CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR)

BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING

SUMMARY REPORT / RECORD OF THE PROCEEDINGS

APRIL 2-3, 2013

ATLANTA, GEORGIA

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
OFFICE OF PUBLIC HEALTH PREPAREDNESS & RESPONSE (OPHPR)
BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING

1600 Clifton Road, NE
Atlanta, GA
April 2-3, 2013

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.

Dr. Khan addressed the BSC

- He thanked the BSC members for their time given their demanding schedules
- Travel
  - CDC's travel budget had been cut in half
  - In light of sequestration, the budget will be cut in half again
  - However, given the extreme importance of national preparedness and the expertise and wisdom the members provide to the agency, travel for the BSC has been preserved
- SNS 2020
  - On meeting day 2, the BSC will meet with the National Biodefense Science Board (NBSB) – an unprecedented event to discuss the recently completed review of the Strategic National Stockpile (SNS) and what it might look like in the year 2020

ROLL CALL AND REVIEW OF FACA CONFLICT OF INTEREST

Samuel L. Groseclose, DVM, MPH, Associate Director for Science, OPHPR and the Designated Federal Official (DFO) for the OPHPR BSC called the BSC meeting to order and took roll. BSC Special Government Employee (SGE) Board Members, ex officio Board Members, and liaison Board Members participating in-person and by phone are listed in Appendices A and B. Quorum was met.

Dr. Groseclose reviewed the duties of the Board per the BSC charter. Dr. Groseclose asked for members to self-identify any conflicts of interest. Dr. Groseclose asked that if, in the process of the two days of deliberations, a BSC Member believed that they did have a conflict of interest, s/he should draw that to his attention.

Dr. Palacio identified that her agency receives indirect funding from CDC through the Public Health Emergency Preparedness (PHEP) cooperative agreement to the states. No other conflicts of interest were identified.

ENGAGING THE BSC: THE NEW OPHPR BSC SHAREPOINT SITE

CDR Christye Brown, MPH, MBA, (OPHPR BSC Coordinator) presented the OPHPR BSC SharePoint Site

- Created to fulfill a direct need expressed by members
- Purpose: keep BSC Members and Liaison Representatives connected with OPHPR's activities throughout the year
- Will allow all BSC materials to be housed in a central repository for immediate, up-to-date access
- Will also provide a real-time communication channel for activities, such as setting meeting dates, commenting on review materials, sharing publications
- Content includes
    - Board and member information
    - Background info on PHPR Divisions
    - Calendar of Events
    - Discussion link to share feedback as necessary
    - Scientific information portal - articles and/or research materials for review
- Voting members and liaisons are asked to
    - Check the site when notified of newly posted documents
    - Notify the BSC Coordinator of profile updates
    - Share information and provide feedback as appropriate

QUESTIONS & DISCUSSION (THE NEW OPHPR SHAREPOINT SITE)

SGE: Please place pre-read materials for upcoming meetings into a simulated binder format, in order to identify actual agenda items.

CDC: One-pagers were included to identify agenda items. Perhaps in the future, an overall document will be more beneficial.

DIVISION OF EMERGENCY OPERATIONS

CRITICAL INFORMATION SHARING: A CONVERSATION WITH THE BSC

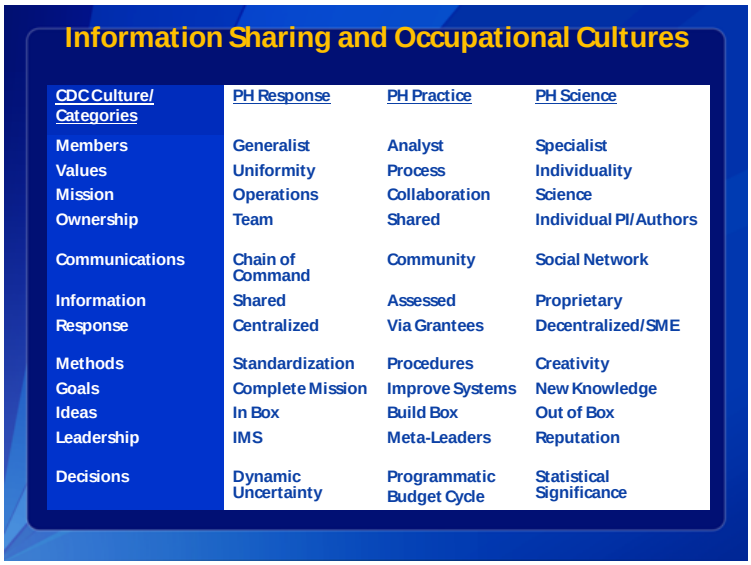
Mark Wooster, PhD, Associate Director for Science, Division of Emergency Operations, OPHPR, presented some of the barriers to public health information sharing, which is a concern for the DEO. He solicited the Board's feedback and advice around the following questions

- How can OPHPR identify and reduce social-behavioral-occupational impediments to information sharing?
- How can OPHPR advance and foster a culture of sharing information?
- How can OPHPR improve its development and use of information sharing triggers such as the Director's Critical Information Requirements (DCIRs)?
- How can the Emergency Management Program and Incident Management System (IMS) increase the value and timeliness of information it receives in order to become more proactive in how CDC responds to public health incidents?

Lack of information sharing results from a lack of trust

Three cultures at CDC

- Public health scientists
- Public health practitioners
- Public health responders



Each of the three cultures has different requirements, propensities, outputs and outcomes

- Differences can lead to issues with the coordination and supply of timely information

Understanding cultures and increasing trust will encourage information sharing and greatly improve CDC's overall situation awareness.

Emergency Management Program

- Includes several essential tasks that are greatly influenced by information, situational awareness, and communication

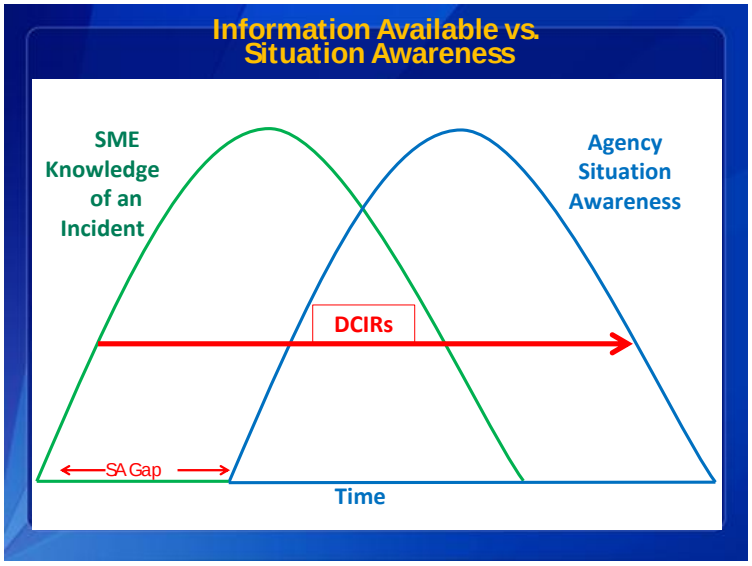
- Director's Critical Information Requirements (DCIRs)
  - Provide a guide for disseminating information and assigning priorities
  - Some are internal to CDC (e.g., accidental deaths or injury; events affecting CDC)
  - Others are pertinent to national and global events (e.g., disease outbreaks ; chemical, biological and nuclear threats or incidents)
  - Also established for specific activations

Criteria to implement the CDC Incident Management System

- Federal level interest
- Number of cases and/or deaths
- International impacts
- Exceeds management / staffing capability of program
- Urgency of event
- Geographical dispersion
- Predictable impact (hurricane)
- Public health threat
- Number of CDC organizations involved
- Media interest
- Need for numerous deployments and/or procurements
- Select agent (anthrax, ricin, botulism, etc.)
- As directed by the CDC Director

Information available versus situational awareness

- Green line: indicates what a subject matter expert (SME) knows at a certain time
- Blue line: what the agency knows
- How might CDC reduce the gap in situational awareness and locate the optimal balance?



QUESTIONS & DISCUSSION (CRITICAL INFORMATION SHARING: A CONVERSATION WITH THE BSC)

- DEO should establish clarity of purpose and share the mission. This will help individuals understand how they fit into the grander scheme. In addition, look for points of alignments to the mission in order to help individuals meet their goals.

