

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC MEETING
June 26, 2012¹
9 a.m. to 4:30 p.m.

VOTING MEMBERS PRESENT

John S. Parker, Major General (Retired), M.D., *Chair*
Nelson J. Chao, M.D., M.B.A.
Jane Delgado, Ph.D., M.S.
David J. Ecker, Ph.D.
Emilio A. Emini, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP, Major
Manohar R. Furtado, Ph.D.
Kevin A. Jarrell, Ph.D.
Steven E. Krug, M.D.
Sarah Y. Park, M.D., FAAP
Betty J. Pfefferbaum, M.D., J.D. (by phone)

EX OFFICIO MEMBERS PRESENT

Kay Marano Briggs, Ph.D., Lead for Genetics and Microbiology, Ecosystems Mission Area, U.S. Department of the Interior (*designated by Lori Caramanian*)
Heather Evans, Ph.D., Policy Analyst, Program and Planning Office, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce (*designated by Dianne Poster, Ph.D.*)
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services
Sam Groseclose, D.V.M., M.P.H., DACVPM, Associate Director for Science, Office of Science and Public Health Practice, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
Lawrence D. Kerr, Ph.D., Senior Bio Advisor, National Counterproliferation Center, Office of the Director of National Intelligence (by phone)
George W. Korch Jr., Ph.D., Senior Science Advisor, Office of the Principal Deputy, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
Randall L. Levings, D.V.M., Scientific Advisor, National Center for Animal Health, U.S. Department of Agriculture (by phone)
Richard A. Martinello, M.D. Acting Senior Medical Advisor, Veterans Health Administration, Office of Public Health and Environmental Hazards, U.S.

¹ To view the full June 26, 2012, NBSB Public meeting over webcast, please visit <http://services.choruscall.com/links/aspr120626.html>

Department of Veterans Affairs (*designated by Victoria J. Davey, Ph.D., M.P.H.*) (by phone)

Bonnie S. Richter, Ph.D., M.P.H., Director, Office of Illness and Injury Prevention Programs, Office of Health, Safety, and Security, U.S. Department of Energy (*designated by Patricia R. Worthington, Ph.D.*) (by phone)

Marc Shepanek, Ph.D., Deputy Chief, Medicine of Extreme Environments, National Aeronautics and Space Administration (*designated by Richard Williams, M.D.*) (by phone)

Amber Story, Ph.D., Deputy Division Director, Division of Behavioral and Cognitive Sciences, National Science Foundation (by phone)

Gwen Tobert, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State (*designated by Kerri-Ann Jones, Ph.D.*)

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

CAPT Charlotte D. Spires, D.V.M., M.P.H., Diplomate ACVPM, NBSB Executive Director

Jomana Musmar, M.S., Senior Management Analyst

Anissa Addison, Executive Assistant

OTHER PARTICIPANTS

Philip AbdelMalik, Ph.D., M.H.Sc., Senior Epidemiologist/Advisor, Situational Awareness Section, Centre for Emergency Preparedness and Response, Public Health Agency of Canada

Jonathan Ban, Policy Analyst, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Greg Burel, Director, Division of Strategic National Stockpile, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Lisa Kaplowitz, M.D., M.S.H.A., Deputy Assistant Secretary for Policy, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Michael W. Latham, Senior Public Health Analyst, Policy and Communication Lead, Biosurveillance Coordination, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jennifer Olsen, M.P.H., Fusion Branch Chief, Office of Preparedness and Emergency Operations, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Curtis Weaver, M.F.A., Action Director, Biosurveillance Coordination Activity, Public Health Surveillance and Informatics Program Office (proposed), Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES

Charlotte Spires, D.V.M., M.P.H., Diplomate ACVPM, Executive Director, National Biodefense Science Board (NBSB)

CAPT Spires called to order the public session of the NBSB meeting, called the roll, and reviewed the conflict of interest guidelines. She explained that the meeting was being

broadcast online, so anyone interested can participate. CAPT Spires pointed out that the agenda includes two public comment periods: one in the morning and one in the afternoon.

WELCOME AND AGENDA OVERVIEW

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker welcomed all the participants.

OPENING REMARKS AND INTRODUCTION OF TASK TO THE NBSB

Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS)

Dr. Lurie said that in the nearly three years she has served as the ASPR, the NBSB has played a profound role in her work. She noted that the NBSB made a significant contribution to the medical countermeasures (MCMs) enterprise review, which was “path-changing” and resulted in new systems of governance and decision-making that are working well. One major recommendation of that review recently came to pass when HHS Secretary Kathleen Sebelius announced the creation of centers of excellence in manufacturing this week. Dr. Lurie said input from NBSB members on the development of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) draft strategic plan has been invaluable, and she looked forward to more input as the accompanying implementation plan is developed.

