls with state and local health officials provided a way to provide them with the latest information. In addition, CDC established liaisons with agencies at the federal, state, and local levels.

CDC had to make major decisions on the basis of limited information within the first few days of the epidemic, including the following:

- When to publish information about cases
- School closure criteria
- Recommendations for antiviral drug treatment and prophylaxis
- Recommendations for personal protective equipment
- Recommendations concerning public health emergency
- Distribution of countermeasures from stockpile
- Warning on travel to affected areas
- Initiation of vaccine candidate development
- Arrangement with industry to produce vaccine
- Funding to states to plan vaccination programs
- Guidance on priority groups for vaccination
- Initiation of vaccine production

Except for the last three items in this list, these decisions had to be made within about the first 10 days of the epidemic, said Redd, when there were still relatively few cases and when basic information such as the rate of human-to-human transmission, the incubation period, the hospitalization rate, the risk factors for the disease, and the fatality rate were still being characterized.

Improvements Under Way

CDC is undertaking a number of steps to improve its procedures in light of the lessons learned during the H1N1 epidemic, including

- developing a systematic method for severity assessment;
- enhancing modeling capacity;
- developing a nimble and accessible way to visualize available data;
- enhancing strategic and scientific virologic surveillance;
- expanding and automating syndromic surveillance; and
- using serologic data for assessment of population immunity.

Redd called particular attention to the need for enhanced modeling capacity and to the expansion and automation of syndromic surveillance. “There is a huge opportunity, with the rolling out of electronic health

records in meaningful use, to transition our existing methods for syndromic surveillance into something that would be faster than what we have been using," he said.

Roles and responsibilities among agencies need to be clarified and clearly assigned, Redd concluded. During the pandemic, a sense of institutional territoriality faded away because of the importance of the problem, but planning and practice are essential for future crises, especially since H1N1 and other influenza viruses continue to pose a threat. "There are new viruses evolving as we speak. We can't lose track of this thing."

Discussion

In response to a question about new strains of the influenza virus that continue to be detected, Redd pointed to several recent cases involving novel viruses. A critical question, said Redd, is whether these detections are the result of better surveillance or whether they point to new and potentially dangerous strains. He also cited the importance of combined investigations between agricultural and health departments in preventing future pandemics, particularly for understanding the epidemiology of swine influenza viruses.

With regard to a question about the best ways to disseminate information in an epidemic, Redd noted that efforts under way to update the website for season influenza could help people customize the information they receive to reflect their needs. A particular problem during the epidemic was conveying information to the private sector about the actions being taken by the federal government and the actions needed from the private sector. A better way of disseminating that information is needed, he said.

Redd's CDC colleague Christopher Braden observed that one problem during the epidemic was that CDC sometimes released information before state and local health officials were briefed. Redd responded that this was a consequence of so much information being generated so quickly. In addition, it sometimes was difficult to share information within states, which led CDC to target different audiences within states to make sure they all had the same information. The relationships and trust that had been established before the epidemic were particularly valuable in enhancing communication with the states, Redd said. In addition, daily calls with state health officers were set up after the pandemic began, when the value of such calls became apparent.

COORDINATING ANIMAL HEALTH ACTIONS ACROSS THE HUMAN-ANIMAL INTERFACE[2]

The One Health concept represents a collaborative effort across the interface of disease complexes that affect animals, humans, and the environment, explained Jere Dick, Animal and Plant Health Inspection Service (APHIS), USDA. As such, it provides a framework to analyze past events and prepare for future ones.

H1N1 Influenza as an Example

In 2005, human and animal health officials began collaborating around the emerging H5N1 virus, known as the avian or bird flu virus. The virus had a substantial impact on people who were raising chickens and ducks around the globe as well as on human health, which required that departments of agriculture and the public health arena work together, said Dick. This interagency collaboration led to a number of initiatives, such as a joint effort by the World Organisation for Animal Health and the Food and Agriculture Organization to form a global network of expertise on animal influenzas.

In 2008, CDC came to USDA and asked to collaborate on gathering data from the national swine herd. APHIS was initially reluctant to get involved, recounted Dick, because influenza among swine had been handled for years by local practitioners and managers and was manageable through the use of vaccines. Also, USDA did not have funding from Congress to do that kind of surveillance. However, CDC agreed to provide the funding if USDA would provide the field force to collect the samples. At that point, APHIS met with the National Pork Board, the American Association of Swine Veterinarians, the National Pork Producers Council, and a variety of swine industry officials and began to work on a surveillance system.

Setting up such a system required answering several questions. What is an influenza-like illness case definition for swine? What is the case definition for people? If the two case definitions were associated, what samples would be taken and under whose authority? Which laboratories would do the tests? How would the data be shared? A Swine Influenza Virus pilot program manual was prepared for field operations, and the

[2]This section is based on the presentation by Jere Dick, APHIS, USDA.

pilot project began in 2009, just a few weeks before the first case of H1N1 appeared in California.

The pilot program had several objectives:

- Share isolates for research activities.
- Monitor genetic evolution and ecology.
- Provide isolates for development of diagnostic reagents, diagnostic assays, vaccine products, and improved biosecurity.

The initial public assumption was that the early cases of H1N1 influenza originated from human exposure to pigs, even though the virus was already demonstrating efficient human-to-human transmission. In reality, humans were exposing the pigs to H1N1, and swine transfer of influenza to humans did not occur to any great extent. At that point, the swine industry suspended surveillance efforts, since surveillance was not mandated.

Lessons Learned

The experience with H1N1 influenza conveys several important lessons, said Dick.

First, an interdisciplinary team of public health and animal health officials needs to talk with industry representatives to understand the ramifications of even minor decisions. "Public health programs and policies have to address the economic concerns and the public perception. We knew that pork was still safe to eat, and yet there was tremendous impact." Industry needs to know about the possible consequences of a positive result, and diagnostic results need to be quickly communicated to everyone. Collaboration on common objectives and messages is essential.

Yet, obstacles to collaboration can block progress. The animal health community and the public health community have different perspectives in defining a problem, the purpose of collaboration, and overall objectives, Dick said. Data confidentiality can be an obstacle, since several laws govern the kinds of information that can be shared. Funding and other resources also can be limited. If USDA does not have a line item funding a particular effort, it does not have the resources to start work on something immediately. APHIS is currently considering the development of a line item for One Health–type activities where staff would be supported to do that work with public health counterparts in all of the states.

In contrast, several things worked well, Dick observed. Collaboration can be very effective, especially if collaborations and trust are developed in advance of an event. As a result, USDA continues to work hard to develop synergies with public health partners. Defining the scope of a collaboration also improves productivity and reduces cost. For example, collaboration within government and with the private sector on a swine influenza virus vaccine shortened development time and saved money.

Future Plans

To continue to increase collaboration, USDA has created a One Health joint working group that meets monthly. APHIS also has a liaison who works at the CDC. A strategic plan, four operational plans, a training plan, a communication plan, and a preharvest and zoonotic disease operational plan are all either finished or being developed.

USDA is also examining its surveillance policies. For example, the Center for Epidemiology and Animal Health in Fort Collins, Colorado, is developing comprehensive swine surveillance that involves a number of data streams. The department also is working to increase voluntary sample submission. Samples are identified geographically but are not assigned to a farm so that data can be shared without violating individual farmers' confidentiality. In this way, USDA can work with health departments to identify areas of the country where a virus may be spreading.

Discussion

In response to a question about the tools that state and local health departments can use to collaborate with their animal health counterparts, Dick replied that APHIS has received funds to support positions within each state (though some positions extend across states). The role of these animal health emergency coordinators, whose contact information is on the APHIS website, is to work with state and federal officials in those states to prepare for a variety of emergencies.

Dick also commented on the need to expand animal surveillance to protect human health. USDA does not get funding to provide animal samples for human health concerns, but if there are associated animal health concerns, the agency can address those under its direct authority.

APHIS also acts as a facilitator with state and local authorities, who have much of the authority to gather animal samples.

Further, Dick pointed out that APHIS has people stationed not only in the United States but also around the world to serve as subject-matter experts and monitor what is going on in the animal health community. In addition, about 500 specially trained veterinarians in the United States can respond within hours to any private or state veterinary practitioner to assist in diagnoses and getting lab samples to be tested. "It goes back to the earlier comment—this is really all about people, and having them positioned and ready to respond."

INTEGRATING COMPLEX NATIONAL MISSIONS: LESSONS FROM THE NATIONAL COUNTERTERRORISM CENTER'S DIRECTORATE OF STRATEGIC OPERATIONAL PLANNING[3]

Robert Kravinsky, Office of the Secretary of Defense, described some of the results of a recent study of the National Counterterrorism Center (NCTC) by the Project on National Security Reform. While the study did not focus directly on biosecurity, said Kravinsky, it provides many lessons that are directly applicable to biosurveillance because of similarities involving multiple agencies, needs, and information flows. As well, counterterrorism, like biosurveillance, serves an important role in protecting the nation. Most national security threats require a high degree of integration, yet the national security system remains structured along functional lines such as defense, diplomacy, agriculture, food safety, and so on. The only place where integration can occur is at the level of the NSS, but this level does not have directive authority. NCTC, which was established by executive order in 2004 under the office of the Director of National Intelligence, has four core missions:

- Analyze terrorism intelligence (except purely domestic terrorism).
- Share and store information.
- Support U.S. counterterrorism activities using information technology.

[3]This section is based on the presentation by Robert Kravinsky, Office of the Secretary of Defense.

- Conduct strategic operational planning (through the Directorate of Strategic Operational Planning).

The Project on National Security Reform focused largely on the fourth of these missions. The mission statement for the Directorate of Strategic Operational Planning (DSOP) calls for it to be the focal point of the national security establishment by orchestrating and harmonizing the appropriate application of instruments of national power (e.g., diplomatic, financial, military, and intelligence activities). Interestingly, said Kravinsky, the 2010 Government Accountability Office report on biosurveillance pointed to a lack of a focal point with authority and resources to guide and develop national biosurveillance capabilities.

The Project on National Security Reform began by examining a concept Kravinsky called "Whole-of-Government Collaboration" designed to orchestrate and harmonize a mission. This is a multifaceted concept that could include the following integrating functions:

- Capturing and cataloging the range of activities and resources
- Developing strategic objectives
- Developing policy options
- Harmonizing and synthesizing plans
- Prioritizing resources
- Assigning roles and responsibilities
- Resolving impediments
- Adjudicating conflicting roles and responsibilities
- Gaming and exercising
- Assessing performance
- Coordinating operations to achieve unity of effort
- Directing operations to achieve unity of command

The project then broke down the concept of "authority" into various components, including authority over processes, resources, personnel, and enabling procedures. In this way, it could compare the different components of authority for different government entities. For example, entities could have the authority to develop strategy, determine requirements, approve reprogramming and transfer of resources, establish professional development standards within the community, and so on. These types of authorities then could be compared to examine the characteristics of collaboration.

The project came to several broad conclusions:

- NCTC is involved in a significant breadth of planning activity, and its role as an interagency team continues to evolve and grow.
- Departments and agencies have a varying degree of awareness of these activities, and the added value of NCTC planning to its customers is not universally understood.
- NCTC's relationship with the NSS is not formalized (though this step was undertaken after the study was published).
- Overlapping authorities have resulted in lack of participation by certain departments and agencies.
- The current congressional committee structure is not equipped to oversee interagency mechanisms, resulting in confusion over jurisdiction and no champion in Congress.
- NCTC workforce needs are challenged by the scarcity of planning competencies across the federal government and the uneven participation of agencies.

As an example of overlapping authority, Kravinsky observed that in 1998 the State Department was given authority over the overall supervision of international counterterrorism authorities' activities. However, NCTC had the same mandate. "Through no fault of either NCTC or the State Department, they had authorities that were never reconciled," Kravinsky said.

The project resulted in a number of recommendations and lessons learned:

- The President should issue an executive order to address the full scope of the counterterrorism architecture.
- Congress should establish a Counterterrorism Working Group in each chamber to look across committee jurisdictional boundaries.
- The President should vest the director of NCTC with responsibility to provide advice on the choices of personnel to lead the entities of the departments and agencies focused on counterterrorism.
- NCTC should partner with the Office of Personnel Management and others to develop training curricula and programs for strategic planners to address the federal government's need for these skills.
- The Office of Management and Budget and the DSOP should develop a consolidated interagency counterterrorism budget display.

- The counterterrorism program and budget guidance should be nested within broader national security guidance.
- NCTC should partner with the Department of Homeland Security to explore opportunities for collaborative planning with non-federal partners.
- Create an interagency coordination mechanism below the level of the NSS that allows seamless and institutionalized linkage between customers in the interagency space.
- Consider "Center" options for other missions (cybersecurity, biosecurity, etc.).
- Mandate a reporting chain to the President to obtain the informal authority associated with proximity to the President that is required to lead an effective interagency team.
- Untangle overlapping mandates and authorities to ensure that all actors understand the need for, and leadership from, an interagency team.
- Ensure strong links between policy, strategy, and resources that are critical to turning policy, strategy, and plans into action.
- Create a government-wide human capital system that provides personnel with the necessary experience and expertise to form an effective interagency team.
- Cultivate champions on Capitol Hill to foster congressional support for the interagency team and streamlined oversight of the national mission.

Kravinsky closed by saying that some of these recommendations could be helpful to the biosurveillance community.

Discussion

Kravinsky made a point regarding resource allocation, noting that such aligning of resources to missions needed to occur within a greater context of prioritization, and not in isolation of other efforts. Similarly, he noted the importance of recognizing territorial issues around duties, responsibilities, missions, and scopes, and finding ways to work around them, potentially by executive order defining exactly who is in which role doing what.

VIEWPOINT OF THE NATIONAL SECURITY STAFF[4]

Matthew Hepburn, of the National Security staff, said that the purpose of the NSS is to support two advisors to the President: the National Security Advisor and the Homeland Security Advisor. Within the NSS are a series of directorates, including the resilience directorate, which handles preparedness and response. Biosurveillance is a top priority of the directorate.

The purpose of biosurveillance is to inform the decisions associated with an event, said Hepburn. Decisions can have major impacts, but there are also low-impact decisions that involve who needs to be notified and what information needs to be conveyed. These decisions vary depending on the target of the information, whether it is the head of a government agency or the public. At all levels, better information creates at least the potential for better decisions.

As an example, Hepburn cited recent reports from the United Nations Food and Agriculture Organization involving the emergence of new strains of H5N1 influenza. "A senior leader needs to understand what this means. Do we need to take any action? Do we need to ban any imports? Do we need to negotiate with foreign governments? Do we need to do something different than we already are based on this report? How do we inform the leadership on that?"

A complete picture of the situation on which to base decisions cannot be obtained from any one government agency, said Hepburn, though many agencies are essential to create such a picture. Rather, analyzing the situation requires multiagency expertise. Thus, a process involving multiple agencies is needed to assemble information rapidly. A policy maker may have just 45 minutes or an hour to prepare for a high-impact announcement, such as would follow the report of a serious *E. coli* outbreak. "We need that collective understanding."

Many audiences can benefit from that assembled understanding, from national and international leaders to local communities. The value of biosurveillance is measured in part by its benefits to these many audiences, said Hepburn, because these audiences will then participate in the process. For example, "we should figure out how what we do has enormous benefit for the private sector. And then they will participate. That is where our creativity and our innovation need to focus."

[4]This section is based on the presentation by Matthew Hepburn, Medical Preparedness Policy, White House NSS.

Discussion

In response to a question about what information should be conveyed to the NSS from agencies, Hepburn noted that biosurveillance has been defined broadly. He advocated setting thresholds for conveying information lower and then learning by experience where they can be raised. "With that exercise we develop the trust and learn how to work together."

Hepburn said that the NSS reads the daily reports generated by the National Biosurveillance Integration Center (NBIC), along with reports from elsewhere in government. He also reaches out to NBIC when he needs information because of a question he has been asked or an anticipated need. "It is much better for me rather than calling three dozen experts across the U.S. government."

Hepburn also emphasized the importance of building local capability. A biosurveillance system needs to be valuable to the communities it serves. "How do we make biosurveillance something that absolutely can't be cut because it is so valuable?"

3

State and Local Experiences

Biosurveillance begins at the local level. Data gathered by health care providers, public health officials, emergency responders, and others are the foundation on which biosurveillance is built. These data then must be analyzed to generate the information and knowledge that drive specific actions.

Three speakers at the workshop—representing state and city perspectives—discussed how people at these levels prepare for and respond to biothreats and events, both from the planning and surveillance perspective and from the coordination and response perspective, highlighting the importance of developing effective collaboration early. Analysis of previous episodes and planning for possible future events are both necessary to uncover and fill gaps.

BIOLOGICAL PREPAREDNESS AND RESPONSE IN NEW YORK CITY[1]

Under normal circumstances, within and between organizations and sectors, information sharing is considered maladaptive, said Joel Ackelsberg, Bureau of Communicable Diseases, New York City Department of Health and Mental Hygiene. Information is power, and sharing of information may lead to loss of control or autonomy. Unidirectional information flows are preferred, especially if that direction is pointed to

[1]This section is based on the presentation by Joel Ackelsberg, Bureau of Communicable Diseases, New York City Department of Health and Mental Hygiene.

oneself and one's organization. As Ackelsberg quipped, a common perception is that "sharing information is for chumps."

In emergencies, however, these generalizations no longer apply. Sharing information supports common missions, goals, and objectives. Multidirectional information flows are preferred to arrive at a common operating picture.

By examining experiences before and after 9/11 from this perspective, questions that were asked before the terrorist attacks can be reframed in ways that are still relevant today.

Responses to an Event

Public health responses to a covert biological release fall into six categories, Ackelsberg observed:

- Detection
- Notification of key partners and the public
- Rapid investigation to confirm diagnoses, identify hazards and risk factors, and track impacts
- Risk communication and safety recommendations
- Coordinated interventions, including mass treatments and prophylaxis
- Recovery

Biosurveillance is typically interpreted to include the first three of these items. However, most biosurveillance today, Ackelsberg posits, focuses on detection and notification, but not characterization. These latter two tasks are "complicated and messy," said Ackelsberg. "It takes people who are experienced to go through information, to share it, to analyze it, to interpret it. It involves instruments, but it goes well beyond gizmos. It's heavy on people and heavy on the skills that they bring to problem solving."

Before and After 9/11

The New York City Department of Health and Mental Hygiene was working on biological preparedness even before 9/11. It had instituted an internal incident management structure and had established interagency coordination with the mayor's Office of Emergency Management, law enforcement, New York City hospitals, and regional public health agen-

cies. It had enhanced surveillance systems and had prepared for the mass distribution of antibiotics. It provided biological threat agent training for providers, worked on emergency communications, and conducted frequent tabletop exercises and drills.

"Exercises are one thing; experience, of course, is another," said Ackelsberg. Though the department was primed for scenarios like the 9/11 attacks and the anthrax incidents that followed, it could never be ready for such events. The agency was nine blocks away from the World Trade Center and had to relocate to its laboratory. "Our assistant commissioner physically carried a couple of computers into the van to bring with her to the lab because it was on those computers that we had our software to broadcast faxes to the medical community." The city had lost its emergency operations center, and communications were almost nonexistent. "We were operating in the dark. We had lost colleagues. We had lost phone service. It was very difficult for the public and our partners to communicate with us."

The department characterized the initial problems after the attack, many of which involved the environment and the need for shelter, and established how best to address them. Large numbers of people who were exposed to harmful substances were evaluated, and the department still maintains a registry that tracks those impacts. The department also had the benefit of Epidemic Intelligence Service officers, Centers for Disease Control and Prevention (CDC) employees in a 2-year training program who respond to requests for epidemiological assistance, who were posted in 15 hospital emergency departments collecting information around the clock.

After the first anthrax inhalation case was identified in Florida, the department started active surveillance with intensive care units, engaged microbiology laboratories, and worked with infectious disease and infection control personnel. When anthrax cases began to occur in New York City, joint public health and law enforcement teams conducted multiple and simultaneous investigations of thousands of suspected cases. Public health liaisons within the criminal investigation made it possible to share ideas, generate hypotheses, and share analyses. "All of this was extremely personnel heavy," said Ackelsberg. "It's people who have to collect the data—or at least interpret the data—go through and clean up the data, and figure out what's going on."

Biosurveillance-Related Gaps

The anthrax investigations revealed a number of biosurveillance-related gaps in the way information is collected and shared, according to Ackelsberg, including the following:

- Outreach is needed to clinical communities to aid in physician reporting and dissemination of information.
- Rapid mobilization capacity is needed across agencies to handle surges in reported cases, including case management and laboratories.
- Enhanced data collection and data management tools are needed, including integration with laboratory systems.
- It is advisable for laboratory and law enforcement personnel to develop relationships prior to an incident.
- It is potentially hazardous to deploy new surveillance systems during emergencies; "alarms" will occur frequently.
- Improved information sharing is needed between investigations located in other jurisdictions.

The underlying conclusion that can be drawn from these gaps, said Ackelsberg, is that reliable communication underlies all effective responses. As a result, communication has been a focus of change since 9/11 in the public health system in New York City. For example, the Department of Health has a protocol—"well exercised, unfortunately"—with the New York Police Department and the Federal Bureau of Investigation. "This is a good example of the way in which information needs to be shared in order for common missions and objectives to be successfully reached." It is leveraging social networks for communications and public health surveillance.

The public health system in New York City has made different amounts of progress in different areas, Ackelsberg concluded. But information sharing will continue to be a major emphasis as the Department of Health prepares for future events. "The more that we can find ways to convince our colleagues, both in our agencies and in others, that information sharing is not for chumps, and that information sharing can actually bring us the knowledge that we need when responding to an incident, the more successful that will be in the long term."

Discussion

In response to a question about data integration centers, Ackelsberg observed that local and state health departments should be seen as customers and not just providers of information. The best people to interpret data are the ones who routinely use the data and are familiar with the patterns that exist at the local and state levels.

He also pointed to the importance of using words carefully. For example, "aberration" is a better term than "alarm." "When we instituted drop-in surveillance in the fall of 2001, we had alarms going off all over the place. We had no baseline, so we decided the first thing we needed to do was to start calling it something else." The terms used should convey the uncertainty of a situation while accurately describing and interpreting the available information. This becomes especially hard when people in different agencies are doing different interpretations or analyses, requiring not only communication but iteration. "What we thought we understood on day one is going to be very different from the way that we understand the situation days into the incident."

Finally, Ackelsberg observed that all public health is local, but it may not be local to the place where a person lives. A place like New York City has millions of people coming in all the time by plane, by bus, and by boat, in which case local is much more expansive than the five boroughs. Meanwhile, the ability to monitor diseases around the world has huge vulnerabilities, despite the potential influence on localities like New York City.

SEEKING ACCESS TO SURVEILLANCE DATA IN MARION COUNTY, INDIANA[2]

Joseph Gibson, from the Marion County Public Health Department—which includes the city of Indianapolis—described his department's experiences in gaining access to three kinds of surveillance data: clinical data, school absenteeism data, and data from the state health department. In doing so, Gibson highlighted issues of sharing and trust, and how to overcome such barriers.

The Health Insurance Portability and Accountability Act has a clause that allows health care providers to give clinical data to public health

[2]This section is based on the presentation by Joseph Gibson, Marion County Public Health Department, Indiana.

agencies. But the clause does not require the data to be shared, so hospitals can be reluctant to do so. "They aren't covered for the risks that they open up themselves to if they do give us the data and something goes wrong," Gibson said. In addition, state laws address how clinical data may be used in research, but omit public health uses, which puts such uses into a gray area.

Similarly, schools are not required to give the public health department absenteeism data. They did so during the H1N1 epidemic out of a sense of civic duty, but schools are strapped just trying to cover their core missions, said Gibson, so they do not have much time or resources for public health activities. Furthermore, when they were willing to share these data, the format and content of the data often varied. As a result, the public health department had to write custom computer programs and use manual processes to make the data useable.

Finally, the relationship between the Marion County Public Health Department and the state health department has varied from close to distant. Generally the state health department has been cooperative, but it needs to be careful not to violate state law, and these laws are not consistent across diseases. Furthermore, state officials have worried about establishing a precedent with Marion County, which is the largest health department in the state and has greater resources, that then would apply to counties with fewer human resources and less ability to protect the confidentiality of the data.

What Does Not Work

Gibson described several approaches that have not worked in requesting data to protect public health at the county level. First, broad requests for data are almost always rejected. "I had to provide specific uses to which I was going to put the data, and then I could start to get the data. And slowly, we've been able to develop more trust and expand those uses, but still, I have to be very specific in terms of what I'm going to use this data for."

Relying on authority, power plays, or legal debate also has not worked. The law generally does not require sharing and is often gray, and recourse to authority often generates resistance.

Not understanding the restrictions faced by senders is a barrier to sharing data, Gibson said. "As I understand what their processes are and understand what their greatest concerns are about this data, I can much

more carefully draft my requests and my processes to fit theirs, so I'm more successful in getting the data."

Finally, it does not work to request data that senders are not already gathering. Requests for data that are not already in the system generally are not successful. "Anything where I'm trying to change their work processes has almost always failed."

What Does Work

The most important element in making data sharing occur, said Gibson, is trust. Understand a provider's data protection rules can help build that trust. Also, finding opportunities to interact with data providers is important. "Whenever I have an excuse to go meet with my counterparts at the state, I go meet with them. Whenever there's some event going on that they might be interested in, I try to get them there, so that we just have more interaction. That interaction builds understanding, and that understanding makes them much more comfortable in sharing the data with me." Finally, it is important to be incremental and start with narrow requests, said Gibson. As the sender recognizes that data are handled carefully, it will be easier to get more data in the future.

The issue of trust is one reason why Gibson can be reluctant to share data with the federal government. His sources of data need to know that he is managing their data carefully. If he violates that trust—for example, by sending data to the federal government for one purpose that are then used for another purpose, such as law enforcement—the data provider might stop providing Gibson with the data.

Another approach that works is to minimize the burden and maximize the value for the sender. For example, Marion County and then the state of Indiana made a substantial effort to get syndromic surveillance data back to hospitals so they could see how the data were being used and use these data themselves. Similarly, schools were included in situation report distribution so they could see how their absenteeism data were being used and could understand the value to communities. For school absenteeism data, every school district received a summary of its absentee data and a comparison to the aggregate for all districts. Hospitals also received ways to compare their information to the information for all hospitals.

Along the same lines, during the H1N1 epidemic the public health department distributed swabs to clinics and then collected them every day to take to the laboratory. "It was really work intensive, and eventual-

ly it was not sustainable. But we tried to set up a system that was going to minimize the amount of work [the clinics] would have to do." Similarly, with the schools, the department accepted absenteeism data in many different formats and then converted the data to a more useful form.

A legal mandate or top executive support is often important, said Gibson. Even institutions that want to provide data need legal coverage to do so. School absenteeism data did not become available until superintendents gave their blessing.

Finally, finding the right person to deliver the data can be critical. In schools, the right person was sometimes an information technology specialist and sometimes a nurse. "We had school nurses doing yeoman's labor to give us the information . . . because it was important to them."

Discussion

A workshop participant asked about the efforts of the Office of the National Coordinator in the Department of Health and Human Services (HHS) to promote sharing among health care organizations through common standards and funding incentives and to build an interoperability framework to house information, suggesting that biosurveillance efforts should be coordinated with such health information systems efforts. Gibson remarked that the states are working hard to ensure that they receive this information as well, but they have very little funding to do so. "At the local and state level, there's a lot of activity around that."

Ackelsberg asked about sharing information while protecting the interests of an agency and its partners, and Gibson responded that "the more you share information, the stronger your community gets." He said that he has a sign on his wall that says, "Information is power, so spread it around." Information is not lost by sharing it—it just builds. However, when data come from somewhere else, it is advisable to direct people to the source, "because we don't want to be sharing somebody else's data; we'd rather have it come directly from them."

This is also an issue when law enforcement becomes involved, because hospitals are unlikely to keep sharing information with a public health agency if that information is then passed on to law enforcement agencies, said Gibson. "They're giving me that information for a very specific use, and if I'm sharing that information in a way that goes beyond that specific use, then they're going to stop giving me the information."

Moderator Lisa Gordon-Hagerty noted that an unwillingness to share means that information will be stovepiped. "The whole idea here is for information sharing, recognizing we're talking about two very different cultures—the public health community and the law enforcement community." How can the wealth and power of information be spread around if barriers exist between agencies? Gibson said that he has to maintain the trust of the people who are providing him with information. "That's the tension that I have to try to work through."

INFORMATION SHARING FOR BIOSURVEILLANCE IN NORTH CAROLINA[3]

North Carolina relies on two main systems to detect disease outbreaks, said Jean-Marie Maillard, North Carolina Department of Health and Human Services (NC DHHS). One is the North Carolina Electronic Disease Surveillance System, which provides case reports and laboratory results. The other is the North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC-DETECT), which gathers information from emergency departments, poison centers, and ambulance runs and is used for syndromic surveillance and situation analysis.

NC-DETECT was started in the 1990s by a group of researchers at the University of North Carolina who were trying to gather information from emergency department visits. The NC DHHS partnered with this group and, after 2001, received increased funding to improve disease surveillance and epidemiologic capacity. The department also worked with the hospital trade organization in North Carolina to ensure that emergency department data would be reportable. In addition, it drew on data from the Carolina Poison Center, which receives about 120,000 calls per year, about 20 percent of which are from physicians and emergency departments.

NC-DETECT provides data in the form of customizable tables, graphs, and maps and is available 24 hours a day. Reports from emergency departments are received twice a day from every hospital reporting to the system, and for the poison center the update is every hour. Users have rights defined by their role, so a local person working with the hospital system could see local data, a regionally based public health professional

[3]This section is based on the presentation by Jean-Marie Maillard, NC DHHS.

could see regional data, and users at the state level could see the statewide picture.

As an example of the type of event seen by NC-DETECT, Maillard cited a 2007 outbreak of salmonellosis caused by contaminated peanut butter. Hospital visits immediately rose, along with a sharp and quick increase in calls to the poison center. The system "allows us to look at different aspects of a health event in the community," Maillard said.

Surveillance networks in North Carolina include local health departments, including communicable disease nurses, hospital-based epidemiologists, laboratory directors, and epidemiologists at the state level who can provide support remotely and on site as needed. For instance, the state has used funding received since 2002 to set up a network of hospital-based public health epidemiologists.

The state also has a system that can look into the electronic medical records of patients in real time. This system scans every day not just for bioterrorism but also for everyday public health issues. Epidemiologists at the state level then can deploy if onsite assistance is needed.

The state has a number of task forces and task-oriented workgroups that allow potential collaborators to meet each other and work together. For example, the Food-Borne Disease Task Force, created by the governor in 2003, combines staff from 20 different organizations who meet six times a year. These groups make it possible to convert data into actionable information, said Maillard. These task forces, which originally started as a means to convene relevant stakeholders around specific issues, also serve the purpose of maintaining connections and relationships.

Finally, North Carolina uses checklists, situation reports, and an incident command system for larger events of public health significance. It has established memoranda of understanding among the departments of health, agriculture, and environmental and natural resources (the latter of which has since been combined with public health). It consults and works with CDC, the Food and Drug Administration, and the Department of Agriculture. It even has a team of student volunteers at the University of North Carolina who are available to help with call lines, interviews, and case control studies.

The System in Action

An example that illustrates the operations of the system was the recall of a brand of chili associated with botulism. Even though a holiday limited the number of staff who were available, Maillard was able to

immediately find 12 patients who met the botulism syndrome case definition. He then further examined these cases to see if they were associated with the food product. The information was shared with the department in charge of the recall, which found that many stores were still displaying the product. Personnel "visited 16,000 stores and removed 35,000 cans of product, which was more than the rest of the country combined."

Another example involves vectorborne diseases such as Rocky Mountain spotted fever, which has a high incidence in North Carolina. In 2003 the West Nile Virus Task Force was created to deal with the spread of the West Nile virus, and the task force was later expanded to be the Vector-Borne Disease Task Force. The task force meets regularly with not only public health staff but also entomologists, local health departments, academicians, and members of the public to share surveillance data, talk about what is known and not known, and share study findings. Similarly, the Disaster Epidemiology Group has worked on hurricanes, floods, wildfires, heat waves, and other events to enhance the epidemiology capacity for disaster response.

The state has learned through successive deployment how to conduct surveillance projects, community assessment projects, and environmental studies quickly, said Maillard. An infection control program in the state has detected disease outbreaks associated with reuse of single-use products that should not be shared among patients. "It works both ways—we tell them about the cluster of outbreaks we are informed about and investigate, and health service regulation tells us about the findings they noticed during inspections."

The North Carolina Intelligence Sharing and Analysis Center provides two-way information sharing with law enforcement through public health staff with security clearances. The state also has signed a memorandum of understanding with the local health departments of the Eastern Band of Cherokee Indians that describes who will do what with regard to information sharing.

Discussion

In response to a question about the usefulness of memoranda of understanding, Maillard responded that they have the benefit of laying out who could get the information and how information will be shared. "We all work from the same large base as quickly as possible," he said.

Regarding a question about collecting information from veterinary

clinics as well as emergency departments, Maillard pointed to several collaborations with the agricultural sector, though funds for such activities have been diminishing. Animal surveillance generally has been at a more basic level than human surveillance, he said, but animal surveillance in North Carolina has had extensive experience with mapping and has been willing to share its mapping structure with public health agencies.

4

Outside Perspectives

Two speakers at the workshop were selected to be somewhat "outside the box," said planning committee co-chair Scott Mugno, with the intention of showing how similar issues in disparate sectors can be addressed with universal processes or approaches. One outside perspective came from an information technology specialist at the Federal Reserve; the second came from a former high-ranking Israeli government official.

KEEPING PACE WITH DATA COLLECTIONS IN A RAPIDLY CHANGING ENVIRONMENT[1]

Peter Purcell, Banking Supervision and Regulation, Federal Reserve Board, pointed to some interesting common threads between the fields of finance and biosurveillance. One is that people count. "Unless you have the people in the field who have an intellectual curiosity to look at the information and get insight and share that, you really don't have anything."

The other common thread is the way that data have changed over time. The Federal Reserve has decades of experience collecting financial data, analyzing it, understanding what it means for the economy, and making it publicly available. But before the 2008 financial crisis, which changed the nature of data and data reporting, it relied largely on static reporting. It engaged in interagency collaboration through memoranda of

[1]This section is based on the presentation by Peter Purcell, Banking Supervision and Regulation, Federal Reserve Board.

understanding. Information security was a critical consideration. Standardized reporting formats allowed effective monitoring and analysis.

Even before the crisis, the world was changing, said Purcell. Data started moving and becoming available much faster. Business processes underwent significant modifications to respond to a changing economic environment. Previously, most reports were quarterly or annual. In the new environment, analysts needed to examine data on a day-to-day basis while still maintaining information security.

After the crisis, new data needed to be monitored and evaluated on an ongoing basis. Large quantities of detailed and aggregate data had to be submitted to new modeling and prediction tools. Improved collaboration and communication were necessary across the agencies while continuing to move quickly. "You can't collaborate casually anymore; you need to have a thoughtful approach to managing massive information. At the same time, you need to be flexible to capture new information you never thought you'd need to go after, because the public policy response to something that's happened Thursday needs to be announced before the markets open on Monday, and it needs to be secure."

Data collection and analysis need support from leadership, Purcell said, and Federal Reserve Chairman Benjamin Bernanke has been providing this support. In recent testimony, Bernanke said, "we have begun an enhanced quantitative surveillance program for large bank holding companies that will use data analysis and formal modeling to help identify vulnerabilities at both the firm level and for the financial sector as a whole. This analysis will be supported by the collection of more timely, detailed, and consistent data from regulated firms" (Bernanke, 2010).

Analysis and communication also requires trust, said Purcell. Memoranda of understanding can define protocols, but leadership and collaboration are essential for people to keep from getting overwhelmed. People cannot fight fires year after year without eventually burning out, he said, which means that systems and procedures need to be in place to take the pressure off them.

Discussion

In response to a question about the Paperwork Reduction Act, Purcell noted that the collection of information has changed drastically in recent years. The broad mandate still holds to not add a burden to respondents

that is greater than the public value obtained from the information collected. "That is still good public policy."

A workshop participant pointed out that one way to secure data from others is to make those data more useful to them—for example, by providing an integrated view of the data. Purcell pointed out that the Federal Reserve often tries to provide data that are useful to financial organizations, though it also has the statutory authority to collect data to do its mission.

With regard to overlapping authorities, roles and responsibilities evolve over time, especially as people adjust to conflicting directives. But it is also possible through law or presidential directives to define who does what.

INFORMATION SHARING: THE ISRAELI EXPERIENCE[2]

"We must share information," said Isaac Ashkenazi, National Leadership Preparedness Initiative, Harvard University. "The price for not sharing might be costly in terms of blood, property, and lifestyle, and in many cases in Israel it is a survival issue." The 1991 Gulf War exposed many weaknesses in civil defense, including limited coordination, inadequate communications, and a lack of information sharing. The Home Front Command was established in 1992 with the responsibility for preparedness and response to home front emergencies.

Sharing occurs on different levels and involves many different types of information. It includes the development and communication of information on national threats, planning scenarios, the national response framework, the security information that is needed, and the same system of continuous and joined training. Also, sharing is not automatic, and it is not a technology problem, he said. It is a deeply embedded psychological and social engineering problem. Society encourages antisharing strategies, and people are taught to be individualists. Organizations and personnel are appraised by how well they hoard information and are evaluated on the basis of their individual missions, which creates a culture of silos.

[2]This section is based on the presentation by Isaac Ashkenazi, National Leadership Preparedness Initiative, Harvard University; former head of the Medical Services and Supply Center for the Israeli Defense Forces (IDF) and former Surgeon General for the IDF Home Front Command.

Solving the Problem

Systems approaches are essential to promote sharing, said Ashkenazi. As such, nations need to develop four key documents. The first is a summary of prioritized national threats in which the medical community develops scenarios based on intelligence. The second is a national planning scenario. The third is a national response framework that details how the emergency systems will work together. The fourth is a medical response framework. The United States does not have a national threat document or planning scenarios informed by the medical community. It does have a national response framework written by the Department of Homeland Security, which Ashkenazi deemed an "excellent document." But it does not have a medical response framework.

"Information sharing requires a common language," said Ashkenazi, as well. For example, acronyms and technical language can get in the way of understanding. "The provider and the receiver should well understand all information implications."

Most important, emergency planners need to share information with the public. "If you share with the public, it means that you know and trust the public," Ashkenazi said. If governments cannot share information with the public, then they will not be able to share information within government.

Leaders cannot pass on the responsibility for sharing, Ashkenazi said. They have a tendency to delegate this responsibility to lower-level managers, but this increases silos and decreases collaborative efforts. In a military environment, commanders expect obedience. But in the civilian environment, obedience does not have any meaning. People can only trust and build relationships.

An attractive environment for sharing includes such features as monthly interactions, a rotation of hosting, building trust and relationships, sharing relevant information, and time for play. Groups should engage in "games, training, learning, crisis games, simulations, drills, and workshops."

Obstacles

Ashkenazi observed that sometimes there is too much information, causing overload. No single organization can control that amount of information, which means that information sharing can be interpreted as a

failure. Furthermore, only about 25 percent of the information that is collected in Israel is ever used, said Ashkenazi, and only 5 to 7 percent is used to determine outcomes. "We are collecting more than 90 percent of the information just to collect it. Start from minimal [needs] and essential sharing, then define the gaps, gives, and gets."

Financing for emergency preparedness is siloed, just as information is. Instead, collaborative funding for emergency preparedness is crucial. Israel decided to support emergency preparedness in general rather than supporting organizations, and organizations were funded on the condition that they shared information. After 2 years of distributing the money by mission, said Ashkenazi, agencies were working together rather than in silos.

Finally, one needs to "start with the end and end with the start." People should start by defining the outcome they desire. They then should define the information gaps needed to achieve that outcome, find information suppliers who can bridge that gap, share and analyze information, and show success. They also should acknowledge the outcomes achieved through that information, especially high-stakes outcomes such as preventing a bioterrorist event.

Discussion

In response to a question from the moderator about cross-border information sharing, Ashkenazi said that Israel shares information even with its enemies. For example, it shares information about diseases, terrorist groups, natural disasters, and other items of mutual interest. "This is about saving lives and resilience; this is not about killing."

When asked about the use of social media in an emergency, Ashkenazi said that the use of social media is "low threat, high benefit," in that the users of social media are generally not in a threatening situation and gain many benefits from sharing information. But in an emergency, information sharing is high threat and low benefit, which reduces the value of social media exchanges.

Finally, in response to a question about government sharing of information, Ashkenazi said that discussions need to occur about which kinds of information the public, law enforcement, the medical community, and the emergency response system should receive.

5

Discussion of a Scenario

To highlight the complexity and importance of collaboration and information sharing, participants from a number of federal agencies engaged in a scenario-based discussed of a fictional disease outbreak moderated by William Raub. The scenario consisted of five moves detailing successive stages in the investigation of the outbreak. Participants in the discussion were Joseph Annelli, Animal and Plant Health Inspection Service (APHIS), Department of Agriculture (USDA); Christopher Braden, Centers for Disease Control and Prevention (CDC); Cory Bryant, Food and Drug Administration (FDA); Selwyn Jamison, Federal Bureau of Investigation (FBI); Donald Kautter, FDA; Teresa Quitugua, National Biosurveillance Integration Center (NBIC), Department of Homeland Security (DHS); Kevin Russell; Armed Forces Health Surveillance Center (AFHSC), Department of Defense (DOD); and Regina Tan, Food Safety Inspection Services (FSIS), USDA.

The scenario posited that in 10 widely separated U.S. cities over a period of several days, patients (adults and children) arrive at hospital emergency departments exhibiting bloody diarrhea. Other children present with symptoms of anemia, abnormal bleeding, and acute kidney failure. In each city, a few of the patients die; most of the remainder require hospitalization—in some cases, intensive care. In a number of cases, particularly among those patients requiring hospitalization, stool cultures are performed.

Across the affected cities, these cases of illness come to the attention of local or state health departments in a variety of ways and in varying time frames. In some instances, physicians who recognize the illness as characteristic of infection with Shiga toxin-producing *Escherichia coli*

(STEC) contact their local health department to report their concerns about possible clusters of this disease. As stool cultures become positive for STEC over 2 to 3 days, laboratories report the positive tests to health departments, in some instances using new electronic reporting capacities.

Over the following week, some clinical laboratories forward specimens to state public health laboratories, which perform DNA fingerprint testing (PFGE testing) and share this information with the national PulseNet system. In other instances, health department syndromic surveillance systems that include monitoring for patients with symptoms of "bloody diarrhea" detect an increase in such illness. As state health departments begin to recognize and assess this situation, because of its severity, they are likely to notify CDC and post their concerns on the Epi-X network (a confidential information-sharing network used by local, state, and federal public health officials). As CDC begins to assess the situation, it enlists FDA and USDA counterparts in a joint investigation.

Simultaneously, local media in some communities are alerted to the situation by parents of ill children, and reporters who contact local hospitals learn of additional cases of similar illness. A wire service editor notes the occurrence of similar reports in multiple local or regional newspapers and publishes a national report, speculating about the possibility of a common cause. Within a few hours of the national wire service feed, Al Qaeda in the Arabian Peninsula claims responsibility, asserting specifically that sleeper cells in the United States were the perpetrators but being ambiguous regarding how the infections were introduced. This announcement triggers widespread coverage by television, radio, and print media.

NBIC, through its daily monitoring of media reports and other open-source information outlets, takes note of the wire service report and the Al Qaeda claim and decides to seek, obtain, and analyze pertinent surveillance information. That same day, CDC, FDA, and USDA apprise NBIC that they are investigating whether the cases in the various cities are related and, in particular, whether they are the result of a foodborne pathogen from a common source.

FIRST MOVE

The first move of the scenario involves tracking the relevant mortality and morbidity, which continues for the duration of the incident. This move also includes investigation of the terrorists' claims of responsibility.

Raub asked specifically about CDC's BioSense, which was designed in part to collect real-time information about prescriptions and over-the-counter pharmacy sales. Could this information provide near-real-time, semiautomated reporting that something might be amiss, as opposed to the information coming from individuals who are motivated to examine and report unusual occurrences?

Braden replied that it depends whether the data BioSense provides are sufficiently specific, because "there's a lot of diarrhea and vomiting out there, and picking a signal out of such a high background is actually not easy to do with syndromic surveillance." The detection of bloody diarrhea, in this particular circumstance, is more helpful, and laboratory information is most helpful. Having that information has been a revolution for CDC, Braden said, in investigating food- and waterborne outbreaks. Public health laboratories are critical in the initial stages of an outbreak. The genotyping systems they use are very good at detecting cases that are related and, just as important, cases that are not related. Laboratory information can detect just a few common cases spread through a collection of states, whereas just a few cases would not trigger a syndromic surveillance system.

Collecting exposure information quickly is important, said Braden, in addition to detecting aberrations above a background level of disease. Having this information is essential in forming realistic hypotheses to pursue in tracking the origins of the disease. If public health officials see something that suggests intentional contamination, Braden continued, they will reach out to law enforcement.

Also, at both the federal and state levels, partner agencies will be involved early. Braden observed that an emergency operation center (EOC) would be stood up early in the scenario, as would an operation center for the Department of Health and Human Services Secretary. CDC and other agencies also would participate in the Multiple Agency Coordination Foodborne Illness Outbreak (MACFIO) process. CDC would ask an FBI agent to participate in the EOC, and it would put someone in FBI headquarters in Washington, DC. "We did that during [the anthrax crisis]; I think that was a lesson learned that you need to do that." Similarly, if municipal drinking water were involved, CDC would have a quick exchange of personnel with the Environmental Protection Agency to ensure that information flows between the two agencies.

Other information flows would be operational as well. PulseNet allows data to be shared widely—for example, these data would be fed into the public health information system at USDA. In addition, a memoran-

dum of understanding with Canada allows data to be exchanged between the two countries, which could be a precursor for a much larger international system.

Braden said that determining the source of the illness and getting people away from that source is a multiagency job. CDC's particular job is to implicate the source using multiple lines of evidence and whatever information is available. When a convergence occurs with other agencies that are doing a traceback, the agencies have something to pursue. "It is multiple prongs of approach—and in a hurry."

Kautter said that FDA relies strongly on CDC and on state and local officials to triage the information that comes to the agency. FDA also has a liaison at CDC, and CDC has one at FDA. In the case of the scenario, FDA would be asking whether the substances would be related to a food or to something else and if a product was regulated by FDA or by USDA.

Tan said that FSIS has a senior epidemiologist embedded in CDC who can help generate hypotheses and relay information to USDA. USDA also has access to data streams that can help track suspected vehicles, such as VetNet and a consumer complaint monitoring system. But USDA needs to be specific in knowing where an organism came from and how it was distributed to consumers. Annelli mentioned that APHIS also has a liaison at CDC who would be immediately involved in the conversations. APHIS would be particularly interested in information tying an outbreak to a farm of origin, which is where it would be directly engaged.

Tan emphasized the importance of the local and state health departments. Using this information, USDA's compliance investigation division would work closely with the applied epidemiology division and with state and local officials to find, as quickly as possible, such information as lot codes, sell-by dates, production dates, and establishments that are involved. The compliance investigations division also works with any cases that might have criminal intent, and it is closely linked with the applied epidemiology division.

Russell said that the AFHSC within DOD also monitors outpatient visits. In this scenario, when a cluster was detected, the center would examine its syndromic surveillance system to look for cases among military personnel. Also, DOD has reportable medical events, and STEC is reportable, which would also be an avenue for information. In addition, the center, like other federal agencies, has a liaison in CDC, and that person would inform DOD about the disease outbreak in the scenario.

Raub asked about the claim of responsibility by Al Qaeda, and Jamison responded that such a claim would generate a threat credibility evaluation process at the FBI, which would rely in part on information from the FBI's liaison at CDC. NSS and DHS also would be engaged in processes to determine whether the incident was intention. *E. coli* would not be an agent of choice for most terrorist organizations, said Jamison, but the agencies still would try to make that determination.

Jamison mentioned that the traceback is the most important information to determine if the event was intentional. To make this determination, a joint investigation with other federal agencies is preferable whenever possible. Interviews done by other agencies could help the FBI. Another consideration, he pointed out, is that once the media have gotten ahold of the story, the people doing the work at the agencies will be receiving calls from their superiors asking for information. "That makes everyone's job that much more difficult, because now you're not only going to be talking to our partners here at the table, but you're going to have to talk to your boss . . . to let them know what's going on, so they can go talk to whoever it is they need to talk to."

At this point in the scenario, NBIC would be getting information from several sources, said Quitugua. Information would be coming in from CDC, from other agencies, and from media reporting. NBIC would be looking for contextualizing information, such as the characteristics of the outbreak. It would seek information from CDC about ongoing actions and from the FBI about its investigations of responsibility. Based on this information, NBIC would determine, in consultation with the involved federal agencies, whether to activate the National Biosurveillance Integration System protocol, which is focused on information sharing, coordination, and collaboration.

SECOND MOVE

In the second move investigations are under way to determine if the cases are related. Though no credible evidence of terrorists' involvement exists, the investigation continues.

Kautter described some of the challenges involved in the food sector. All that is known initially is that there are common symptoms that may or may not be related. The purpose of the investigation is to go from many unknowns to pinpointing specific food, the specific agent, the specific lot, or whatever information is needed to get that food off the mar-

ket as fast as possible, but even that is a difficult process. "If I asked you, right now, what you had as a side dish Saturday night, and what were all the different ingredients in that side dish, who could answer that question? . . . These are the kinds of questions that we would need to address to pinpoint: one, is it even food, and then, two, is it one common food?"

Braden drew a distinction between data and information. Some data remain at the local level and never go to the state or federal level, and that is appropriate, since there is no need to bring together all of the data in one place. However, the information derived from those data does need to come together. The curation of this information extends from the media relations staff to the scientific staff, all of whom are responsible for part of the task.

Braden described three data streams: laboratory, epidemiologic, and environmental. Each of those data streams can be very broad. A questionnaire searching for common elements may come up empty, requiring that the questionnaire be changed and that new cases and controls be interviewed. Doing this work can take time, Braden said, and a database that can be used to sort out this kind of information has not been established.

In response to a question about whether computerized systems could combine information from different sources to detect linked cases that rise above a background level, Braden pointed to some of the difficulties with food. A food product can end up 100 miles from where it is produced before it ends up 2 miles from where it is produced. Furthermore, symptoms are the result of self-reporting, and "especially for GI [gastrointestinal] illness, people are notoriously inaccurate about where they think they got an illness."

In response to a question about communication with and among the states, Braden observed that PulseNet is constantly detecting clusters that need to be assessed. In many of these cases, CDC asks states for information, and the states then go to local health departments to find what information has been gathered. Based on that information, a cluster may be judged an outbreak, in which case further investigations begin. For some clusters, such as botulism or *E. coli* O157 that is causing deaths among children, the EOC would be stood up very quickly, whereas other outbreaks do not require that level of response.

CDC also has conference calls involving lots of people, said Braden. All of the investigators and partners are on the calls, so "information sharing occurs early and often and on the phone." Kautter added that 50-state conference calls may occur two, three, or more times per week. "Good old-fashioned conference calls—you can get a lot of really good

information that way, and it allows the states to report some of the information [they have], and for all the states to hear that latest information as well."

Early in the process, said Braden, CDC, through its EOC, would be taking many of the calls. Later, in the scenario described and according to the current structure, the MACFIO would be in charge.

Regarding the provision of information, Braden said that CDC has learned that the web can be extremely helpful. "We will put as much information as we can out on the web about the number of cases, how severe they are, where they are, all those types of things, pretty early in this investigation. And we would update that probably daily."

In response to a question about how government officials should respond to endless requests for information generated by media accounts of possible terrorist involvement, Bryant emphasized partnerships among agencies as a way of handling requests for information. Even before this outbreak was linked to a food, the FBI would be in contact with FDA through its Office of Criminal Investigation, as well as with other agencies. The FBI and CDC also would be working together under such circumstances.

Annelli pointed out that the biological assessment threat response (BATR) process would likely be involved in this scenario. Any federal agency can call for the BATR process, and all agencies should be in the loop as it proceeds. White House communicators also would be involved, and, as Annelli said, "quite frankly, from what I've seen in other events, the communicators end up driving some of that external messaging and communications more than the operations folks do. We'd have a completely parallel kind of organization working on the messaging piece, while the operations folks are trying to figure out what's really going on."

In response to a question about the MACFIO, which emerged from the Food Safety Working Group of the Domestic Policy Council to create a higher level of coordination, Tan said that relationships and communications structures exist now outside the MACFIO. The MACFIO would be stood up in extreme circumstances, but the day-to-day work of liaisons and hosts makes things run smoothly. "What is critical for the investigation is what's happening on the ground at the local and state health departments, what information they're getting, and what hypotheses they're generating. . . . That's where it all comes together on a national scale." Tan said that USDA has an Office of Public Affairs and Congressional Relations that would handle requests for information from the public while also engaging in cross-agency coordination. However, Russell pointed out that there still is no one interagency location to go to

for information in the situation described. DOD and NSS are both interested in such a capability, he said.

DOD's involvement, said Russell, would not yet be determined at this point in the scenario, but it would be providing information to CDC and ensuring that communication occurs within DOD. "We feel strongly a responsibility to our own service members, and that would not be neglected at the expense of handing it over to the CDC."

A questioner asked specifically about the curation of information that extends beyond public health to the national security arena, and several panelists pointed to a tension that exists in this area. Russell, for example, said that DOD is divided between the public health sector and the security sector. "Efforts are under way to see if those communities can communicate better, but it's an uphill battle." Trust will be essential for these different communities to be at the table together without being threatened or jeopardizing trusted relationships.

In response to a question about the investigation of terrorist involvement, Jamison said that if the situation is domestic and involves terrorism, the FBI will have the lead for the investigation. But until terrorism is established, it would be conducting a joint investigation.

Raub observed that many government officials have experienced what he called "communication with our partners by press release, which is not exactly conducive to collaboration." He then asked Quitugua how NBIC would be seeking to establish situational awareness. Quitugua replied that NBIC would be engaged primarily in collecting and assembling information, "because we have a very small group internally, and we can't possibly replace the expertise of all the authorities that are already working it." NBIC would be trying to establish the size of the event, how bad is it, and whether it is going to get worse. It would reach out to other agencies for modeling results, for example, or for other information. It would be particularly interested in turnaround times—what information might be available, and when will it be available. "We're not doing an independent analysis of a completely separate data set," said Quitugua. "We're trying to link people who may have data sets that need to be brought together. A lot of them already are linked. But sometimes there are new things that become available."

In response to a question about who would be curating information at each agency, Tan said that the curator at USDA would be the operational team. Braden said that the situational awareness team at CDC would be putting information together from different sources. Kautter said that the FDA has established a new Coordinated Outbreak Response and Evalua-

tion program, which is now the repository for information in food safety events. In DOD, said Russell, each of the services has the responsibility of reporting to their chain of command through to their service Surgeons General, but also the Assistant Secretary of Defense for Health Affairs and the AFHSC.

Audience members offered some insight regarding their expertise and local context. Joel Ackelsberg of the New York City Department of Health said that in a scenario such as the one described, state and local public health departments would be "ramping up their resources." These kinds of cases would catch people's attention. If necessary, the New York City Department of Health would activate its incident command and be able to bring in resources from across the agency. The foot soldiers who are collecting information and helping to generate hypotheses would be at the local level.

Stephen Redd of CDC observed that external communication needs a structure to ensure that the information being released is consistent. Also, he said, it is important for the spokesman to be a scientist to enhance credibility. "That's something that we learned with H1N1 is really important for trust."

THIRD MOVE

In the third move, the source of the exposures turns out to be bean sprouts contaminated with *E. coli*. There is no credible evidence of terrorism, but the investigation continues.

Braden emphasized the difficulty of identifying such a source. Implicating bean sprouts could mean finding a person who ate bean sprouts, knows where the bean sprouts were bought, and had a shopping card linked to a shopping card database to show when the bean sprouts were bought. "Getting that kind of information is quite hard. People don't remember that they ate bean sprouts—it's often kind of a stealth vehicle." Yet an accurate trace back is essential to keep partner agencies from being led astray.

Braden also observed that identifying a specific pathogen increases the ability to predict what is going to happen. For example, *E. coli* can produce different types of Shiga toxins, which will influence the characteristics of the outbreak. This information in turn would need to be conveyed to public health authorities at all levels. He also pointed out that this system is currently threatened, because more and more clinical laboratories are adopting non-culture-based diagnostics, which means that

cultures are not available to characterize infectious organisms. "We're not going to have that isolate and be able to characterize it to be able to know what to do."

Braden also described the difficulty of acting as a communicator at CDC while participating in an investigation. "Sometimes the incident commander is spending half the time in the studios in front of the cameras." Joint press conferences with all of the involved agencies on the phone, along with as many as 150 reporters, also take up time.

Tan reiterated that the epidemiological information starts with state and local health departments. USDA can rely on internal databases to investigate hypotheses, but without enough information the investigation cannot proceed. "The boots-on-the-ground element cannot be underestimated, because there's often not enough information for us really to understand exactly what establishment [was involved], what were the production dates, what are the lot codes. Often, people unwrap their food and then they toss the package, and all of our information goes into the garbage. And our folks on the ground are not adverse to going into the garbage and getting the information for us. They can, they have, they remind me often."

Kautter observed that implicating bean sprouts is a significant advance because it provides a path to pursue. Bean sprouts are not particularly seasonal, but if the contaminated food were seasonal, the first question to ask would be where the food is grown that time of year. If the food was imported, were import samples taken, or are there domestic samples that can be tested? Can the genetic fingerprint of an infectious organism from the food be linked to a clinical sample? Also, once a source is known, industry calls become much more numerous, because industry or trade associations could have information about the origins and treatment of the food.

On this point, Quitugua said that NBIC would not necessarily have all of the information that other agencies have. For example, NBIC does not have access to PulseNet, though it does have information conduits to the agencies. NBIC was originally envisioned as a place with liaisons from all of these agencies, but agencies are spread very thin and expertise is difficult to retain. Instead, the relationships are virtual through emails, phone calls, and collaboration that does not require people to see each other every day. "Face time is preferable, but I spent a long time running a reference laboratory, where I only saw three people all day. . . . People are completely capable of doing that."

Standing Committee member Merrie Spaeth of Spaeth Communications pointed out that in the foreseeable future, people will not go to the cameras, but the cameras will come to them, in the form of small webcams that can post images directly to the web. She also applauded the involvement of communications experts being involved in the information dissemination process.

In this scenario, Raub emphasized, the President, the Cabinet secretaries, and a host of other people are leaning on the National Operations Center, on NBIC, and on the pertinent agencies. "Who's got what, and what do you have, and what can you get and what do you need, all become part of the issue."

FOURTH MOVE

The fourth move focuses on the effort to determine the site or sites at which contamination of the bean sprouts occurred. No evidence of contamination during processing or distribution appears.

Until the identification of a source, said Braden, CDC would lead the investigation, with the incident manager who stood up the EOC coordinating the overall investigation. If an investigation were to become a criminal investigation, the FBI could take over, or if a facility were identified as the origin of the contamination, USDA could take the lead. But until then, CDC would be the lead agency. Braden said that CDC would be doing targeted testing of sprout samples. Random testing early in outbreaks is not very productive, but once a target has been identified, tests can look for specific organisms.

Kautter said that if a positive sample were taken of the sprouts either in a restaurant or at someone's home, FDA would work with its federal, state, and local officials to try to determine whether it was one brand or numerous brands, one distributor or numerous distributors, or perhaps a single lot. Trace backs would investigate the sprouting facilities, the source of the seeds, and the companies involved. FDA also would be bringing in industry members that are sprouters and their trade associations to help get information faster and sooner. At this point, CDC and FDA would probably be conducting joint press communications, with regular updating to keep the public informed.

The situation would be somewhat different if the seeds were imported from another country, Kautter added. If so, the appropriate countries would

be involved in the investigation. FDA also would communicate with DOD to see if military personnel were affected.

Mugno asked when the information about bean sprouts would be communicated to the public. Kautter said that the issue with food safety events is always how much information to convey when information is uncertain. Telling the public not to eat a food product can be a major economic burden, but the FDA leans on the side of caution for public health. With 10 cities and a number of deaths, "we are going to get more information out sooner than later," he said. However, no food safety outbreak is the same as another. "It is really a discussion point between usually CDC and FDA regarding the public messaging," said Kautter. "It would be nice to have a one-stop shop template for all outbreaks, . . . but every single outbreak is different and the information that we get from every outbreak is different. We have to triage that and determine where our public messaging is."

In response to a question about how quickly information would be delivered to the public, Quitugua said that in significant events, DHS personnel may have just 60 minutes to prepare the Secretary to talk with the press, and that "all efforts" are made to ensure interagency coordination. Spaeth emphasized the importance, in the current media environment, of making immediate public contact to establish that the situation is being managed. She also emphasized that "there is an enormously rich amount of [communications] resources today at your disposal which ought to be factored into the planning at some point."

Quitugua noted that the information being collected is also what NBIC wants to know. In addition, it wants to know what kinds of questions agencies are being asked, because if one agency is being asked those questions, other agencies are likely to get them, too, and some agencies but not all may have answers. In this way, NBIC could act as a clearinghouse to provide people with a common operating picture. Information "doesn't always get spread evenly," said Quitugua. A cross-check by NBIC could ensure that everyone has the same information.

Meanwhile, said Jamison, the information being gathered by other agencies would be the same information the FBI would need to assess the possibility of intentional contamination. The bureau would be looking at individuals who work with the bean sprouts in the processing plant or in the farm to try to determine if they have a terrorist connection. For instance, once a strain was identified, an investigation could determine whether individuals had access to those strains.

Nancy Carter-Foster, representing the State Department, said that the State Department would be involved in this episode and would expect to work closely with the FBI, DOD, and others. "We are part of the security agencies as well as the diplomatic agencies," she said. Also, the terrorist claim would make this outbreak a national security incident, and the State Department would be investigating it in that context as well. Finally, the messages conveyed to the public need to be as verified as possible. Messages should "let people know what the problem is as well as what it is not." For example, a recent salmonella outbreak led to the destruction of an entire crop of Mexican tomatoes and peppers, causing losses of hundreds of millions of dollars, but tomatoes and peppers turned out not to be involved. "The food industry is a global industry. Things that you think are just messaging to protect our health can have much broader implications."

A workshop participant asked if agencies have ways of integrating information that is received *before* an outbreak occurs. Jamison replied that the FBI has procedures and liaisons throughout the government to respond to intelligence pointing toward an attack. The exact response depends on the information received and the source of the information. But the FBI would let the public know about a possible incident, as it has with credible evidence for terrorist events in recent years.

Russell observed that DOD also has organizations that are ready to receive such information, such as the regional commands throughout the world. But, he added, procedures to do so at the AFHSC remain suboptimal, even though this is an organization that needs to work well.

Quitugua also expressed a concern that the conduits for intelligence information are not clear. "I don't know for a fact exactly how I would get that information from the FBI. I have a feeling it would go a very secure route that would take a long time and maybe completely bypass the center and a number of NBIC partners." People may say that they are going to share information, but they do not exercise those communications routes in each event.

Jamison agreed, though he also described the Interagency Policy Committee through which intelligence information would be communicated to agency representatives. "At that point it is incumbent upon each department and agency to let their respective officers know what they need to know, and that is often where the breakdown occurs." Also, he observed, public health departments are often left outside the loop. "We are working to alleviate that problem, but we are definitely not there yet."

Tan observed that USDA has a specialized part of the organization that is equipped to receive classified information, but getting clearances elsewhere in the organization so that information can be disseminated can be a problem. Annelli reiterated that USDA has systems to acquire classified information. The challenge is converting classified information into actionable information that can be more widely distributed for use. "How do we take that information and get it to the people who need to know regardless of their level of security clearance . . . and then down to the state and local level?" Raub added that information can occur in different versions. One version might be promulgated broadly, while another version goes only to people with the appropriate clearance.

Annelli pointed out that the person who has information is often the one deciding who else needs to know it, yet that person often does not know what other people need. For example, USDA's Food and Nutrition Service does not buy bean sprouts for the school lunch programs. This piece of information would be useful to add to the messaging, but it may not necessarily be conveyed without special attention to interagency communications.

Kautter reminded the workshop participants that with a claim by terrorists of involvement, as in this scenario, FDA or CDC are probably not going to be the main source of news. Rather, department secretaries or even the President will be on the news. A good protocol is available for more routine episodes, but this episode is dramatically different "if CNN is running this 24/7 that terrorists have contaminated the American food supply." On this point, Jamison noted, the terrorist claim would certainly create the public perception that the FBI is leading the investigation.

Jamison said that the agencies have discussed having a single spokesman, whether someone from NSS, from DHS, or from CDC. In this way, all agencies could be represented and could all provide the same message.

Kautter said that information exchanges with the FBI are not a problem at FDA, which has numerous people with the necessary clearances. Ackelsberg noted that New York City has people with the necessary security clearances. Furthermore, based on the relationships built over the years, city officials would be confident that they would be told of a threat regardless of their security clearances. Gibson, however, was less confident that his agency would get the information it needs as they prepare for the 2012 Super Bowl in Indianapolis, partly because the law enforcement and health care communities do not necessarily understand the needs and role of public health.

FIFTH MOVE

In the fifth and last move, no signs of contamination are found in the processing, packaging, and distribution systems. Instead, the source of contamination turns out to be a particular farm. Meanwhile, investigators determine that terrorism is very unlikely.

USDA has sources of information involving plant and animal production systems, said Annelli, but it does not necessarily have the authority to investigate these systems unless the cattle are shedding *E. coli* into water supplies, said Annelli. USDA may have the expertise, but it also may need to exercise that expertise under someone else's authority, such as FDA or CDC. USDA also would be working with state agricultural counterparts who have local expertise. For example, it has a veterinary assessment team that could look at farm sites and perhaps do some sampling to locate the organism and the route of contamination. Gibson observed that county public health directors have remarkable amounts of authority in cases where there is a threat to public health. If experts indicate that something needs to be done, "there is huge power at the county health director level," he said.

Braden pointed out some of the complications with bean sprouts, which are sprouted in facilities from seeds that often come from overseas and are not considered a food. The first part of the investigation would go to the sprouting facility, and FDA would probably be leading that investigation with its local counterparts. But experience would suggest that the seeds were actually contaminated before coming into the facility. In response to a question about how information is communicated up the chain of command at an agency, Braden said that information is communicated in many different ways. Multiple reports would come out of the emergency operations center for different audiences. During conference calls with other investigators the information will be more detailed, but information is summarized for reporting up the chain of command. Russell described the need to make information "pertinent and actionable." He added that compiling exact numbers for an outbreak can become counterproductive as time goes on, and agency personnel may need to resist the demand for numbers from authority figures.

Kautter said that FDA and its state and local counterparts would be taking samples of the water, the seeds, and the final sprouts. If the trace-back pointed to a specific facility, investigators would determine what other products that facility was producing that could be contaminated. Once a

particular sprouting firm was identified, recall recommendations would be issued for products, including other products made at that facility.

Quitugua noted the difficulty in some episodes of tracking the many kinds of information that are relevant. Agencies may craft exactly what they want to say, but as that information gets aggregated and summarized, the underlying messages can change.

Ackelsberg noted that a very similar process would be occurring at the state and local level as at the federal level. Jurisdictions would establish incident command centers so that they would be able to gather information and respond to questions as best as they can. Formal communications would be going up and down command structures, with informal communications across agencies. Public messaging would be a major focus with a disease like this that is contagious and can cause secondary infections. State and local public health departments would be working with their partners to find the source of the outbreak and stem its spread as quickly as possible.

Ackelsberg reiterated that a biosurveillance system already exists—at the local, state, and national levels—and it is being used every day. "This isn't the time to start reducing the capacities of these systems that have been built up over the last 10 years with great investment. We are doing good work. That often goes unseen because it is just what we do every day."

6

Concept of Operations

In the final session of the workshop, four speakers presented elements akin to a concept of operations—or CONOPS—for the Department of Homeland Security's National Biosurveillance Integration Center (NBIC), based in part on their analysis of the preceding discussions. Each presented a slightly different view, providing a multidimensional perspective. In this way, they were able to summarize and highlight some important points made from the previous day and a half of presentations and discussion, as well as add their own expertise to the issues.

A FOCUS ON PERFORMANCE IMPROVEMENT[1]

As standardized by the Institute of Electrical and Electronics Engineers, a CONOPS document has seven components, said Leslie Lenert, University of Utah School of Medicine:

1. Scope
2. Reference documents
3. Current system or situation
4. Justification for and nature of changes
5. Concepts for the proposed system
6. Operational scenarios
7. Summary of impacts

[1]This section is based on the presentation by Leslie Lenert, University of Utah School of Medicine.

Though NBIC was created in 2004, it has not yet developed the system specifications defined in a CONOPS document. It needs to do so, said Lenert, for several reasons.

First, a CONOPS would define the National Biosurveillance Integration System (NBIS) within which NBIC operates. The workshop uncovered a great deal of information about how agencies communicate with each other, but it did not reveal a game plan for how NBIS operates. "We need an overall strategy for that," said Lenert.

Second, a CONOPS would define the strategy with which NBIC adds value to NBIS. NBIC can add value in many different ways, said Lenert, but it needs to demonstrate its ability to do so.

Third, a CONOPS would define the rules of engagement of NBIC when using other participants' data. Given that trust is essential in the communication of biosurveillance data, the rules of engagement need to be clear. "If the releases of information and the political perspectives aren't represented within the concept of operations, the trust won't exist and the information won't flow."

Finally, a CONOPS would define the information products NBIC produces. In turn, these information products would determine the usefulness of NBIC.

Goals and Outcomes

The goal of NBIS was to create a system where all relevant information was collected into a central fusion center, Lenert observed. There the information would be analyzed, producing a common operations picture that can inform decisions in partner agencies and the National Operating Center. This solution was largely based on technology, according to Lenert. The largest investments were in elaborate information systems that were supposed to integrate information. But the problem was not technological, said Lenert. It was "a communications and a trust problem across different organizations."

The authorizing legislation for the Implementing Recommendations of the 9/11 Commission Act of 2007 established the primary mission of the NBIC as follows:

> To enhance the capability of the Federal Government to (A) rapidly identify, characterize, localize, and track a biological event of national concern by integrating and

> analyzing data relating to human health, animal, plant, food, and environmental monitoring systems (both national and international); and (B) disseminate alerts and other information to Member Agencies and, in coordination with (and where possible through) Member Agencies, to agencies of State, local, and tribal governments, as appropriate.

However, the legislation did not empower NBIC to work top down to organize NBIS as an information supply chain. Agencies were to participate voluntarily in the NBIC subject to memoranda of understanding. Funds were provided for the data center and administrative staff but not for the subject-matter experts from the agencies, so agencies were paying for their own people to be detailed. As a result, said Lenert, "agencies had to pay to send their data to NBIC, which created a set of disincentives. . . . But NBIC persisted in operating in this way because of its mission authority from Congress."

The situation today is problematic, Lenert said. NBIC is out of the loop of early information flows. It receives only final information products from partner agencies, does not have unique independent data sources, and has inadequate expertise and authority. An analysis of the Food and Drug Administration's and the Department of Agriculture's emergency operations plans reveals that NBIC has little or no role in the agencies' operations. And NBIS governance has been ineffective in helping NBIC achieve its aims.

Trust issues also have hampered the NBIC's mission, Lenert noted. He quoted the Government Accountability Office's (GAO's) 2009 investigation: "A related issue that came to light during the tabletop exercise and was a theme in interviews with NBIS officials is the extent to which NBIS partners trust NBIC to use their information and resources appropriately. According to the exercise after-action memo, participants repeatedly raised concerns about trusting NBIC with data, and participants also expressed concern that NBIC would reach the wrong conclusions or disseminate erroneous data or reports" (GAO, 2009).

Three Solution Models

Lenert described three possible solution models, which he summarized as follows:

1. Leadership: Empower NBIC to lead NBIS in a top-down fashion through Presidential leadership and "mission-based" funding to support systems integration with agencies.
2. Service: Change the focus of NBIC to that of being a service organization supporting the NBIS partners' data fusion activities.
3. Performance Improvement: Refocus NBIS/NBIC on curation of knowledge and information from evolving events for system monitoring and performance improvement.

Lenert expressed some skepticism that the leadership model would work. The problem is cultural, and forcing the culture to change will be very difficult. "I would ask you to dismiss this solution from the beginning based on what we have heard."

The second model is more plausible but raises the question of whether NBIC has the resources to serve this role. NBIC would have to create the information services and incentives for effective collaboration, with state and local officials also involved. In addition, other agencies have or would need data fusion centers, which would need to communicate with each other. "There is not enough money to do this in the current budget," Lenert concluded.

The third model is the most innovative. It posits that NBIC could be a source of ground truth. It could capture and save the information state of each participating agency in NBIS on a daily basis, help other people monitor processes, find when processes are going astray, and alert the appropriate management. In essence, it could produce a metadata picture of the response process that would make it possible to identify process failures and communications, retrace the steps of diagnostic errors, and bring new people up to speed. Because it is outside the different communication chains, it could play the valuable role of improving performance for the whole system. "There is a role within its budget for NBIC as a curator of knowledge and information for performance improvement."

NBIC cannot know all of the facts, Lenert concluded. It is a myth, he said, that all of the data can be gathered into a single place to achieve a God-like view. But NBIC could make sure that things are working according to plan and could fulfill its congressional mandate through improving the performance of the biosurveillance system.

OPERATIONAL AND ORGANIZATIONAL IMPACTS[2]

William Stephens, Tarrant County, Texas, Advanced Practice Center, elaborated on the changes that the model proposed by Lenert would accomplish. He, too, started by defining what a CONOPS provides:

- An analysis that bridges the gap between operational needs or visions and the system developer's technical specifications.
- Documentation of a system's characteristics and operational needs in a manner that can be confirmed by the user without requiring any technical knowledge.
- Documentation of desires, visions, and expectations without requiring the provision of quantified, testable specifications until later in the system life cycle.
- Opportunity for quality improvement on business processes to satisfy new needs, as well as providing flexibility for satisfying anticipated business drivers.
- A mechanism to express thoughts and concerns on possible solution strategies, to record design constraints and the rationale for those constraints, and to indicate the range of acceptable solution strategies.

Stephens focused on the fourth item in this list: the opportunity for quality improvement to satisfy not only current needs but new needs. The revised system, from this perspective, would function primarily as a quality improvement engine to collect information in a central repository to capture the sequence of events, the timing of decisions, and response outcomes for system and provider utilization and improvement plans. Quality improvement is a comprehensive and quantitative way of establishing system definitions and then changing the system continuously in response to feedback, Stephens explained. "It is something that you build into your systems so that everything you do has a constant evaluation piece in [it] to see if it is meeting the objectives." This evaluation mechanism is then used to improve the system to achieve the objectives more effectively.

[2]This section is based on the presentation by William Stephens, Tarrant County, Texas, Advanced Practice Center.

Operational Impacts

Stephens highlighted six operational impacts of the proposal:

Changes in procedures. Changes in procedures could provide detection and identification processes with earlier, less refined data that are shared with other stakeholders for appropriate mobilization. Information does not need to be perfect, but it needs to move with the event as more is learned. Multidisciplinary teams are needed for data collection and communication, with collaboration on common objectives and messages throughout the response. The ultimate outcome is quality improvement to achieve NBIC's mission, said Stephens.

Use of new data sources. State and local health department data are critical, and these data depend on the people at the state and local levels. Decisions that are being made at the top level need to flow down to state and local health departments in a timely fashion. Laboratory data are often a leading indicator, and the investigation process is often accelerated by the flow of these data. But much larger quantities of data will be involved in the future—hundreds of terabytes.

Changes in quantity, type, and timing of data to be input into the system. The same data need to be shared with all partners and stakeholders. While some data sets may be translated into metadata for better understanding, there needs to be consistency across the different layers and the different agencies that are sharing data. Data need to add value to keep people engaged.

Changes in data retention requirements. Security needs to be a critical part of data acquisition, storage, and transmission. For example, many data providers are already dealing with this issue on a daily basis because of Health Insurance Portability and Accountability Act and Health Information Technology for Economic and Clinical Health provisions.

New modes of operation based on emergency, disaster, or accident conditions. The new system could be prototyped using data and experiences from regions with mature systems such as Marion County, Allegheny County, or Tarrant County. Stakeholder data structures that are already in place could be refined and adapted for expansion on a national basis. In this learning lab model, best practices and ideas are developed,

refined, and evaluated over any time from 1 to 3 years. "This could be a very good and effective model for developing the next phase of the NBIS and NBIC," Stephens said.

Changes in operational budget. Budgets may increase but should be tied to a strategic plan and be justified by risk-benefit or return-on-investment models. Collaborative funding will be very important.

Organizational Impacts

Stephens briefly described three organizational impacts:

Modification of responsibilities. There needs to be improved definition of a recognized and respected oversight agency for biosurveillance to accelerate planning and implementation of meaningful data sharing and decision processes. This requires leadership, said Stephens, that recognizes the importance of doing things differently.

Addition or elimination of job positions. Overlapping or redundant positions at higher level agencies may be eliminated to improve decision processes while resources increase for investigative and response roles.

Training or retraining. Cross-training will be needed within and across agencies for continuity of operations. This will help build a human capital system that provides a broad base of expertise for interagency teams.

Stephens concluded that crafting a CONOPS for NBIC oriented around quality improvement provides enough positive impacts to move forward. "Despite some of the challenges that it will represent, it gives a strong motivation for proceeding this way."

OPERATIONAL REALITIES[3]

Today's biosurveillance system is built on several assumptions, said biodefense consultant Bob Kadlec. The first is that relevant data exist in the public health, medical, food, veterinary, and environmental arenas.

[3]This section is based on the presentation by Bob Kadlec, Biodefense Consultant.

Second, the data are readily accessible. Third, the data can be shared. Fourth, sharing would benefit the involved disciplines, agencies, and departments. And, fifth, NBIS would be a "sharing place" for biosurveillance data.

Each of these assumptions turned out to be at least partially mistaken, Kadlec observed. First, the relevant data often do not exist. "Oftentimes what you want is not what you are going to get, and what you need is not going to be available." Furthermore, the data may not be available in a timely fashion. Epidemiology does not occur in real time. It is retrospective and based on collections of data that take time to assemble.

Agencies have an obligation to ensure that the information they provide is correct, which involves checking who collected and analyzed the data and how they were verified. More substantively, agencies do not want high-impact decisions to be made based on preliminary information. Thus, agencies are unlikely to share raw information. "A bureaucratic impediment is that knowledge is power," said Kadlec, and "it impacts our budget."

An additional complication is that the data do not necessarily reside in the federal government. They can reside at the state and local levels or in the private sector.

Operational Considerations

A CONOPS for NBIC needs to take national security considerations into account, said Kadlec. During a conflict, leaders rarely have clarity about what is happening. Reports from the field are generally wrong, and the "fog of war" distorts and obscures reality. Furthermore, even the simplest things are hard to do in a crisis. The reason the military tries to simplify its activities or decisions is that simple actions are much more likely to be executed successfully.

Increasing the speed of analysis increases the risk of overlooking the obvious. When a system is pressured to produce information that is only partly analyzed, mistakes are more likely.

With public health issues, decisions can quickly be elevated to the highest levels of government. Public health is increasingly considered a national security issue, and national security information is expected to be accurate and timely. Yet these characteristics are rarely available in an epidemiological investigation.

Kadlec described what he called the OODA loop, which is an acronym for "observe, orient, decide, and act," and is a process used by military pilots to continually assess their environment as an influence in decision-making. For the U.S. government, the cycle time of the OODA loop is defined by the media. The government attempts to get ahead of a story and set policy before the media send the public in a different direction. Also, the orientation phase of an OODA loop involves existing cultural traditions, bureaucratic procedures, previous experiences, and other factors, some of which act in opposition to information that is currently coming in. Often this orientation is done by people who are not familiar with epidemiology or other factors involved in biosurveillance, particularly relevant to new information, which can lead to faulty decisions.

National security decision makers have a distinct set of priorities, according to Kadlec. They need to be in control or at least appear to be so, since it is bad politics to appear disengaged or uninformed. They need to stop the suffering, bleeding, and dying, because the people being affected "are all registered voters," Kadlec said. They need to prevent future attacks or incidents. And they need to convey reassurance and confidence, which in turn breeds public comfort and financial market stability.

Catastrophic bioterrorism poses an immense challenge, Kadlec concluded. The 2001 anthrax attacks caused 22 illnesses and 5 deaths. An aerosol release over an American city could cause half a million illnesses, with a substantial portion of those people dying, and incur costs of trillions of dollars. Decision makers would have to respond quickly and effectively. An effective CONOPS needs to reflect these tremendous stakes.

A REGIONAL SOLUTION[4]

Integrated biosurveillance is a relatively new idea that is still diffusing into practice, said Michael Wagner, University of Pittsburgh, and the rate of diffusion depends on factors such as perceived relative advantage, compatibility, and complexity. Some ideas spread quickly and plateau, while others take a long time to catch on.

The rate of diffusion also depends on the social structure in which an innovation is appearing. In the case of NBIC, 12 federal agencies are

[4]This section is based on the presentation by Michael Wagner, University of Pittsburgh.

involved that are expected to share information. These 12 agencies are situated within a much broader governmental context that includes not just other parts of the federal government but state and local governments. Government itself is situated with the broader health care system, food and water distribution systems, and so on. "It is no big shock that diffusion has taken as long as it has," said Wagner.

Biosurveillance requires a focal point and authority if it is going to happen, according to Wagner. These attributes were available in the Manhattan Project and the Apollo Project, but they are not in the case of biosurveillance. Also, the people who know how to build such a system work largely in informatics and in the health care system, and these people for the most part have not been involved.

A Regional Focus

As described by the previous speakers, a CONOPS involves describing the limitations of the existing NBIC, which include the fact that agencies are not sending data to NBIC. A CONOPS also involves proposed concepts for the system being analyzed, which requires a description of the modified system and of the motivation for change.

With the CONOPS process in mind, Wagner proposed that a biosurveillance data integration center should function as a regional data integration center for one or two cities, counties, or states. It also could have a repository function at a national level, but that would depend on the resources available. Focusing on a regional level would enable solutions to be developed for many of the technical problems of data integration. Which other systems would be involved also could be worked out. Finally, it could provide an example of what could be realized at the federal level if resources were devoted to the task. "Integrated biosurveillance is a massive data and knowledge integration problem," said Wagner. "We can make the most progress toward solving it if we focus on one city."

DISCUSSION

During the discussion period, Braden observed that many of the data analyzed as part of biosurveillance are created on the fly. Some data sources are constant and can be monitored, he said, but "a lot of the data that we need at CDC we have to create de novo at the local level, at the state lev-

el, or at our level." As a result, it is difficult to do quality improvement on the data collection and analysis system because no such system exists. In addition, data should be analyzed by the people in the best position to do so, after which the results of that analysis should be available to others. "It is not just that the data resides here and is owned there. It is a matter of expertise of handling the data."

In response, Lenert suggested using a framework of "data, information, and knowledge" to analyze these activities. Tracking the state of knowledge of agencies is easiest; tracking the state of information takes more work; and understanding raw data may be very difficult. Kadlec added that, in a crisis, experienced analysts of data are in very high demand but are distributed, and ways need to be found to bring together their expertise. This is the purpose of the biological assessment threat response (BATR) process, which Hepburn described as an iterative interagency process to arrive at a decision about what should happen next. The BATR process is not biosurveillance, he added, but rather is designed to produce decisions.

Ackelsberg reiterated the idea that data need to be collected, analyzed, and converted to information at the local level so the best knowledge possible can be provided to those who need to make decisions. For that reason, fusion centers are just as useful at the local level as at the federal level. Maillard, too, observed that local public health departments create the instruments needed to gather data on the fly and share information with others rather than raw data.

Gibson asked whether the high-level knowledge being created by NBIC would be of use at the local level, and Wagner asked in response whether Marion County would benefit from the kind of information, including intelligence information, that an NBIC working closely with the county could provide. Gibson agreed that more data would help in preparing for the 2012 Super Bowl. In general, he said, additional data provide new and often unanticipated capabilities. "With syndromic surveillance, we never expected it to be valuable in detecting things, but it has proven to be valuable in a lot of different ways that makes it worth doing every day."

Ashkenazi pointed out that decisions depend on perceptions, understanding, and prediction. About 80 percent of leadership mistakes, he said, are because of perceptions. Too much information can lead to a cognitive overflow that skews perceptions. And people have a tendency to rely on computers to make perceptions, but computers have no ability to do that. Lenert mentioned as well the cognitive flaw of thinking that a

given situation is similar to a past situation, which is where perception and knowledge can go astray.

Tan observed that data emerge from different systems and with different speeds and have different levels of reliability. When data are shared, the uncertainties associated with those data need to be shared as well.

Annelli said that gaps in information sharing need to be identified before they can be filled. During this process, one question that must be asked is whether a gap exists because an existing system broke down. Addressing that question would help determine the need for CONOPS in different agencies.

Wagner replied that it is not yet clear what data need to be collected. Until people have a chance to build an end-to-end system that leads from data to decisions, the necessary links will not be fully known.

Ackelsberg also emphasized the possibility of catastrophic events—a "bio-Katrina type of situation." The needs in such a situation would be extraordinarily different. "I don't think any local entity, any local jurisdiction, or any combination of the agencies in a local setting is going to be able to immediately address the analytic requirements for that." The analytic capacity still needs to be built at the local level to assess what would be needed in such a situation.

Finally, Sally Phillips, Department of Homeland Security, thanked the speakers and workshop participants for their contributions. The challenges are enormous, she said, not only in structuring a biosurveillance system but in funding it. But "we have learned a lot of lessons today and yesterday, and we have some great ideas on the table and some good analysis." Biosurveillance is needed, she said. People already use on a daily basis the information that exists, and decision makers crave more information. "We need to figure out what is the next step" while keeping the ultimate goal in mind, she said, "because this is certainly going to be longer than a short-haul fix."

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A

Workshop Agenda

20 F Conference Center
20 F Street NW
Washington, DC 20001

DAY 1 – SEPTEMBER 8, 2011

8:00 A.M. Check-in and Registration

8:30 Opening Remarks

William Raub, *Retired, Senior Advisor to the Secretary, Department of Health and Human Services*
Scott Mugno, *Managing Director of Corporate Safety, Health, and Fire Prevention, FedEx Express*

8:50 **PANEL: CHALLENGES AND EXPERIENCES IN MEDICAL READINESS AND RESPONSE—OPPORTUNITIES FOR BIOSURVEILLANCE**

Situational Awareness in the H1N1 Pandemic

Stephen Redd, *Director, Influenza Coordination Unit, Centers for Disease Control and Prevention*

Q&A with Dr. Redd

9:20 **Biological Preparedness and Response in New York City**

Joel Ackelsberg, *NYC Department of Health and Mental Hygiene Bureau of Communicable Diseases*

Coordinating Animal Health Actions Across the Human-Animal Interface

Jere L. Dick, *Associate Deputy Administrator and Chief of Field Operations*, *Animal and Plant Health Inspection Service Department of Agriculture*

10:00 Q&A moderated by **Merrie Spaeth,** *President, Spaeth Communications*

10:30 **BREAK**

10:50 Introduction to Panels on Models of Information Sharing and Collaboration

Scott Mugno

11:00 **PANEL: MODELS OF INFORMATION SHARING AND COLLABORATION**

Biosurveillance in North Carolina

Jean-Marie Maillard, *Medical Director, North Carolina DHHS, Communicable Disease Branch*

Keeping Pace with Data Collections in a Rapidly Changing Environment

Peter Purcell, *Senior Associate Director, Division of Banking Supervision and Regulation, Federal Reserve*

Integrating Complex National Missions: National Counterterrorism Center

Robert Kravinsky, *Defense Policy Analyst, Office of the Secretary of Defense for Policy; Study Director, Project on National Security Reform*

12:00 P.M. Discussion moderated by **Mark E. Teachman,** *Director, Interagency Coordination, National Center for Animal Health Emergency Management, Anima and Plant Health Inspection Service, Department of Agriculture*

12:30 **LUNCH**

1:30 **PANEL: MODELS OF INFORMATION SHARING AND COLLABORATION**

Health Department Experiences in Seeking Access to Surveillance Data

P. Joseph Gibson, *Director of Epidemiology, Health & Hospital Corporation of Marion County, Indiana*

Psychology and Sociology of Information-Sharing: Israeli Experience

Isaac Ashkenazi, *Former Surgeon General, Home Front Command, Israel; International Expert for Crisis Management & Leadership; Director, Urban Terrorism Preparedness, NPLI, Harvard University*

2:10 Discussion moderated by **Lisa Gordon Hagerty,** *President, LEG Incorporated*

3:00 **BREAK**

3:15 **SCENARIO: DISEASE OUTBREAK OF UNKNOWN ORIGIN**

Moderated by **William Raub**

Panelists

Joseph F. Annelli, *Senior Advisor for Agriculture and Health Systems, Animal and Plant Health Inspection Service, U.S. Department of Agriculture*

Christopher R. Braden, *Director, Division of Foodborne, Waterborne and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention*

Cory Bryant, *Policy Analyst, Office of Food Defense, Communication, and Emergency Response, Center for Food Safety and Applied Nutrition, Food and Drug Administration*

Selwyn R. Jamison, *Program Manager, Bioterrorism Prevention WMD Directorate, Federal Bureau of Investigation*

Donald Kautter, *Supervisory Consumer Safety Officer/CORE Prevention Director, Center for Food Safety and Applied Nutrition***,** *Food and Drug Administration*

Teresa Quitugua, *Acting Director, National Biosurveillance Integration Center, Department of Homeland Security*

Kevin L. Russell, *CAPT, U.S. Navy, Director, Armed Forces Health Surveillance Center, Department of Defense*

Regina Tan, *Director, Applied Epidemiology Division, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture*

5:00 Discussion moderated by **William Raub**

5:30 **ADJOURN**

DAY 2 – SEPTEMBER 9, 2011

8:30 A.M. Welcome and Overview of Day 1

William Raub, *Retired, Senior Advisor to the Secretary, Department of Health and Human Services*

Scott Mugno, *Managing Director of Corporate Safety, Health, and Fire Prevention, FedEx Express*

8:40 **SCENARIO, CONTINUED: DISEASE OUTBREAK OF UNKNOWN ORIGIN**

Moderated by **William Raub**

Panelists

Joseph F. Annelli, *Senior Advisor for Agriculture and Health Systems, Animal and Plant Health Inspection Service, U.S. Department of Agriculture*

Christopher R. Braden, *Director, Division of Foodborne, Waterborne and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention*

Selwyn R. Jamison, *Program Manager, Bioterrorism Prevention WMD Directorate, Federal Bureau of Investigation*

Donald Kautter, *Supervisory Consumer Safety Officer/CORE Prevention Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration*

Teresa Quitugua, *Acting Director, National Biosurveillance Integration Center, Department of Homeland Security*

Kevin L. Russell, *CAPT, U.S. Navy, Director, Armed Forces Health Surveillance Center, Department of Defense*

Regina Tan, *Director, Applied Epidemiology Division, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture*

10:00 **BREAK**

10:30 Discussion with **Matthew Hepburn,** *Director, Medical Preparedness Policy, White House National Security Staff*

10:50 Introduction to CONOPS Panel: Guidance for Biosurveillance

William Raub

11:00 CONOPS Panel: Guidance for Biosurveillance

Moderated by **William Raub**

Panelists

Robert Kadlec, *Vice President, Global Public Sector, PRTM Management Consultants*

Leslie Lenert, *Professor of Medicine and Biomedical Informatics, Department of Medicine, University of Utah School of Medicine*

William Stephens, *Manager, Southwest Center for Advanced Public Health Practice, Tarrant County Public Health*

Michael M. Wagner, *Associate Professor of Biomedical Informatics and Intelligent Systems, Department of Biomedical Informatics, University of Pittsburgh*

12:00 P.M. Open Discussion

Moderated by **William Raub** and **Scott Mugno**

1:00 **ADJOURN**

B

Speaker Biographies

Joel Ackelsberg, M.D., M.P.H., is a medical epidemiologist and Bioterrorism Surveillance Coordinator for the New York City Department of Health and Mental Hygiene's (NYC DOHMH's) Bureau of Communicable Disease (BCD). After completing the Centers for Disease Control and Prevention's (CDC's) Epidemic Intelligence Service (EIS) in 2000, Dr. Ackelsberg came to NYC DOHMH as Medical Director of the Emergency Readiness and Response Unit, which coordinated key aspects of the agency's biological emergency preparedness and response planning. At various times during the past decade, he has overseen development and evolution of NYC DOHMH's Health Alert Network; hospital public health emergency preparedness activities; surveillance and epidemiologic response planning for biological emergencies locally and regionally; planning and readiness for joint investigations with local and federal law enforcement of suspected or confirmed biological threat agent incidents; and coordination of biodetection (e.g., BioWatch) activities, including management of projects that specifically addressed biosecurity in the NYC subway and commuter rail systems. These activities have included significant participation in interagency efforts to coordinate planning at all government levels. Most recently, Dr. Ackelsberg has coordinated the development of NYC DOHMH's biological threat agent response plan, including biological incident and functional annexes. Dr. Ackelsberg has taken part in all NYC DOHMH emergency responses to suspected or confirmed biological incidents over the past decade, including anthrax, severe acute respiratory syndrome (SARS), and pandemic influenza. He is a member of NYC's Joint Terrorism Task Force. Dr. Ackelsberg received his medical and public health degrees

from Tufts University in Boston, Massachusetts. He completed an internal medicine residency at Temple University Hospital, Philadelphia, Pennsylvania, and followed that with subspecialty training in infectious diseases at the University Medical Center/Cooper Hospital in Camden, New Jersey. He completed his 2-year EIS fellowship with the New York State Department of Health (Albany, New York) in its Bureau of Communicable Disease Control.

Joseph Annelli, D.V.M., M.S., is currently the Senior Advisor for Agriculture and Health Systems, or "One Health Coordinator" for short, located in the Office of the Deputy Administrator for Veterinary Services (VS) at the Department of Agriculture (USDA), where he leads their One Health Coordination Office and assists VS and USDA in implementing the One Health principles of applying an interdisciplinary approach and joint strategies to resolve issues at the human-animal-ecosystem interface to improve both human and animal health. The core of Dr. Anelli's work involves providing senior level leadership and coordination for USDA, the Animal and Plant Health Inspection Service (APHIS), and VS's One Health Working Groups. These working groups are responsible for coordinating strategic policy, plans and actions for all USDA agencies and offices as they relate to the interrelationships of the human-animal-ecosystem interface and its impact on agriculture and public health. Prior to this, Dr. Annelli was Director of Emergency Programs for VS when he and his staff activated National Disaster Medical System resources to assist in an avian influenza outbreak in Virginia and deployed 350 veterinarians to the United Kingdom to assist with a major foot and mouth disease outbreak. He was also instrumental in rewriting ESF-11 of the National Response Plan to include care of pets in disasters. At the beginning of the global concerns for highly pathogenic H5N1 avian influenza and the possibility of an emerging pandemic, Dr. Annelli was detailed to the Office of the Secretary as liaison to the White House Homeland Security Council on Avian Influenza issues for USDA, and also served as Director of the International Avian Influenza Coordination Center before returning to VS in his current position. He was ideally positioned to continue in this role through the 2009-H1N1 influenza pandemic, building upon the networks and partnerships developed through the National Strategy for Pandemic Influenza and the response to highly pathogenic H5N1 avian influenza. Dr. Annelli attended veterinary school at Araneta University in the Philippines and completed his studies at the University of Tennessee in Knoxville and received his second master's degree in

veterinary epidemiology and public health at the University of Minnesota. His first master's degree is in ecology and oceanography from Long Island University's C.W. Post Campus in Greenvale, New York.

Isaac Ashkenazi, M.D., is an international expert on disaster management and leadership, community resilience, and mass casualty events with both extensive professional and academic experience. He is considered one of the world's foremost experts in medical preparedness for complex emergencies and disasters. Dr. Ashkenazi is the Director of the Urban Terrorism Preparedness Project at the National Preparedness Leadership Initiative, Harvard School of Public Health, a joint program of the Harvard School of Public Health and Harvard Kennedy School of Government. He is also a Professor of Disaster Medicine at Ben-Gurion University in Israel and a consultant to Harvard University, CDC, the U.S. Department of Health and Human Services (HHS), the U.S. Department of Homeland Security (DHS), and other national and international agencies. Dr. Ashkenazi is the former head of the Medical Services and Supply Center for the Israeli Defense Forces (IDF) and served as the Surgeon General for the IDF Home Front Command. He received his M.D. degree, summa cum laude, from the Hebrew University in Jerusalem and, in 1982, Dr. Ashkenazi volunteered to the paratrooper forces in the IDF as a military doctor. After 4 years of intensive military training, treating wounded soldiers and working under fire, Dr. Ashkenazi started his residency in ophthalmology at Sheba Medical Center. In 1992, he received a license to practice ophthalmology, from the Israeli Medical Association. One year later, he received his M.Sc. in ophthalmology, summa cum laude, from the Faculty of Medicine at Tel-Aviv University. In 2000, he went on a sabbatical to Boston, Massachusetts, where he received an M.P.A. (master of public administration) from the John F. Kennedy School of Government at Harvard University. Subsequently he received a master's degree (summa cum laude) in national security from Haifa University. Over the past 20 years, Dr. Ashkenazi has become increasingly interested in disaster management and has served in humanitarian missions in Asia, Africa, South America, and Europe. He has given courses in disaster medicine, disaster management, crisis leadership, urban terrorism, preparedness and response for mass casualty events, and individual and community resilience. He has published more than two hundred papers in medical and scientific journals, and presented his work in the United States, South America, Africa, Europe, Asia, and Middle East countries. In the last 15 years, Dr. Ashkenazi

has received Presidential Medals of Honor for Humanitarian Assistance from Turkey and Greece; the President of Rwanda; the Jewish Community in France, Turkey, Italy, and the United States; and the UJC.

Christopher Braden, M.D., is a medical epidemiologist at the Centers for Disease Control and Prevention (CDC). He currently serves as the Director, Division of Foodborne, Waterborne and Environmental Diseases. Previously, Dr. Braden has served as the Associate Director for Science in the Division of Parasitic Diseases, and Chief, Outbreak Response and Surveillance within the Enteric Diseases Epidemiology Branch, Division of Foodborne, Bacterial and Mycotic Diseases. Dr. Braden also served as a medical epidemiologist in the Division of Tuberculosis Elimination. Dr. Braden earned his B.S. at Cornell University and M.D. at the University of New Mexico School of Medicine. He completed his internship and residency in internal medicine then fellowship in infectious diseases at Tufts New England Medical Center in Boston, Massachusetts. He went onto become an Epidemic Intelligence Officer at CDC in 1993. He is a commissioned officer in the U.S. Public Health Service, a member of the American Society for Microbiology, and an associate editor for the *Emerging Infectious Diseases* journal. His major areas of interest include molecular epidemiology of infectious diseases, infectious diseases surveillance and outbreak investigation, and national programs in food and water safety.

Cory M. Bryant, Ph.D., currently leads food defense international outreach efforts and intentional contamination regulatory development under the Food Safety Modernization Act. In 2009, he served as an outbreak response coordinator and Acting Team Leader of the Center for Food Safety and Applied Nutrition's (CFSAN's) emergency response team. Prior to joining FDA (2003-2008), Dr. Bryant held the position of Senior Research Scientist with the Institute of Food Technologists (IFT) in Washington, DC. Focus areas included scientific review, allergen cross-contamination control, and food defense. From 2000 to 2003, he served as a research investigator with International Flavors and Fragrances in Union Beach, New Jersey, where his research yielded five patents for encapsulation systems. Dr. Bryant holds B.S. and M.S. degrees in food science from Purdue University and a doctorate in food science from the University of Massachusetts. He was awarded a Certificate in International Food Law from Michigan State University in 2006.

Jere Dick, D.V.M., is the Associate Deputy Administrator (ADA) and Chief of U.S. Field Operations for the Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS). In this critical position, he leads APHIS's effort to protect, sustain, and improve the productivity, marketability, and health of the nation's animals, animal products, and biologics. Moreover, Dr. Dick plays an integral role in protecting the nation from the introduction of dangerous and costly pests and disease by cooperating closely with states, foreign governments, industry, and other organizations to ensure that APHIS fulfills its vital mission of safeguarding American agriculture. Before becoming the ADA for Field Operations, Dr. Dick served as the ADA for National Animal Health Programs and Policy (NAHPP) Staff. His responsibilities included oversight of all of VS's disease control and eradication programs. Prior to that, he served in several management positions in the eastern region, up to and including director. Dr. Dick possesses the field experience that is necessary to balance his perspectives: he has served as Area Veterinarian in Charge, Area Epidemiologist, and Field Veterinary Medical Officer in the past, as well as Incident Commander and Regional Incident Commander on two different disease eradication campaigns. Dr. Dick began his VS career as a field Veterinary Medical Officer in Helena, Montana, in 1988, after owning and operating two private veterinary practices in the State of Washington for nearly 10 years.

Joseph Gibson, Ph.D., designs and directs studies and program evaluations; designs and implements analytic systems and tools for use for the Marion County Public Health Department (MCHD) and the community; collaborates in research with faculty at several universities; and directs the Epidemiology group in similar work. His experience includes leading research teams for creating new lines of research, running a multimillion-dollar study, serving as scientific lead on a variety of projects, and creating an outcomes tracking and reporting system for disease management programs in 12 disease states for clients representing 9,400,000 lives. Dr. Gibson's areas of expertise include maternal and child health issues, access to health care among Medicaid and uninsured populations, schizophrenia, medical and pharmacy claims database analyses regarding both health care costs and utilization, and secondary data analysis. Much of Dr. Gibson's focus has been on public health informatics and preparedness. He has also developed an increasingly broad, standardized analytic system of datasets and tools within MCHD, and introduced a user-friendly analysis tool that is gaining enthusiastic use among MCHD administrators.

He has experience is programming and development of systems ranging from a real time, mainframe processing system for huge volumes of pharmacy claims to simple web-based information systems.

Lisa E. Gordon-Hagerty, M.S. (standing committee), is president and chief executive officer of LEG Inc., a consulting firm providing strategic advice and counsel in domestic and national security, global energy issues, counterterrorism, crisis and consequence management, strategic planning and assessment, and homeland security. Since 2003, Mrs. Gordon-Hagerty served as executive vice president and chief operating officer of USEC Inc., a leading supplier of enriched uranium fuel for commercial nuclear power plants. In that role, she was responsible for USEC's day-to-day operations. In 1998, Mrs. Gordon-Hagerty joined the White House National Security Council (NSC) staff, as director for combating terrorism, overseeing and coordinating U.S. government activities to deter, disrupt, prevent, and respond fully to conventional, chemical, biological, radiological, and nuclear terrorist attacks. Prior to joining the White House NSC staff, Mrs. Gordon-Hagerty served for 6 years as the U.S. Department of Energy's (DOE's) Director, Office of Emergency Response, leading efforts for emergency preparedness and technical/operational emergency response to all radiological or nuclear events, and as Acting Director, Office of Weapons Surety, responsible for the safety and security of the country's nuclear weapons program. Prior to DOE, she served as a professional staff member of the U.S. House of Representatives, Committee on Energy and Commerce. Mrs. Gordon-Hagerty began her professional career as a physicist at the Lawrence Livermore National Laboratory. Mrs. Gordon-Hagerty holds a master's degree in health physics and a bachelor of science degree, both from the University of Michigan, Ann Arbor. She serves as a Director of Independence Federal Savings Bank, Federation of American Scientists and Boys and Girls Club of Greater Washington, DC. She is a member of the Council on Foreign Relations, Advisory Board of Scripps Institution of Oceanography, Economic Club of Washington, DC, and Washington Institute of Foreign Affairs. Mrs. Gordon-Hagerty has been named to *Fortune* Magazine's "Most Powerful Women" in 2004, 2005, and 2006.

Matthew Hepburn, M.D., is an active duty U.S. Army infectious diseases physician, currently serving on detail to the National Security Staff. Dr. Hepburn's prior assignments have included two assignments at the United States Army Medical Research Institute of Infectious Diseases

(USAMRIID) directing domestic and international clinical studies, Chief Medical Officer at Level II clinic in Camp Taji (Iraq), and liaison officer to Defence Science and Technology Laboratories (United Kingdom). Prior to these assignments, Dr. Hepburn was stationed at Brooke Army Medical Center at Fort Sam Houston Texas for residency training in internal medicine, chief residency, and fellowship training in infectious diseases. Dr. Hepburn received his medical degree from Duke University.

Selwyn Jamison is currently serving as the Program Manager for Bioterrorism Prevention in the Weapons of Mass Destruction Directorate of the Federal Bureau of Investigation (FBI). He provides the FBI position during Interagency Policy Committee (IPC), subIPC, and working group level meetings and ensures their equities and interests are represented. He comes to the FBI from Science Applications International Corporation (SAIC) where he provided subject matter expertise, thought leadership, and strategic planning to support a wide range of actions in support of the Defense Threat Reduction Agency (DTRA) primarily in the area of national nuclear weapons accident and incident response policy, planning, requirements, training, and interagency coordination, with specific expertise in Combating Weapons of Mass Destruction (CWMD). Prior to that position he served over 20 years in the U.S. Army.

Bob Kadlec, M.D., spent 26 years as a career officer and physician in the U.S. Air Force serving in several senior positions in the White House, the U.S. Senate and the Department of Defense (DOD). Most recently, Dr. Kadlec served as the Special Assistant to the President and Senior Director for Biodefense Policy on the Homeland Security Council. He also served as staff director for Senator Richard Burr's subcommittee on bioterrorism and public health in the 109th Congress. In this capacity, he was instrumental in drafting the Pandemic and All-Hazard Preparedness Bill that was signed into law. Dr. Kadlec also previously served at the White House from 2002 to 2005 as a director for biodefense on the Homeland Security Council where he was responsible for conducting the biodefense end-to-end assessment, which culminated in drafting the National Biodefense Policy for the 21st Century. Dr. Kadlec holds a bachelor's degree from the United States Air Force Academy, doctorate of medicine, and master's of tropical medicine and hygiene from the Uniformed Services University of the Health Sciences and master's degree in national security studies from Georgetown University.

Donald Kautter, Jr., M.S., began his career as a project microbiologist at the National Food Processors Association, (NFPA). His government career began 16 years ago with the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN), where he held several positions. In his first, as a Consumer Safety Officer, Mr. Kautter provided technical support to the Division of Field Programs Director in establishing hazard analysis and critical control points (HACCP) concepts in Agency programs; provided technical assistance in the development of model HACCP systems for Agency programs, initiatives, and regulations; technical support for the Agency in food microbiology and thermal processing policies, standards, procedures, and guidelines, and acted as primary reviewer of regulatory compliance activities and microbial issues submitted to FDA. His most recent post at CFSAN was as Deputy Director, Office of Compliance (OC), where he also served as one of the focal points between the Center and the field through interaction with the Office of Regulatory Affairs and the Office of Enforcements. Prior to his position in OC, Mr. Kautter served as the team leader of CFSAN's Food Defense Oversight Team, where he provided technical support in establishing food defense concepts in Agency programs; oversight and leadership in the development of vulnerability assessments for Agency programs. He was also the primary coordinator of the FDA portion of the DHS document, "National Infrastructure Protection Plan" (NIPP). He was selected to lead the FDA portion of the Federal Bureau of Investigation (FBI)/Department of Homeland Security (DHS)/Department of Agriculture (USDA) joint initiative, the Strategic Partnership Program on Agroterrorism, for its first year. In this role, Mr. Kautter collaborated with private industry and the states to assess vulnerabilities in the food supply and promote potential mitigation strategies. He left FDA briefly in 2010 for the USDA's Food Safety Inspection Service (FSIS), where he was a senior food defense analyst, in charge of numerous vulnerability assessments of FSIS-regulated foods, as well as a senior technical subject matter expert on intentional contamination of food products. He returned to CFSAN this year as CORE's Manager on the Prevention side. Mr. Kautter holds a B.S. in biology from George Mason University, and an M.S. in food microbiology from the University of Maryland.

Robert Kravinsky is a Defense policy analyst in the Office of the Secretary of Defense (OSD). Most recently he served as the Principal Director for Rule of Law and International Humanitarian Policy, providing strate-

gic direction on a broad array of national security issues including mass atrocity prevention, international criminal justice, rule of law doctrine, and promoting good governance through security cooperation. Prior to that position, he served as a Senior Advisor at a leading non-profit think tank, the Project on National Security Reform, formulating strategic direction for the project and advising on matters of national security policy. In that capacity, he led a study effort to evaluate the effectiveness of the National Counterterrorism Center's interagency planning capability. Prior to that position, Mr. Kravinsky served as the Director of Strategic Planning for Homeland Defense in OSD, overseeing homeland defense equities in the Quadrennial Defense Review, the National Implementation Plan for Counterterrorism, the National Response Framework, and other national strategies.

Leslie Lenert, M.D., is Professor of Medicine and Biomedical Informatics at the University of Utah. After completing medical school at University of California Los Angeles, Internal Medicine residency at University of Texas Southwestern Medical School, and fellowship training in Clinical Pharmacology and Medical Informatics at Stanford University, Dr. Lenert was appointed Assistant Professor of Medicine at the Stanford University School of Medicine. In 1997, he moved to University of California San Diego, where he was promoted to Professor of Medicine, and was an Associate Director of the California Institute for Telecommunications and Information Technology. In 2007, Dr. Lenert became the founding Director of the National Center for Public Health Informatics at the Centers for Disease Control and Prevention (CDC). As the head of a 650-person Center with a $110M budget, he led CDC efforts to develop national electronic disease surveillance systems and to integrate public health information systems into the Nationwide Health Information Network. In September 2010, Dr. Lenert joined the Department of Medicine at the University of Utah, where he is working to integrate population health strategies to specialty and primary care practices. The author of more than 120 publications, Dr. Lenert is currently involved in research on the informatics solutions for population health care, wireless electronic health records systems for first responders, and patient empowerment through computers in clinical relationships. Dr. Lenert is Fellow of the American College of Medical Informatics; a past member of the Board of Directors of the American Medical Informatics Association (AMIA); a member of the editorial boards of JAMIA, the *Journal of Biomedical Informatics*, and the *International Journal of Medical Informatics*; and

has served on study sections for Agency for Health Research and Quality and the National Library of Medicine. He has won awards for his research work from the Pharmaceutical Manufacturers Association, the American Federation for Clinical Research, and AMIA.

Jean-Marie Maillard, M.D., M.Sc., joined the North Carolina Department of Health and Human Sciences' (NC DHHS's) Division of Public Health in 1992. He served as medical epidemiologist for disease control and surveillance in the Communicable Disease Branch from 1992 to 2002, then was in charge of epidemiology and surveillance capacity building from 2002 to 2008, and became director of the Medical Consultation Unit of the Communicable Disease Branch in 2008. Prior to joining the NC DHHS, he was external consultant for the World Bank in four consultations in Madagascar in 1990-1991; Regional Medical Officer in Botswana for 4 years (1986-1989), and District Medical Officer in Saint Lucia for 18 months (1983-1984). Both of these assignments were under bilateral government agreements. Dr. Maillard received his M.D. in Paris, France, in 1983, his M.Sc. in epidemiology from the London, UK, School of Hygiene and Tropical Medicine in 1992, and his North Carolina M.D. license in 1999. He is board certified in public health and preventive medicine since 2004.

Peter Purcell, M.B.A., has responsibility for Technology for the Board of Governors' Division of Banking Supervision and Regulation. Over his 35-year career, Mr. Purcell has held executive positions in technology and retail banking. He started his career at the Federal Reserve Bank of Boston, where he held successive technology positions of increasing responsibility.

Teresa Quitugua, Ph.D., currently serves as the Acting Director for the National Biosurveillance Integration Center (NBIC) within the Department of Homeland Security's (DHS's) Office of Health Affairs. She leads a multidisciplinary team in coordination of interagency biosurveillance information sharing across the National Biosurveillance Integration System (NBIS) interagency community in accordance with Presidential Directives and Public Law. Dr. Quitugua previously worked as the Director of the Molecular Mycobacteriology Laboratory for the Texas Department of Health and as an assistant professor in the Department of Microbiology and Immunology at the University of Texas Health Science Center at San Antonio (UTHSCSA). In these positions, she coordinated public health

and research interactions with private and public health care providers and laboratories at city, regional, state, national, and international levels for clinical and molecular epidemiologic investigations of tuberculosis. She also directed the development of tuberculosis (TB) and Valley Fever vaccine, pathogenesis, and immunology studies; molecular TB drug susceptibility testing methods; and new TB genotyping methods. Dr. Quitugua also served as a member of the *Infection and Immunity* editorial board and as chair of the UTHSCSA Institutional Biosafety Committee. Dr. Teresa Quitugua earned her B.S. in microbiology from the University of Illinois in 1990 and her Ph.D. in microbiology from the University of Texas Health Science Center at San Antonio in 1996.

Stephen C. Redd, M.D., Rear Admiral and Assistant Surgeon General, U.S. Public Health Service, is Director of the Centers for Disease Control and Prevention's (CDC's) Influenza Coordination Unit. The unit was formed in 2006 to provide a central focus for pandemic influenza preparations at CDC. Dr. Redd was responsible for developing plans for pandemic response, exercising those plans, tracking progress in developing specific capabilities needed for an influenza pandemic, and communicating progress in these capabilities. In April 2009, shortly after the H1N1 virus was identified, Dr. Redd was appointed Incident Commander of CDC's H1N1 pandemic influenza response, providing daily direction to all of CDC's pandemic response efforts from detecting the virus through the H1N1 vaccination program. More than 3,300 CDC staff participated in the response during the 11-month activation of CDC Emergency Operations Center. Dr. Redd joined CDC in 1985 as an Epidemic Intelligence Service Officer, following clinical training. He has published widely in the control of respiratory diseases, malaria control, measles epidemiology and elimination, environmental health, and asthma. Dr. Redd has received numerous awards including the Public Health Service Distinguished Service Medal for leading CDC's pandemic response and the Charles Shepard Award, an annual award for the outstanding manuscript published by CDC authors. Dr. Redd received his undergraduate degree from Princeton University and his medical degree from Emory University. He trained in internal medicine at the Johns Hopkins Hospital and practices internal medicine at Grady Memorial Hospital and the Cherokee Indian Hospital.

Kevin Russell, M.D., graduated from University of Texas Health Science Center San Antonio Medical School in 1990; after a family practice

internship he was accepted into the Navy Undersea Medicine program. He was stationed in Panama City, Florida, at the Experimental Diving Unit where he worked in diving medicine research from 1991 to 1995. After a preventive medicine residency with a master's degree in tropical medicine and hygiene, CAPT Russell was transferred to Lima, Peru, where he became head of the Virology Laboratory. His portfolio included febrile illness (largely arboviral in origin) and HIV surveillance studies in eight different countries of South America, as well as prospective dengue transmission studies. In 2001 he moved back to the United States and became the Director of the Respiratory Disease Laboratory at the Naval Health Research Center in San Diego, California. Febrile respiratory illness surveillance in recruits of all services was expanded into shipboard populations, Mexican border populations, support for outbreaks, and deployed settings. Validation and integration of new and emerging advanced diagnostic capabilities, using the archives of specimens maintained at the laboratory, became a priority. Projects expanded in 2006 to clinical trials support as CAPT Russell became the Principal Investigator for the Navy site in the FDA Phase 3 adenovirus vaccines trial, and more recently to support the Phase 4 post-marketing trial of the recently Food and Drug Administration (FDA)–approved ACAM2000 Smallpox vaccine. In July of 2008, CAPT Russell assumed the responsibilities of Director, Department of Defense Global Emerging Infections Surveillance and Response System (DOD-GEIS), and Deputy Director, Armed Forces Health Surveillance Center (AFHSC). He is tasked with the responsibility of melding the GEIS network into the attributes of the AFHSC; his priorities have been standardization, greater affiliations with world militaries, and continuing to introduce scientific rigor into the network. CAPT Russell assumed the duties of Director, Armed Forces Health Surveillance Center in June 2011. His priorities have expanded to explore ways to provide an even more comprehensive product for the military community that the AFHSC serves.

Merrie Spaeth, M.S. (standing committee), is President of Spaeth Communications, Inc. Her background is in media, government, politics, business, and the entertainment industry. She is a pioneer in communication theory and executive training, and acknowledged as one of the preeminent crisis management strategists in the country. She founded Dallas-based Spaeth Communications, Inc., in 1987. The firm provides communication training and consulting for a wide range of companies and institutions. She is also the founder and president of the Institute for

Strategic Communications, a not-for-profit foundation devoted to studying and reporting on business communication issues. In the early 1980s, Ms. Spaeth served as a White House Fellow and worked for FBI Director William Webster. She served 2 years at the Federal Trade Commission as Director of Public Affairs, and in 1984 she served as Director of Media Relations at the White House. During her tenure, she introduced satellite communications to the White House and launched the electronic White House News Service. Ms. Spaeth has worked in every area of print and electronic media. She's been a radio and television talk show host, a producer for ABC's *20/20*, and a reporter for many magazines and papers. Her honors include *Glamour*'s 10 Outstanding Working Women of America and the National Council of Women's Citation of Accomplishment. A cum laude graduate of Smith College, she holds a master's degree from Columbia Business School and was awarded the school's Overall Achievement Award.

William F. Stephens, M.S., has managed the advanced practice center at Tarrant County Public Health for over 7 years in the area of public health preparedness, informatics, and development of preparedness capacity and capabilities. His areas of focus have been in biosurveillance system development and evaluation, and radiological/nuclear disaster preparedness including psychosocial/behavioral and risk communication. He has also served as a technical advisor for pilot testing and implementation of an electronic medical records system now in final implementation in several clinics at Tarrant County Public Health. Under his leadership, the Tarrant County center has made significant contributions in biosurveillance systems development, health information exchange for outbreak detection and situational awareness, and in building health care disaster response core competencies for all hazards. Mr. Stephens has served on the Centers for Disease Control and Prevention's (CDC's) national biosurveillance advisory subcommittee, as an advisor on medical preparedness for a nuclear detonation workshop and report sponsored by the National Academy of Sciences (NAS) Institute of Medicine (IOM), and was a member of the CDC/Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) Board of Scientific Counselors from 2007 to 2010. Prior to joining Tarrant County Public Health Mr. Stephens worked in senior management roles in the scientific/biomedical imaging industry and in several strategic defense systems programs. He contributed to product development for the first commercially available digital mam-

mography systems, and for image sensors used in mapping the human genome. He holds an M.S. from Texas Tech University, Lubbock, Texas.

Regina Tan, D.V.M., has more than 10 years of public health experience in preventive medicine and epidemiology, and joined the Food Safety and Inspection Service (FSIS) from the MITRE Corporation, where her management of a team of engineers was essential to developing innovative data architecture research and development across the federal government. Dr. Tan began her career as a Commissioned Corps officer in the U.S. Public Health Service and worked with the Centers for Disease Control and Prevention (CDC), first as an Epidemic Intelligence Service Officer then as a Preventive Medicine Fellow. She joined FSIS's then–Human Health Sciences Division (now the Applied Epidemiology Division) as a veterinary epidemiologist in 2003, where she managed the Consumer Complaint Monitoring System team and hurricane response components. In 2005, Dr. Tan rejoined CDC, as a liaison with the Armed Forces Medical Intelligence Center. Dr. Tan has led or served on numerous public health advisory committees, interagency teams and working groups pertaining to threats to public health. Dr. Tan earned her D.V.M. and M.S. from Purdue University and her bachelor of science in biology from the University of Maryland. She is also a Diplomate of the American College of Veterinary Preventive Medicine.

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Planning Committee Biographies

Scott A. Mugno, J.D. (*Co-chair*) is the Vice President, Safety and Vehicle Maintenance at FedEx Ground. Mr. Mugno and his department of 200 employees focus to create a safe work environment for all employees, contractors, and the public, eliminating accidents and injuries while maintaining regulatory compliance. They are responsible for ensuring all equipment meets Department of Transportation requirements and is operational to service the transportation needs of the company. They manage fuel inventory reconciliation, retail pricing, and administration of a fleet retail fuel card. Mr. Mugno has been in the environmental, health, safety, or transportation arenas for more than 20 years. He joined FedEx Express as a senior attorney in the Legal and Regulatory Affairs Department. He was promoted to the position of Managing Director, Safety, Health and Fire Prevention, where he worked in Memphis before accepting his current position at FedEx Ground in Pittsburgh. Prior to FedEx, Mr. Mugno was division counsel at Westinghouse Electric Corporation's Waste Isolation Division and deputy staff judge advocate for the Eastern Region U.S. Army Military Traffic Management command. He has held other legal positions in the Army JAG Corps and in private-practice law firms. Mr. Mugno regularly represents FedEx at various trade and safety association and committee meetings and is a frequent speaker before those and other groups.

William F. Raub, Ph.D. (*Co-chair*), retired in January 2009 after more than 42 years in the employ of the Federal Government, primarily the Department of Health and Human Services (HHS). Current activities include advising the U.S. Postal Service on public health emergency pre-

paredness, advising HHS on vaccine safety infrastructure, serving as Adjunct Staff for the RAND Corporation, serving on the Science Advisory Board of George Mason University, and performing volunteer work for St. John's Church, Chevy Chase, Maryland. Dr. Raub held a wide variety of positions within the federal government, including Science Advisor to the Secretary, HHS (1995-2009); Science Advisor to the Administrator of the United States Environmental Protection Agency (1992-1995); Special Assistant within the Office of Science and Technology Policy, Executive Office of the President of the United States (1991-1992); Acting Director, National Institutes of Health (NIH) (1989-1991); and Deputy Director, NIH (1986-1991). Dr. Raub received numerous awards, including the Presidential Distinguished Executive Rank Award, the Presidential Meritorious Executive Rank Award, the HHS Distinguished Service Award, the American Medical Association's Nathan Davis Award, and the Society of Research Administrators' Award for Distinguished Contribution to Research Administration.

James W. Buehler, M.D., is the director of the Public Health Surveillance Program Office (PHSPO) at the Centers for Disease Control and Prevention (CDC). From 1981 to 2002, Dr. Buehler served as a medical epidemiologist in the U.S. Public Health Service (PHS) at CDC, where he worked in general field epidemiology, maternal and child health, HIV/AIDS prevention, and, for a short period in 2001, anthrax. His work in public health surveillance has spanned analysis, methods development, surveillance system design and management, assurance of ethical practice, and linkage of surveillance and other scientific evidence to program management, policy development, and community-based prevention planning. In 2002, he joined the faculty of the Epidemiology Department at the Rollins School of Public Health at Emory University, where he focused on the role of epidemiology in public health preparedness and response programs and on the emerging field of public health systems research. In 2009, he returned to CDC to contribute to surveillance of pandemic H1N1 influenza. Since 2010, he has served as the Director of PHSPO, which is responsible for managing several national surveillance systems, including the Behavioral Risk Factor Surveillance System, BioSense, and the National Notifiable Diseases Surveillance System, and for providing a focal point at CDC for advancing surveillance science and practice in support of public health programs.

Joseph Kielman, Ph.D., serves as Science Advisor in the Science and Technology Directorate (S&T) at the Department of Homeland Security (DHS), where he is the Chief Scientist for the Infrastructure Protection and Disaster Management Division (IDD) and also Chief of its Visualization Analytics Technologies Branch. He also manages two Centers of Excellence for the S&T Office of University Programs. Dr. Kielman established and directs the National Visualization and Analytics Center; manages the Precision Information Environments program; and oversees joint programs with the National Science Foundation (FODAVA), Defence Research and Development Canada, and the German BMBF. Immediately prior to joining DHS, Dr. Kielman worked for 20 years at the Federal Bureau of Investigation (FBI), where he was successively Chief of the Advanced Technology Group in the Engineering Section, Chief of Research and Development for the Technical Services Division, and Chief Scientist and also Chief Architect at the Information Resources Division. His work at the FBI included development of advanced information collection and surveillance systems, microelectronic and micromechanical design capabilities, advanced computer architectures, and information processing and analysis technologies. Dr. Kielman has an undergraduate degree in physics and graduate degrees in biophysics and did postdoctoral work in genetics. In 2006 he was awarded the Presidential Rank of Meritorious Senior Professional.

Richard C. Larson, Ph.D., is the Massachusetts Institute of Technology (MIT) Mitsui Professor in the Engineering Systems Division. He is founding director of the Center for Engineering System Fundamentals. He has focused on operations research as applied to services industries, primarily in the fields of criminal justice, technology-enabled education, urban service systems, queueing, logistics, workforce planning, and planning for and response to disasters. He is Past-President of INFORMS, INstitute for Operations Research and the Management Sciences. He is a member of the National Academy of Engineering, an INFORMS Founding Fellow, and a recipient of the INFORMS President's Award, Lanchester Prize and Kimball Medal. From 1995 to mid-2003, Dr. Larson served as Director of MIT's CAES, Center for Advanced Educational Services. He was founder, with Glenn Strehle, of MIT World (http://mitworld.mit.edu). He is founding Director of LINC (http://linc.mit.edu), Learning International Networks Consortium, an MIT-based international project that has held five international symposia and sponsored a number of initiatives in Africa, China and the Middle

East. With Elizabeth Murray, he recently started LINC's newest and largest initiative, BLOSSOMS, Blended Learning Open Source Science or Math Studies (http://blossoms.mit.edu).

Mark E. Teachman, D.V.M., is Director for Interagency Coordination in the National Center for Animal Health Emergency Management, which resides in the Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS). He leads a team of subject-matter expert liaisons that are either imbedded in another federal agency or liaise with other agencies as needed. These subject-matter experts are focused on identifying assets (people, teams, information, or other tools) that can be used to support a response to an animal health emergency. They also provide the agencies they liaise with appropriate information about National Center for Animal Health Emergency Management (NCAHEM) activities and animal health emergency response requirements. Dr. Teachman graduated from Michigan State University, College of Veterinary Medicine, in 1984. From 1984 until joining the federal government, Dr. Teachman was in private practice and involved in a family computer business. In 1988, he joined the USDA, APHIS, VS, and was assigned to APHIS, VS Headquarters on the Import-Export Staff working animal import issues. He worked on trade related issues on the Import-Export Staff for three years before transferring to the Centers for Epidemiology and Animal Health (CEAH) in Fort Collins, Colorado. At CEAH, Dr. Teachman focused on information management, epidemiology, and animal production food safety for 3 years. In 1997, he returned to APHIS, to work for the VS, Emergency Management & Diagnostics (EM&D) Staff in Riverdale, Maryland. Dr. Teachman focused on long-range strategic planning, liaison, or outreach activities to explain APHIS response actions or recruit resources to help in a global response, and defining information management strategies for animal health emergency management community. As a Staff Officer on EM&D, he developed, implemented, and participated in many international and national exercises to evaluate and improve the nation's ability to respond to animal health emergencies. Some of the groups he exercised with over the years include the Department of Homeland Security (DHS), Food Safety and Inspection Service (FSIS), Department of Defense (DOD), various states, Australia, New Zealand, Canada, and Mexico. He also promoted the use of modeling tools such as APHIS, VS's North American Animal Disease Spread Model to support animal health emergency management-response planning, and was inti-

mately involved in an interagency working group to develop a long term vision for research and development of animal disease spread models.

Michael M. Wagner, M.D., Ph.D. (P.I.), is an Associate Professor of Biomedical Informatics (primary appointment) and of Intelligent Systems (secondary) at the University of Pittsburgh. Dr. Wagner is the Director of the Real-Time Outbreak and Disease Surveillance (RODS) Laboratory of the Department of Biomedical Informatics of the University of Pittsburgh. He obtained a B.S. in biology from the State University of New York (SUNY) at Stony Brook in 1975, an M.D. from the New York University (NYU) School of Medicine in 1979, and a Ph.D. in artificial intelligence from the University of Pittsburgh in 1995. Dr. Wagner's primary research interest is informatics in public health. Since 1999, he has been developing information technology to detect outbreaks. He has served as principal investigator on several large grants involving the University of Pittsburgh and Carnegie Mellon University (CMU) to develop and deploy advanced methods of biosurveillance. He was chief editor and a principle contributor to *Handbook of Biosurveillance*. At present, Dr. Wagner is principal investigator on a grant entitled "Decision Making in Biosurveillance," and of the University of Pittsburgh's Center of Excellence in Public Health Informatics, funded by the Centers for Disease Control and Prevention (CDC). Dr. Wagner has served on two Defense Science Boards (2001, 2002) in the areas of intelligence for biological warfare and on defense against biological attacks. The Defense Science Boards advise the Joint Chiefs of Staff and the Secretary of Defense about science priorities for the Department of Defense (DOD). After the Anthrax attacks of October 2001, Dr. Wagner testified before the House Committee on Energy and Commerce, Subcommittee on Hearing of the Oversight and Investigations (November 1, 2001), and, with Dr. Andrew Moore, briefed President Bush, Secretary Thompson, and Governor Ridge on the RODS research (February 5, 2002).

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