- CDC's outface has greatly improve in the realization that information does not have to actually be perfect before it is shared. Make sure that this concept is also communicated internally, which may provide some relief. Give clear guidelines on how to share information, triggers for sharing information, and with whom to share information. Training is vital and should be conducted with the usual and unusual suspects.
- There is a lack of understanding at the "worker bee" level of the impact of data sharing on confidential matters. In the past, there were incidents where information shared was then released in a way that could possibly have identified individuals affected in an outbreak. This eroded trust. It also slowed down reports to CDC. Information is now reviewed before being shared to prevent similar mishaps. Worker bee level individuals do not truly understand what amount of information should be shared. CDC should provide more training for its staff to ensure that they understand data sharing agreements.
- Information sharing should be a reciprocal relationship. The Laboratory Response Network and public health departments would like to know about events or cases that happen in other areas.
- There should be a Chief Information Officer, who makes a map of the organization, to figure out where things are bogged down. Are there rewards for sharing? Information sharing should not be used against staff. Are there crosscutting themes? Someone on each team needs to be able to cross share. This must be a circular organization – meaning those at the top are one team with those at the bottom. The board must take on an active role by having cultural surveys, studies on the organizational climate, etc. It is not just the overt issues but also the fuzzy signals. Who receives information? Is it directly related? This is why many organizations have a permanent CIO. CDC has a CIO but more from an IT perspective. CDC also has to be a learning organization and this relates to the strategic plans of the organization.
- There is a difference between peace-time data sharing and crisis response data sharing. There are three things to avoid:
    - Why did they not tell me they needed this information weeks ago?
    - Why do they need to know that?
    - I just gave that information to so and so.
- There needs to be a common operating picture to cut down on errors that cause breakdowns in communication.
- There should be a mechanism to post aggregate data, which is available all the time, and another for information that is not ready to be shared. This should be handled separately and not open to the public.
- One SGE indicated that her agency has a strong relationship with the Federal Bureau of Investigation (FBI). The weapons of mass destruction coordinators understand the importance of two-way information sharing and that sharing protects the community. There is no pride of ownership. Each respects the other's capabilities to help get to a common goal.
- One of the key variables is to look at the tone that is set within the organization. How competent is the leader? This includes emotional proficiency. Work with the top people in the organization on their management style.
- People should feel that their input is helpful and welcome. This can be ensured by providing active feedback to staff. Otherwise, people will not feel inclined to share.
- There needs to be a summary of what is going on at the federal command center level. It would be extremely helpful. In an investigation, there should be state calls every day.
- Scientists should be trained on how to deal with uncertain factors and working with practitioners to move towards a decision.
- Cross-functional teams should be involved starting at day one. Personal data and personal motive are essential. These elements cannot be separated and they are not equal.

- Having an awareness of why the information should be shared is important. In addition, give states a feeling of prioritization or a timeline. In small states, staff is limited, so this would help them to prioritize information to CDC and ensure that the states work efficiently and effectively within their organizations.
- In the clinical world, successful clinicians ask their patients if there is anything else they need to know. CDC should adopt this same practice. This helps to tease out fuzzy areas. It encourages people to say what they think is a priority. CDC should also share insight on things that were not successful. In the airline pilot world, not sharing information about a near miss causes serious consequences. CDC should have the same kind of practice. Experimental failures will inform others on what not to do.

NATIONAL HEALTH SECURITY PREPAREDNESS INDEX (NHSPI) UPDATE

Jim Blumenstock, MA, Chief Program Officer, Public Health Practice, Association of State and Territorial Health Officials (ASTHO) and Acting ASTHO Liaison Representative to the BSC; ***Catherine Ordun***, Booz Allen Hamilton; and ***Cathy Slemp, MD, MPH***, NHSPI Stakeholder Communications Workgroup Chair, presented an update on NHSPI

NHSPI measures developed to provide a composite picture of the nation's preparedness status

- Measuring preparedness articulates where the nation is and where it needs to be (identifies gaps)

Many different benchmarks measuring numerous aspects of preparedness exist

- What is currently missing is a composite picture of capabilities across the health system

NHSPI: Origin and intent

- Provides a means for evaluating relative levels of factors like economic health and quality of life
- Consists of a set of indicators that have been combined into a mathematical formula and result in a single value or an index score
    - Resulting score can be used to compare communities' preparedness status
- Preparedness and response system is dynamic and complex and needs to be simplified into a number that can be understood
- Organized groupings of measures paint a more complete picture of complex systems as compared to individual measures on their own

NHSPI: Guiding developmental principles

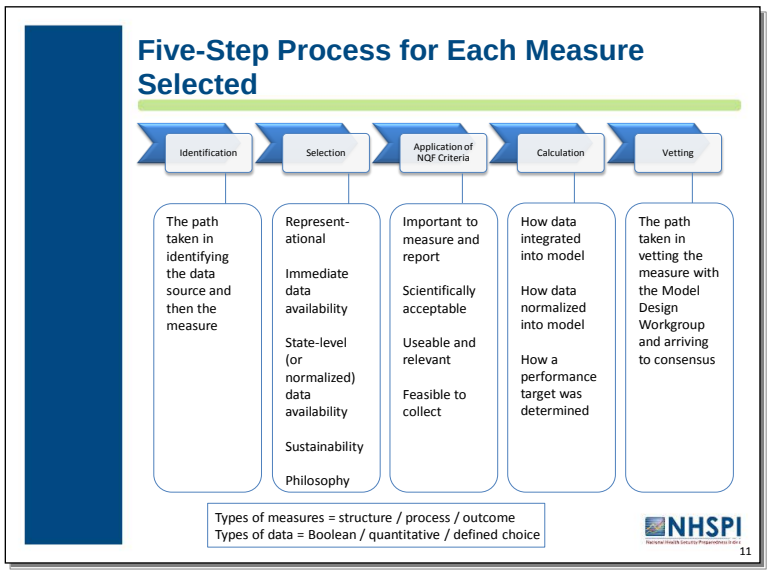
- Create no new administrative burden
- Be owned and embraced by the practice community
- Be better than what we currently have
- Must continuously improve; cannot be a one-time effort
- Avoid unintended consequences as much as possible

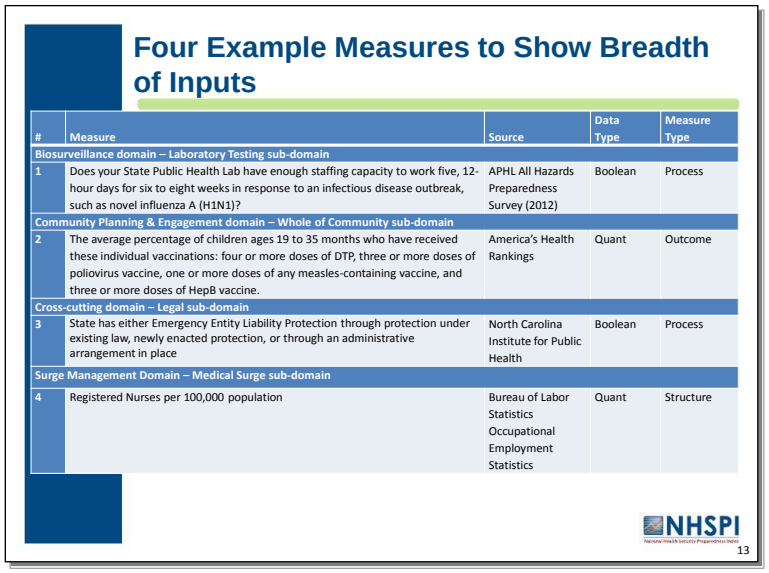
NHSPI: Development history

- Association of State and Territorial Health Officials (ASTHO) – the leading developer of NHSPI via a CDC cooperative agreement
- NHSPI developed in conjunction with over 75 experts from different stakeholder communities, such as public health, emergency management, private sector, nonprofit, government, and academia
- NHSPI: a composite index reflecting a range of elements affecting national health security preparedness
- Initial focus: public health and the healthcare systems
- Over time, NHSPI has also incorporated additional elements of national security
- Is broader than the Public Health Emergency Preparedness (PHEP) and Hospital Preparedness Program (HPP) and is not tied to funding