Dr. Lurie said she is putting in place a robust system for scientific response in the context of emergency response, thanks to NBSB’s recommendations. She also appreciated the Board taking on the challenging task of deliberating about studying anthrax vaccine in pediatric populations; as a result of the Board’s recommendations, the Secretary asked that the Presidential Commission on the Study of Bioethical Issues review the matter further. In May, Dr. Parker gave a presentation to the Commission on the issue.

At this meeting, the Board will consider two new tasks from the ASPR, both of which are priorities:

- Review and evaluate the Public Health and Healthcare Situational Awareness Strategy and Implementation Plan (SIP); and
- Form a joint working group with the Centers for Disease Control and Prevention’s (CDC’s) Office of Public Health Preparedness and Response (OPHPR) Board of Scientific Counselors (BSC) to review the future needs of the Strategic National Stockpile (SNS)

The initial Pandemic and All-Hazards Preparation Act (PAHPA) called on HHS to develop a public health strategic plan. The CDC addresses biosurveillance in its National Strategy for Biosurveillance for Human Health (NSBHH). However, said Dr. Lurie, since the H1N1 influenza pandemic, it appears there is more to do. The Public Health and Healthcare Situational Awareness SIP will be national in scope and focus more on situational components than on critical infrastructure. The SIP should provide a common

approach to build capacity for rapid decision-making and response at multiple levels. Similar to the process for the PHEMCE SIP, NBSB members will have an opportunity to give input throughout the development process, with the collaboration of participating CDC advisory committees. She looked forward to the Board's recommendations.

Dr. Lurie thanked the Board for its hard work and reiterated that its recommendations make a difference for the Department and for the country. She hoped that when time permitted, the Board would raise other important issues that HHS has not yet addressed. Dr. Lurie welcomed CAPT Spires, saying she was thrilled to have an NBSB Executive Director with such a strong commitment to making an impact on public health.

EXISTING SITUATIONAL AWARENESS AND STRATEGIES: AN OVERVIEW

Jonathan Ban, Policy Analyst, Office of Policy and Planning, ASPR, HHS

To develop the Public Health and Healthcare Situational Awareness SIP, HHS is reviewing many existing strategies and plans. Mr. Ban summarized some of the key documents:

- The **National Health Security Strategy (NHSS)** and Implementation Plan describes public health and healthcare situational awareness broadly, focusing on health threats and health system and response community resources for decision-making. It identifies four outcomes of situational awareness: a common national approach, awareness of evolving incidents, awareness of resources and anticipation of needs, and multidirectional communication. The NHSS could serve as a good framework for the Public Health and Healthcare Situational Awareness SIP.
- The **NSBHH** complements the NHSS-identified outcome of awareness of evolving incidents. It uses the Homeland Security Policy Directive (HSPD) 21 definition of biosurveillance but focuses on human health. The NSBHH specifies six priority areas and numerous activities to address them. Notably, the biosurveillance workforce of the future is a priority area.
- The **National Strategy for Biosurveillance** (forthcoming) addresses all-hazards threat information for human, animal, plant, and environmental health. It describes guiding principles and core functions, but the strategy is still in draft form, and the draft implementation plan has not been completed.
- The **National Biosurveillance Integration Center (NBIC) Strategic Plan** (forthcoming) outlines numerous objectives and goals in the service of its vision of leading an integrated biosurveillance effort that facilitates early warning and shared situation awareness of biological events. The NBIC resides in the Department of Homeland Security (DHS).
- **HSPD 21** includes a widely-used definition of biosurveillance and requires the establishment of a national epidemiologic surveillance system and Federal advisory committee on biosurveillance.

Mr. Ban concluded that if PAHPA is reauthorized, requirements under PAHPA may change. He concluded that the NHSS is a very good starting point for the Public Health and Healthcare Situational Awareness SIP.

SITUATIONAL AWARENESS: AN OPERATIONAL PERSPECTIVE

Jennifer Olsen, M.P.H., Fusion Branch Chief, Office of Preparedness and Emergency Operations, ASPR, HHS

Situational awareness is a mix of perception, comprehension, and projection; ideally, it is used to facilitate decision-making and resource allocation, early detection of incidents, and anticipation of future events. Ms. Olsen said she and her colleagues are constantly dealing with three types of threats related to preparedness:

- The known, such as a hospital's loss of power. In such cases, the problem is clearly defined, understandable, and replicable, so planners can focus on how to respond.
- The partially known, such as the H1N1 influenza pandemic. Many emergency planners anticipated the threat of H5N1 influenza from Asia, not H1N1 influenza from Mexico. Many questions had to be answered, but some relevant strategies were already in place.
- The unknown unknowns, that is, situations that are not anticipated but could arise at any time.

