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DAY 1

WELCOME / INDIVIDUAL INTRODUCTIONS / OPENING REMARKS

Thomas Inglesby, MD; Chair, OPHPR BSC, and Ali Khan, MD, MPH, OPHPR Director, welcomed all participants to the BSC meeting.

Sam Groseclose, DVM, MPH, Associate Director for Science, OPHPR, and the Designated Federal Official (DFO) for OPHPR’s BSC called the BSC meeting to order and took roll. BSC Special Government Employee (SGE) board members, ex officio board members, and liaison representatives participating in-person and by phone are listed in Appendix B. Quorum was met.

Dr. Inglesby commented on BSC’s past level of productivity
  • Past 12 months: BSC provided OPHPR with plans and recommendations for several of their programs and activities
  • Past 18 months
    o BSC completed a number of formal program reviews
    o BSC has interacted with OPHPR staff to learn more about programmatic efforts and strategies

Dr. Khan
  • Welcomed Margaret Brandeau as a new BSC member and Ellen MacKenzie who was re-appointed to the BSC (and unable to attend this meeting)
  • Thanked retiring BSC members Sharona Hoffman, Robert Ursano, Louis Rowitz for their service to OPHPR and CDC
  • Thanked all BSC members, ex officio members, and liaison representatives for their time
  • Recognized all BSC members as being “superheroes” in helping to improve our nation’s health security
REVIEW OF FACA CONFLICT OF INTEREST

Dr. Groseclose

- Reviewed duties of the Board per the BSC charter
- Asked for members to self-identify any conflicts of interest; none noted
- Asked that any voting member who believed that s/he had a conflict of interest on any matter to bring it to his attention
- Asked voting members to remain in the room or on the call in order to participate during voting portions of the meeting, as required
- Requested that only BSC members, ex officio members and liaison representatives participate in the discussions
- Requested that other meeting attendees make comments during the Public Comment period
OPHPR INTERNATIONAL ACTIVITIES

Kevin M. DeCock, MD; Director, Center for Global Health, CDC

Center for Global Health (CGH) at CDC
• Established in 2010
• Considers global health through the lens of development, public health and security
• Vision: a world where people live healthier, safer, and longer lives
• Mission: protect and improve health globally through science, policy, partnerships, and evidence-based public health action

Short history of global health at CDC
• 1958: traveling overseas to assist with smallpox and cholera outbreaks in Southeast Asia
• Global AIDS epidemic and 2003 severe acute respiratory syndrome (SARS) outbreak led CDC to expand global health efforts
• Over the last decade, with the help of the President’s Emergency Plan for AIDS Relief (PEPFAR) CDC has invested substantial assets around the world – PEPFAR provides the financial backbone to several CGH projects
• 2009: Dr. Frieden appointed CDC Director
  o Created the CGH to support consolidation of CDC’s largest global health programs into one organizational unit
  o Kevin M. DeCock, MD, appointed CGH Director

CGH organizational structure
• Very similar to that of CDC: director, two deputy directors, associate directors
• Five divisions: Global Immunization; Global HIV/AIDS; Parasitic Diseases and Malaria; Global Disease Detection (GDD) and Emergency Response; and Public Health Systems and Workforce Development
• October 2011: CDC has 304 assignees in 50+ countries, including 40 staff detailed to international organizations
• Total staff of 1100

CGH works with several internal and external partners to achieve strategic goals
• Internal (i.e., CDC)
  o Division of Global HIV/AIDS
  o Office of Public Health Preparedness and Response
  o National Center for Emerging and Zoonotic Infectious Diseases
• Reliance on long-standing and productive external partnerships with multilateral health organizations
  o Engagement with countries at the invitation of Ministries of Health (MOH) and their partners
o Collaboration, with other organizations, such as U.S. Agency for International Development (USAID), Department of State, Department of Defense (DoD), World Health Organization (WHO), World Bank, Gates Foundation

CGH Governance Document
• CGH endeavors to ensure governance of CDC interactions with foreign jurisdictions and their Ministries of Health using a Governance Document
• Governance document
  o Provides guiding principles for a “One CDC” approach to global health
  o Defines the selection process, roles/responsibilities, and supervision regarding the CDC Country Director and Deputy for Management and Operations
  o Describes the in-country headquarter support structure
  o Developed with input from headquarters and CGH’s Overseas Advisory Group
  o Helps to ensure that CDC processes are conducted in a coordinated way and reduces fragmentation

Global Health Strategy released by CGH
• Four goals: health impact, health security, health capacity, and organizational capacity
• Health Security (Goal #2): improve capabilities to prepare for and respond to infectious diseases, other emerging health threats and public health emergencies
  o Objective 2.1: Strengthen capacity to prepare for and detect infectious diseases and other emerging health threats
    ▪ Increase country capacity to comply with the International Health Regulations (IHR) by providing in-country support and technical assistance with planning efforts, including the development of plans for IHR implementation
    ▪ Improve early detection for emerging threats through enhanced surveillance, communication, clinical diagnosis, event analysis, and response
    ▪ Improve laboratory capacity to detect unusual pathogens by improving their capacity to identify endemic pathogens accurately
    ▪ Provide technical assistance and guidance to improve the detection of disease in vulnerable populations
    ▪ Improve methods for detecting and preventing emerging pathogens that result from social and demographic trends that increase human contact with animals, vectors, and poor sanitation
  o Objective 2.2: Respond to international public health emergencies and improve country response capabilities
    ▪ Control and reduce spread of disease by conducting and supporting outbreak investigations at the invitation of the MOH or other partners
    ▪ Facilitate rapid deployment of multidisciplinary CDC response teams to assist WHO and MOHs for outbreak responses
    ▪ Build in-country emergency response capabilities to prepare and respond to disease threats by providing technical assistance and planning, including rapid response team development and coordination with the IHR National Focal Point
Health Security (Goal #2) actions are best illustrated by CGH’s current work on Ebola and ongoing recovery efforts in Haiti

Global Health Strategy goals and objectives achieved by
- Working through GDD Regional Centers and other CDC programs to detect and respond to new disease threats
  o CDC has formal offices in 45 countries – offices provide important platforms from which to conduct and coordinate CDC’s international work
  o 7 to 8 CDC GDD Regional Centers
- Providing public health support to US government (USG) security and development organizations
- Working with other USG agencies to support national and international health and security strategic partnerships (G8 Global Partnership, Biological Weapons Convention, United Nations Security Council resolution 1540)
- Working with agencies to build global capacity for IHR implementation
  o NOTE: Most countries have not met requirements for IHR

Opportunities for future collaboration in improving global health security
- Exportation of key domestic health security programs and models
  o Emergency Operations Center (EOC) development
  o International expansion of CDC’s Laboratory Response Network (LRN)
  o Curriculum and policy development support for Biological Select Agents and Toxins program and Strategic National Stockpile
  o Joint CDC/FBI epidemiology investigations curriculum
- IHR-based planning and coordination
- Development of stand-alone training materials
- Development of regional train-the-trainer curricula

Future distinction between what is CDC’s domestic health security strategy and what is global is going to become less distinguishable
- Processes to address global health must be well coordinated and integrated

QUESTIONS & DISCUSSION (OPHPR INTERNATIONAL ACTIVITIES: CENTER FOR GLOBAL HEALTH)

SGE: Where we have international treaties, are there tiers of responsibility or electiveness in how you respond?

CDC: Yes, there are different levels of obligation and certainly different interpretations can lead to variable levels of responsibility. These are typically interpreted as collaborative agreements rather than something that is enforceable by law. Response means different things in this context. In the sharing of people and resources, it is a “when-asked” situation. During H1N1, the President committed 10% of the flu vaccines, but those efforts were not as successful because
countries were not prepared to distribute, and some of the country’s legal regulations proved to be barriers.

SGE: There’s been talk of the use of technology to speed up the response process. So what kind of infrastructure improvements have you investigated or implemented to help in sharing?

CDC: We are extremely well connected to WHO, so those links exist. For tracking events, our Global Disease Detection group has ongoing scanning for international events of public health interest, and they generate and disseminate daily reports and weekly maps.

SGE: I would suggest an infrastructure be in place so that scientists across the world can collaborate on novel vaccines, for example.

CDC: It is difficult to have all things, in place, because you do not know what all the needs will be at that time. Something close to what you are describing is in place in the influenza and polio networks. What you recommend illustrates the need for increased global infrastructure to be able to deal with the unpredictable events. We need basic public health strengthening, on a global basis.

SGE: I would recommend you look at the book called Reinventing Discovery.

Liaison: I did not hear you describe global supply chain.

CDC: When we, at CDC, talk about health system strengthening, we spend a lot of time talking about what we offer to this effort. Supply chain management, on a global basis, is not where we have advanced. USAID and the UN system, through UNICEF, have more capacity addressing the medical supply chain than we do. If you have recommendations for that, we will be glad to hear them.

Liaison: Several states have reported shortages in pharmaceuticals and it is an area requiring further investigation.

CDC: We also see an issue with counterfeit drugs and intervening for that is more the lane of the Food and Drug Administration, who is trying to become more global.