NHSPI: Structure, goals, objectives

- Objective, evidence-based measures to help drive strategies, policy and practice
- Should measure community resilience
- Aligned to Presidential Policy Directive 8; reflects the full system of national health security
- Six domains: 1) biosurveillance; 2) countermeasures; 3) community planning and engagement; 4) incident and information management 5) surge management; and 6) cross cutting measures
- Within the 6 domains, 15 sub domains have been identified, resulting in over 120 unique evidence-based measures
- Additional domains and sub domains will be identified over time
- Evidence-based measures were selected from a wide range of data sources
    - Measure selection process: identification, selection, application of National Quality Forum Criteria, calculation, and vetting





#	Measure	Source	Data Type	Measure Type
Biosurveillance domain – Laboratory Testing sub-domain				
1	Does your State Public Health Lab have enough staffing capacity to work five, 12-hour days for six to eight weeks in response to an infectious disease outbreak, such as novel influenza A (H1N1)?	APHL All Hazards Preparedness Survey (2012)	Boolean	Process
Community Planning & Engagement domain – Whole of Community sub-domain				
2	The average percentage of children ages 19 to 35 months who have received these individual vaccinations: four or more doses of DTP, three or more doses of poliovirus vaccine, one or more doses of any measles-containing vaccine, and three or more doses of HepB vaccine.	America's Health Rankings	Quant	Outcome
Cross-cutting domain – Legal sub-domain				
3	State has either Emergency Entity Liability Protection through protection under existing law, newly enacted protection, or through an administrative arrangement in place	North Carolina Institute for Public Health	Boolean	Process
Surge Management Domain – Medical Surge sub-domain				
4	Registered Nurses per 100,000 population	Bureau of Labor Statistics Occupational Employment Statistics	Quant	Structure

NHSPI: Characteristics

- Shows a more deliberate and rigorous process of vetting
- Peer driven
- Reflects a whole community approach – addresses other issues to show community health status
- States involved early in the process in NHSPI development – initial focus: state public health community and then broadened
- April 2013 release
    - Developmental draft version with limited release to state health officials and preparedness directors for review, comment, and feedback
    - Each state will have access to its own data and national ranges
    - Preparedness directors will be able to share the draft with internal subject matter experts and external partners
    - Two-month review period (April to May, 2013) using a structured feedback form to collect commentary
    - Feedback due May 31, 2013
    - State feedback and input will be analyzed and a feedback report will be released to all NHSPI working groups and the Model Workgroup for review and approval
    - Report will move to the Steering Committee for endorsement
- http://www.NHSPI.org includes
    - NHSPI information, conceptual framework, structure, updates
    - An idea sharing form
    - Meeting presentations, conference calls, listserv, etc.

NHSPI: Developmental draft goals and expectations

- Engage a wide variety of stakeholders in further development of NHSPI
- Initial review: really about the model and shaping the model, not the number
- Feedback from the state review form, website feedback form, and conference/meeting discussions will be channeled to the appropriate workgroups to guide further index development
- This is the start of a broader and ongoing process to include
    - Stakeholder engagement on the NHSPI model and its use
    - Expansion of the breadth of NHSPI to make it a more robust and comprehensive tool for measuring health security
- Ongoing continuous improvement is anticipated

QUESTIONS & DISCUSSION (NHSPI UPDATE)

Overall, the Board was very impressed by the amount of work that has gone into the Index and the progress made thus far. It was expressed that the Index would eventually be useful in helping policymakers advocate for more funding, as well as inform states on where to direct resources. What is still an open issue for the NHSPI workgroup is how the Index will be displayed publicly. Several models have been suggested and are under discussion.

OPHPR POLICY UPDATE

Angela Schwartz, BS, MBA, Associate Director, Office of Policy, Planning and Evaluation (OPPE), OPHPR spoke to the BSC about General Accounting Office investigations around OPHPR

The OPPE presentation was in response to a previous request from the BSC for updates on General Accounting Office (GAO) investigations and results since the last BSC meeting (Aug 2012)

- Oct 2012: GAO closed the investigation on perimeter security of BSL4 labs
  - Investigation began Jan 2008
  - Report published Sep 2012
  - Proposed recommendations have been completed
    - Recommended that US Department of Agriculture (USDA) and CDC take action to implement security perimeter controls for BSL4 labs
    - Oct 2012, CDC and USDA published a proposed rule for a tiered-security approach, with security standards for labs at the BSL4 level including physical security measures
    - Final rules went into effect Oct 2012 and GAO has closed the engagement
- Jan 2013: ***Federal Inspections of Entities Registered with the Select Agent Program*** (http://www.gao.gov/assets/660/651730.pdf) published by GAO
  - Addressed duplication and overlap of federal inspection of facilities handling select agents
  - Duplication defined as multiple federal agencies conducting inspections within a two-year time period at the same facility, which was the case in 15% of the 374 entities
  - GAO recommendation: CDC and the Animal and Plant Health Inspection Service (APHIS) should work with Homeland Security, the Department of Transportation (DOT), and the Department of Defense (DoD) to
    - Coordinate inspections
    - Conduct joint inspections
    - Accept each other's inspection results
    - Conduct cross-agency training to ensure consistent application of standards
  - CDC has undertaken several actions to improve coordination with other federal agencies including
    - Initiating a Joint Inspection Program
    - Memoranda of understanding (MOU) to share inspection data
    - Cross-training of other federal inspectors
- Mar 1, 2013: GAO opened a new engagement looking at technical and scientific methods around the 2001 anthrax attacks
  - Nothing more to report at this time, kickoff has not yet occurred

- March 22, 2013: ***Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals*** (http://www.gao.gov/assets/660/653259.pdf) published by GAO in response to a question about the effects of federal support on state and local response capabilities
    - GAO
        - Assessed awardee progress in meeting Hospital Preparedness Program (HPP) goals and how the Office of the Assistant Secretary for Preparedness and Response (ASPR) measures that progress
        - Assessed awardee progress in meeting the Public Health Emergency Preparedness (PHEP) goals and how CDC measures that progress
        - Identified the mechanisms HHS uses to ensure that awardees are meeting application, financial, and reporting requirements
        - Reviewed HPP and PHEP guidance, performance measures, and other documents; interviewed HHS officials; and analyzed HPP and PHEP data for fiscal years 2007 through 2011
    - GAO recommendations to HHS
        - Develop objective and quantifiable performance targets and incremental milestones tied to HPP and PHEP performance measures
        - Ensure that measures remain consistent and comparable to sufficiently measure progress
    - HHS generally agreed with GAO's recommendations but indicated that it would not be able to fully implement them for several years
        - CDC introduced 40 of 47 PHEP performance measures beginning fiscal year 2012
        - Of the 40, only four had targets
        - CDC emphasized the need to establish targets for the remainder

OPPE also sought feedback on the ***2012 State-By-State Report on Laboratory, Emergency Operations Coordination, and Emergency Public Information and Warning Capabilities*** (http://www.cdc.gov/phpr/pubs-links/2012/documents/2012%20State-By-State_Preparedness_Report.pdf)

- CDC's fourth preparedness report
- Review is conducted annually along with the report
    - Stakeholder groups consulted including partners, current and former congressional staffers, Department of Public Health Partnerships (DPHP) Executive Committee Members, ASTHO and others
    - Desire was to increase the value the report itself and to find out if the reporting cycle made sense in light of the budgeting process
    - Changes in response to feedback
        - State fact sheets will be distributed in advance as a private release to the states, in December 2013
        - Full report will be released in January 2014 to coincide with the release of the President's budget
        - Report will use less technical language and integrate more graphics

        - Report will highlight more of the resource investment into the states
        - More narratives in the front of the report to tell the story of preparedness and how federal, state, and local governments come together in planning and response and to increase usage by policymakers and the general public
- OPPE is seeking BSC reactions/suggestions to the latest report
- In all previous reports, data about the entire laboratory system, PHEP-funded or not, has been reported
    - Should non-PHEP funded labs continue to be included as a part of the report?