Ms. Olsen said the obstacle to defining and understanding the environment is not a lack of information but rather the difficulty of getting the right information to the right people at the right time. As more data are available, the complexity of the problem grows. At the Federal, State, and local levels, decision-makers are "drowning in content," said Ms. Olsen, and need help pulling out the key nuggets of information. The NBSB can help the ASPR identify what can be informed by situational awareness, how to enable decision-making, who should do the work and how, and the boundaries of public health and medical situational awareness. Moreover, the Board can consider how to share knowledge and insight across States, local entities, and tribal territories.

The 17 core functions of public health outlined in Emergency Support Framework 8 cover a lot of ground, and situational awareness is needed to know what decision is required in a given setting and what roles and responsibilities the stakeholders have. Timing is key; depending on the role, a decision-maker may need situational awareness constantly or for a brief time. Situational awareness may require understanding how all of the parts of the whole affect one another. Ms. Olsen said that even for sudden disasters, such as an earthquake or hurricane, one may have some insight from what has happened in the past and predictions about what may happen in the future, but situational awareness focuses on learning what is happening in the present to inform decision-making.

Ms. Olsen referred to some of the common components, metrics, and data sources of situational awareness. It is important to understand when some sources are more valuable than others and what formats are useful for delivering and displaying information. One must also ask whether the utility of a format varies depending on the decision-maker's

purpose and circumstances. One also must have sufficient day-to-day information to identify a threat when it emerges, said Ms. Olsen.

Situational awareness may mean linking multiple systems together, as is already being done between States and Federal authorities (e.g. MedMap and HAvBED). In such cases, States emphasize the need to consider information in a local context. What may sound concerning (e.g., 95 percent of hospital beds are full) may be a normal occurrence for that community. Ms. Olsen also identified the need to develop internal situational awareness and integrate external content and expertise into it. More Federal grantees are forming coalitions, said Ms. Olsen, which affects information exchange and situational awareness. Knowing where information goes is not sufficient for situational awareness, she added.

Ms. Olsen concluded that situational awareness informs understanding and enables action, but it is only valuable if provided in a meaningful and useful way. HHS is convening an interagency working group to define the key decisions for which data are needed, review the landscape of current systems, identify key data elements, and determine the best course for analytic capability.

BIOSURVEILLANCE: AN OPERATIONAL PERSPECTIVE

Michael W. Latham, Senior Public Health Analyst, Policy and Communication Lead, Biosurveillance Coordination, CDC, HHS

By way of background, Mr. Latham explained that HSPD 21 identified biosurveillance as one of the four pillars of effective surveillance and response. In developing the NBSHH, CDC focused on managing human health-related data and information toward its goal of providing early warning and rapid characterization of threats on which decision-makers can act. CDC believes that biosurveillance is an important component of situational awareness. Presidential directives have mandated national, integrated biosurveillance capability, which Mr. Latham said was “easier said than done.”

Mr. Latham said that a fully integrated national approach to biosurveillance has not been developed because there is no overarching national strategy and no common objectives. National security staff are drafting the National Strategy for Biosurveillance (with input from HHS, CDC, and other Federal agencies), but the draft depicts a high-level strategy. Mr. Latham anticipated that the accompanying implementation plan would spell out the details of the strategy. He pointed out that given the complexity and magnitude of biosurveillance, full integration is challenging and may never be achieved, but efforts to determine how to mine data from multiple systems for valuable information that decision-makers can use for emergency response are improving.

A realistic operational perspective must recognize the complex, expansive nature of biosurveillance and the need to include stakeholders outside of Federal agencies, such as State, local, and tribal authorities. Mr. Latham pointed out that workforce cuts at the State and local levels have hit biosurveillance efforts hard. The National Biosurveillance Advisory Subcommittee recently reported that government biosurveillance responsibilities and authorities are widely dispersed, exist in silos, and frequently lack integration.

A State official suggested that fixing the biosurveillance systems at the Federal level would have a positive impact on State and local authorities. To that end, CDC formed a biosurveillance working group with representation across government agencies. That group is focusing on understanding the Federal biosurveillance landscape as the first step toward integration. In addition, the Department of Defense (DoD) is attempting to create a registry of surveillance activities, and CDC hopes to partner with DoD as appropriate.

Mr. Latham said much effort is underway, but much of the biosurveillance capacity is beyond Federal control, as it occurs through public health surveillance programs. The nation's healthcare system is the cornerstone of biosurveillance data, but the quality of case reporting is inconsistent. The information is out there, said Mr. Latham, but the question is how to integrate it.

Finally, Mr. Latham summarized the ongoing challenges of biosurveillance:

- Identifying active, ongoing surveillance activities
- Demonstrating the value and utility of biosurveillance to ensure participation (e.g., using cloud storage to allow users to retrieve as well as submit data)
- Improving collection, flow, and interpretation of data in a timely way
- Recognizing that biosurveillance is bigger than any Federal or State agency or information technology (IT) system and that the obstacles to developing an integrated IT system that can collate information and provide an answer are “insurmountable”
- Building on existing capabilities and relationships while investing in innovation, which is particularly challenging with tight budgets

SITUATIONAL AWARENESS: A GLOBAL PERSPECTIVE

Philip AbdelMalik, Ph.D., M.H.Sc., Senior Epidemiologist/Advisor, Situational Awareness Section, Centre for Emergency Preparedness and Response, Public Health Agency of Canada

Dr. AbdelMalik explained that public health in Canada is a shared responsibility between the Federal and provincial authorities; however, most data are collected and reported at the provincial level only. He described the organizational structure of Canada's Federal health entities, noting that as a result of recent reorganization, regulatory affairs (e.g., laboratory safety) is now directly linked with emergency preparedness. Another recently renamed section combines emergency operations and the incident management system with situational awareness. Dr. AbdelMalik further mapped out the authorities responsible for emergency surveillance, detection, assessment, communication, and response.

Public health intelligence comes from two realms: event-based information that the Public Health Agency of Canada's Situational Awareness Section gathers from a variety of sources and then filters (with attention to verification of information and reliability of sources) and indicator-based information from surveillance systems (e.g., mandatory laboratory reporting) that describe real incidents.

One source of event-based information is the Global Public Health Intelligence Network (GPHIN), which provides situational awareness and early warning using a global, all-hazards approach. GPHIN combines a web-based tool with the expertise of multidisciplinary, multilingual, multicultural analysts who network beyond Canada and with external partners to assess potential threats. GPHIN identifies events reported in traditional news media across numerous categories (e.g., human and animal diseases, plant diseases, unsafe products, natural disasters), and analysts assess them. Dr. AbdelMalik noted that before evidence-based reports identify an outbreak, informal, online sources (e.g., blogs, social networks) reveal some trends (e.g., influenza outbreaks); thus, it is important to incorporate new media into analysis.

GPHIN allows the user to build queries focused on specific issues to watch. It scans information from around the world and applies a scoring system to identify relevant items. Verification of information occurs through numerous mechanisms, including the in-house analysts, outside experts, and media. Twice a day, the GPHIN staff gather to discuss their findings. A flow-chart style assessment tool helps narrow down the assessment to pinpoint potential public health emergencies. From there, the staff apply the International Health Regulations (IHR) assessment tool (five questions) plus additional questions specific to Canada (together, the IHR-Plus) to develop a risk profile.

The information gathered is presented at a daily meeting of public health intelligence leaders, who have their own event indicators and priorities. GPHIN can send automated reports to users—alerts for identified risks and “FYIs” for serious incidents that only affect a limited group.

Dr. AbdelMalik said efforts are underway to:

- improve and update GPHIN dashboard reporting so that users can customize their screen views to get the information most salient to them;
- incorporate social media;
- expand spatial intelligence beyond the basic geographic system;
- incorporate more metrics and analytics to identify baselines, spikes, and signals;
- and improve the algorithms used for detection, relevance, and scoring.

GPHIN requires a lot of resources, including multidisciplinary staff (who are challenged to maintain work/life balance while operating a system that evaluates global incidents 24/7). Other issues of concern are managing unpredictable situations, vendor relations and interoperability, volume and quality of data, accounting for noise and completeness (type 1 and 2 errors), understanding variations in language and style, and the impact of focusing resources on one event. Dr. AbdelMalik closed with an example of how keyword searching can yield misleading results, reinforcing the need to improve algorithms.

SUMMARY OF EXISTING REPORTS ON HOW TO IMPROVE THE BIOSURVEILLANCE ENTERPRISE

Michael W. Latham, Senior Public Health Analyst, Policy and Communication Lead, Biosurveillance Coordination, CDC, HHS

Mr. Latham said improving the biosurveillance enterprise is a daunting task, but efforts are further along now than when PAHPA first took effect. He noted that some of the reports do not incorporate recent IT advances (e.g., social media, cloud networks). Many of the reports propose action steps, some of which are already underway or can be readily addressed.