SGE: Many drugs are manufactured in other countries, and the shortages tend to move from one area to another. There is active work going on to help states find coping strategies during shortages. ASTHO has been very active, in this.

Liaison: Our work has also been on coping strategies and not root-causes.
SGE: In terms of health security, where does that work fit in, in the Center?

CDC: When there is an international event and CDC is asked for help, the request ends up in CGH who then turns to CDC programs, in general, for their help. CGH has some resources, and then we look to the entire agency. For example, we, as an agency, don’t have plans to look at climate change on a long-term basis.

SGE: Is there any work being done around forecasting, known industrial risks, or a hot list of priorities and things that might go bad?

CDC: No, we look to other agencies to help with forecasting. We also do not do much modeling. Scenario-based work is done more broadly across the Agency.

SGE: Regarding the budget, is there a certain amount of money set aside for international response?

CDC: Yes, we have a restricted budget for international requests. The programs, throughout CDC, have to make daily choices about what they can and cannot do.

Dr. Khan and Dr. DeCock reported working together many times, in the past, on smallpox, Ebola, and several other outbreaks. U.S. dollars are used predominantly for domestic planning, but CDC also recognizes the need to support CGH activities. Helping CGH, in its activities, also helps to protect the U.S. from global health threats.

CDC is seeking feedback and opportunities to support the work of CGH. CDC is also working with partners.

SGE: It would be helpful to hear from Department of Defense (DOD) on global health, since global health is mainly around security. Where that coordination happens is important.

Liaison: In your mission and work plans, where do Caribbean territories sit, in priorities, for response? We want to assist, engage, and have a conversation with you, on advancing global safety.

CDC: Caribbean territories are considered domestic (not global). The 55 countries where we have staff were not entirely selected in consultation with CDC. Some countries were prioritized by the U.S. government, through the President’s Emergency Plan for AIDS Relief (PEPFAR). Placement of global assets is not always by clear strategic thinking directed by CDC.

SGE: The level of information sharing is chaotic. Is there a role for CDC to create some type of data sharing mechanism? There are a number of us that struggle in this
area, and this (data sharing) can be useful in the long run and not terribly expensive.

CDC: Some CDC subject matter experts (SMEs) help facilitate that role, as well as SMEs at WHO.

SGE: You also talked about global infrastructure. Is something going to be done for countries that are not able to move forward with IHR?

CDC: We can do two things: keep working and make incremental improvements or address systematically. This is a policy issue that needs to be examined. Aiming to have such a process is not outside the realm of possibility.

SGE: What would you do if you had reduction in your budget?

CDC: Some of our work would be more affected than others. We’d have to prioritize and figure out what can and can’t be done. Identifying and implementing those decisions is not entirely in my power. It would involve the CDC Director, as well.

Peter Rzeszotarski, BS, MA; Operations Branch Chief, Division of Emergency Operations, OPHPR

Mr. Rzeszotarski discussed OPHPR’s
  - Organizational missions and relationships that assist CGH’s mission
  - Activities in the Division of State and Local Readiness (DSLR), Division of Select Agents and Toxins (DSAT), Division of Strategic National Stockpile (DSNS), and the Division of Emergency Operations (DEO)

Organizational missions among groups tasked with conducting global public health at CDC
  - **OPHPR**: Foster collaborations, partnerships, integration, and resource leveraging to increase the CDC’s health impact and achieve population health goals
  - **DEO**: Coordinate with all CDC Centers / Institutes / Offices (CIOs) with planning, training, exercising, reporting, and coordinating logistical support during pre-response activities and during responses
  - **CGH**
    - Execute CDC’s global health strategy (supported by OPHPR and DEO missions)
    - Support CDC global efforts to strengthen public health systems abroad and build essential infrastructure in host countries
    - Support requirements of the revised International Health Regulations
    - Coordinate management and oversight of critical global health preparedness and emergency response activities across CDC

International Health Regulations (IHR)
• Where global health missions at CDC overlap
• “Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1.”

Organizational relationship between CGH and OPHPR
• CGH Global Health Strategy
  o Oversight of global health preparedness and response activities at CDC
  o IHR capability-driven
• OPHPR public health preparedness and response strategy
  o Oversight of domestic preparedness and response activities
  o Public health emergency preparedness (PHEP) capability-driven

Examples of OPHPR international activities
• OPHPR hosts international visitors, provides training to health security fellows and international students
• DSLR
  o PHEP funding and technical assistance to Freely Associated States & Territories
• DSAT
  o Assessments of biosafety and biosecurity at foreign labs working with select agents and toxins (working through NIAID)
  o Proposed project in Pakistan submitted to Department of State Biosecurity Engagement Program
  o Proposal to to develop lab evaluation guidelines submitted to DOD Cooperative Biological Engagement Program
• DSNS
  o International Sharing of Medical Countermeasures Policy Group – DSNS and HHS/ASPR co-chair
  o Public health responses in Japan, Scotland, Haiti, Panama, Mexico, England, Germany and Thailand – staff and medical countermeasures deployed by DSNS
  o Emergency preparedness and response meetings and conferences in France, Switzerland, and Israel to share promising and best practices – DSNS participated
  o Taiwan and Britain – DSNS hosted visitors from stockpiling entities for extended exchanges of processes and practices
• DEO
  o Manages international responses for CDC through Emergency Operations Center (EOC) activation
  o Enables program level international deployments
  o Supports call center activities for international contact tracing
  o Maintains / exercises connections with WHO’s Center for Strategic Health Operations (SHOC) and other international EOCs
  o Serves as conduit for IHR reporting
International technical assistance and consultations addressing emergency operations (conducted on a routine basis and in coordination with CGH)

- WHO Western Pacific Region Office (WPRO)
  - Consultation on establishment of a regional EOC & incident management system (IMS) and participation in technical advisory group (TAG) to assess progress and develop recommendations to member states on implementation of Asian Pacific Strategy for Emerging Diseases (APSED)

- WHO Regional Office for South-East Asia (SEARO)
  - Consultation on regional APSED implementation

- Pan-American Health Organization (PAHO)
  - Consultation on guidelines for drills and simulations

- European Centers for Disease Control (ECDC)
  - Workshop on preparedness planning

- China
  - National assessment of public health security
  - National and provincial training on incident command structure (ICS) implementation
  - Exercise development

- South Korea
  - 2012: Participation in ABLE RESPONSE (biodefense exercise)

**QUESTIONS & DISCUSSION (OPHPR INTERNATIONAL ACTIVITIES: OPHPR)**

**SGE:** It would be helpful to the Board to know some of dilemmas that have occurred due to the number of recent deployments. This would be things like how many people are deployed, what length of time, how many people have had DEO interaction and training. It would also be helpful to look at sustainable person capacity, which speaks to the capability of this office. For example, can DEO continue on at this pace? And not only at this pace but if things increase?

**CDC:** We can get you the specific numbers on deployments. We have seen an increase in the last couple of years in international deployments, assistance to staff across the Agency, and deployment of DEO staff in targeted assistance visits. So the demand is increasing. In addition, as countries are moving toward the deadline for IHR compliance, we are going to see further increase in interest from individuals reaching out to CDC for technical assistance. So do we have adequate capacity in-house right now? I do not think so if we continue with various activations that we currently have and other activities we are supporting in the background.

**SGE:** How often does CGH say “no”?
CDC: About two thirds of the requests for global help are declined because we do not have capacity.

SGE: So DEO’s capabilities are not limited by CGH?

CDC: No, but staffing is an issue for DEO.

SGE: When you work with other countries, are there questions, with regard to liability, legal responsibility, etc?

CDC: We are coming in as a request. We provide countries with advice and the Ministry of Health decides what gets implemented.

SGE: Do you sign any kind of paperwork saying that you only providing advice to international partners?

CDC: Not that I’m aware of.

SGE: In domestic cases, if you provide advice and harm is caused, you can be sued or held liable. I think it would be wise to have some form of protection when providing advice to international partners.

CDC: In our work in China, we provided caveats that said this is what worked for us in the U.S. and that China needed to determine what can work for the Chinese system. We always provide those caveats and state that our recommendations need to be tailored to the country’s specific needs.

Liaison: Can you speak on including U.S. state and local staff in your engagements?

CDC: Where it makes a lot of sense, we can do that. In China, for example, we found ways to engage with our state and local colleagues.

SGE: Can you update us on consultations on ethical issues that arise during a public health response?

CDC: Within the incident management infrastructure, we have an Ethics desk to address ethical issues that arise. That advice is given to the incident manager.

SGE: Has that resource been called on recently?

CDC: During the H1N1 response and Haiti response it was.

SGE: Did it function well? Did its voice reach the appropriate person?
CDC: We have not done a formal evaluation, but it did reach the ethics manager.

SGE: I would suggest that there is a formal review to make sure that those processes are working efficiently.

Liaison: I think that that component does become critical, particularly with release of information to the media. In Ohio, we released information about three children with H1N1, to CDC. In that information were the ages of the children. The counties where the children lived were very small, and there was a risk of those children possibly being identified. For future processes, we decided it would be better to release only that the individuals affected were children and not their ages, in an effort to cut down on identity risks.
HOT TOPICS IN EMERGENCY PREPAREDNESS AND RESPONSE: BIOSURVEILLANCE AND SITUATIONAL AWARENESS — ARE WE THERE YET?

James W. Buehler, MD; Director, Public Health Surveillance Program Office, Office of Surveillance, Epidemiology and Laboratory Services

Public health surveillance
- People responsible for public health programs need reliable, on-time, and ongoing information about the health of the populations they serve

Biosurveillance
- People responsible for preparing for and responding to urgent public health situations need surveillance and other health-related information to direct their work
- Information supporting biosurveillance includes
  - Surveillance systems specifically designed for this purpose, but often have more general use
  - Systems designed for more routine use, that might augment our understanding in specific situations

Since 2001, U.S. government has intensified biosurveillance in a policy context
- CDC charged with advising the government, at large, to think about how to shape the surveillance agenda going forward
  - Recommendation: have a clearer focal point for biosurveillance
    - Pandemic and All-Hazards Preparedness Act (PAHPA) legislation requested that ASPR/HHS take a leading role
  - Variety of advisory groups at CDC rarely looked at one another’s work
    - Efforts to increase collaboration began

2002: BioSense 1.0
2010: BioSense 2.0
- Epi Info 7
- Electronic laboratory and health records
- Meaningful Use Syndromic Surveillance Message Guide
- National Public Health Surveillance and Biosurveillance Registry for Human Health
- PHTweet & situational awareness (SA) dashboard prototypes
- National Notifiable Diseases Surveillance System (NNDSS) redesign

Biosurveillance systems
- Extant systems have everyday applications in monitoring public health indicators
- Relationship to illness, death, environment,微生物s, viruses, biological signals and health care capacity can be monitored
- Inputs include sociodemographic overlays, physical feature information, and critical infrastructure objects
- Public health indicators provide all-hazard health incident information to local, state, and national decision makers on how to best protect the public’s health
  - Novel biosurveillance systems
    - Lots of interest in how social media can be used in biosurveillance but much research will be needed to make it effective for CDC’s work

Public Health Surveillance and Informatics Program Office (PHSIPO) mission and structure
- Mission: To advance the science and practice of public health surveillance and informatics
- Structure/function
  - Three different systems managed by PHSIPO
    - National Notifiable Diseases Surveillance Systems (NNDSS)
    - BioSense 2.0
    - Behavioral Risk Factor Surveillance System (BRFSS)
  - Additional activities
    - Informatics and IT infrastructure services
    - Supports preparedness and crisis response
    - Supports states and CDC programs in attaining benefits of health information automation, including “Meaningful Use” of electronic health record (EHR) technology
    - CDC home for addressing crosscutting surveillance and informatics issues

BioSense System / BioSense Cloud
- Robust syndromic surveillance systems depend on state participation to be effective
  - States receive information from emergency departments in their jurisdictions
- BioSense cloud
  - States access and share syndromic surveillance system information using BioSense cloud
  - Everything has been moved to the BioSense cloud because the amount of data overwhelmed CDC servers
  - Recently used for influenza surveillance
  - CDC EOC also using BioSense cloud
- BioSense cloud allows states to
  - Have more access to data management resources
  - Share information with CDC and other states
  - Share tools and resources

Building blocks for a robust biosurveillance system
- Well-trained workforce
• Core disease monitoring
• Electronic lab reports
• Syndrome monitoring
• Electronic health records

Biosurveillance at the state level
• Requires linked systems established through data use agreements with neighboring states participating in the BioSense 2.0
• CDC assistance required
  o High resource costs for data management infrastructure
  o Need for efficient information sharing
  o Scientific and technological know-how

Syndromic surveillance system (an example)
• System looks at patient demographics, examines chief complaints, and explores diagnosis codes
• System can then draw out disparities from that information
• In Boston, this system is used for monitoring a variety of health outcomes including influenza-like illness (ILI) and bicycle-related injuries

Question to the BSC: Where might OPHPR effectively engage and invest in biosurveillance?
• State level
  o Advanced workforce training and education
  o Disease and syndromic monitoring systems/method support
  o EHR migration
• CDC
  o Science and technology programming and support
  o Public information exchange platforms (cross-agency, state, local, tribal and territorial)
• Public Health Surveillance & Informatics Program Office (PHSIPO) (proposed)
  o Update, maintain, enhance and leverage existing systems designed to support the original mandates of HSPD-21 with respect to biosurveillance
  o Enhance cross-agency communication in order to avoid duplication of work and ease the requirements placed on our partners

QUESTIONS & DISCUSSION (HOT TOPICS IN EMERGENCY PREPAREDNESS AND RESPONSE: BIOSURVEILLANCE AND SITUATIONAL AWARENESS — ARE WE THERE YET?)

SGE: I think this is an important step. We are hearing that, with meaningful use, people will be able to send a lot more data, almost more than we can receive. I
also suggest that a focus on workforce training and development needs to stay in place. In addition, people don’t see the importance of population health metrics and its importance needs to be emphasized. Wired Magazine has a conference coming up that may be helpful to look to for information.

SGE: I have comments about language and messaging. There are definitions of surveillance and biosurveillance that also incorporate information for modeling. The definitions I’ve heard thus far do not include that. We need to align the definitions. We also need to develop comfort with information sharing. There’s a need to get better, with respect to situational awareness, with social media tools. Our office has done competitions to prompt people to work with social media. This will cause continuous improvement and take these skills to the next level. Do you have ideas of how to do this better?

CDC: We need to address your comments regarding definitions and give more attention to evaluation. We also want to do a better job of making our information available. We would love to be a part of any conversations to make that better.

SGE: Social marketing piece is complicated but an invaluable tool. You have to consider data quality, so I hope you have experienced people working on this to look at the complexities.

Liaison: I would like to celebrate the value of PulseNet. In Massachusetts, we had a Listeriosis outbreak associated with milk. PulseNet was very instrumental in decreasing harm done to the public. We need to enhance the system to make it faster and more intensive. We need to get it to share with Laboratory Response Network (LRN) labs. We should identify gaps in the system that need to be filled and identify how PulseNet can best support our work to respond to bioterrorism. We should strengthen the LRN and enforce their ability to enhance. It would greatly improve the system. We’re losing too much time due to the speed of the system.

SGE: There’s a movement in government to want to look at discovery of new information. We need to find ways to make data more available and accessible, so people can discover.

Liaison: We have seen how PulseNet assists. In NY, we received a lot of help in salmonella outbreaks. Your group can help our public health labs by establishing the protocols. Also, some programs established have been wonderful, like the APHL fellowship program. I applaud efforts for increased communication with responsiveness to requests for data and more data entry.
SGE: We’re always creating new tools. How do we keep the incentive to keep using these tools over time? We have to look at instruments that will give us the best bang for our buck. So many tools are developed and then pushed away and then another tool is developed. In addition, workforce development is needed and more training of the workforce.

SGE: Workforce health surveillance during a response is critical, and we need states to do that more effectively. We also need to look at access to care. It is also important to look at decision support and the effective tools for handling that.
SELECT AGENT REGULATIONS — AN UPDATE

Robbin S. Weyant, PhD; Director, Division of Select Agents and Toxins, OPHPR

Currently two significant policy issues
- Amerithrax related-biosecurity
- Biocontainment laboratory expansion

Brief history of select agent regulations
- 1996: Antiterrorism Act Select Agent Program
- 2001: Anthrax attacks in US
- Post-2001 legislative policies
  - Patriot Act
  - Bioterrorism Act
  - Select Agent Final Rule
  - 2009: Executive Orders 13486 and 13546
  - October 2011: Proposed Rule

Executive Orders 13486 and 13546 (2009)
- Signed by President Bush
- Requested gap analysis of US biosecurity
- Established interagency working group to review effectiveness of existing Biological Select Agent and Toxins (BSAT) laws, regulations and policies
- Requested examination of physical, facility, and personnel security practices
- Report compiled, which included the assessment of BSAT laws, regulations, and policies and recommendations for new legislation, regulations or guidance
- Recommendations for select agent regulations
  - Review/stratify select agent lists
  - Improve coordination of inspections
  - Provide guidance on inventory management and record keeping

Personnel security recommendations
- Federal level: enhance security risk assessment process
- Local level: require continuous monitoring of supervisor accountability and self-peer reporting

Physical security recommendation
- Develop minimum prescriptive security standards for regulated entities

Executive Order 13546
- Optimized security of biological select agents and toxins in the US
- Created a tiered/reduced select agent list
- Federal Expert Security Advisory Panel made recommendations on strengthening
o Personal reliability of BSAT workers
  o Physical security at BSAT facilities
  • Agency and department BSAT policies streamlined; inspections coordinated

October 2007 review of DSAT resulted in
  • More rigorous oversight of laboratory review process
  • Enhanced inspections
    o Pre-visit document review
    o Employee interviews
  • Non-routine inspections
    o Compliance verification
    o Response to concerns or complaints
    o May be announced or unannounced
  • Internal Entity Risk Assessment: identifies entities (i.e., laboratories which may work with BSATs) for more extensive oversight
  • Entity Performance Improvement Plan

Changes in DSAT oversight
  • More proactive incident responses
    o Active follow-up of theft, loss, release reports
    o Active surveillance of reports of identification of select agents in diagnostic samples
  • More outreach provided through guidance documents, scientific meeting participation
  • More emphasis on training

DSAT protocols for unannounced inspections
  • Authorized under 42 CFR Part 73.18
  • Unannounced inspections
    o Shorter in duration
    o Focus
      ▪ Previous inspection findings
      ▪ Specific security or safety areas
      ▪ “Real time” regulatory compliance
  • 2011: nearly 80 unannounced inspections conducted by DSAT

October 2011: HHS Select Agent and Toxin Proposed Rule published
  • In response, DSAT proposed
    o Tiered Select Agent List
    o Specific physical and cyber security requirements for Tier 1 BSAT
    o Personnel suitability programs for Tier 1 BSAT
    o Occupational health programs for Tier 1 BSAT

There have been several proposed additions and deletions to the HHS Select Agent List.

QUESTIONS & DISCUSSION (SELECT AGENT REGULATIONS – AN UPDATE)
Liaison: What’s the current comfort level with the new Proposed Rule and who provides information to states for planning?

CDC: DSAT sent communications to state health officers on two occasions and have gotten 10-12 states interested in learning more about its implications.

SGE: It would be helpful to have an external review regarding how agents are added or removed and current guidance regarding publication of research studies on dual use to make sure these processes are vetted by the public board.

Liaison: What you’re developing is a list of requirements for a reliability program?

CDC: Yes, we are learning what works best and have developed guidance related to the reliability program. We are putting together what we think will be helpful document. This is a mechanism for sharing best practices.

Liaison: There may be a lot expertise on the board to help with that guidance.

CDC: **BSC Request for Information (RFI):** If the board would like to see draft versions we can make those available.

Liaison: Do you have plans to analyze the data on unannounced inspections?

CDC: In the beginning of the year, we saw differences in inspection findings, for example with record keeping. As the year progressed, that list got smaller. I think that was because people saw we were very serious about this issue.

SGE: I think it bears watching this space very carefully. I suggest thinking about implications and longer term how to position programs at CDC to look at this. People should look at guidance for institutions, what’s covered and what’s not going to be covered. Expert controls may not be covered.
PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE) AND CDC’S SMALLPOX VACCINE PROGRAM — PART I

Richard J. Hatchett, MD; Chief Medical Officer and Deputy Director for Strategic Sciences, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services

Brief history of US biodefense efforts

- Mid-1950s: Department of Defense (DOD) and chemical defense programs
- Events of 2001 resulted in
  - Project BioShield
  - Public Readiness and Emergency Preparedness Act (PREP Act)
  - Pandemic and All Hazards Preparedness Act (PAHPA) legislation
- 2006: PAHPA led to the creation of
  - Biomedical Advanced Research and Development Authority (BARDA)
    - Goal of BARDA: fill gaps and create a more unified approach to biodefense
    - August 2010: publication of year-long review containing recommendations concerning emergency medical countermeasures
  - Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

PHEMCE: Organization and Mission

- US federal government interagency
- Organized under the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Coordinates oversight structure that aids in full life cycle management of medical countermeasures intended to prevent or respond to high consequence threats
- Addresses requirements to produce and have drugs, vaccines, diagnostic materials and medical supplies available during public health emergencies

PHEMCE: Mandate

- Covers established chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and novel and emerging threats
- Does not cover major endemic public health issues and rare or low impact public health threats
- Only partially covers needs related to the growing problem of antimicrobial resistance

PHEMCE: Systemic Challenges

- Complex problem space: define, design, develop, deliver and dispense medical countermeasures to reduce adverse health consequences of public health emergencies
- Significant technical challenges: long timelines from target identification to product emergence
  - Project BioShield
- Designed to expedite medical countermeasure research and development
- Enhance the availability of needed products by providing FDA the authority to issue Emergency Use Authorizations for unlicensed products

- **Economics**
  - Drug development is expensive, takes a long time, high risk
  - Limited, if any, commercial value associated with medical countermeasures designed to address specific, critical threats to national security

- **2004: Special Reserve Fund of Project BioShield**
  - Established by Congress as guarantee against market failure
  - Provides necessary funds and authority to address pressing public health and national security needs
  - Intended to foster development of a robust biodefense industry

**PHEMCE: Understanding and Defining Requirements**
- Decisions about what threats require countermeasure development are based on Department of Homeland Security (DHS) Material Threat Determinations
- PHEMCE assesses the level of impact of a particular threat on public health
  - Scenario-based
  - Employs advanced modeling techniques
- Requirement determinations for particular threats include
  - Predicted extent of population impact
  - Determination of the best medical countermeasures approach
  - Development of scenario-based requirements
  - Formal approval process
  - Product-specific requirements (PSR) for use by the Acquisition Program

**PHEMCE: Trade-Off Considerations**
- Top-Priority Threats vs. All Threats
- Traditional/Known vs. Emerging/Engineered Threat
- Fixed vs. Flexible Defense
- Specific vs. Broad-Spectrum
- Prevention vs. Treatment
- Acute vs. Chronic Effects
- First-Available Countermeasures vs. Next-Generation
- General vs. Special Populations
- Domestic vs. International
- Sustainability

**2010 PHEMCE Review provided revisions to the business model and proposed initiatives**
- Enhancements in regulatory innovation, science, and capacity
- Provision of core development and manufacturing services to innovators and MCM developers
- Expansion of flexible, surge-able manufacturing capacity
• Novel ways to work through public–private partnerships and support for pre-competitive collaborations
• Financial incentives for MCM development
• Addressing roadblocks from concept to advanced development
• Improved management and administration

QUESTIONS & DISCUSSION (PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE [PHEMCE])

SGE: ASPR is a maturing organization. I’m pleased ASPR is implementing a governance and organizational process. It is no longer the case that we will deliver a product without receiving input on how it will be used. H1N1 taught us the importance of end-user input. We also want to work with the developers at the front-end.

SGE: You showed the HHS side of the MCM enterprise, but there are some DOD parts.

Ex Officio: Many vaccines fall into that DOD unique space. We meet regularly with DOD to look at the aggregate portfolio. We have not solved the dilemma of special immunization. We have collaborated with DOD to provide a government-owned space where we can.

SGE: When you’re looking at MCM acceptability, we need to make sure we have the pediatric piece right. This is where acceptability is very important.

Ex Officio: And we are doing that currently with anthrax MCMs for pediatric populations to make sure we have addressed that in the revised pediatric plan.

PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE) AND CDC’S SMALLPOX VACCINE PROGRAM — PART II

Richard J. Hatchett, MD; Chief Medical Officer and Deputy Director for Strategic Sciences, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services

Smallpox countermeasures
• PHEMCE Mission: To develop and provide medical countermeasures for USG response in a smallpox emergency
• Medical countermeasures and indications include
  o Vaccines to break chain of transmission
  o Vaccines suitable for special populations
  o Antivirals to treat symptomatic population
  o Vaccinia Immune Globulin (VIG) for vaccine adverse events
• Ongoing efforts:
- Establish sustainable and appropriate mix of smallpox MCMs
- Conduct studies to inform utilization policies and procedures
- Draft utilization strategies for effective/efficient MCM deployment

Smallpox vaccine development over past decade
- 3 new vaccines: ACAM2000; Modified Vaccinia Ankara (MVA) Liquid Frozen Bavarian Nordic; MVA Freeze-Dried Bavarian Nordic
- 2 antivirals under development: ST-246 (SIGA) and CMX001 (Chimerix)

2010: Smallpox progress review
- Smallpox vaccine response strategy – includes triggers for action
  - Scientific and policy approval almost complete
- Smallpox vaccine utilization policy – includes considerations of all stockpiled vaccines
  - Initiated Spring 2012
- Smallpox scenario-based analysis – originally finalized in 2008
  - Revalidation in progress
- Smallpox antiviral product specific requirements – originally finalized in 2008
  - Revalidation in progress

There still exist outstanding issues in the following areas
- Vaccines
- Antivirals
- Diagnostics
- Adverse events related to policy requirements, science, and development

Current PHEMCE priorities
- Complete utilization plans and Product Specific Requirements for various MCMs
  - Requirements include
    - Input from PHEMCE partners and additional funds
    - Combinatorial studies to determine interference/enhancement
- Replenish MVA stockpile and long term life cycle maintenance with freeze dried MVA
  - Requirements include
    - Leadership concurrence on national response
    - Acquisition strategy to provide stop gap until transition to freeze-dried product
- Secure resources to bring ST-246 to licensure – FDA has provided a path forward
  - Requirements include
    - Additional funding
  - Additional clinical and non-clinical trials
- Continued dedication to special populations
  - Requirements include
    - Leadership concurrence on national response
    - Expand treatment of special populations with IMVAMUNE® (non-replicating smallpox vaccine candidate)
• Submission of data package for oncology patients
• Intravenous administration of ST-246

PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE) AND CDC’S SMALLPOX VACCINE PROGRAM — PART III

Inger Damon, MD, PhD; Poxvirus and Rabies Branch, National Center for Emerging and Zoonotic Infectious Diseases

Dr. Damon reviewed
• Public health role and goals regarding public health response to smallpox threat
• Associated medical countermeasures
• Challenges faced in achieving goals

CDC goals
• Address smallpox priority action items in the PHEMCE process
• Identify public health preparedness and response challenges for smallpox MCMs
• Align challenges to proposed 2012 PHEMCE strategy goals and objectives

Priority action items identified
• Smallpox vaccine response strategy
  o CDC co-led draft strategy development
  o 28 stakeholders from academia briefed on the draft strategy; 22 commented
  o Major issues identified
    ▪ Limited trained personnel
    ▪ Limited operational and implementation capabilities
    ▪ Lack of clear clinical guidelines
    ▪ Less reactogenic vaccine needed for persons other than HIV+ population
  o Revisions incorporating stakeholder input are pending
• Smallpox vaccine clinical utilization policy
  o Advisory Committee on Immunization Practices (ACIP) has agreed to update guidelines for laboratory personnel only
  o CDC is identifying terms of reference for workgroup and participating members
  o Terms of reference must be approved by ACIP leadership
  o Draft white paper on clinical utilization has been developed
  o Identification of external clinical guidance process and funding mechanism underway

Additional critical issues identified in last 12-18 months
• PHEMCE: multiple smallpox-related activities impact CDC SMEs and program
• BARDA: Intensive modeling effort to evaluate MCM operational and policy assumptions
• Smallpox Integrated Program Team (IPT): sub-workgroup for VIG needs assessment
• Regulatory and SME development/review of emergency use authorizations (EUAs) and investigational new drug applications (INDs) for smallpox vaccines and antivirals
• MVA licensure: need to support evaluation of regulatory path forward including variola neutralization

CDC activities relative to identified critical issues
• Smallpox MCM utilization planning, guidance and response strategies
• NOTE: Lack of leadership concurrence on national vaccine response strategy is preventing movement on other response planning activities
• Establishing external clinical meetings to discuss
  o Specific clinical utilization policy for ACAM2000, MVA, VIG and antivirals
  o Needed prioritization policy for use of MVA, VIG, and antivirals

Communication – a critical lynchpin
• Communication, training and educational materials dependent on finalized strategies and clinical guidance
• Lack of identified resources and personnel to develop and update supporting medical countermeasure-related materials
• Training required to ensure a prepared workforce

Proper/appropriate use of smallpox MCM: Research Needs
• Comparative studies between smallpox antivirals
• Combination antiviral therapy versus monotherapy with different mechanisms of action
• Assessment of emergence of antiviral resistance
• Regulatory review of diagnostics
• Antiviral effect on vaccine efficacy (i.e., co-administration of antivirals and vaccine)

Current licensure plans do not match public health utilization needs or plans

Real or near real-time safety and efficacy data in a response is another required element
• CDC and FDA have established a workgroup to identify strategies for adverse event monitoring
• Resources and personnel needed to address and plan for evaluation of efficacy data collection and analysis
• Post-administration monitoring and evaluation requires whole of PHEMCE engagement and commitment (not just CDC and FDA)

QUESTIONS & DISCUSSION (CDC’S SMALLPOX VACCINE PROGRAM)

Liaison: To elicit partner comment was a very structured and organized process. I appreciate that and would encourage you to use that process for best practice. It would be nice to let people involved in this process know where you are now.
SGE: I have general comments about the medical countermeasures. There are gaps on behavioral/risk communication side. We have to modernize strategies regarding communication.

Ex Officio: This is an issue we lived through in 2009. We worked with the Models of Infectious Disease Agent Study (MIDAS) group and would love to have a model developed to address this issue. Communications is a continuous challenge.

Liaison: I am struck by the difference in the way smallpox is discussed versus anthrax. There is discussion about use of the vaccines. I’m struck by the way decisions are being made and risk is being determined.

Ex Officio: We have begun to increase, in a number of our areas, engagement with end-users. We’re also looking for best practices.

Liaison: It may be good to look at your different approaches.

SGE: How do you prepare?

CDC: We can’t do everything. If you think there are areas where we are missing the boat, we need your direction to identify those areas.

SGE: Does your strategy call out an international strategy?

CDC: It needs to be exercised, and, on a contingency basis, it needs to occur soon.

ADJOURN

Dr. Inglesby officially adjourned Day 1 of the BSC meeting.
DAY 2 – MORNING SESSION

WELCOME / CALL TO ORDER / OPENING REMARKS

Thomas Inglesby, MD; Chair, OPHPR BSC, welcomed all participants to Day 2 BSC meeting, morning session.

Sam Groseclose, DVM, MPH, Associate Director for Science, OPHPR, and the Designated Federal Official (DFO) for OPHPR’s BSC called the BSC meeting to order and took roll. BSC Special Government Employee (SGE) board members, ex officio board members, and liaison representatives participating in-person and by phone are listed in Appendix B. Quorum was met.

OPHPR NATIONAL POLICY INITIATIVES

Angela Schwartz, BS, MBA; Associate Director, Office of Policy, Planning & Evaluation, OPHPR

Ms. Schwartz described
- Alignment of PHPR Divisions with national policy
- Congressional interest in PHPR Divisions
- Budget and legislative updates
- Innovative policy efforts
- Launch of an evaluation strategy

OPHPR services
- Support national framework for 2011 Presidential Policy Directive 8 (PPD-8)
  - Prevent, Protect, Mitigate, Respond, Recover
- Prevention activities: DSAT
- Protecting national health security: DSAT, DSNS, DSLR, DEO
- Mitigating and minimizing impact: DSNS, DSLR, DEO
- Response: DSNS, DSLR, DEO
- Recovery: DSLR, DEO

Congressional and media interest in what CDC is doing to address national health security
- Opportunities for OPHPR to tell its story are beneficial to CDC
- 23 Congressional inquiries: interest tends to focus on DSAT and DSNS
- A lot of interest in funding
- Additional inquiries: select agent list, funding cuts, and what’s in the stockpile?
- 15 GAO inquiries: Countermeasures, laboratory safety, and laboratory inspections
Revised Pandemic All Hazards Preparedness Act (PAHPA)
- House and Senate each passed their version of PAHPA
  - Similarities: additional FDA authority
  - Differences: HHS redeployment of personnel authority
  - Bills must be reconciled – reconciliation not expected until after 2012 elections

PHPR Funding by Appropriations Budget Line (2005-2013)

OPHPR policy efforts
- Align with national initiatives
- CDC has been revamping its Partner Strategy and demonstrating return on investment
- National Health Security Preparedness Index (NHSPI) intended to exhibit accountability and return on investment

Partnerships
- The point of partnerships: tell the preparedness and response story
- CDC is seeking to improve partnership relationships using strategic approach
  - Strengthen and support national public health security
  - Integrate Public Health, Healthcare, Emergency Management, and Private Sector
  - Enhance existing partnerships
• Expand PHPR’s partner network
• Clear value propositions for partners using structured, programmatic approach
  o 8 value propositions why people partner (CDC will select 3)
    ▪ Brand/visibility
    ▪ Convenience
    ▪ Credibility
    ▪ Expertise
    ▪ Funding
    ▪ Lack of bias
    ▪ Reach
    ▪ Relationships
• Partnership stratification: influencer, promoter, indifferent, supporter
  o Some partners may fall into all four categories
  o May be appropriate to move partners from one tier to the next

Telling the preparedness and response story: qualitative vs. quantitative
• Qualitative
  o Showcases nature of preparedness and response challenge
  o Illustrates public health contribution
  o Supports evidence base or demonstrates return on investment
• Quantitative (OPHR working to improve on this)
  o Want to align CDC measures against national policies
  o Examples
    ▪ DSLR working to put 7 more capabilities into OPHPR’s annual state-by-state report
    ▪ National Health Security Preparedness Index (NHSPI)

Partnership strategy benefits
• Stronger alliances: help identify broader group of motivated organizations to speak on behalf of emergency preparedness and response issues
• Storytelling: create a structured way to collect and create impact stories
• Policy products: helpful for Division and Program offices
• Partner site: tool for online collaboration

QUESTIONS & DISCUSSION (OPHPR NATIONAL POLICY INITIATIVES)

SGE: What are you evaluating? Why?
CDC: We do have a lot of measures and a lot places we have to report those to, so we need to align objectives. Now that we’ve released the OPHPR strategic plan, we want to align our measures to that strategic plan. We also hope that the Index will be the single measure, going forward, for demonstrating success and return on investment. We need to think about the four Divisions and the impact of our measures on those Divisions.

CDC: We use some measures to report on of how we’re spending our money. Initially we’re looking at the value of our program, but it’s not exclusive to that perspective. We want to think about this in the broader context.

SGE: Is the intent of the Index to provide a carrot and stick for funding?

CDC: We are trying to demonstrate accountability for the funding that we get. It is the trend right now to demonstrate impact and accountability of the investment, and we have to do that in a much more rigorous way. It may be appropriate to say that some activities are not a priority for my state, for example, and that’s why my performance is lower, which is okay. But, performance, or the measure, may be lower because the necessary resources are not available.

SGE: Nowhere on the PowerPoint slides does planning shows up as a word. Put that somewhere on your graphic presentation. Second, the crosswalk on what’s going on in preparedness and public health, in general, should be added. Case studies can be very important qualitative techniques employed, as well.

SGE: It seems that part of the initiative is looking to protecting critical programs. Linking the evaluation/partnering component with the Index is a marvelous way to accomplish that.

Liaison: We may need to celebrate the role that labs are playing in ruling out potential threats. You should add laboratories into your prevention category. I would be glad to help you add that in.

Liaison: In the desire to demonstrate improvement, we’ve forgotten the need to maintain. It costs more money to maintain. We have to figure out the right tools to tell the story of how much it costs to maintain systems and performance and where do those costs lie. Is it states, CDC, or locals? Most of us at the state and local level don’t know how to calculate hidden costs, and we could use your help to identify those.

Liaison: I hope that partners help with advocacy and accountability, which are important. It is also important to keep in mind the difference between outcome evaluation and process evaluation. The PHEP and capabilities are really process measures,
and we can’t use those to get to outcomes. We also need impact measures. Also, there’s the possibility that PHEP measures may not ever totally align to CDC measures, and that’s okay.

SGE: We need to be more compelling. What measures are already being assessed? Show us those and explain them. We can tell you what’s missing. I also agree that PHEP measures are not going to align perfectly.
PREPAREDNESS AND EMERGENCY RESPONSE LEARNING CENTERS (PERLC) — HISTORY AND OVERVIEW

Joan P. Cioffi, PhD; Associate Director, Learning Office, OPHPR

The Preparedness and Emergency Response Learning Centers (PERLC) are a sister program to the Preparedness and Emergency Response Research Centers (PERRC)

Dr. Cioffi asked for the Board’s thoughts on how to move the program forward in light of limited funding

PERLC program objectives align to support the national policy by

- Developing and maintaining proficiency of the public health workforce in support of national health security
- Collaborating with state, local, territorial, and tribal public health authorities to define and address gaps in worker competency and organization/system capabilities
- Developing core competency-based training in preparedness and response for the public health workforce
- Ensuring that public health training systems that support national health security are based on the best available science, evaluation, quality improvement methods and the PERRC/PERLC collaborative efforts
- Building on the Evaluation Framework to conduct evaluations for the purpose of continuous improvement of state, local, territorial and tribal public health preparedness and response competencies and capabilities

PERLC: Structure

- 14 PERLCs: Cover 36 states plus Washington, DC, Puerto Rico, US Virgin Islands
  - 5 locations have both PERRC and PERLC awards
- Program evaluation plan
  - Covers the entire program
  - All grantees required to have an evaluator on their team
  - Evaluators meet quarterly
  - Workgroup develops recommendations for evaluating each PERLC across the program
- Workgroup
  - Anticipated that the workgroup will publish some of their products
  - Linking education and training to impact is difficult
  - Emphasis on evaluation and metrics has stimulated some efforts to measure impact

PERLC: Funding

- PERLC FOA is currently in Year 3, of a 5-year program
- Very diminished funding for year 3 (see graphic)
Funding History

The PERLC FOA is currently in Yr. 3 of a 5 year program.

PERLC: Impact
- PERLC education and training programs have reached 90,000 learners
- PERLC program has contributed at national, regional, state, tribal and local levels
- Several PERLC have the capacity to use GIS capability for rapid community assessments
- NACCHO Project: PERLC recommended methods to improve administrative preparedness process at the state and local level
- Evaluation and strategic efforts in pediatric surge capacity in the southeast region

PERLC: Program Origins, Core Efforts, Linkages
- Program origins: built on lessons learned from the Center for Public Health Preparedness (CPHP) Program
- Core efforts
  - Multi-sector partnerships
  - Access to academic expertise
  - Sustainable and scalable learning infrastructure
- Linkages (largest return on investment)
  - PHEP FOA and Capabilities
  - NACCHO Preparedness Portfolio
  - Advanced Practice Centers (APCs)
  - Public Health Law and Preparedness Project
  - HRSA Public Health Training Centers
  - Preparedness and Emergency Response Research Centers (PERRCs)
Proposed topics for discussion with the BSC
- Dissemination: What else can be done to share the PERLC products/services?
- Learning Infrastructure: PERLC/CPHP legacy represents a core infrastructure for preparedness education for public health. What can be preserved? How?
- Targeted Investments: What are the appropriate tools or methods to support workforce preparedness training?

QUESTIONS & DISCUSSION (PREPAREDNESS AND RESPONSE LEARNING CENTERS [PERLC] – HISTORY AND OVERVIEW)

Liaison: A focus on the next generation of workforce training and getting people interested in the field is critical. I commend the work being done in this area.

SGE: I like the work that the PERLCs have undertaken, but we still need to talk about workforce involvement in the field. We still have silos there. We need ways to figure out what the impact is and how to get a better impact on investment.

Liaison: There are states where partnerships don’t exist, so consider best practices of some of the labs, for example. Export them to some of the other training programs, and do it so people don’t have to be onsite to access training. I think that would be a great product to create.

Liaison: Remember where local preparedness programs rest. Those individuals are often separate from decision makers. Look also at public health accreditation and finding ways to get better tracking with some of these tools. I don’t think CDC does a good job of publicizing those tools and tracking their use, as well. Local health departments are often not aware of the tools. Don’t make this a passive system. You have to play a more active role in making people aware of your tools.

SGE: Since you’re working with universities, can you take advantage of the structures they already have, like mailing lists, newsletters, and media relations, for example. Make it known that they could assist CDC with distribution.

Liaison: I would recommend using liaisons to broaden your catalog of strategic partnerships. ASTHO and others will be willing to support you in that.

SGE: I don’t think the word training itself describes the need. I think you need to be more explicit about the consequence of diminished training, so that it conveys urgency to Washington.
[The workgroup adjourned the morning session.]
DAY 2 – AFTERNOON SESSION

WELCOME / CALL TO ORDER / OPENING REMARKS

Thomas Inglesby, MD; Chair, OPHPR BSC, welcomed all participants to Day 2 BSC meeting, afternoon session.

Sam Groseclose, DVM, MPH, Associate Director for Science, OPHPR, and the Designated Federal Official (DFO) for OPHPR’s BSC called the BSC meeting to order and took roll. BSC Special Government Employee (SGE) board members, ex officio board members, and liaison representatives participating in-person and by phone are listed in Appendix B. Quorum was met.

NATIONAL HEALTH SECURITY PREPAREDNESS INDEX (NHPI) UPDATE

John Lumpkin, MD, MPH; NHPI Steering Committee Chair

NHPI: Background
- Preparedness field lacks a composite picture of capabilities across the public health spectrum
- Association of State and Territorial Health Officials (ASTHO)
  - Initiated development of a National Health Security Preparedness Index
  - Created a project team structure to design and launch the Index
  - NHPI developed under CDC cooperative agreement
- NHPI intended function and scope
  - Span breadth of preparedness domain topic (i.e., scope is much more than CDC/ASPR grant performance measures)
  - Embrace already established relevant and applicable metrics and only create metrics where gaps exist
  - Include viewpoints and feedback from broader preparedness community

NHPI: Mission
- Present an accurate portrayal of public health and health system preparedness
- Provides relevant, actionable information to drive decision-making and continuous improvement of the nation’s health security

NHPI: Activities and Structure
- Addressing public health component (1st) and healthcare system preparedness (2nd)
- Steering Committee
- Provides high-level guidance and makes decisions
- Goal: Prepare an index that can be rolled up into a single public health lane

**Governance workgroup**
- Membership reflects that of the Steering Committee
- More “hands-on” than the Steering Committee
- Reviews/approves recommendations and products coming from the two workgroups prior to elevating to Steering Committee

**NHSPSI: Purposes**
- Assess investments made to date and inform future funding decisions
- Identify current public health and health system capabilities, assess gaps, and identify best practices for the purpose of quality improvement
- Serve as a one-stop shop for measurement and a single tool resource for states and locals to measure preparedness
- Provide consistency over time
- Demonstrate how well a state can be prepared at a certain level of funding

**NHSPSI: Version 1.0**
- Will not be a finished product
- Will be the first step down “the one public health lane”
- Will continue to evolve and improve
- Goal: make it easier to explain preparedness.

**NHSPSI: Building the Index**
- All 3 workgroups currently working on Phase II: index design
- Plan is to refine the index, share it, and refine it again over the next 6 months
- Nearing completion: research into existing types of indices and what range of metrics to consider
- PERRCs
  - Completed an annotated bibliography in coordination with the Association of Schools of Public Health (ASPH)
  - Drafting a White Paper
- First version of the public website: [www.astho.org/preparednessindex](http://www.astho.org/preparednessindex)

**NHSPSI Governance Workgroup activities**
- **Identify where the index belongs** long-term, who will own it, who will manage it
  - Entity that ultimately “owns” NHSPSI needs
    - Authority, Credibility, Impact
      - Endorsed and respected by the health community
      - Capable of engaging/influencing stakeholders
      - Able to drive consensus across preparedness community on modifications, improvements, needed resources
    - Resources
• Staff and funding to annually administer Index
• Support ongoing efforts to drive continuous improvement

  ▪ Objectivity
  • No appearance of bias
  • Conducts work in an open manner

  ▪ Accountability
  • Accepts ownership of process and drives results
  • Incorporates stakeholder feedback in model revisions

  ▪ Competency
  • Able to manage sensitive information
  • Experienced in a variety of health disciplines
  • Able to translate technical language to lay people

• Making recommendations on how Steering Committee will vote
  o Steering committee operates by general consensus
  o Resolution sought by simple majority vote
  o Workgroup chairs included as voting members in Steering Committee decisions

Proposed agenda for upcoming Governance Workgroup webinar scheduled for 08/28/2012
• Finalize list of desired owner characteristics
• Discuss compiled list of suggested owner organizations and pros and cons
• Discuss recommended ownership structures
• Review draft of Stakeholder Communications Plan
• Review recommendations from Model Design workgroup

NH SPI: Stakeholder communications
• Message maps for Index-related Frequently Asked Questions (FAQs)
  o Beta-testing FAQs now before posting them to NH SPI website
  o FAQs to be updated regularly throughout Index development process
• September 2012
  o Open-ended feedback questions to be posted on NH SPI website for general comment
  o Draft Strategic Communications Plan to be finalized by September 5, 2012
  o September 5: in-person meeting agenda
    ▪ Finalize Stakeholder Communications Plan
    ▪ Review recommendations from Model Design workgroup
    ▪ Finalize the stakeholder engagement calendar and feedback platforms

NH SPI: Model design
• Index to fulfill two functions: demonstrate accountability, drive quality improvement
• Focus on identifying indicators that can be compiled into a single-number index
• Primary unit of analysis: the “state” – the 62 Public Health Emergency Preparedness (PHEP) and Hospital Preparedness Program (HPP) jurisdictions, including States, directly-funded cities, territories, and Washington, DC
• Primary components of the Index: measures of the 15 PHEP Capabilities

NHSP[1]: As-Yet Unresolved Topics regarding Model Design
• Data sources
• Methodology for creating a summary score
• Weighting methods
• Indicators to be included in Index calculation
• Methodology for swapping measures in/out of the Index

NHSP[1]: Next Steps
• Workgroup has grouped the 15 PHEP Capabilities into five sub-groups
• Teams assigned to identify and select measures in the following domains
  o Biosurveillance
  o Community resilience
  o Countermeasures and mitigation
  o Incident management and information sharing
  o Surge management
• Workgroup team approaches and selected measures to be discussed on
  o August 28: Governance workgroup webinar
  o September 5: Stakeholder Communications Workgroup
  o September 18: Steering Committee webinar

Proposed topics for discussion with the BSC
• What factors would make the Index most useful for state and local health departments?
• Are there measures that should be considered for development for use in a future Index even though they are not measurable right now?
• What stakeholder groups are the most important for us to reach during Index development?
• What are the pitfalls we should avoid in development and rollout of the Index?

QUESTIONS & DISCUSSION (NATIONAL HEALTH SECURITY PREPAREDNESS INDEX [NHSP[1] UPDATE)

SGE: Now is a really important time for the community to respond. If you all think there should be a change, things we should reach for, we should talk about that now.

Liaison: I would like to reflect on comments about how we grade people. People have expressed issues of wanting to look good, but not too good. Maybe we don’t assign a number and instead say that improvement is advanced two thirds of the
way toward preparedness. Show them on a continuum of improvement maybe from no improvement to reasonable improvement, a sliding scale kind of model. This is just a fuzzy recommendation.

SGE: Do not forget to include legal preparedness and include legal experts to look at liability risk and to protect yourself.

Liaison: I think it’s important that the model is not restrictive to quantitative numbers. There are also some demographic issues that need to show up in a state’s profile. The index was supposed to be a relative ranking, not a ranking against an absolute. I would also add that other stakeholders could be key legislative members, governors, policy advisors, homeland security advisors, etc. Give states a relative sense of how they compare with their peers.

SGE: I suggest that you need to have a way of mapping metrics to real outcome and doing sensitivity measures. I’m not sure exactly what model you use, e.g., hurricanes or plumes, but I think it’s a way to try to get at outcomes.

SGE: You can go and look at past events and see how states responded.

SGE: The devil is in the details. Preparedness for what? It is different for different locales. So to what extent is one’s healthcare system prepared to respond? We could do regional partnerships so no state or hospital can identify itself. The issue of who owns the NHSPI is critical also. The model is good for right now, but because data changes, the model will change, so who changes that model is important. Lastly, get comments from and get the community involved.

Liaison: In response to question1, take state specific reps and look at the way they measure. We still don’t know how states will roll up local health department information, but it will make a difference in how they look. On question 2, find objective criteria for what worked, in real life, and how did they do in that scenario.

SGE: The politics of this index are as important as the tools and stakeholders and the data rolled out to them. Showing what is it that your community would stand to lose if funding is not made available. Make sure that this is not punitive, as well. The level of preparedness from rural areas are different from those of metro areas, so variability should be reflected accurately. You need to measure practice from a planning perspective.

Liaison: It’s important for local entities to have a baseline. In the case of a lab, we may not be able to do more than say that the lab is capable of doing “blank” versus how many things can they produce.
SGE: One way to validate the Index is to look at data on previous events to see if the Index would have predicted the outcome. Look at media coverage and news stories. You can see how communicating the risk management plan worked. The Index has to consider where states and localities start.

Liaison: I would like to see a component of lessons learned shared across state lines. I feel we do that to some degree but not enough.

SGE: Trust for America’s Health and the State Ranking Model are not the best, but it is something we can build upon. I read the Ready or Not Report. The 2011 report says the states are less prepared now than previously. Who fills out those forms make a difference in how that report looks. Locals will also be angered, if they feel the rankings are not correct. Some feel that they are doing much better than how the states are ranking them.

Liaison: Regarding other measures, After Action Reports (AARs) or some peer-driven rapid assessment post response could help validate the model or generate data. Going forward, do we finesse the way the public health community reports versus how FEMA reports the national preparedness scheme? We need to understand why there are differences. Are they good enough to have a useful model prepared and used by this coming March? We don’t want to put something out just for the sake of putting something out. How do we manage achieving this objective considering the limitations we’re working under?

Liaison: There are a variety of opinions on that. Don’t let perfect be the enemy of good enough. We can talk about what is perfect. We can create a framework and continue to move forward. I also don’t see the FEMA issue as a complete barrier. So there are a number of opinions. And we are assessing whether we’re at “good enough.”

Liaison: That’s why I’m an advocate of measuring success and figuring out which logic models are the best.

SGE: Coarsen the visible data. You can tell states that if they provide their data, they can get access to other state’s data.

CDC: There’s an idea that states don’t want to be measured. But, we are already being measured. If we don’t do it ourselves, someone will do it for us. How do we use our expertise to come up with something good enough for now to tell our stories instead of somebody else telling out story?
PREPAREDNESS UPDATES FROM BSC LIAISON REPRESENTATIVES

Association of Public Health Laboratories (APHL)
Mary JR Gilchrist, PhD and Christine Egan, PhD, CBSP

Dr. Gilchrist: APHL is currently assessing the state of laboratory preparedness.
Dr. Egan: APHL has to continue to work to enhance funding and to enhance capacity. They will to continue to monitor and foster those efforts.

Association of Schools of Public Health (ASPH)
The ASPH Liaison was unable to attend and provided a written update.

Association of State & Territorial Health Officials (ASTHO)
Jean C. O’Connor, JD, DrPH

ASTHO has been working on a several items
• Recent meeting with CDC to discuss Anthrax Vaccine Prioritization Project
• Engaging national subject matter experts to discuss coping strategies for drug shortages
• Projects related to Japan nuclear power plant disaster
  o June 2012: Report released – see especially key recommendations and leveraging opportunities
  o Early 2013: planning a tabletop exercise to test protocols developed in response to nuclear power plant disaster
• Creating toolkits on navigating legal barriers (for state health officials)

Council of State & Territorial Epidemiologists (CSTE)
Patricia Quinlisk, MD, MPH

• CSTE’s biggest issue: dwindling financial resources
  o Grant funding is decreasing
  o CSTE is prioritizing and locating areas that give the greatest return on investment
  o Concerns over science being given less weight than politics
• Measuring preparedness can also be achieved by looking at response to everyday events

National Association of County & City Health Officials (NACCHO)
Karen Smith, MD, MPH

• NACCHO working with PERRCs at ways to disseminate best practices and tools
• How to help local jurisdictions
  o Navigate performance measures (everyone seems to have different measures)
  o Tailor performance measures to unique, individual, locale-specific situations
National Indian Health Board (NIHB)
The NIHB Liaison was unable to attend. No update provided.
SNS 2020 FORESIGHT REVIEW — AN UPDATE

Donald Burke, MD; Co-Chair BSC-NBSB SNS 2020 Joint Working Group

Dr. Burke provided a very brief update on the Board of Scientific Counselors – National Biodefense Science Board Strategic National Stockpile 2020 Joint Working Group

Workgroup members include
  • Donald Burke, Margaret Brandeau, Hermania Palacio (BSC)
  • John S. Parker, Emilio Emini, Steven Krug (NBSB)

Work group is currently in the formative stage and has had two conference calls

There will be a report created in six months.

PUBLIC COMMENT PERIOD

The BSC received no public comments.

MEETING RECAP AND EVALUATIONS, ACTION ITEMS, FUTURE AGENDA

SGE: Do you all have thoughts on how we can make better informed discussions?

SGE: We need to pose questions. We may not answer all of them, but they can provide structure and allow us to give more information as a board.

SGE: Presentations are high quality, but they often go over, limiting our ability to provide feedback. There should maybe be a moderator for time management purposes.

CDC: What I want to encourage is that we have more discussion that builds on each person’s comments and will ultimately lead to a group recommendation.

SGE: That is hard to achieve with the discussion format we’re using.
SGE: Maybe we address it via a process change, e.g. wave the card if you are building on a previous comment.

CDC: We want to have more coalescing of comments and recommendations from the board, and it will require structural changes. Do you have suggestions for those?

Liaison: One way to restructure is have the speaker frame questions about things to consider and action items. We may need to add in a break, so that we can think about action items or have time to discuss them and report back our thoughts after the break.

SGE: I found it difficult to prepare because there were no specific action items to guide my focus. I got a lot of information, but needed more direction in that area. And we need more time for discussion.

SGE: Maybe have read ahead materials and point out those areas where you would like our advice. Then we can come prepared to provide feedback.

SGE: At the foundation, we use a chat process, where you can ask questions. This preserves questions, and people can answer questions.

Ex Officio: We could have a working lunch for group members to sit and talk.

Liaison: Pick out hot topics and set more time for those hot topics.

SGE: We spend too much time on slides. Speakers should tell us things that are not on the slides and get right to discussion. We can read slides in advance and come prepared to discuss. In the meeting, we should have seven or eight slides of things we haven’t seen or something synthetic, and then we’d have 45 minutes of discussion. Presenting a huge amount of information will cause people to comment on one or two slides but not allow for a lot of deep discussion.

SGE: Not all discussion will be the same. It may be brainstorming, options, input, or a decision tree, for example.

Ex Officio: Going forward, this is an opportunity for your staff to bring their challenges to this board. We can be their sounding board. Provide those challenges to us ahead of time, so we’re teed up with answers for them. You can maybe have some key presentations, but we don’t need to hear from all of them all the time.

Liaison: Give us things that you need consensus on.
Liaison: I hope that the read-ahead materials are not slides but the textual materials. It sounds like you are getting different perspectives from different stakeholders and knowing that ahead of time can help us better frame our discussion.

SGE: For future meetings, provide a brief synopsis on PAHPA, IOM and other outside-body reports that are influencing the OPHPR work, as well.

CDC: Early in the meeting Dr. Lumpkin provided the name of a book. Maybe we discuss leveraging and liberating data and share what you’re doing around that topic. We can, for example, look at our own bureaucratic scientific administrative environment (e.g. institutional review board [IRB], Office of Management and Budget [OMB] requirements, etc.) and discuss how to make science available faster. We can identify, frame the vision for the work, collaborate, and think about the pieces to address that will allow us to improve and do discovery. Then we brainstorm, pull out key pieces, and define action items for our organization to address. Is that reasonable and how can we develop that more here?

SGE: Reinventing Discovery is the book he was referencing. I think it is an important topic and the right direction to go. I think there will be dramatic changes to how we use data. Using this group to think about those would be great, and you are in a position to move the field. I would enjoy participating in that.

Liaison: I like the idea. It will stretch us, in finding out how to do that. Everybody is trying to find a way to break silos. Resilience and recovery is another issue we need to tackle.

CDC: Do you have thoughts about that or is it not the top priority since we are still trying to figure out preparedness?

Liaison: Public health will have to start measuring that, and it’s showing up, in the PHEP agreement, but that’s only why I bring that up. We can put energy in other areas. If it’s not a priority, I’m okay with that.

CDC: And priority doesn’t necessarily mean important.

SGE: The other subtopic is manpower. What will manpower requirements be in ten years? We need to factor that into plans, and my perception is that CDC isn’t doing that quite as well.

SGE: I underscore those comments. It has not been really well developed, but there have been advancements. Risk management strategies and workforce underscores the importance of that piece because it is crosscutting.
Dr. Khan thanked the Members for their comments on how to conduct future meetings and ways to be more effective.

Dr. Inglesby also conveyed appreciation for the great discussions and advice. His desire is that this group continues to collaborate going forward in order to be more helpful to CDC.

ADJOURN

With no further business raised or discussion posed, Dr. Inglesby officially adjourned Day 2 of the BSC meeting.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the August 21-22, 2012 meeting of the OPHPR Board of Scientific Counselors are accurate and complete.

_______________________ Date ____________________________

Thomas V. Inglesby, MD
Chair, OPHPR BSC
Appendix A. OPHPR BSC Membership Roster

Chair

Thomas V. Inglesby, M.D.
CEO and Director
Center for Biosecurity – UPMC
Baltimore, MD

Designated Federal Official

Sam Groseclose, DVM, MPH, DACVPM
Associate Director for Science and Public Health Practice
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention

Special Government Employees (SGE) Board Members

Margaret Brandeau, MS, PhD
Coleman F. Fung Professor
School of Engineering
Stanford University
Stanford, CA

Donald S. Burke, MD
Dean, Graduate School of Public Health
University of Pittsburgh
Pittsburgh, PA

Sharona Hoffman, JD, LLM
Professor of Law and Bioethics
Case Western Reserve University School of Law
Cleveland, OH

John R. Lumpkin, MD, MPH
Senior Vice President and Director
Health Care Group
Robert Wood Johnson Foundation
Princeton, NJ

Ellen MacKenzie, PhD
Professor and Chair
Department of Health Policy and Management
Bloomberg School of Public Health
Johns Hopkins University
Baltimore, MD
Herminia Palacio, MD, MPH
Executive Director
Harris County Public Health and Environmental Services
Houston, TX

Louis Rowitz, PhD
Director
Mid-America Regional Public Health Leadership Institute
University of Illinois at Chicago, School of Public Health
Chicago, IL

Robert J. Ursano, MD
Chairman, Department of Psychiatry
Uniformed Services University of Health Sciences
Bethesda, MD

Elaine Vaughan, PhD
Research Professor and Professor Emerita
Department of Psychology and Social Behavior
School of Social Ecology
University of California, Irvine
Irvine, CA
Ex Officio Board Members

*US Department of Health and Human Services*
  RADM Nicole Lurie, MD, MSPH
  Assistant Secretary for Preparedness and Response
  Washington, DC

  CAPT Charlotte Spires, DVM, MPH, DACVPM (Alternate Representative)
  NBSB Executive Director
  Office of the Assistant Secretary for Preparedness and Response
  Washington, DC

*US Department of Homeland Security*
  Alexander Garza, MD, MPH
  Assistant Secretary for Health Affairs and Chief Medical Officer
  US Department of Homeland Security
  Washington, DC

  Sally Phillips, RN, PhD (Alternate Representative)
  Deputy Director, Health Threats Resilience Division
  Office of Health Affairs
  US Department of Homeland Security
  Washington, DC

*US Department of Defense*
  CDR Jesse Geibe, MD, MPH, MBA (Acting Representative)
  Defense Department Liaison Officer
  Centers for Disease Control and Prevention
  Atlanta, GA
Liaison Representatives

**Association of Public Health Laboratories (APHL)**
Mary J. Gilchrist, PhD, DABMM
Consultant, Public Health
Solon, IA

Christina Egan, PhD, DBSP
Chief, Biodefense Laboratory
Wadsworth Center
Albany, NY

**Association of Schools of Public Health (ASPH)**
James W. Curran, MD, MPH
Dean, Rollins School of Public Health
Co-Director, Emory Center for AIDS Research
Emory University
Atlanta, GA

**Association of State and Territorial Health Officials (ASTHO)**
Jean O’Connor, JD, DrPH
Deputy Director, Public Health Division
Oregon Health Authority
Portland, OR

James Blumenstock (Alternate Representative)
Chief Program Officer, ASTHO
Arlington, VA

**Council of State and Territorial Epidemiologists (CSTE)**
Patricia Quinlisk, MD, MPH
Medical Director and State Epidemiologist
Iowa Department of Public Health
Des Moines, IA

**National Association of County and City Health Officials (NACCHO)**
Karen Smith, MD, MPH
Public Health Officer and Director of Public Health
Napa County Health and Human Services Agency Public Health Division
Napa, CA

**National Indian Health Board (NIHB)**
Stacy A. Bohlen, MA
Executive Director, NIHB
Washington, DC
## Appendix B.

**Board of Scientific Counselors (BSC)**  
**Office of Public Health Preparedness and Response (OPHPGR)**  
**Centers for Disease Control and Prevention (CDC)**  

**BSC Voting, Ex Officio, and Liaison Membership Attendance**  
**BSC Meeting – Atlanta, GA – August 21-22, 2012**

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<tr>
<th>Last name, First name</th>
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### Appendix C. Acronyms

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<td>ARRA/HITECH</td>
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