QUESTIONS AND DISCUSSION (OPHPR POLICY UPDATES)

- Narratives to tell the story are great and should be utilized
- CDC does not have control over all labs, and this could hinder addressing inefficiencies
    - Focus on PHEP-funded labs only
- Measures have to be carefully worded
    - These are just public health labs
    - Measures have to be changed to show those that are actually doing the work
- Going forward the challenge is to play up the compatible complementary nature of the index and not that this report and the NHSPI are interchangeable or redundant
    - These are two different projects and resources of information and should be used for different purposes
    - It is important to make sure policymakers and practitioners understand that
- It can be a disservice to capture things outside of the funding line, but it can also be a service because there are jurisdictions making enormous investments to further preparedness
    - The failure to capture any of that work is a disservice to those jurisdictions because the total state of preparedness is not being portrayed
    - Those jurisdictions are trying to leverage the funding line to make the whole greater than the sum of the parts
- Beware of any single-modeling approach
    - In some corporations, two teams develop a model and at the end, the teams have a battle of the models to see which one survives
    - The teams then build from there
    - This is to avoid having one set of assumptions
    - Clarity of purpose is not the ultimate answer
    - Both sides have equal clarity of purposes; this is why the debate is needed
    - Another thought is to approach the most contentious part and look at it in two radically different ways to aggregate and measure and determine the outcomes
- OPPE could develop one of these for each sub domain every year or use it to satisfy GAO reporting requirements and just state that improvement is needed in measuring grant performance
    - The issue is what is to be accomplished with the final product

DIVISION OF SELECT AGENTS AND TOXINS

ESTABLISHING LEVELS OF RISK FOR SELECT AGENT HANDLING FACILITIES

Von McClee, MS, Chief, Program Services Branch/Microbiologist, Division of Select Agents and Toxins (DSAT), OPHPR spoke to the BSC about risk assessment software

DSAT recently garnered media attention – a reflection of the importance of this Division's work

This presentation

- Recent regulatory changes
- Recently developed risk assessment tool (work done in conjunction with the Sandia labs)

Challenge of "doing" risk assessment

- Employing a uniform approach to assessing risk that will cover the small laboratories, as well as the large, complex laboratories

October 2012: DSAT published the HHS Select Agent and Toxin (SAT) Final Rule

- Tiered/reduced select agents list developed
- Updated Responsible Official (RO) and Alternate RO duty requirements
- More guidance provided for specific physical and cyber security requirements for Tier 1 biological select agents and toxins (BSAT)
- Additional regulatory requirements added under Personal Suitability Programs for Tier 1 BSAT and Occupational Health Programs for Tier 1 BSAT
- Broader definition of restricted experiments have been developed and as well as an update to transfer requirements

Tier 1 Select Agents and Toxins (Sec. 3 and 4):

- Ebola and Marburg viruses
- Variola minor and Variola major viruses
- *Francisella tularensis*
- *Yersinia pestis*
- *Bacillus anthracis*
- *Burkholderia mallei* and *B. pseudomallei*
- Botulinum neurotoxin and neurotoxin-producing strains of *Clostridium botulinum*
- Foot-and-Mouth Disease virus
- Rinderpest virus

Security plans must

- Be designed according to a site-specific risk assessment
- Provide graded protection in accordance with the risk of the SAT, given its intended use

2010: Federal Experts Security Advisory Panel established as a result of Executive Order 13546

- Panel formed to provide recommendations for BSAT
- Panel recommendation: To develop a government-furnished risk management tool for all entities to use as part of their Site Specific Risk Assessment to ensure that facilities are consistently evaluating their vulnerability to particular threats, are implementing security measures appropriate to their level of risk, and to enable consistent inspections activities across multiple regulatory and oversight agencies

DSAT

- Took the initiative to develop its own tool
- Also received information on a tool being developed by Sandia National Laboratories
- Conducted a side-by-side comparison of both tools and identified the Sandia tool to be more comprehensive

Areas of concern prior to the development of the risk assessment tools

- Evaluation of risk not standardized, systematic, repeatable
- Inconsistent self-determination of threats, vulnerabilities and consequences by entities
- Inspections challenging for government agencies
- Entity misclassification

Likelihood and consequence (definitions based on the ***Biosafety*** Risk Assessment)

- Likelihood: the likelihood of exposure via an infectious route and infection from a biological agent
- Consequence: the consequence of a disease to the at-risk population

Likelihood and consequence (definitions based on the ***Biosecurity*** Risk Assessment)

- Likelihood: the likelihood of biological agent theft from a facility
- Consequence: severity of the consequence of an attack with that agent

Biosafety Risk Assessment – areas of concern for humans

- Risk to individuals performing direct manipulation of agents (in vitro and in vivo)
- Risk to individuals working in same laboratory
- Risk to persons within facility
- Risk to community of primary exposure
- Risk to community of secondary exposure

Biosafety Risk Assessment – areas of concern for animals

- Risk from breach of containment
- Risk from secondary exposure

Biosecurity Risk Assessment Model (BioRam) – Sandia National Laboratories

- Process consists of four evaluation components
  - Biological agents that exist at the facility
  - Facility processes and procedures
  - In place bio-risk mitigation measures
  - Potential adversaries of the facility (adversaries can be internal or external)
- Scoring is from zero to four
  - 4 = absence of risk mitigation
  - 0 = ideal biosecurity risk mitigation
- Areas of focus
  - Physical and personnel security
  - Transport security
  - Material control and accountability
  - Information security and management

BioRAM tool

- Brief demonstration provided
- Developed for use by any laboratory
- Common criteria: select agent regulations
- Contains over 100 questions and is suitable for use with humans and animals
- Provides graphs and proposes ways to improve risk mitigation
- Not mandatory for entities to use this tool, many labs already have a risk assessment tool
- Can be used to guide those who do not have a risk assessment tool in knowing what should be included, in a risk assessment tool

QUESTIONS AND DISCUSSION (ESTABLISHING LEVELS OF RISK FOR SELECT AGENT HANDLING FACILITIES)

The BSC asked several questions of, and provided recommendations to, Mr. McClee and ***Rob Weyant, PhD***, Division Director, Division of Select Agents and Toxins.

- It would not be hard for someone to lower a score for terroristic purposes. The tool does not have the ability to pick that up because that lies outside the parameters of the tool. Unless there is a good read that the culture can be trusted, tools should be viewed with skepticism.
  - Dr. Weyant replied that DSAT does not plan to change its inspection regime with the tool. Inspections will occur as normal. The tool is geared toward biosafety versus biosecurity.
- To the extent that the tool covers biosafety, there will still be some debate about how to answer the questions posed by DSAT. The way the questions are answered will determine an agent's characterization as maximum or non-risk. However, the questions cannot be resolved by the tool.
- If this was not work performed on a regular basis, some of the questions may be hard to answer, for example likelihood that a terrorist group in the past had an interest in a particular select agent as a weapon. Many labs have not spent much time on the history of biological weapons, etc. Things that are independent of the facility could be filled in by a consensus workgroup or by CDC. Make the variability be around what agents the facility has, what the facility looks like, and the facility's personal liability.

- PayPal is moving towards biometrics. The only way to get access to the system is through a retinal or thumbprint scan. This could be a security measure used.
- DSAT was applauded for deciding to use Sandia's tool, which is more robust, versus their homegrown system. It speaks to DSAT's interest in achieving the best results.

DIVISION OF STATE AND LOCAL READINESS

MEASURING OPERATIONAL READINESS: A CONVERSATION WITH THE BSC

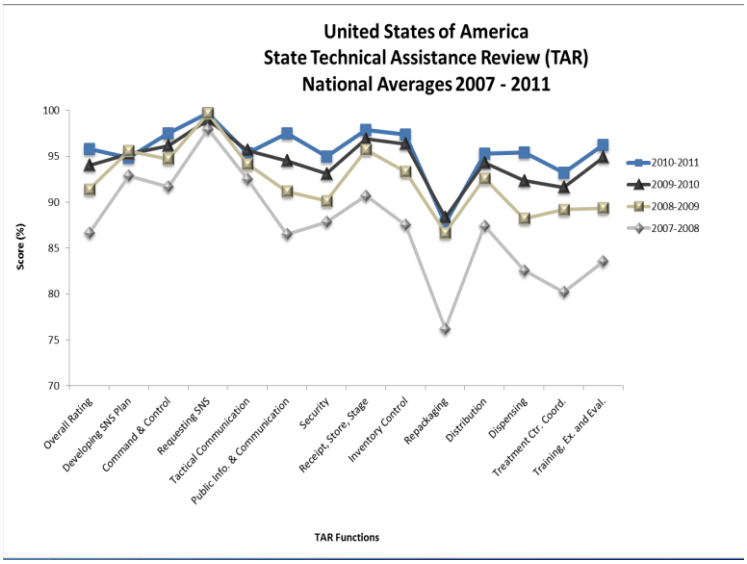
Jeff Bryant, MS, MA, Chief, Program Services Branch, Division of State and Local Readiness (DSLR), OPHPR engaged the BSC in a discussion about assessing operational readiness.