The various biosurveillance reports recognize the magnitude of the endeavor and have some common themes:

- Improve efficiency in collaboration and sharing of information and data (new technology helps).
- Focus on key sectors to ensure greatest impact (especially with constrained budgets).
- Ensure strong leadership at the top (e.g., the National Strategy for Biosurveillance).
- Recognize the global nature of threats.
- Ensure the availability of a qualified, interdisciplinary workforce (trained personnel needed to manage systems and analyze data; workforce capacity is diminishing as a result of budget cuts).
- Success depends on collaborative interaction among all elements of the enterprise.

Mr. Latham presented the NBSB with a detailed list of documents and reports for reference on biosurveillance. While much work must be done, the details are well documented, he concluded.

DISCUSSION

Dr. Parker confirmed that the Board accepted the task of reviewing and evaluating the Public Health and Healthcare Situational Awareness SIP. Board members posed various questions for clarification to the presenters in a free-flowing discussion, organized here by topics.

GPHIN and Related Systems

Dr. AbdelMalik said GPHIN collects information from over 20,000 news feeds around the world via a news aggregator service, then filters the information through built-in mechanisms. For verification, analysts may consult experts in the field or colleagues (through twice-daily meetings), for example, but the analysts have a good sense of reliable sources. He gave a detailed description of how the GPHIN staff assess the potential risk of identified threats. Dr. AbdelMalik acknowledged that the initial assessment is always subjective, and there is discussion about implementing some sort of risk assessment formula.

Dr. AbdelMalik said GPHIN has 16 analysts (working in shifts) who spend most of their time sifting through articles to identify real threats. GPHIN is constantly working to improve algorithms to filter out noise. Ms. Olsen said her office frequently sifts through tidbits gleaned from social media; to limit the volume of input, she and her colleagues focus on items that are uniquely useful. For example, grave disinterment might be overlooked by traditional situation reports and is sometimes picked up by news outlets but would be noticeable to individuals, who remark on it using social media.

Dr. AbdelMalik said GPHIN does use bioinformatics to seek out “known unknowns,” but the process is difficult and yields a lot of vague data. Ms. Olsen said her office is just beginning to explore the use of word distance analysis to understand social media messages. Dr. AbdelMalik said human analysis is invaluable, but there are efforts to automate GPHIN assessments whenever possible. Ms. Olsen noted that text input into electronic health records (EHRs) is easier to analyze than facebook status updates, for example, because the challenge lies in how people talk about well-being. Dr. AbdelMalik said coded data from EHRs allow for standardization.

Global Health IT Exchange

Mr. Latham said CDC and DoD both gather global data on potential threats. Curtis Weaver of the CDC said relationships can affect the exchange of information, but many international efforts are in place, such as CDC’s Center for Global Health and its Division of Global Disease Detection and Emergency Response. Mr. Weaver said CDC is exploring more ways to collaborate and share information with global partners.

Despite having a national healthcare system in Canada, Dr. AbdelMalik noted, provinces have jurisdiction over healthcare, which poses challenges. There is an effort to create a multilateral data sharing agreement to address information exchange. Privacy issues have proven more complex to resolve than ownership of the data, said Dr. AbdelMalik.

Communication and Dissemination of Information

Steven E. Krug, M.D., solicited advice on best practices for partnerships that could improve the situational awareness of healthcare providers on the front lines. Ms. Olsen believed that many partnerships already exist to disseminate information and teaching tools to emergency department (ED) personnel, but she agreed that there is room to improve the coordination and flow of information to and from EDs. She added that the ASPR uses some CDC systems to encourage providers in the National Disaster Medicine System to report information. Mr. Latham noted that BioSense interacts with ED personnel, and the number of people who use BioSense has increased seven- or eight-fold in recent years.

Ms. Olsen said her office does consider how systems address the needs of special populations; for example, information can be sent to responders describing the demographics of an affected area in terms of special needs populations. Ms. Olsen said a lot of changes have been made to operations systems, and she suspected they would be tested by the next major storm or hurricane.

Mr. Latham emphasized the importance of understanding what information Federal, State, and local entities all find valuable. Mr. Weaver added that sharing data without putting the information in context is not helpful.

Regarding syndromic surveillance, Sam Groseclose, D.V.M., M.P.H., said there are specifications of information from the ED record that should be reported to public health agencies, although those records often are not specific; analyzed in the aggregate, public health officials may be able to use them to see patterns and create case definitions on the fly. Each jurisdiction decides how to use surveillance resources, and some do not have the capacity to analyze data. The BioSense system uses a cloud-based mechanism in an attempt to improve efficiency, and CDC hopes jurisdictions will report data using BioSense. The system meets meaningful use criteria for hospitals and enables analysis in a cost-effective way. Dr. Groseclose said CDC is paying attention to closing the information loop by, for example, getting community outbreak information back to community healthcare providers to screen patients.

Leveraging EHR Data

Mr. Weaver said that CDC's Public Health Surveillance and Informatics Program addresses both biosurveillance and meaningful use of EHRs, which should be helpful in ensuring the topics are linked. Dr. Olsen said that during the H1N1 influenza pandemic, HHS created a system for collecting information, but there has not been an opportunity to use it since then. The NHSS' focus on data collection and reporting may signal to States, local agencies, and private providers what information and systems are needed to fill the current gaps. Sometimes asking about data sources reveals the existence of better sources. Kevin A. Jarrell, Ph.D., said integrating databases and automating data collection could allow Federal agencies to identify patterns more quickly without direct contact from State and local entities. Dr. Olsen agreed but also noted that it is difficult to interpret granular data accurately without knowledge of the local context. Mr. Weaver added that CDC monitors systems and communicates with State and local entities daily.

Dr. Groseclose said that through the implementation of meaningful use criteria for EHRs, there are some indicators that provide key data for biosurveillance, such as electronic laboratory reporting and reporting to immunization information registries.

Daniel B. Fagbuyi, M.D., asked whether any efforts are being made to let private EHR developers know what data the biosurveillance community needs. Also, he asked whether there are systems that facilitate automatic updating. He noted that coalitions are having a big impact on healthcare, at least in the Washington, D.C., area, and leveraging networks can be very useful for situational awareness. Also, Dr. Fagbuyi suggested that data-mining approaches to EHRs should look beyond the chief complaint to the symptoms.

Aligning Biosurveillance Systems

Sarah Y. Park, M.D., hoped that CDC's efforts to better align its own multiple surveillance systems would include some attention to minimizing the amount of duplicate data that States are required to report, thus improving alignment at the State level as well. Mr. Weaver said a registry established in 2010 is helping CDC understand what systems

are being used and what information is being exchanged; it has identified 30 ways to submit reportable data to CDC. The goal of the registry is to identify overlap and increase efficiency. Mr. Weaver also said that CDC is working to make information from the registry more readily available to State and local agencies. Mr. Latham added that the first step has been understanding the landscape so that various agencies can determine what data are available from whom; with that, Federal agencies can answer questions and develop comprehensive situational awareness.

Clarification of NBSB Task

Emilio A. Emini, Ph.D., asked for clarification about the endpoint, that is, what would sufficient, appropriate situational awareness look like? Mr. Latham said that a common interpretation of good situational awareness is the ability to identify rapidly information needed to characterize events and to provide that information to decision-makers to determine a response. Timeliness is key, and Mr. Latham said it would be defined as the time needed to ensure a rapid response that mitigates the effect of a threat on public health. Another participant asked for clarification of the key areas of concern. He also asked whether the evidence base is solid enough to support decision-making and how the success of biosurveillance efforts would be evaluated.

There are real issues about how data are used once they are shared, Dr. Groseclose said, and he hoped NBSB would consider some of those issues. Also, there are some clinical networks of interest, but they are limited in scope, and NBSB may want to investigate them further, he said.

PUBLIC COMMENT

Penny Hitchcock of the Tauri Group (previously of the UPMC Center for Biosecurity), said there are different kinds of epidemics (e.g., influenza and severe acute respiratory syndrome [SARS]). QFLU, a project developed by the emergency medical service in the United Kingdom, collects information from EHRs (while protecting the individual's identity) on patients' gender and the zip codes of their providers as a strategy for getting good, population-based data throughout the United Kingdom. The automated system collects daily the records of patients with a chief complaint of influenza and looks for clusters of events that do not fit the normal profile of influenza (e.g., wrong age or wrong time of year). Analysts review and present the information to the Prime Minister daily. The system went into play when H5N1 influenza began cropping up in Europe and authorities worried about the ability to detect an outbreak early enough to address it. With influenza, infected people spread the virus before they show symptoms, so early detection is important for impact.

On the other hand, people with the SARS virus do not shed the virus until they show symptoms of the disease, usually not until the symptoms become severe and require hospitalization. With SARS, a system similar to GPHIN detected the threat. Thus, different threats require different biosurveillance approaches, Ms. Hitchcock pointed out. Early detection linked to EDs cannot help individual patients but can, for example, prevent the spread of disease throughout the hospital if personnel use personal protective equipment.

Ms. Hitchcock also said the World Health Organization's International Health Regulation (IHR) is the first international public health policy, but it is an unfunded mandate at the local level, which is a big deal for developing countries (and others, considering the global economic situation). The United States has many systems but not necessarily the resources to invest in biosurveillance. The NBSB's effort to identify what works and how to piece together an international system is key; without the NBSB's involvement, said Ms. Hitchcock, the enterprise would flounder for many years.

AFTERNOON SESSION - INTRODUCTION OF JOINT TASK TO NBSB

Nicole Lurie, M.D., M.S.P.H., ASPR, HHS

Dr. Lurie said biosurveillance and situational awareness represent one end of the spectrum of public health emergency response (gathering and forwarding data to inform decision-making), while the SNS represents the other end (getting MCMs to the people who need them). The SNS is housed in and operated by CDC and contains medicines, supplies, and countermeasures to protect the public in an emergency should local supplies run out. When Federal authorities agree it is warranted, the SNS MCMs are delivered rapidly. CDC has worked hard on its plans to get MCMs from the SNS to the people. Major issues that affect the SNS include better MCM development and procurement of products for the SNS and concerns about the costs to produce and procure MCMs, store them safely, and restock them as needed. Maintaining the SNS is expensive, said Dr. Lurie, so it is important to consider whether it can run more efficiently. (Dr. Lurie pointed out that Greg Burel, director of the Division of SNS [DSNS] has instituted many efficiencies in the past few years.)

In addition, it is important to consider what the SNS may look like in 2020, what capabilities it might need, and what missions it might support. Because the ASPR oversees preparedness policy while CDC manages the daily operations of the SNS, it was agreed that advisory committees from each agency should evaluate these issues. Dr. Lurie said the NBSB and the CDC's BSC represent different areas of expertise. The two committees will work together to evaluate whether the SNS is using the most modern and efficient ways to maintain preparedness and security. Dr. Lurie said the charge to the NBSB and the BSC has three parts:

1. Project the responsibilities of the SNS in 2020 on the basis of past experience. Consider potential changes in the world and related programs (such as Vaccines for Children). The members of the advisory committees bring their knowledge of how people view the SNS, the fluidity of its roles, and the responsibilities it takes on. Dr. Lurie hoped the committees would help project the future of the SNS.
2. Recommend approaches to meet the SNS responsibilities as efficiently as possible. Since Mr. Burel began, there have been tremendous innovations in the private sector that are evolving at a rapid pace (e.g., supply chain, storage). How can the SNS harvest the best of those innovations? Consider various mechanisms to meet the responsibility (e.g., stockpile, vendor-managed inventory approach, user-managed inventory approach) with maximum efficiency while ensuring public access. Consider which approaches work best under which conditions.

3. Propose metrics for assessing and improving performance. Dr. Lurie said HHS is serious about continuous improvement, and while she believes that robust, tested measures to evaluate the SNS are in place, there may be others. She noted that some improvement can be made in “the last mile”—that is, delivering and administering MCMs to individuals, but that is beyond the charge.

In addition to the last mile, Dr. Lurie said HHS does not need input at this time about what products to purchase for the SNS. Thanks to the NBSB, a process is in place to assess the stockpile needs.

Because of budget imperatives and a commitment not to compromise national security, Dr. Lurie hoped the committees could complete their charge in seven to ten months. Within that timeframe, she hoped the two committees would hold a joint public meeting to reach consensus. Finally, Dr. Lurie said she was delighted that NBSB Chair Dr. Parker and BSC member Donald Burke, M.D., have agreed to serve as co-chairs of the joint working group in this endeavor.

STRATEGIC NATIONAL STOCKPILE: AN OVERVIEW

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

Mr. Burel explained that despite the United States’ robust system for drug development, the Federal government keeps a stockpile of drugs sufficient to address rare occurrences and that are not commercially viable to produce. The U.S. pharmaceutical industry operates on a just-in-time model, in which drugs are produced rapidly to fill a specified need. Such a model would probably not be sufficient to reach affected populations in an emergency, so the SNS is prepared to respond. Often, the commercial supply chain is not optimized to dispense products at the level that would be required during a big emergency event.

Members of the Healthcare Distribution Management Association (HDMA) store, manage, and deliver about 87 percent of all prescriptions in the United States, and those members distribute nine million products each day. By comparison, in an emergency, responders might be called on to provide MCMs to 15 million people in the New York City metropolitan area alone in one day. HDMA members keep enough inventory to fill orders for 30 days, on average. Mr. Burel pointed out that the commercial market does not produce or store enough supply in one place to meet the anticipated needs in a crisis.

The DSNS does not divulge the specific products stocked as a matter of national security. Products include medications, medical supplies, and medical devices. The SNS mission has expanded beyond meeting the needs of a chemical, biological, radiological, or nuclear (CBRN) event to all hazards. Mr. Burel described the original authorization and budget for the DSNS. Thanks to NBSB recommendations, there is a robust system in place for determining the formulary. The DSNS relies on commercial partners for storage, maintenance, and rapid transport of materials and Federal partners for purchasing and security. It provides technical assistance to State and local agencies on the management and use of deployed materials and evaluates their capacity to handle the job.

Responsibilities have been added to the DSNS mission over the years. In 2006, PAHPA added a requirement for annual review and a governance structure for the SNS. The SNS has been the subject (directly or indirectly) of 97 audits and reviews, including 43 external reviews. From 2003 through 2011, funding for the DSNS increased annually, but it has decreased in 2012 and will again for 2013. Mr. Burel said more money is needed, and the DSNS must look at new ways to manage its funds. An assessment of the allocation of funds indicates that the direct product costs for the SNS are almost \$400,000. The most expensive aspect of the SNS is buying and replacing product, Mr. Burel emphasized.

Mr. Burel briefly summarized how the PHEMCE sets the requirements for the development of the formulary in its annual review, from SNS content review to integrated gap analysis to prioritization of gaps to a corrective action plan approved by the PHEMCE Executive Senior Council. In terms of material readiness and response, Mr. Burel said the DSNS aims for a balance between the vendor-managed system and the SNS-managed system of inventory. The SNS often packages MCMs with the devices and supplies required to administer them. Mr. Burel believes that a stockpiled inventory is the best option to meet SNS responsibilities, but there is a role for a vendor-managed inventory. If the market is large enough for a given MCM, vendors would be willing to stock sufficient quantities. However, vendors may not be able to transport MCMs rapidly enough to where they are needed.

Mr. Burel described some of the activities the DSNS conducts to support partners, including creating clinical guidance and policies specifying the responsibilities of the DSNS as well as offering regulatory guidance. The DSNS provides subject matter experts for all phases of surveillance, diagnostics, formulary design, acquisition, and utilization. The DSNS is tasked with using the existing supply chain and creating and managing alternative methods to meet unique situations. Mr. Burel said the DSNS does have some support from private entities that prefer to remain anonymous.

The DSNS developed a community resilience training program to address some of the barriers to effective partnerships, such as limited State and local health department staff for MCM planning or distribution. The DSNS is working with other Federal agencies to identify some solutions. For example, the Internal Revenue Service offered to set up closed point-of-dispensing systems (CPODS) and provide volunteers to take some burden off of local public health staff during an emergency.

Looking toward the future, Mr. Burel said the DSNS is working on realigning storage sites and developing alternative distribution methods to better meet current needs, reducing operating costs, and improving performance. He noted that the SNS can further reduce acquisition costs by leveraging the power of the Federal government to negotiate bulk purchase prices. It can also reposition materiel to support increased capabilities at the State and local levels. The SNS could invest in innovation, such as the following:

- Improved technology for long-term storage
- New methods for cold chain shipping

- Radiofrequency identification (RFID) and bar coding (as the costs come down and use becomes more common)
- Stockpile in Motion Across the Nation simulation training program
- Enterprise resource planning system improvements
- Systems for MCM management after deployment

QUESTION-AND-ANSWER SESSION

Board members posed various questions for clarification to Mr. Burel. BSC Chair Thomas V. Inglesby, M.D., and BSC members Dr. Burke and Herminia Palacio, M.D., M.P.H., joined the discussion by phone.²

PUBLIC COMMENT

No public comments were made.

AFTERNOON SESSION WRAP-UP AND CONCLUSIONS

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker concluded that he and Dr. Burke would meet with Mr. Burel and staff of the DSNS to discuss further several issues regarding the SNS. He thanked the NBSB staff and all those involved in organizing the meeting, the speakers, the Board members, the ex officios, and other participants. Dr. Parker reiterated that the Board had accepted both tasks assigned by Dr. Lurie. In the context of the review of the Public Health and Healthcare Situational Awareness SIP, he said, the NBSB will consider where biosurveillance efforts overlap and whether recommendations can be made to improve efficiency.

ADJOURNMENT

Charlotte Spires, D.V.M., M.P.H., Dipl ACVPM, Executive Director, NBSB

CAPT Spires thanked all of the participants and adjourned the meeting at 3:54 p.m.

² To view and hear the full question and answer session, please visit the archived webcast of the June 26, 2012, NBSB Public meeting, available at <http://services.choruscall.com/links/aspr120626.html>