Technical Assistance Review (TAR)

- Annual assessment of state and local medical countermeasure programs
- Processes and tools have been in place for more than a decade
- As of 2012, states are averaging a score of 96%

Below is a graph of the last four years of data (2012 data will be added in about two months)

- 13 scored elements are listed on the X-axis
- Since its inception, much progress has been made; 2012 results are expected to continue this trend



TAR: strengths/weaknesses

- Able to measure a state's ability to ***plan and prepare*** for a mass dispensing mission within 48 hours of an incident
- Does not currently assess a state's ability to execute the plan
- Next version will allow for better measurement of the ability to execute
- One of OPHPR's most objective assessment tools

Statement of Need

- DSLR is seeking a new assessment model
- Model should better measure ***operational readiness*** of Public Health Emergency Preparedness (PHEP) cooperative agreement awardees
    - What is PHEP awardee ability to perform medical countermeasure distribution and dispensing functions and related public health preparedness capabilities?

- How does DSLR ensure that jurisdictions can execute their emergency response plans?

Factors to consider

- Timeline
  - A new assessment model needed by mid-January 2014
- Funding
  - DSLR wants to balance any requirements it places on states with the reality of decreased funding
- Pre-existing models
  - Readiness tools available that the BSC can highlight?
  - Should DSLR expect states to conduct tabletop or full-scale exercises, real incidents, or proxies?
- Frequency of assessment
  - Every year or every two years with interim self-assessment?
- Sustainability
  - Management, staff, funding, and scheduling

DSLR has already considered several potential operational readiness assessment models

- ***Peer evaluation model*** – based on emergency management services (EMS) experiences
- ***Internal jurisdictional model*** – includes collaborating with state or local emergency management agencies
- ***DSLR assessment model*** – a homegrown approach, including traveling assessment teams with subject matter experts

QUESTIONS AND DISCUSSION (ESTABLISHING LEVELS OF RISK FOR SELECT AGENT HANDLING FACILITIES)

- One option is the peer evaluation model. That notion is getting a lot of positive reaction, but it is uncertain if it is compatible with DSLR's other considerations, like timeline, balance, frequency, etc. It's not a deal-breaker but something worth exploring.
- With real life events, the challenge is standardization. Finding the key building blocks that need to be assessed requires more thought than do the tools presented. Also, note that when doing full-scale exercises, many of the partners may not be available to participate, particular if it is a no-notice or short-notice type of exercise.
- Ideally, it would be nice to have a national crisis day across the country, with a simulation, and the locale would have to mobilize on the one day they're least prepared, but that's not likely. Tabletops are not very realistic, and a full-scale exercise is not practical. Something in the middle would be ideal. Are there certain communities that will buy-in to doing a simulation? Maybe some sort of incentive could be tied to participation.
- Social psychologists set up experiments all the time, where they try to do everything in their power to disrupt the experiment and make it go wrong, in order to test how the group copes with disruptions. When trying to do a mock test, if you could simulate those disruptions, it could be a good way to test the coping skills of the state and bring to the surface the areas that are still confounding.

- Some states have developed proxies like distributing water (instead of medications). It can be expensive, but if resources were available to the states once every couple of years, that may be an option.
- Many entities often struggle with doing these types of exercises because response depends on participation of partners from outside the entity's infrastructure. To ask partners to divert from their daily activities to "go play with you" during drills might not be practical in resource-restricted environments; especially for very low probability events.
- If you want to look at the whole system, you have to look at the whole system. It's important to understand what the issues are. The challenge is the minimal notice piece. Individuals at a very high level would have to have some notification and they would have to require other partners to participate, but of course not including everybody. It's important to give states and locals some flexibility.
- Look at the possibility of using a natural disaster for an assessment. If there is already an emergency situation occurring, some things might be easier to deal with. Some locals experience more natural disasters than others; put a team there for the purpose of doing exercises.
- Look for the small fixes. For example, in the case of a disaster or a no-notice exercise, the one person responsible for unlocking the doors may not report for work on a Saturday. It's those types of small fixes that need to be examined. Seemingly small things like that will slow or shut a response down for several critical hours. Those are the areas where testing needs to occur to make sure that there are capabilities to address them.
- Reach out to some operation researchers to look at the framework. They can point out areas for process improvements and identify useful models. Think about what kind of observations can be built into existing, real-world events.
- Can there be lessons learned from other jurisdictions? Important lessons learned in different jurisdictions often get lost. Use them to help enhance practice. There are no national registries of lessons learned from events. This may be something to consider.
- The crisis prepared organization is proactive. They plan for crisis. Moreover, it's not just what lessons are learned, but what has been modified in the day-to-day activities as a result of what was learned. What are the plans for extraordinary events that will affect day-to-day processes? This is key and can even lead to more efficient use of resources.

PUBLIC COMMENT PERIOD (DAY 1)

No public comments were made.

ADJOURN DAY 1

DAY 2: JOINT NATIONAL BIODEFENSE SCIENCE BOARD (NBSB) AND OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR) BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING

OPHPR BSC WELCOME / OPENING REMARKS

Thomas Inglesby, MD, Chair, OPHPR BSC, called the meeting to order.

ROLL CALL AND REVIEW OF FACA CONFLICT OF INTEREST

Samuel L. Groseclose, DVM, MPH, Associate Director for Science, OPHPR and the Designated Federal Official (DFO) for the OPHPR BSC took roll. BSC Special Government Employee (SGE) Board Members, ex officio Board Members, and liaison Board Members participating in-person and by phone are listed in Appendices A and B. Quorum was met.

Dr. Groseclose reviewed the duties of the OPHPR BSC per the BSC charter. Dr. Groseclose then asked for any voting board member (OPHPR BSC or NBSB) to self-identify any conflicts of interest. Dr. Groseclose asked that if any voting board member believed that they did have a conflict of interest, s/he should draw that to his attention.

Dr. Palacio identified that her agency receives indirect funding from CDC through the Public Health Emergency Preparedness cooperative agreement to the states. Dr. Burke's university receives funding from CDC's Preparedness and Emergency Response Research Center Program. No other conflicts of interest were identified.

NBSB WELCOME / OPENING REMARKS

John Parker, MD, Chair, NBSB, acknowledged the great opportunity to have two boards working together on a common mission. He expressed his pleasure in serving on the working group. He also emphasized that the support of Dr. Kaplowitz, Dr. Khan, Dr. Sosin, and Dr. Lurie signified the magnitude of this issue to the nation.

ROLL CALL AND REVIEW OF FACA CONFLICT OF INTEREST

With the request for conflict of interest attestation having already been provided by Dr. Groseclose, CAPT Charlotte Spires, DVM, MPH, Designated Federal Official, Executive Director, NBSB, Captain Spires took roll for the NBSB. NBSB Special Government Employee (SGE) Board Members, ex officio Board Members, and designated ex officio alternates are listed in Appendix C. Quorum was met.

STRATEGIC NATIONAL STOCKPILE 2020: LEADERSHIP REMARKS

Ali Khan, MD, MPH, OPHPR Director thanked both boards for their presence

- Federal Advisory Committees working together is what the nation expects, particularly around very concerning issues like public health threats
- CDC has significantly fewer dollars to ensure preparedness
- Boards coming together to help HHS think through critical issues is essential and areas in the budget should be preserved to allow Advisory Committees to come together to confer on these serious issues, even in light of recent budget cuts/sequestration
- CDC plans to duplicate the concept of Advisory Committees working together given the success of this endeavor

RADM Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response (ASPR), US Department of Health and Human Services, thanked the members for coming together and for their work

- Dr. Lurie was unable to attend the meeting in-person due to the sequestration, but looked forward to reviewing the report of the meeting.
- Thank you to Drs. Parker and Burke for their work on this task
- The work that has been produced is a true example of group alignment to achieve a common goal in the face of imperative circumstances
- ASPR looks forward to weighing in on the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) requirements

ANTICIPATED RESPONSIBILITIES OF THE STRATEGIC NATIONAL STOCKPILE (SNS) IN THE YEAR 2020: AN EXAMINATION WITH RECOMMENDATIONS. A JOINT REPORT FROM THE NATIONAL BIODEFENSE SCIENCE BOARD AND THE OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE BOARD OF SCIENTIFIC COUNSELORS

John Parker, MD, Chair, NBSB and Joint Working Group Co-Chair
Donald Burke, MD, BSC Member and Joint Working Group Co-Chair

Co-chairs presented the findings of the Joint Report to both Federal Advisory Committees Joint SNS 2020 Working Group membership composed of industry representatives, NBSB, and BSC members (see Appendix E [final report] for the full list of SNS 2020 Working Group members)

June 1, 2012

- NBSB and OPHPR BSC charged with three tasks by ASPR and Director, OPHPR
- Three tasks
    - Task 1: Identify anticipated responsibilities of the SNS in the year 2020
    - Task 2: Recommend approaches for meeting those responsibilities as efficiently as possible
    - Task 3: Propose metrics for reporting program capability and informing improvement

SNS 2020 Working Group Summary (see Appendix E [final report] for full details)

- Task 1: Identify anticipated responsibilities of the SNS in the year 2020
  - Secure the public health of the US
  - Augment security posture of the US
  - Maintain a cache of medical countermeasures (MCMs) and materiel necessary to support a robust response to the widest possible spectrum of public health emergencies
  - Due to mutual and critical dependence existing between SNS and state and local public health agencies, SNS should be increasingly enhanced to meet public health responsibilities
  - NBSB and OPHPR BSC do not foresee either a reduction in SNS responsibilities or a reduction in the cost of fulfilling these responsibilities
- Task 2: Recommend approaches for meeting those responsibilities as efficiently as possible
  - Increase reliance on state-of-the-art risk management and applied science
- Task 3: Propose metrics for reporting program capability and informing improvement
  - Derive program capability metrics from actual performance data (where such information exists), results of exercises, and computational modeling and simulations
  - Program capability assessment metrics should identify not only gaps and strengths in distribution of MCMs, but also delivery to the public
  - SNS should carry out rigorous exercises of their current capabilities as part of a wholly integrated national response system
  - Performance assessments should be expanded to include the desired outcome: delivery of critical countermeasures to the public

Ten recommendations emerged from the workgroup

- Articulate a vision for SNS 2020
- Tailor SNS surge capacity
- Use science as a key strategic and tactical management tool
- Enhance critical review processes (for example risk-benefit analyses, requirement generation process)
- Continue to move to a single appropriation model – enhance fiscal management of the SNS
- Use cost versus benefit decisions as integral component of management
- Make greater use of computational modeling and simulation
- Recognize SNS and BARDA as sole purchasers – and SNS as sole distributor – of certain MCMs
- Improve coordination among federal, state and local public health partners
- Apply laboratory science and animal models to inform SNS stockpile requirements

QUESTIONS AND DISCUSSION (ESTABLISHING LEVELS OF RISK FOR SELECT AGENT HANDLING FACILITIES)

Some Working Group members provided further clarification to questions posed by the boards
Summary of comments/discussion is as follows

- Some important decisions have to be made on the quality and quantity of what goes into the SNS because, for some of those items, the SNS is the only possessor of them. This goes to the review of risk versus benefit, and which emergencies the SNS will have to respond to. SNS is part of a system and has to function correctly in order for the entire system to function well.
- It's important to recognize the SNS is not a static item. It's not just a storage room of things, but rather a living, breathing accumulation of therapeutics, medical devices and items that are up to the standard of care and even ahead of the standard of care for the future. The best tool to tone and shape the SNS is science.

- A determination must be made as to the number of disasters the SNS can handle simultaneously. There needs to be an assessment of what it can and can't do so that tough calls can be made.
- The purpose of the SNS should be defined. As the move towards funding requirements to maintain the SNS continue, cost effective supplies should be considered, in addition to the risks CDC is willing to assume by having or not having those supplies.
- There are certain laws that allow for government to apply for product shelf life extensions, but that privilege has not been extended to the states. Cost and efficiency reviews should also consider shelf life extensions.
- The SNS is the sole customer of some commodities. If CDC chooses to purchase less of that commodity, the producer may decide to stop producing it; therefore, careful consideration needs to be taken.

Dr. Parker reminded the Boards that

- The report is the product of Advisory Committees
- Getting into the details of funding are not within the scope of either committee
- The Report will be provided to the HHS Secretary, Dr. Lurie, and Dr. Khan, to do with as they see fit
- It is critical that the report be shared with the public, the media, and with policymakers

Dr. Khan commented that CDC will be routinely reporting back to both Advisory Committees, on the progress being made in implementing the recommendations.

PUBLIC COMMENT PERIOD (DAY 2)

No public comments were made.

NBSB/OPHPR BSC VOTE ON THE JOINT SNS 2020 REPORT AND RECOMMENDATIONS

John Parker, MD, Chair, NBSB and ***Thomas Inglesby, MD***, Chair, OPHPR BSC

Dr. Burke motioned to approve the report along with the recommendations for transmittal to the HHS Secretary, ASPR and OPHPR Director. Dr. Benjamin seconded the motion. Dr. Inglesby called for a vote from the BSC which unanimously approved the motion. Dr. Parker called for a vote from the NBSB, which also unanimously approved the motion. Dr. Inglesby informed the members that the Report will be transmitted after it is signed by both Dr. Inglesby and Dr. Parker.

With the Joint Board business concluded, Dr. Inglesby adjourned the joint meeting at 12:45 PM.

Dr. Inglesby called the BSC meeting back to order at 12:50 PM

Dr. Groseclose conducted roll call

- Quorum was not met
- Following a review of the agenda and discussion with the BSC Chair, a determination was made that no votes were anticipated for the afternoon session

Dr. Inglesby adjourned the official meeting

The OPHPR BSC Meeting Day 2 afternoon session was conducted as an informational session only and remained open to the public

UPDATES FROM LIAISON REPRESENTATIVES

Association of Public Health Laboratories (APHL): *Christina Egan, PhD*

Dr. Egan thanked the Board for being allowed to be a part of the deliberations. She has chaired the Committee for Public Health Preparedness and Response, and it's been tremendous to see the people at CDC participating on the committee and engaging with the public health laboratories. It has been very helpful.

APHL activity updates

- APHL has provided guidance on the evaluation of performance measures and has participated in a strategic planning meeting for DHS for the integrated consortium of laboratory networks
- APHL is working on the Select Agent Program Policy Updates
  - Implementation at the state and local level is difficult
  - It is important for the BSC to continue to engage the Select Agent Program and for APHL to continue to hear updates
  - There have been several conference calls and guidance documents created – these were useful to the lab but difficult to implement
  - It would be interesting to hear feedback at the next meeting on how that has worked
- APHL has had to update its Occupational Health Programs, implement Personnel Reliability Programs and is working with its membership to provide different options to hear feedback

Associations of Schools of Public Health (ASPH): *James Curran, MD, MPH*

ABSENT

Association of State & Territorial Health Officials (ASTHO): *James Blumenstock, MA*

Mr. Blumenstock presented information about several on-going ASTHO projects.

Coping with and Mitigating the Effects of Shortages of Emergency Medications
(http://www.astho.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=7924)

- After six months, a document was completed that reflects the best judgment and wisdom on coping strategies from public health, emergency medicine, and EMS
- The document is to serve as a menu of options, not recommendations, and talks about issues such as the good and bad side of using expired drugs, pharmacy compounding, and tapping into state and federal strategic stockpiles
- The report was issued in January and has been endorsed by ten North American associations
- It provides a compendium of policies, procedures, and executive and standing orders that different practitioners have used
- More information can be found on the ASTHO website.

In the post H1N1 pandemic improvement activities, ASTHO is looking for alternatives to anti-viral distribution and is identifying ways to reroute some countermeasures to the commercial supply chain

- ASTHO has done testing at a few sites including pharmacies and so far, the results have been positive

Nurse Triage Line Project

- Intended to relieve the burden to the primary and emergency care community
- Several stakeholders being engaged to look at developing a national network to screen for conditions, issues prescriptions, and provide referrals

Respiratory emergency equipment in acute care hospitals

- Work is being done with the American Hospital Association to conduct an inventory assessment on the amount of mask and respirators in the field today and to assess whether that amount be sufficient in the case of an epidemic

Influenza Coordination Unit (ICU)

- Joint project with ICU to develop plans in the case of another pandemic
- Lessons learned are being examined
- Looking at using an assessment tool to quantify the agency's cost to address the 15 capabilities and to identify gaps
- This effort just started, but there should be some preliminary data in the next couple of months

Conversations around actions to be taken in the case of contamination of passengers on airplanes due to potential acts of terrorism

- Series of protocols developed by liaison associations and the Council of Radiation Control Program Directors to develop screening tests and a referral protocol
- Tabletop exercise of these protocols to occur later this month

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

Dr. Quinlisk thanked CDC for allowing CSTE to provide comments on the SNS.

Comments from Jeff Engle, CSTE Executive Director

- Dr. Engle became a member of the NPHSI Model Design Working Group representing CSTE's interest with the Index
- Dr. Rich Danila is serving on the NHSPI steering committee

Comments from Rich Danila

- CSTE's Cross-Cutting Committee has provided feedback to CDC on PHEP surveillance and epidemiologic performance measures
- CDC seemed to be genuinely and honestly interested in revising and changing the measures based on the group's feedback

CSTE Executive Board held a meeting in Washington a few weeks ago

- Dr. Alexander Garza (DHS) updated the CSTE Executive Board on the BioWatch Program

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

Dr. Smith provided a brief update from NACCHO.

NACCHO has been advocating for the ability of governors, in the case of an emergency, to reassign federal employees to activities, in order to respond

- NACCHO is using the reauthorization as an opportunity to reeducate local health departments on all the other items included in the Pandemic and All-Hazards Preparedness Reauthorization Act

2013 NACCHO summit

- Very successful
- >1700 attendees, in spite of budget cuts
- A number of people expressed that the large meetings are one of the few chances for CDC to interact with its programs
- If there's any way that NACCHO can be of assistance, please let them know
- Holding the summit in Atlanta allowed for more CDC attendees

NACCHO Policy Preparedness Group

- Comprised of health officials and preparedness managers
- NACCHO relies on this group for a number of things
- Survey conducted among group members looking at
    - The value of various indicators
    - The burden associated with the indicators
    - Whether they are helpful
- Vast majority of performance measures were supported by the group
- This is an ongoing project and comments are being solicited from other partners

Project Public Health Ready

- Another important NACCHO tool
- States apply to have their processes evaluated
- Evaluation is very much tied to the PHEP and HPP grant deliverables and measures
- NACCHO is looking at ways to make it sustainable including introducing a fee to help offset expenses

Lessons Learned

- NACCHO is reviewing recent events like the drought in Texas and Hurricane Sandy

National Indian Health Board (NIHB): Stacy Bohlen, MA

- ABSENT

SNS FORMULARY OPTIONS: MODELS USING CBRN RISK ASSESSMENT

Dan Sosin, MD, MPH, Deputy Director OPHPR, introduced the next presentation

- A work in progress
- Important to get the BSC's feedback
- About a year ago, CDC began collaborating with DHS to look at risk assessment
- Interested in identifying a methodology to estimate the probability of events occurring
- In light of limited funding, CDC can use a validated methodology to figure out what countermeasures provide the best buy-down in terms of risk

Rocco Casagrande, PhD, Managing Director, Gryphon Scientific, presented on work being done to develop a risk assessment tool that can be used to inform CDC's decision-making related to SNS assets

Risk information on CBRN incidents

- Proof of principle study conducted to determine if risk information on CBRN incidents can be used to inform SNS product configurations
  - Future budgetary concerns motivated the analysis
  - Product expiration increases resource demands while budgets are declining
- Risk information can help inform discussions on SNS acquisitions

CDC's approach to using risk information on CBRN incidents

- Craft approach with HHS stakeholders and collect data on medical response
- Use DHS-sponsored tool to provide exposure data that describes the entire CBRN risk space
- Leverage and adapt models of the public health response to translate CBRN exposures into mitigated and unmitigated casualties
- Quantify risk reduction of current and alternate CDC formularies stocked with currently available MCMs

Homeland Security Presidential Directive 18 (HSPD-18)

- Mandates that DHS provide integrated CBRN risk assessment to facilitate risk-informed decision-making
- Integrated Terrorism Risk Assessment (ITRA) provides a comparison of terrorism risk across CBRN threat areas

ITRA

- Uses best available intelligence data on terrorist CBRN threat
- Estimates probability of particular attacks and associated consequences
- Examines entire CBRN risk space to support comparison of threats across the spectrum
- Provides content for decision-making by
  - Incorporating uncertainty
  - Reducing impact of errors in modeling that may bias results toward a particular agent
- Uses harmonized models – not one answer or one number

Proof of principle study

- ***Task 1***: Construct an approach to answer the question, "How does public health affect response?"
  - Questions addressed through focused discussions with CDC and HHS stakeholders
    - What metrics should be used to understand risk?
    - How is the stockpile formulary allowed to vary?
    - What is the relevant part of the threat space
  - CDC and HHS SMEs also gathered data on the concept of use of the various countermeasures.
- ***Task 2***: Use ITRA to provide scenarios reflecting CBRN risk space
  - ITRA is complex and considers millions of CBRN scenarios
  - Subset of scenarios that best represent risk were chosen for analysis
- ***Task 3***: Leverage and develop models
  - Models that examine the health consequences of an attack for a subset of agents
    - Developed by BARDA
    - Vetted by a rigorous working group process within HHS
    - Take exposure data from ITRA and predict causalities under a set of conditions

To help ascertain the optimal stockpile – current vs. alternative formularies

- Mitigated consequences determined across risk space for various formulary configurations
  - What is the overall ability of a particular formulary to mitigate risk over the entire risk space?
  - This metric can be described by a single number if understood in terms of risk
- Analysis considers uncertainty in parameters: agents, actors, targets, public health response timelines
- Several formularies will be tested to identify those that best reduce risk over the entire threat space
  - What is the relative value of particular investments?
  - How might different SNS formularies reduce risk from CBRN attacks?

Investment decisions about preparedness

- Approach is broadly applicable
- Research has uncovered areas where future planning is needed
  - Define the concept of use of particular countermeasures
  - Establish fair principles for use when stocks are limited
- The work has improved public health response models used across the medical countermeasures enterprise

QUESTIONS & DISCUSSION (DSNS PROGRAMMATIC REVIEW)

- This is a huge leap forward and has tremendous potential in helping to understand parameters around tradeoffs
  - There should be discussions around uncertainty, particularly concerning ITRA assumptions
  - Some assumptions cause skepticism
- It is exciting to characterize uncertainty
  - Knowing what is not known is incredibly informative, as decisions are being made under uncertain circumstances
  - The most useful thing is to know what the brackets are around uncertainty

- This allows public health entities to give the political infrastructure good information about what is known and not known and about how decisions are made
    - Cuts down on unrealistic expectations
- A terrorist would love to get a hold of this model and screw around with the parameters so that it would under-predict everything
    - This brings about the thought of the Operating Room (OR) squared phenomenon, where one OR team studies the first OR team
    - The second OR team has an opportunity to watch the first make a lot decisions, leading to an improved model
- Why not use the intelligence community as a source of information?
    - There are also other types of communities that can provide input into the model
- Modeling requires stepping out of the modeling community, in order to do it correctly
    - In addition, testing is critical
- All decisions are based on mental and computational models
    - Somebody has to take the information and process it to bring about a decision
    - The model is part of the decision making process and not a separate entity
    - Make assumptions explicit; what are the estimates of uncertainty, etc.?
- This is an elegant model but the outcomes being measured seem very unscientific and lacking.
    - How is feedback displayed in a way that is useful?
- The modeling effort needs to be expanded to include how people respond to the models
    - It is not possible to separate and take out the modeler from the model
- I think this can be paralyzing when looking at uncertainty
    - If the uncertainty factors are too numerous, it will still be challenging to help inform decisions
    - Another factor to remember is language, which will change the interpretation of the risk
- You designed the model around some people and not others
    - It would be interesting to know information about both groups
    - It would also be interesting to know how the model learns over time

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CLOSING REMARKS, ACTION ITEMS, FUTURE AGENDA

Samuel Groseclose, DVM, MPH
Designated Federal Official, OPHPR BSC and Associate Director for Science, OPHPR

Dr. Groseclose thanked everyone for joining the meeting. The discussions were productive and he looks forward to using the new SharePoint site to further engage with the BSC. BSC program review reports will be posted on the CDC internet soon.

Thomas Inglesby, MD
Chair, OPHPR BSC

Dr. Inglesby announced that Dr. Palacio is stepping down from her service on the BSC. Dr. Inglesby thanked Dr. Palacio for her contributions and wished her well on a new chapter in her life.

The Board was also asked to share ideas about topics they'd like to hear discussed at future meetings

- Resilience
  - Measuring, conceptualizing, modeling, etc.
- What happens when the CDC hands SNS assets off to states?
  - There's a need for creative ways or models on how to distribute
  - What is the role of FEMA and DoD in helping dispense SNS assets to the community-at-large?
- Risk management
  - What are the different ways of conceptualizing risk?
  - How do advanced management models enter into that?

Dr. Inglesby thanked the Board for its suggestions and rich discussion. He then adjourned the informational session.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the April 2-3, 2013 meeting of the OPHPR BSC are accurate and complete.

July 2, 2013 /S
_____Date _____

Thomas V. Inglesby, MD

Chair, Board of Scientific Counselors, OPHPR

APPENDIX A: OPHPR BSC MEMBERSHIP ROSTER

Chair

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

Designated Federal Official

Samuel L. 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 Employee Board Members

Ruth G. Bernheim, JD, MPH
Chair, Department of Public Health Services
William Hobson Associate Professor of Information Sciences
University of Virginia School of Medicine
Charlottesville, Virginia

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

Don Burke, MD
Dean, Graduate School of Public Health
University of Pittsburgh
Pittsburgh, PA

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
Johns Hopkins University Bloomberg School of Public Health
Baltimore, MD
Ian I. Mitroff, PhD

Adjunct Professor, College of Environmental Design
Research Associate, Center for Catastrophic Risk Management
Haas School of Business, University of California, Berkeley
Oakland, California

Carol S. North, MD, MPE
Professor of Psychiatry and
Director, Division of Trauma and Disaster
The University of Texas Southwestern Medical Center
Dallas, Texas

Herminia Palacio, MD, MPH
Executive Director
Harris County Public Health and Environmental Services
Houston, TX

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

Ex Officio Members

US Department of Health and Human Services

RADM Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
Washington, DC

Lisa Kaplowitz, MD, MSHA (Alternate)
Deputy Assistant Secretary for Policy
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
Washington, DC

Sally Phillips, RN, PhD (Alternate)
Deputy Director, Health Threats Resilience Division
Office of Health Affairs
Washington, DC

US Department of Defense

Col Steven P. Niehoff, DVM, MPH, DACVPM
(USAF) Director, Global Health Surveillance
Force Health Protection & Readiness
Defense Health Headquarters (DHHQ)
Falls Church, VA

CDR Jesse Geibe, MD, MPH, MBA (Alternate)
(USN) Defense Department Liaison Officer
Centers for Disease Control and Prevention
Atlanta, GA

Liaison Representatives

Association of Public Health Laboratories (APHL)

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)

James Blumenstock (Alternate)
ASTHO Chief Program Officer
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
NIHB Executive Director
Washington, DC

APPENDIX B:

BSC Meeting Attendance Roster
Atlanta, GA – April 2-3, 2013

NAME	AFFILIATION	DAY 1 (APRIL 2, 2013)	DAY 2 (APRIL 3, 2013)
Inglesby, Thomas	Chair and SGE	In person	In person
Bernheim, Ruth	SGE	By phone	By phone
Brandeau, Margaret	SGE	Absent	absent
Burke, Don	SGE	Absent	In person
Lumpkin, John	SGE	Absent	Absent
MacKenzie, Ellen	SGE	In person	In person
Mitroff, Ian	SGE	In person	In person
North, Carol	SGE	In person	Absent
Palacio, Herminia	SGE	In person	In person
Vaughan, Elaine	SGE	Absent	Absent
Kaplowitz, Lisa	Ex officio (HHS)	In person	In person
Niehoff, Stephen	Ex officio (DoD)	By phone	By phone
Phillips, Sally	Ex officio (DHS)	By phone	By phone
Blumenstock, Jim	Liaison (ASTHO)	In person	In person
Bohlen, Stacy	Liaison (NIHB)	Absent	Absent
Egan, Christina	Liaison (APHL)	In person	In person
Quinlisk, Patricia	Liaison (CSTE)	In person	In person
Smith, Karen	Liaison (NACCHO)	In person	In person

APPENDIX C:

JOINT NATIONAL BIODEFENSE SCIENCE BOARD (NBSB) AND OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR) BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING
Atlanta, GA – April 3, 2013
NBSB Attendance Roster

NAME	AFFILIATION	APRIL 3, 2013
Parker, John	Chair and SGE	In person
Benjamin, Georges	SGE	In person
Bradley, John	SGE	In person
Delgado, Jane	SGE	By phone
Ecker, David	SGE	By phone
Emini, Emilio	SGE	In person
Fagbuyi, Daniel	SGE	In person
Furtado, Manohar	SGE	In person
Jarrell, Kevin	SGE	In person
Krug, Steven	SGE	In person
Park, Sarah	SGE	In person
Pfefferbaum, Betty	SGE	By phone
Khan, Ali	Ex Officio (CDC)	In person
Levings, Randall	Ex Officio (USDA)	In person
Maher, Carmen (alt. for Luciana Borio)	Ex Officio (FDA)	By phone
Martinello, Rick (alt. for Victoria Davis)	Ex Officio (VA)	By phone
Richter, Bonnie (alt. for Patricia Worthington)	Ex Officio (DOE)	In person
Shepanek, Mark (alt. for Richard Williams)	Ex Officio (NASA)	In person
Sorenson, Robert (alt. for Kerri-Ann Ann Jones)	Ex Officio (DOS)	In person

APPENDIX D: ACRONYMS

AMT	Anthrax Management Team
APHL	Association of Public Health Laboratories
ARRA/HITECH	American Recovery and Reinvestment Act/Health Information Technology for Economic and Clinical Health Act
ASPH	Association of Schools of Public Health
ASPR	Assistant Secretary for Preparedness and Response (HHS)
ASTHO	Association of State and Territorial Health Officers
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CEFO	Career Epidemiology Field Officer
CSTE	Council of State and Territorial Epidemiologists
DEO	Division of Emergency Operations (CDC)
DHS	US Department of Homeland Security
DoD	Department of Defense
DSAT	Division of Select Agents and Toxins (CDC)
EHR	Electronic Health Record
ERPO	Extramural Research Program Office (CDC)
ExO	Ex Officio
FACA	Federal Advisory Committee Act
FDCH	Federal Document Clearing House
FOA	Funding Opportunity Announcement
FRO	Financial Resources Office (CDC)
HPP	Hospital Preparedness Program
HHS	US Department of Health and Human Services
IOM	Institute of Medicine
IT	Information Technology
LO	Learning Office (CDC)
LRN	Laboratory Response Network
MASO	Management Analysis and Services Office (CDC)
NACCHO	National Association of County and City Health Officials
NCEH	National Center for Environmental Health
NCEZID	National Center for Emerging and Zoonotic Infectious Disease
NCIRD	National Center for Immunization and Respiratory Diseases
NIHB	National Indian Health Board
NIH	National Institutes for Health
OD	Office of the Director
OID	Office of Infectious Diseases (CDC)
OPHPR	Office of Public Health Preparedness and Response (CDC)
OPPE	Office of Policy, Planning, and Evaluation (CDC)
OSPHP	Office of Science and Public Health Practice (CDC)
PERRC	Preparedness and Emergency Response Research Center
PAHPA	Pandemic and All-Hazards Preparedness Act (PL 109-417)
PHEP	Public Health Emergency Preparedness

APPENDIX E: SNS 2020 REPORT

Anticipated Responsibilities of the Strategic National Stockpile (SNS)In the Year 2020
An Examination with Recommendations - A Joint Report from the National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors
http://www.phe.gov/Preparedness/legal/boards/nbsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf