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
OCTOBER 7-8, 2015
ATLANTA, GEORGIA

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CDC OPHPR BSC MEETING
Building 19, Auditorium B3
Roybal Campus, Tom Harkin Global Communication Center
1600 Clifton Road, NE,
Atlanta, GA 30303

Wednesday, October 7, 2015

Welcome & Call to Order / Introductions & Opening Remarks (Day 1)
Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby called the Board of Scientific Counselors (BSC) Meeting to order at 9:36AM. He expressed eagerness to hear from the managers of the programs of OPHPR and thanked CDC leadership and its staff for putting together the meeting.

Roll Call & Review of FACA Conflict of Interest
Samuel Groseclose, DVM, MPH; ADS, OPHPR and DFO, OPHPR BSC

OPHPR leadership, as well as BSC Members, and Ex Officio members, were instructed to introduce themselves and their agencies. Quorum was present.

Members must be present during any voting periods; therefore, members were asked to notify Dr. Groseclose before leaving portions of the meeting to ensure that quorum is maintained. The meeting was led by Dr. Inglesby, the Chair. Discussions and deliberations were among BSC Members, Ex Officio Members, and Liaison Representatives. The public was allowed to comment during the Public Comment portion of the agenda only. All speakers were asked to identify themselves. All participants agreed to have their comments monitored and recorded.

Dr. Groseclose reviewed the BSC responsibilities as per its charter. All Confidential Financial Disclosure Status Reports are up to date, but if there is a need to make changes, members are to contact Ms. Christye Brown. Members were asked to identify any conflicts of interest. Dr. Tom Inglesby has two funded CDC-OPHPR projects:

Hurricane Sandy Preparedness and the Response to Ebola and another project on Hospital Preparedness funded by the National Center for Environmental Health (NCEH), which has now shifted to OPHPR. No other conflicts of interest were indicated.

Dr. Ellen McKenzie's term has ended and there was no request for re-nomination. Dr. Richard Smith resigned from the Board in June 2015 due to other obligations. In addition, Dr. Frederick Burkle resigned from the Board in August 2015. Nomination packages are being submitted to Department of Health and Human Services (HHS) for review and approval of replacements. Terms are also ending for Drs. Inglesby and Margaret Brandeau. Re-nomination for both has been submitted to HHS for review. Members of the BSC as well as individuals from the CDC community were also encouraged to submit their recommendations for new Board members as well to either Dr. Groseclose or Ms. Christye Brown.

Dr. Suzet McKinney just accepted a position as Director of the Illinois Medical District Commission but will remain on the Board. One new Ex Officio Member, Jody Wireman (Department of Defense, [DoD]), and two new Liaison Representatives, Ms. Michele Askenazi (National Association of County and City Health Officials, [NACCHO]), and Ms. Kristin Hill (Tribal Epidemiological Centers) were welcomed to the Board.

Several observers and CDC staff attended and provided introductions.

OPHPR 2015 Priorities

OPHPR Updates from March 2015 BSC Meeting

RADM Stephen C. Redd, MD; Director, OPHPR

This is the ninth month Dr. Redd has been in his new role as director. He described OPHPR's work and discussed what he has learned since becoming OPHPR Director in January 2015.

The mission of OPHPR is to be ready to respond to any threat and to execute flawlessly during a response. In executing the emergency response, the office has to be ready to adapt plans and make immediate decisions. Dr. Redd has realized that OPHPR has to have a collaborative approach, unlike some other Centers or Offices at CDC, in order to achieve its mission.

Dr. Redd acknowledged that he has also learned a lot as the OPHPR Director. Giving tours of the Emergency Operations Center (EOC) played an instrumental role in learning about OPHPR. While doing tours, Dr. Redd realized that OPHPR has, in fact, less of an operational responsibility and a larger role facilitating the management, dissemination, and interpretation of information to support good decision-making and guidance development.
At the last meeting, the BSC had questions about measuring the impact of preparedness work; called for a follow-up on the public health system's role in addressing mental and behavioral health issues following a disaster; requested a report on select agent releases in the U.S. and an update on DSAT's work; desired an update on the SNS 2020 vision, which will be given in a future meeting; wanted to examine the policy agenda for public health preparedness and response (PHPR), which will be briefly touched upon during the meeting with a more in-depth discussion to occur in the future, and requested to examine a series of issues related to risk communication and communication, in general. He added that being able to respond is not a firm metric; however, it is the way that OPHPR is being scored.

Dr. Redd described three OPHPR priorities. The first is getting to zero with Ebola. Currently, there are very few cases in Liberia with the last case occurring in July 2015. Cases are continuing to occur in Guinea. The work is very intense but no longer garners the type of media attention that has a crisis overtone. OPHPR is very focused on sustaining capabilities established during the response. Ultimately, the desire is for every country to have the capability to detect and respond to threats, like Ebola. Some internal staffing issues need to be addressed to sustain our efforts and plans are being developed to institutionalize staff positions and newly identified functions. A Deployment Risk Mitigation Unit has been established, which will be memorialized and also internalized. The unit will provide training to safety officers, ensure the safety of those deployed, and develop a standardized

approach to integration for individuals returning from deployment. The process is undergoing continuous refinement.

The second priority is to measure the impact of our public health preparedness and response (PHPR) investments. This will be examined in more depth on Day 2 of the meeting.

The third is to take a more deliberate approach to partnership development. OPHPR has created a way of tracking interactions with its partners in an effort to better identify key individuals and assess communication mechanisms and messages with partner agencies. Another desire is to identify new groups that should be added to its list of partnerships.

Dr. Redd then reviewed the agenda.

He closed with a review of events that have occurred since the last meeting. In March, OPHPR was in the last stages of an investigation in Louisiana regarding the identification of primates that acquired Burkholderia pseudomallei (etiologic agent of meloidiosis). It was determined that a common exposure in the veterinary clinic providing care to the primates caused the animals to become infected. The investigation has been brought to a close.
Another incident that led to a Select Agent program investigation was the shipment of non-inactivated anthrax spores. DoD identified anthrax spores located in the laboratory in a place where they should not have been implying environmental contamination. Indirectly, as part of the investigation, a series of issues related to the identification of strains of Yersinia and anthrax as well as Venezuelan encephalitis virus and eastern equine encephalitis virus nucleic acids were uncovered. This is an ongoing investigation along with the DoD and the findings are being finalized. Dr. Frieden requested a review of the Select Agent Program. A report from an internal CDC review committee is to be delivered to Dr. Frieden next Tuesday and will be made public once internally cleared. Included in the report is a series of recommendations to improve the program to make it more effective.

In a similar vein, OPHPR has reviewed the Public Health Emergency Preparedness (PHEP) Program with internal experts. A presentation will be giving during the meeting in that regard. New priority areas have been identified as well as ways to strengthen ties within CDC, while ensuring that silos are not being created in state and local health departments.

The Division of Emergency Operations (DEO) is working on EOC development overseas as part of the Global Health Security Agenda. The Strategic National Stockpile (SNS) is working with the Institute of Medicine (IOM) on ways to improve the SNS. Each of these efforts has a beginning and end and a specific deliverable with the mission of improving the work being conducted.

Dr. Redd ended by thanking the BSC for lending its time and expertise to help OPHPR improve its efforts. He asked that the Board be very candid in its recommendations and comments. He expressed hope that the board does recognize the changes being made in response to BSC recommendations.

Questions in regards to Dr. Redd's presentation were as follows:

Member: When can we expect to hear more about the Global Health Security Strategy, the agenda, and plans for rolling it out?

Dr. Redd: We can place that issue on the agenda for the next meeting. Although the Global Health Security Agenda strategy was already being implemented before Ebola, it has been influenced by our Ebola response experience and is now viewed as the transition plan for the Ebola response. More funding was acquired for the Ministries of Health and its partnership groups. It's an incredible global effort that has broad global participation, and has been embraced by the World Health Organization (WHO). It will be used as a mechanism to assist in implementing the International Health Regulations.

OPHPR is focusing on EOCs and emergency operation systems. These capabilities allow the Ministries of Health to respond more effectively.

Member: Can we have a session on some of the lessons learned from the Ebola response since there is some distance from the initial onset of the Ebola outbreak? In addition, we need to talk about developing public health systems. A lot has been learned from the President's Emergency Plan for AIDS Relief (PEPFAR).

Dr. Redd: There were many comments about communications at the last meeting, which is a fundamental competency for emergency response. There are a wide variety of after action review examples, like those used by the DoD and HHS that could be discussed in the next meeting. CDC has not yet prepared a formal after action review because the Ebola response is still in progress, but some of the findings that have been identified thus far could be shared at the next meeting as well.

Interval Updates – OPHPR Division Directors

Jeff Bryant, MS, MSS; Director, Division of Emergency Operations

Presentation focused on the status of the Ebola outbreak and the progress made, as well as the legacy systems that were created or modified during the Ebola response that should be carried forward for future responses. Lastly, an alternate response model was presented.

Mr. Bryant provided the two maps to illustrate the change in the nature of the Ebola outbreak between January 31, 2015 (Figure 1) and September 27, 2015 (Figure 2). The maps illustrate the jurisdictions by the number of days since last confirmed case and indicate the number of confirmed Ebola cases reported in the past 21 days. As the figures indicate, significant progress has been made.

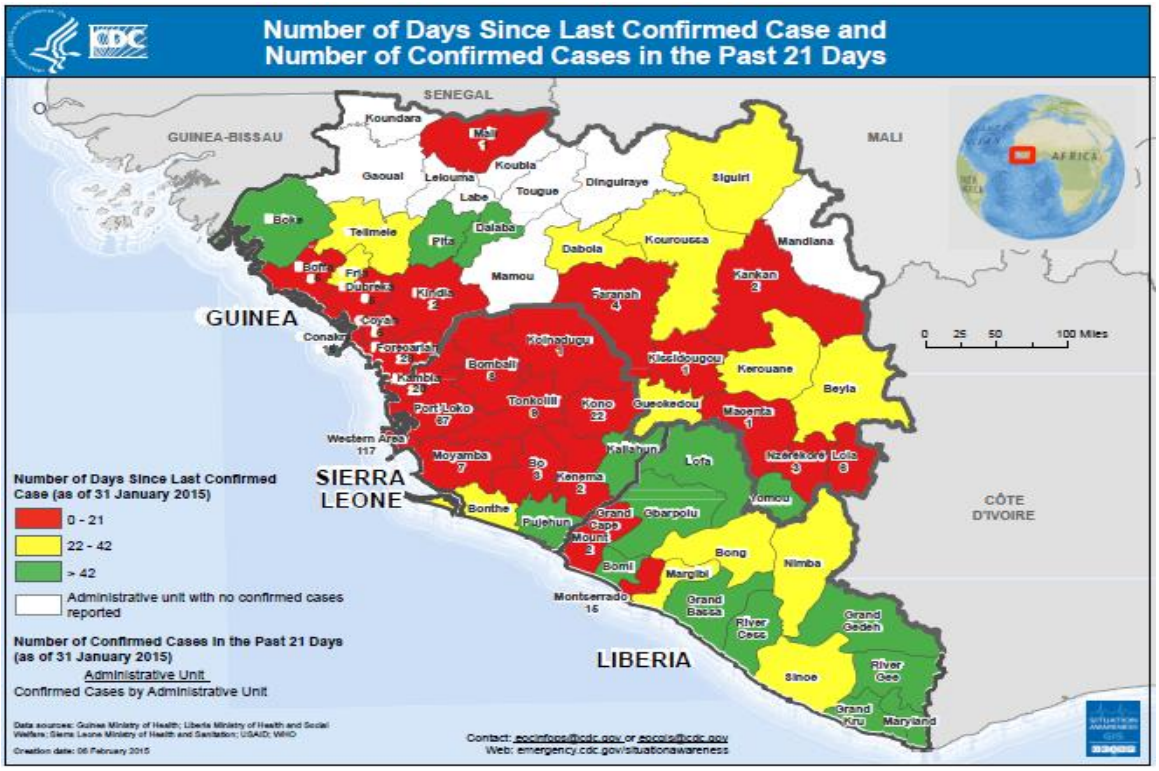


Figure 1

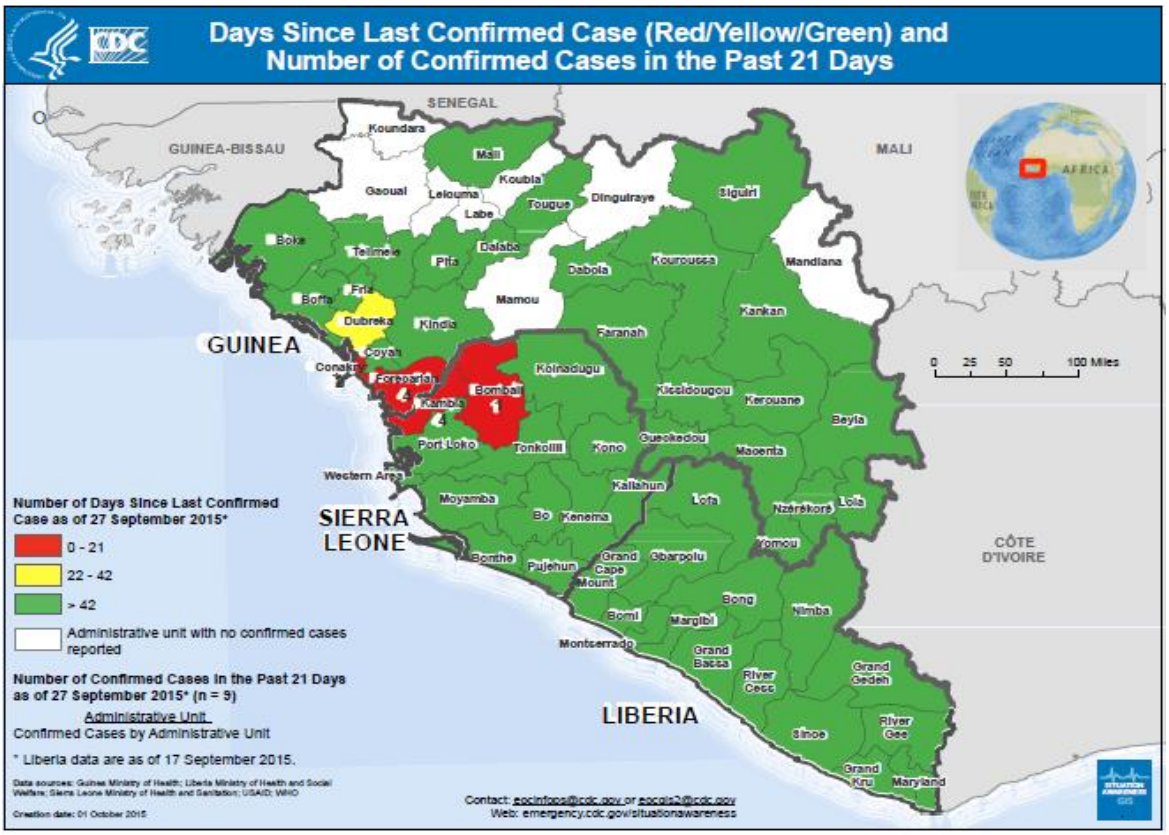


Figure 2

Domestic deployment has decreased from the early response period, but deployment levels have remained constant for the last year. This indicates that there is still significant work that needs to be done. The staff in West Africa is leery about sending response staff home because it takes some weeks to get them back if needed. The number of those deployed is now 135 and by the end of the week, it will be at 133. This number is monitored daily. After action reports will be completed as well as documentation of lessons learned and response activities. But, right now, Ebola response transition planning is in progress.

The Division is attempting to answer several questions:

- How did the Division make progress against Ebola?
- What are the legacy systems used during the response that the Division wants to endure beyond the response?
- How does the Division institutionalize those systems?

Reponses come at a cost and deploying individuals to Africa for this amount of time is challenging. Forty-three percent of the Division's request for individuals is coming from individual taskforces within the Incident Management System (IMS). By-name requests represent 21% of the requests for deployment. Almost 100% of the by-name requests are being filled. These are normally individuals who already have existing relationships with key ministry officials, WHO, and the United States Agency for International Development (USAID). Some individuals in this group have deployed as many as seven times to West Africa mainly for Guinea due to language translation issues (French:English). Lastly, 36% of requests are for non-CDC deployers, who are mainly external partners from the Council

of State and Territorial Epidemiologists (CSTE). The non-CDC deployers have been specifically helpful in the French-speaking countries that CDC is working in not only for Ebola but also for global health security all around.

The Deployment Risk Mitigation Unit was developed to respond to several issues that were occurring such as:

- Embassies overwhelmed
- Safety/welfare concerns
- Deployment processes
- Balanced deployments
- Deliberate reintegration
- Supervisor insensitivities

Lessons learned from other institutions were utilized when forming the unit. The goal is to also institutionalize this process.

The CDC Ebola Response Team (CERT) was put in place after the Dallas Ebola patient was identified and the U.S. health care system was fully engaged in the response. The team is rostered monthly and CIOs have been instrumental in staffing the team. The team is focused on infection prevention/ control and safe work. It is multidisciplinary and includes epidemiologists, infection prevention subject matter experts (SMEs), and microbiologists, just to name a few. The team responds for a specific period of time and when done may not be on call for several months. Since the Ebola response began, there has been one deployment not related to Ebola for the New Jersey Lassa fever case. The CERT has been tolerated well by the agency and therefore institutionalization is forthcoming.
The Division feels that it has executed risk communication well, but finds that each response is unique in its challenges. Using the West African response, as an example, messages conveyed directly to the village level leaders proved to be successful. Having a trusted agent enhances compliance and decreases resistance. Therefore, the idea is to gain a better understanding of the social mobilization process to inform the next response.

There were also two lower intensity responses: the largest HIV outbreak in Southern Indiana and the MERS-Korea response. To absorb these incidents into the EOC in light of the other active responses would have been extremely difficult. Instead, DEO collaborated with the CIOs and Divisions that ran the responses and provided them with only what was needed to establish and support its own IMS-based response structure, e.g., logistical support, communication support, response planning support, and a chief staff. This was a success. The process also kept the CIOs in their own physical space rather than bringing their staff into the already-activated CDC EOC. This model will also be memorialized as well.

After a series of clarifying questions, the following recommendation(s) were made by the BSC:

- Take some of the lessons learned from the responses and share those with your state and local stakeholders who have not become efficient at responding to emergencies. In addition, highlight best practices and offer strategies that can be implemented in their settings to enhance response performance.

- Great efforts were made to debrief staff as they returned to CDC but the same level of debriefing was not performed in the HHS departmental debriefs. In future, recommend using whatever mechanisms are required to share the lessons learned and elevate them for action at that time because people's memories can be short.

- I am struck by the transformation in what DEO was doing four years ago compared to what it is doing now. There are frequent complete EOC activations, and this seems to be the new normal, which can cause a lot of stress on the organization. Capacity needs to be increased in order to normalize the system, understanding that budget complications can be a barrier to that being accomplished.

Interval Updates – OPHPR Division Directors - Continued

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

DSAT is responsible for two core programs, Selection Agent Regulatory Program and the CDC Import Permit Program. Dr. Weyant updated the Board on major incident investigations conducted in 2015 by DSAT, examined the evolution of CDC Import Permit Program, described DSAT's support provided for the Global Health Security Initiative, and reviewed highlights from the Outreach Program.

Several major select agent and toxin (SAT) investigations took place in 2015: One of those was the Tulane National Primate Research Center, where *B. pseudomallei* was released from a registered laboratory into naive non-human primates. Another investigation was conducted at the Life Sciences Testing Facility in the Dugway Proving Ground, where radiation-inactivation failures resulted in shipments of live *B. anthracis* to multiple laboratories over multiple years. At the Life Sciences Testing Facility, a production laboratory was also found to be contaminated with *B. anthracis*. Lastly, the DoD Critical Reagents Program was determined to have sent an unauthorized shipment of regulated SAT nucleic acids to another facility. In addition, a DSAT inventory found record-keeping discrepancies at three DoD research/production facilities. There have been several incidents that have national and international implications that DSAT has responded to this year. Dr. Weyant welcomed a rigorous discussion and recommendations from the BSC on how BSAT can move forward.

The Division has learned the impact that significant investigations have on its staffing and fiscal resources. The Division was not designed to sustain long duration investigations because of the amount of resources they demand for conducting the investigation, writing the report, reviewing of responses, and following-up on-site visits. Investigations occur with short notice and they typically require involvement of higher-level DSAT and entity leadership. Moreover, normally, many conference calls and meetings are required during the investigation and post-investigation. They also require the highest skill- and knowledge-level DSAT inspector staff to be in attendance. They disrupt the performance of routine inspections, which have to be postponed, and routine inspection reports often are delayed as staff work on the incident-related investigation. Lastly, inspectors have to identify serious violations and/or critical issues and monitor remediation or response to recommendations resulting from the investigation.

Figure 3 illustrates the number of inspections – both total (routine and unannounced) and unannounced -- conducted from 2003 to September 2015.

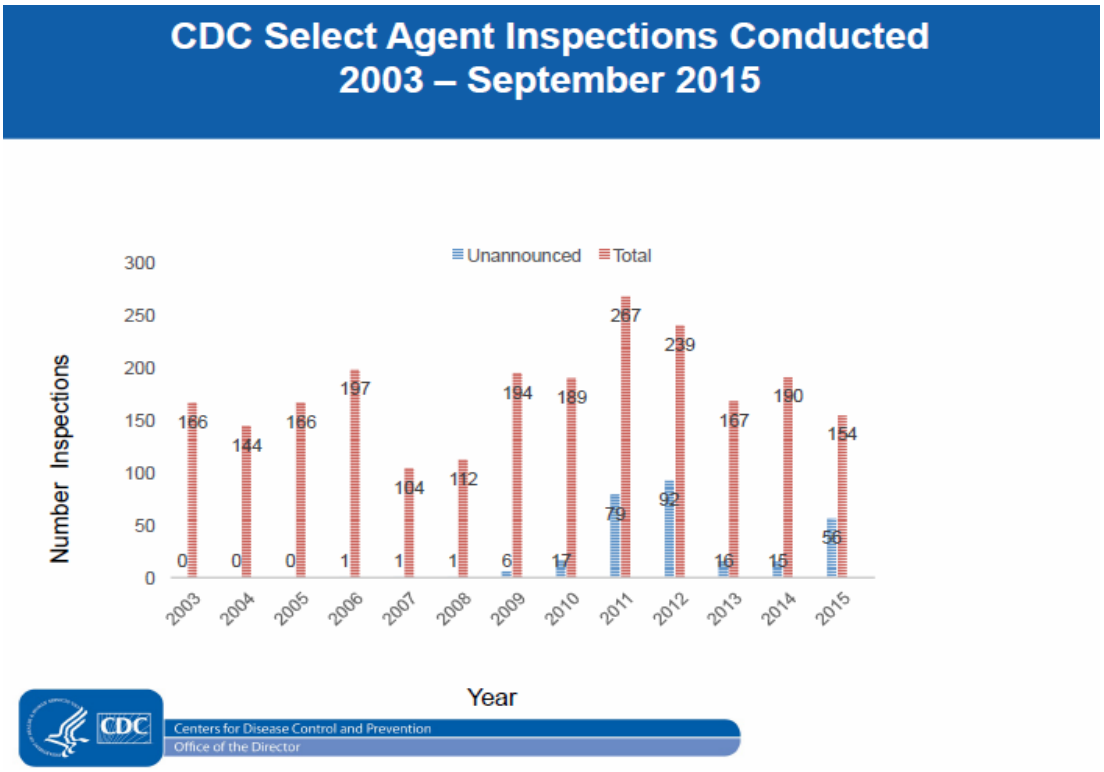


Figure 3

The CDC Import Permit Program has undergone some upgrades. Inspection programs for high-risk importers were up to 46 inspections in 2015 versus no inspection component in 2012. The permit database has been updated to be compatible with the International Trade Database System per the Safe Ports Act of 2006. DSAT's IT systems have been modified to integrate legacy systems. The Division also created an interagency import group (Departments of Agriculture, Homeland Security, and Commerce), as a result of the Ebola response. One of the major goals of the group is to share information and lessons learned based on experience with critical biological specimens being brought into the U.S. for analysis as well as for the shipment of critical medical countermeasures. The team has been very effective and the idea is to formalize the process.

Figure 4 illustrates the number of permits issued from 2000 to 2015.

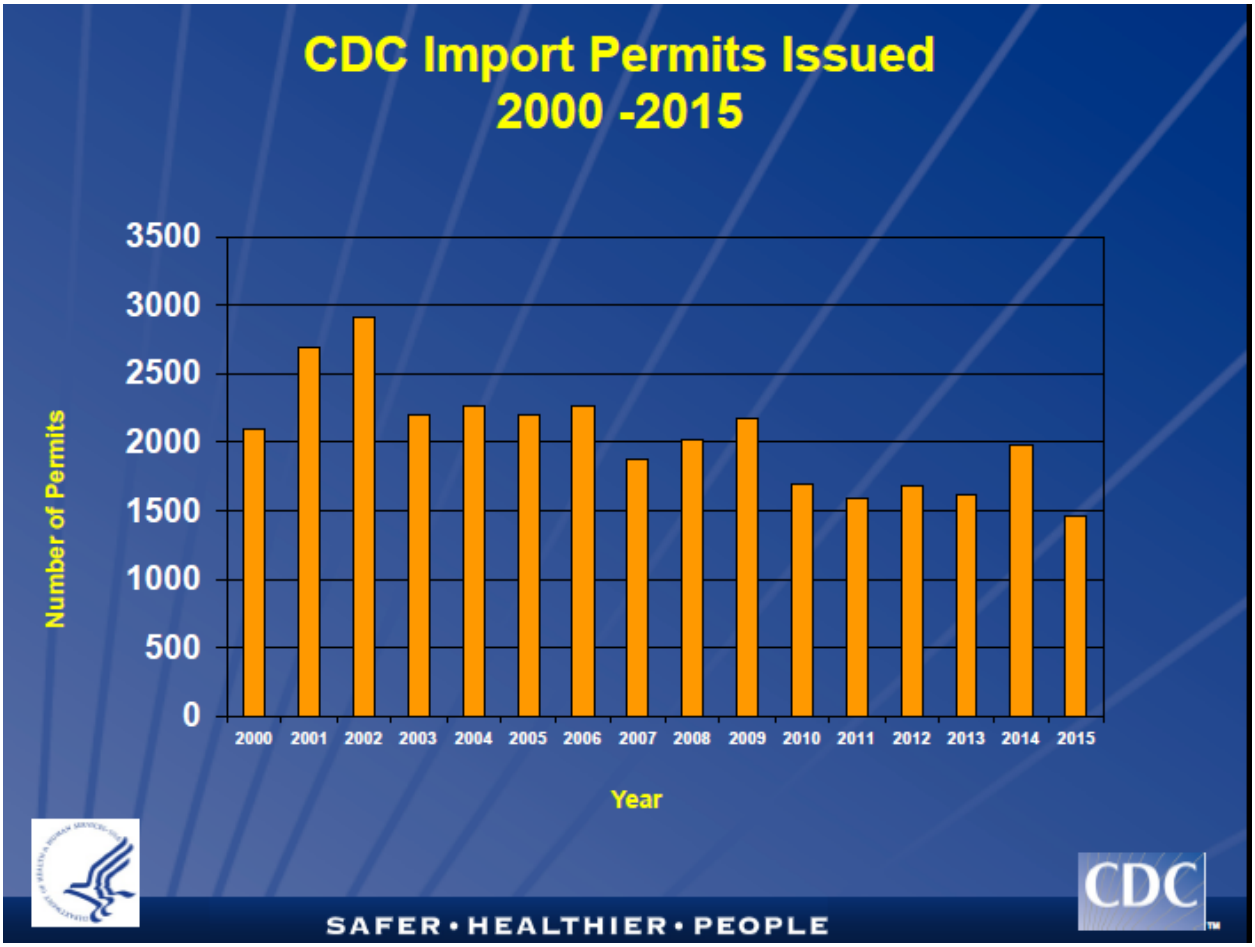


Figure 4

In assisting with the Global Health Security Agenda, DSAT has worked with South Africa to streamline lab biosafety and biosecurity business practices. For example, South Africa previously used information collected on 22 forms to monitor and evaluate its process for importing biological specimens; that process now requires the use of only2 to 3 forms. DSAT is also assisting South Africa with developing an IT-based system to further increase efficiency. In Thailand and the Republic of Georgia, DSAT has helped develop regulatory protocols for the oversight of dangerous pathogens. In

addition, preliminary discussions have held with China with regard to establishing a laboratory biosafety monitoring program.
On September 16, 2015, DSAT hosted a Federal Partner Import/Export Regulations Webinar, which included participants from the following organizations:

- CDC, Import Permit Program
- CDC, Division of Global Migration and Quarantine
- Assistant Secretary for Preparedness and Response/BARDA
- Department of Transportation (DOT)
- Customs and Border Protection (CBP)
- United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS)
- Food and Drug Administration (FDA)
- Department of Commerce

One of the DSAT outreach highlights is the International Group of Experts in Biosafety and Biosecurity Regulation Meeting that occurred August 3-5 in Berlin. The Division has also increased transparency of its work by publishing two peer-reviewed papers: a review of restricted experiment requests (discussed DSAT's system for vetting high-risk experiments or restricted experiments) and a descriptive analysis of the Program's experience with the transfer of select agents and toxins in the U.S.

Clarifying questions were asked after Dr. Weyant's presentation. No formal recommendations were made by the BSC.

Chris Kosmos, RN, BSN, MS; Director, Division of State and Local Readiness

Ms. Kosmos reviewed DSLR's recent activities and accomplishments, as well as the challenges and goals. The presentation described the future direction for DSLR by examining the results of the internal CDC Public Health Emergency Preparedness (PHEP) Program Review (conducted in 2015), the development of 2017-2022 program announcement, and DSLR's organizational approach to supporting state and local public health.

The mission of the Division is to assure the nation's public health system is prepared to respond to and recover from a public health event or emergency. Most of the Division's work is centered on domestic activities focused on preparing and sustaining the nation's public health system. Figure 5 presents a timeline that shows the evolution of Public Health Emergency Preparedness from 1999 to 2012 -- from responding to the events of 9/11 to preparedness and response for a broader range of hazards (all-hazards approach).

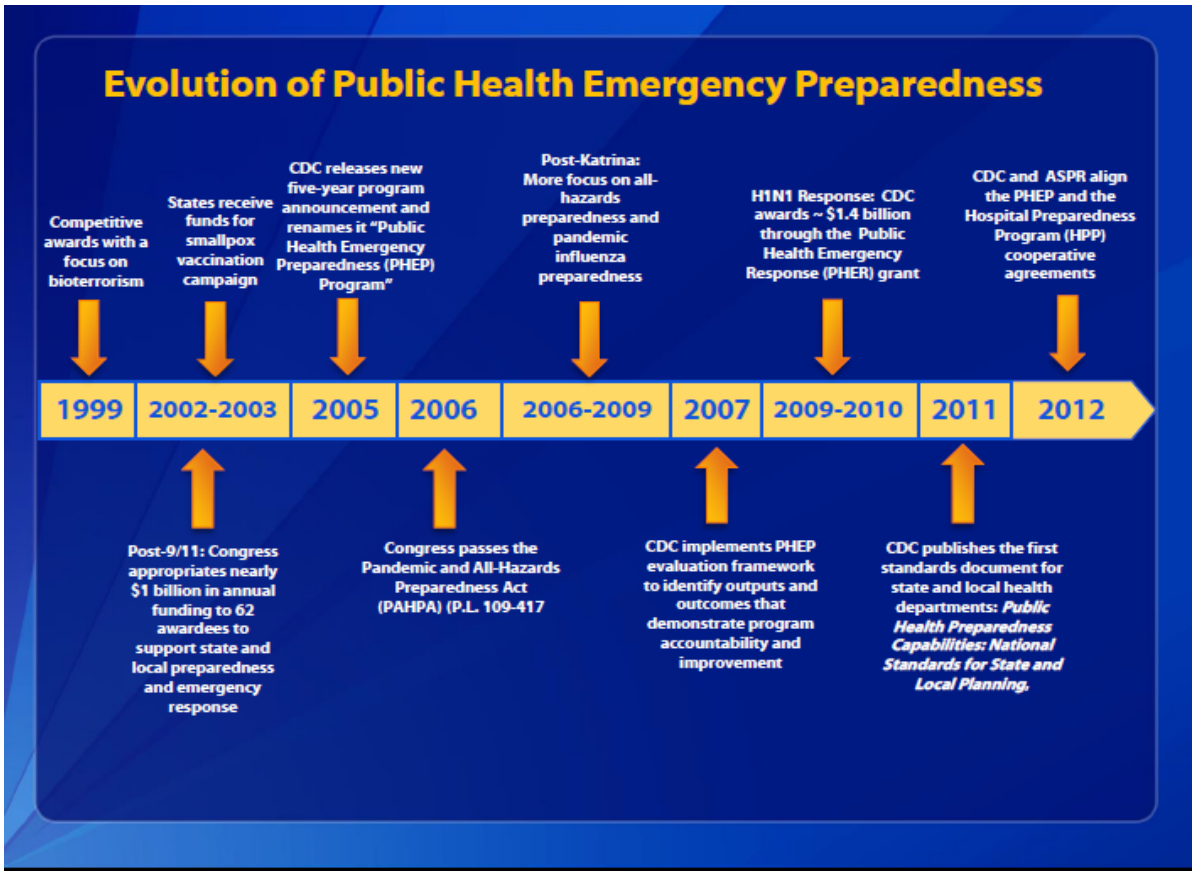


Figure 5

DSLR's desire is to learn from the past program successes and challenges in order to design it in a way that is responsive to a number of emergency-related issues. In 2012, capabilities for state and local public health agencies were identified and described to serve as a playbook for forming a capable public health emergency preparedness program within a public health agency. DSLR also has a close collaboration with its sister program, the Hospital Preparedness Program (HPP) within the Office of the Assistant Secretary for Preparedness and Response (ASPR).

The PHEP program's intent is to establish robust, organized, and capable public health emergency preparedness/emergency management programs at the state, local, and territorial levels and support key public health capabilities necessary for emergency planning and response. It's also to assure response readiness within the nation's public health system for public health emergencies and disasters and the health security of the communities.

Over the last year, DSLR has had several successes. Below is a list of accomplishments for 2015.

- Advanced state and local operational readiness for large-scale medical countermeasure events
- Deployed DSLR MCM Operational Readiness Review tool
- Deployed Pandemic Influenza Readiness Assessment
- Improved technical assistance to state and local jurisdictions
- Established new Capacity Building Branch (CBB)

- Led project with state and local awardees and partners to better define the impact of the PHEP program on state and local readiness and response
- Developed key messages defining the impacts
- Designing communication/education strategy
- Led major aspects of CDC's domestic Ebola response: State Coordination Task Force (SCTF)
- Designed systems for tracking and monitoring travelers from West Africa
- 30,000+ travelers
- Designed tiered healthcare strategy
- Provided funding to 62 awardees for Ebola response

There are still challenges. One is managing the evolution of a maturing PHEP program. This is a challenge as we work to:

- Provide a culture of continuous improvement and development
- Assure a reliable/valid process for evaluating state and local readiness for a large-scale medical countermeasure event
- Collaborate with CDC subject matter experts and ASPR to improve healthcare system readiness and response
- Continue to improve systems for performance measurement and evaluation
- Assure PHEP program achieves maximum impact
- Improve program development
- Assure accountability

DSLR's has set forth several goals. One is to develop better mechanisms for funding state and local public health response. A system will be designed to build in flexibility in making funding available to ensure timely response to urgent events. The Division will also work with CDC subject matter experts to develop more specific guidance for the next PHEP project period, which is from 2017 - 2022. This includes the development of targets or benchmarks for specific capabilities, such as informatics, epidemiology/surveillance, laboratory, and healthcare system response.

Concerning the PHEP Program Review, CDC senior leaders reviewed the PHEP program over a series of discussion-based meetings that took place from April to June 2015. During the meetings, the group reviewed the PHEP's current status, including coordination with other CDC programs, and developed recommendations for strategic improvements. The PHEP Program Review Committee was comprised of the following CDC organizations:

- Office of Infectious Diseases
    - National Center for Emerging and Zoonotic Infectious Diseases
    - National Center for Immunizations and Respiratory Diseases
- Office of Non-communicable Diseases, Injury, and Environmental Health
    - National Center for Environmental Health
- Office of Public Health Scientific Services
- Office for State, Tribal, Local, and Territorial Support
    - Division of Public Health Performance Improvement
- Office of the Chief Operating Officer

- Office of the General Counsel
- Office of Safety, Security, and Asset Management

From the review, several recommendations emerged that should further strengthen the overall public health impact of the PHEP program across three objectives: enhance day-to-day public health impact of the PHEP program, assure accountability of PHEP investments, and identify opportunities for continued program development (Figure 6).

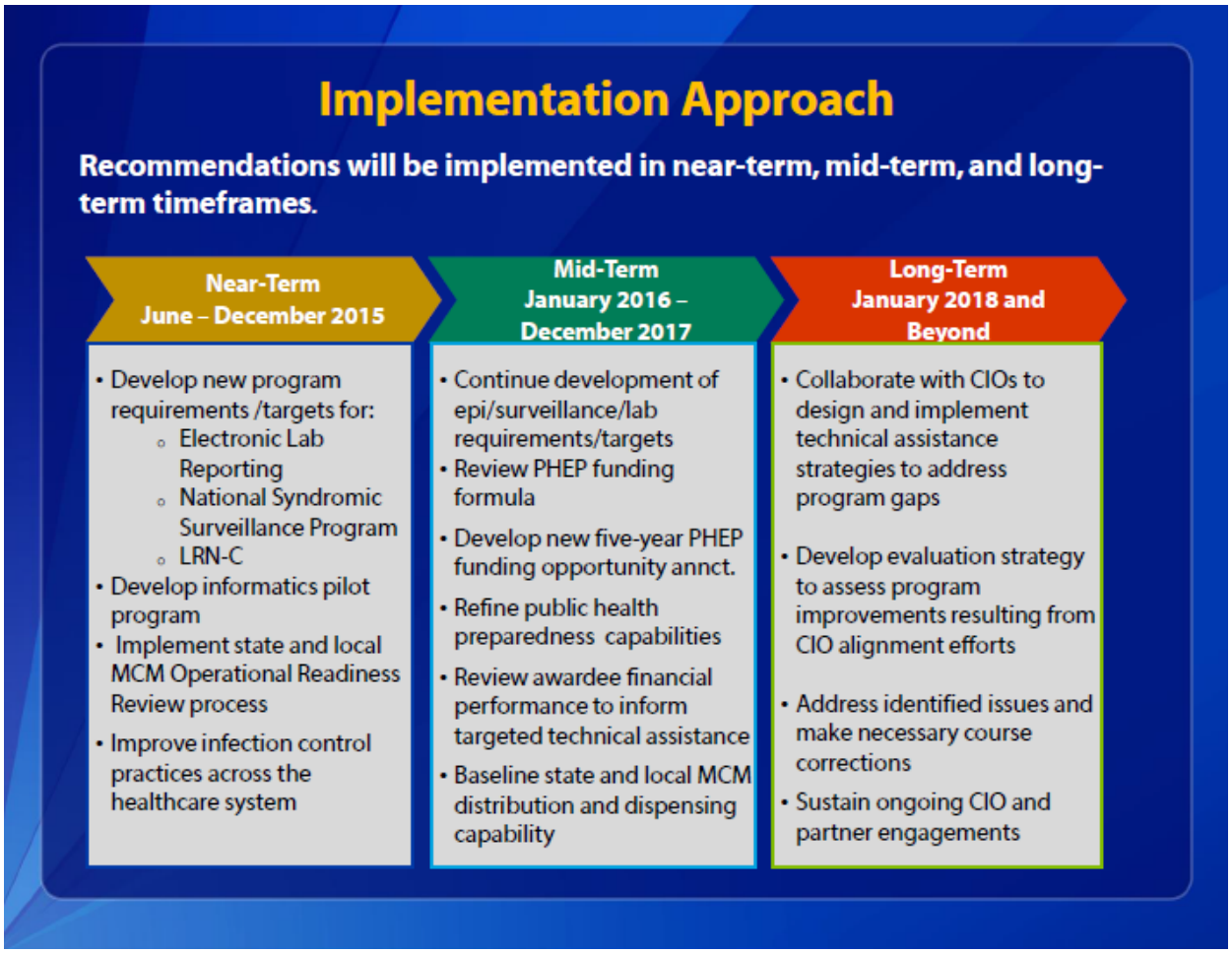


Figure 6

An example of surveillance and informatics challenges to be addressed was given to illustrate what DSLR expects to accomplish. The goal is to identify shared metrics with the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) and the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) for inclusion in the PHEP fiscal year 2016 continuation guidance. Accomplishments realized so far included drafting language for the PHEP fiscal year 2016 continuation guidance to support the following metrics:

1. CSELS: Increase from 45% in 2014 to 75% in 2018 the proportion of emergency department visits nationally that are captured by the National Syndromic Surveillance Program (NSSP)
2. NCEZID: Increase from 67% in 2014 to 80% in 2016 the proportion of laboratory test results that public health agencies receive electronically.

Ms. Kosmos ended her presentation by reviewing the proposed PHEP logic model for 2017-2022 (Figure 7).

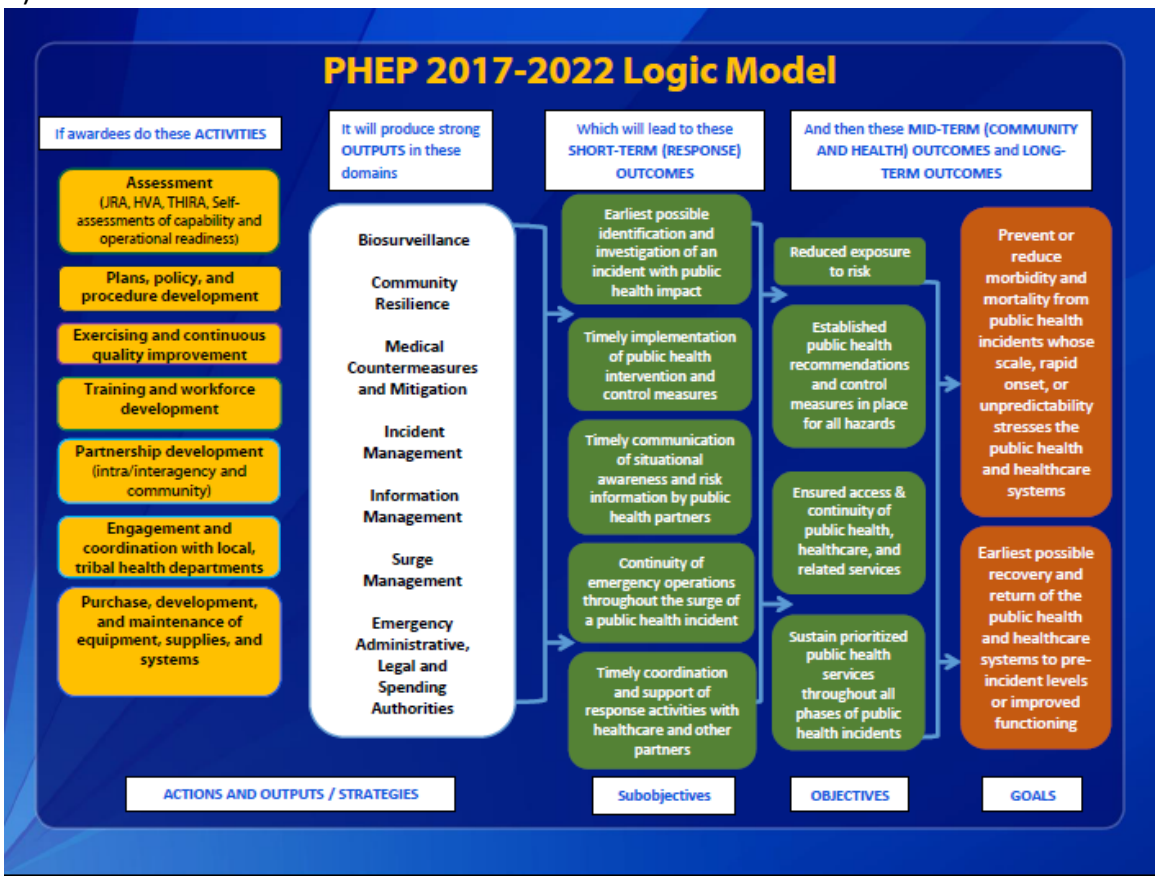


Figure 7

After a series of clarifying questions, the following recommendation(s) were made by the BSC:

- Funding provided to the state PHEP programs that is intended to address tribal concerns is not making its way to the tribal communities for the most part. The Tribal Epidemiological Center liaison requested to work with DSLR on this issue and would invite others to assist in addressing the issue.

- The goals and objectives of the PHEP program are rational but how do you get the unity of effort between the disjointed funding of the local, state, and federal level? Local PHEP programs typically respond to smaller emergencies, e.g., wildfires, rather than global pandemics. It would be important to work with local public health authorities to determine how multiple response entities can best support PHPR.

- It is probable that there are different models of how countries, regions, and locales respond to emergencies and different barriers to response. It would be helpful to: 1) classify the approaches and the barriers to response, 2) rate each response as illustrating high, medium, or low performance, and 3) document the assumptions or explanations for each performance

level). What pre-existing conditions might explain the rating? How have jurisdictions reached their performance level? What are the barriers to overcome to enhance performance?

Greg Burel; Director, Division of Strategic National Stockpile

DSNS has been engaged in some of the Global Health Security Agenda work regarding MCM stockpiling and the management of product. Mr. Burel reviewed DSNS's accomplishments:

- Improving preparedness for Ebola and other highly infectious diseases
  - Specific Personal Protective Equipment (PPE) items continue to be hard to source
  - Ebola Supplemental funds were used to order additional quantities of hard to source personal protective equipment (PPE) items (e.g., powered air purifying respirators [PAPRs])
  - SNS capacity will support 260 patients simultaneously for up to 4 days of care once all orders are received
- Collaboration with DoD to meet Nerve Agent Antidote Requirements
  - To meet immediate needs prior to scheduled delivery of new DuoDote nerve agent antidote auto injectors, coordinated with DoD to utilize available antidote treatment nerve agent auto injectors (ATNAA) from DoD stock
  - Solution averted the planned reduction of CHEMPACK container capacity
- MCM Supply Chain Engagement
  - Continuing work started in Ebola Response, DSNS is expanding coordination with commercial supply chain representative
  - Work with Health Industry Distributors Association (HIDA) to identify opportunities to work together and improve overall capacity to respond
- Private-sector dispensing exercise with Costco
  - DSNS supported a successful public point of dispensing (POD) demonstration exercise with Costco, the Virginia Department of Health, and the Prince William Health District in June 2015
  - 200 volunteers were processed through a POD established inside a Costco store, staffed by Costco pharmacy staff, with oversight for dispensing operations provided by local public health
  - Proved that private sector partners can provide rapidly scalable resources to support local public health

Mr. Burel also highlighted some challenges. The IOM review of SNS Distribution Capabilities included two meetings of the IOM Standing Committee for the SNS, which were conducted in fiscal year 2015. The meetings incorporated an in depth review of the current composition and processes of the SNS, as well as, a review of the MCM supply chain outside of the SNS, as presented by representatives from the private sector, state and local, and other federal agencies that participate. Additional meetings will be convened in 2016 and will incorporate issue-focused workshops.

DSNS desires to shift the SNS to a global MCM supply chain. There are opportunities to influence access to MCMs beyond SNS holdings. As a part of the change, the Division will transition the staff and resources to DSLR to support state and local dispensing guidance and activities and align its activities and priorities to address the full spectrum of the supply chain. While discussing auto injector issues with the DoD, DSNS realized that the partners could and should leverage everything that they possess

as a group to meet a response need. This will make the supply chain a more efficient process. DHS is also helping to facilitate the discussion among the partners.
The IOM Review that was called out in the 2014 Congressional appropriation is not a challenge but an opportunity to make MCM distribution a success. However, the review does call into question some of the issues around supply chain. There will be more meetings pertaining to this issue and DSNS will update the BSC as they occur. Mr. Burel also asked the BSC to recommend ways to perform the major shift to having a bigger affect overall in a supply chain and address response needs.

After a series of clarifying questions, the following recommendation(s) were made by the BSC:

- To the extent that you can find people like Costco and others who want to play a role in MCM distribution, there may be an opportunity to incentivize private sector participation in MCM distribution in ways we haven't thought about, which can reduce potential budget costs at large. It may involve collaboration with Department of Commerce or others but I think there are models established as a result of the Defense Production Act and others mechanism where we've done that. So think through ways to incentivize from regulatory or other requirements that are levied on the private sector.

- There are a number of pharmacy incentives going on right now and pharmacies have really been interested in collaborating. HHS is now responsible for handling rating of all health resources and is collaborating with agencies like commerce, defense, etc. Having Greg on board is a fantastic asset because he understands the private sector.

OPHPR Policy Update

Kathryn Gallagher; Associate Director, Office of Policy, Planning & Evaluation (OPPE), OPHPR

Ms. Gallagher provided the Board with an update on the work of the policy group and the initial priorities for her office. She also provided a preview of the comprehensive policy strategy, which will be presented with more detail at a future meeting. She welcomed recommendations from the BSC.

OPPE is in the middle of formulating the President's budget for 2017. They are working with the Office of Management and Budget (OMB) as well as the OMB Examiner to answer her questions and explain the public health need for the office's services and the thought process behind its request. The budget release date is for early February 2016.

The office is also working with the Appropriations Committee doing work similar to that with OMB to give them information to support the budget request and answer any questions to assure them that OPPE is making the best use of the money received.

OPPE has done a lot of work with the Select Agents and Toxins (SAT) Program in response to Congress' request. Dr. Sosin testified before the House Subcommittee about anthrax release incidents and answered questions on laboratory safety. There is a lot of Congressional interest in the program and the outcome of the 90-day CDC internal review of the SAT Program.

The office also provided technical comments on a number of fronts. It has engaged in the GAO and OIG investigations. Across the programs of OPHPR there is interest in the investigations. OPPE is not the lead but are supporting some of the investigations, which is a large bit of the office's work. The Planning and Evaluation team is doing the Snapshot Public Health Preparedness Report, which will be out in January. It will be shared with the BSC as well as OPHPR's partners. The office also is contributing to the definition and modification of the Healthy People 2020 Preparedness Goals.

Finally, the Partnership Team has completed a good bit of assessment of its partnership list to determine a partnership strategy including identification of non-traditional partners. The Partnership Group is working with our partners to understand their policies, needs, priorities, and how they align with OPHPR to create advantage.

Ms. Gallagher has begun to consider a comprehensive policy strategy, which will examine the various lanes of policy and opportunities to impact public health preparedness and response through the policy channels. This requires looking at the priorities and goals, assessing the strategic planning process, and finding the core priorities for the agency. It's also essential to determine how the office affects other programs, task forces, and impact projects that inform the priorities. The OPPE will also review the top legislative branch priorities. Does it need additional authorities and what changes need to be made to move the priorities forward?

By our next Board meeting, OPPE will have more specifics about its findings and provide more information to the BSC. BSC members offered the following recommendations:

- Endorse activities which address finding new ways to tell the broader story of OPHPR. There is rich work going on at the state and local levels and I don't think that work is relayed well.

- Encourage attention to disseminating and translating the good scientific work that goes on in the different Divisions into the FEMA regional response and recovery plans.

- Consider developing a narrative around the horizontal work that goes on across OPHPR or the agency as a whole. People don't really understand or hear about that perspective – the complexity of the system and how the different components support preparedness and response.

IOM Forum on Medical and Public Health Preparedness for Catastrophic Events
Jack Herrmann, MSEd; Senior Program Officer, IOM
Suzet McKinney, DrPH; BSC Member

Mr. Herrmann began with an overview of the Institute of Medicine (IOM) and its preparedness portfolio. One of Mr. Herrmann duties at the IOM is to look for ways to ensure that the work conducted is of value to the sponsor and substantive in advancing the agency's missions and priorities.

Another responsibility is to convene subject matter experts to address issues that have an impact on research, policy, and practice in public health and healthcare preparedness. The BSC was given a document that provided a summary of the preparedness portfolio within the IOM's Health Science

Policy Board. It includes a forum on public health preparedness, a variety of standing committees, and other activities.

The Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events brings together leaders from academia, industry, government, foundations, associations, and representatives of patients and consumers who have a mutual interest in addressing the issues surrounding preparedness, resilience and response of the public's health. The Forum provides a neutral venue for broad-ranging policy discussions that serve to facilitate coordination and cooperation among the public and private stakeholders in developing and enhancing the nation's medical and public health preparedness. Below is a list of the sponsors involved in the forum.

- Administration for Children & Families (HHS)
- American College of Emergency Physicians
- American Hospital Association
- Association of State and Territorial Health Officials
- Centers for Disease Control and Prevention (HHS)
- Food and Drug Administration (HHS)
- Infectious Disease Society of America
- Martin, Blanck & Associates
- Merck Sharp & Dohme Corp.
- National Association of Chain Drug Stores
- National Association of County and City Health Officials
- National Association of Emergency Medical Technicians
- National Highway Traffic Safety Administration (DOT)
- National Institute of Allergy and Infectious Diseases (NIH)
- National Institute of Environmental Health Sciences (NIH)
- National Library of Medicine (NIH)
- Novartis Vaccine and Diagnostics
- Office of the Assistant Secretary of Defense for Health Affairs (DoD)
- Office of the Assistant Secretary for Preparedness and Response (HHS)
- Office of Health Affairs (DHS)
- Pharmaceutical Research and Manufacturers of America
- Robert Wood Johnson Foundation
- Target Corporation
- Trauma Center Association of America
- Uniformed Services University of the Health Sciences (DoD)

Figure 8 illustrates the composition of the forum by type of sponsor organization.

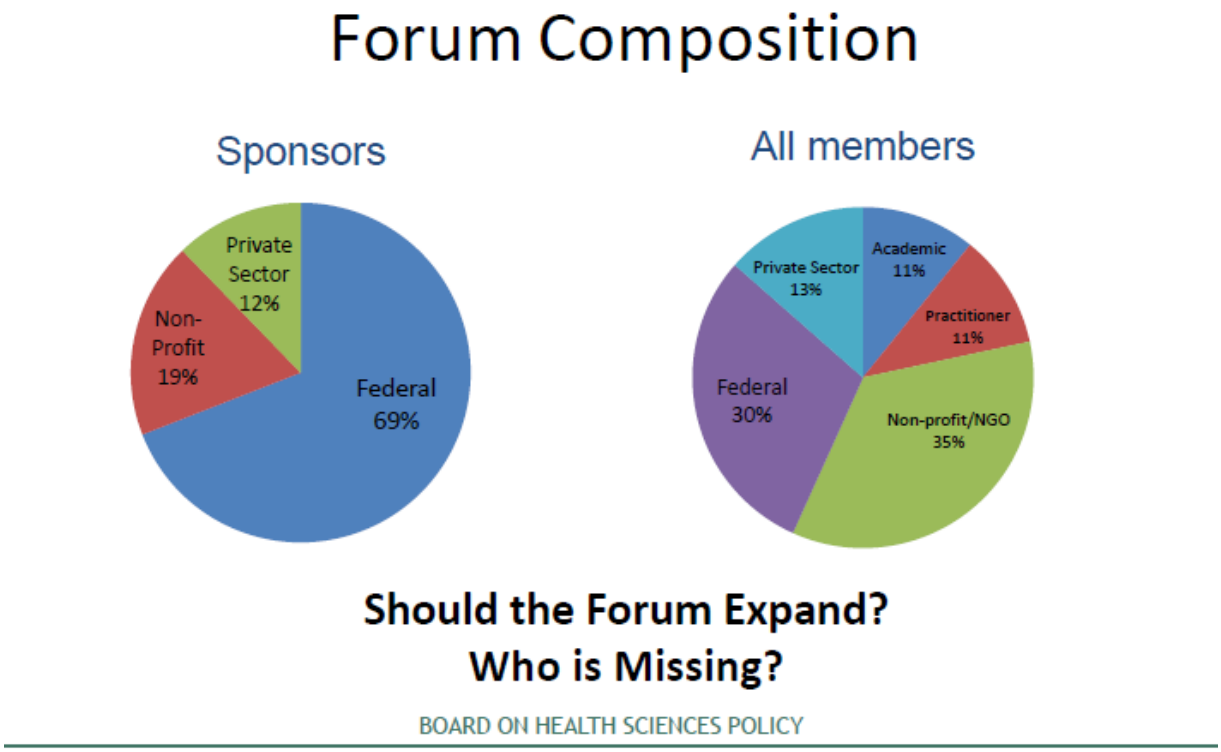


Figure 8.

Several meetings and workshops have been convened by the IOM Preparedness Forum. The Forum generates briefs or highlights of outcomes produced in the meetings and workshops but does not give recommendations. Past meetings covered subjects such as:

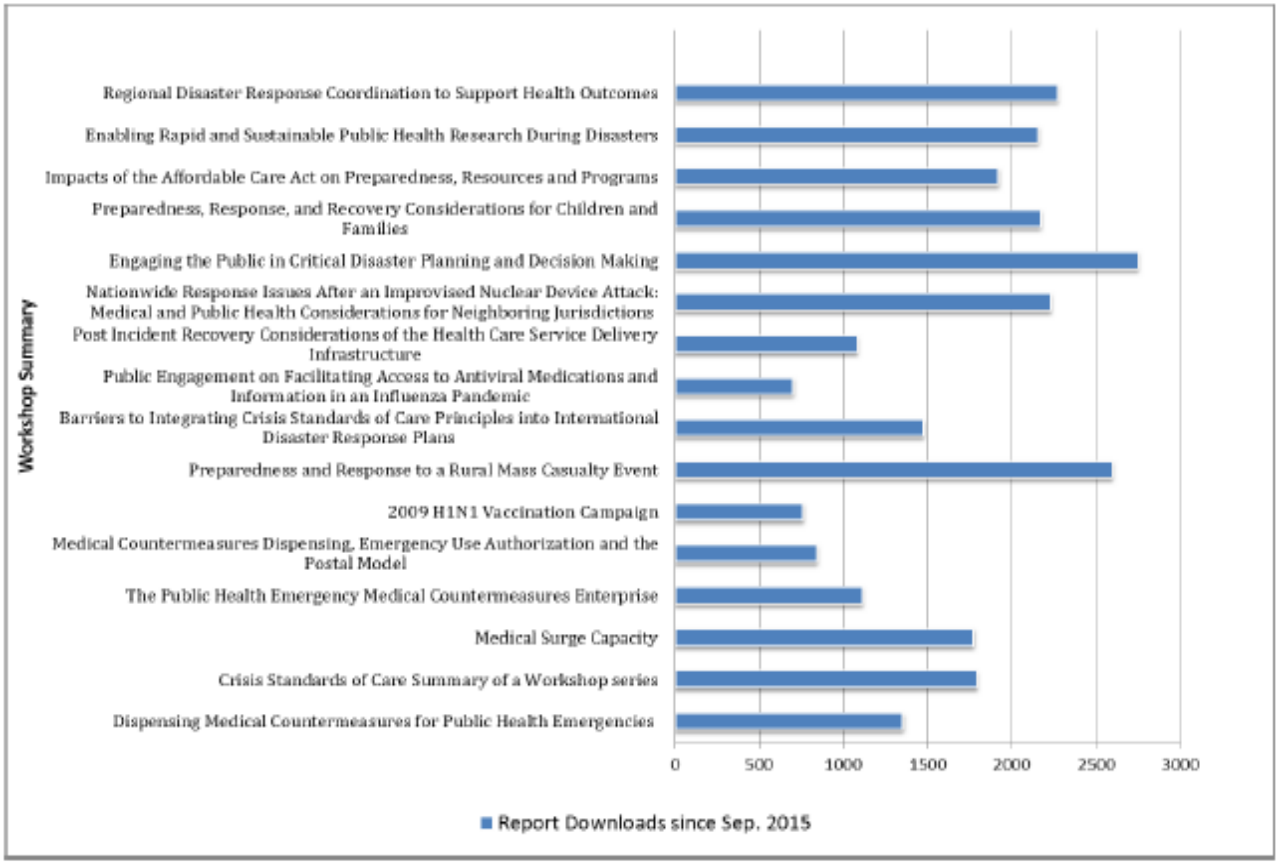
- Medical Surge Capacity
  - Medical Surge Capacity (2010)
  - Crisis Standards of Care: Summary of a Workshop Series (2010)
  - Crisis Standards of Care: Lessons from Communities Building Their Plans (2014)
- Disaster Preparedness Training
  - Preparedness and Response to a Rural Mass Casualty Incident (2011)
  - Barriers to Integrating Crisis Standards of Care Principles into International Disaster Response Plans (2012)
  - Post Incident Recovery Consideration of the Health Care Service Delivery Infrastructure (2012)
  - Nationwide Responder to an Improvised Nuclear Device Attack (2013)
- Community Resilience and Engagement
  - Public Engagement on Facilitating Access to Antiviral Medications and Information in an Influenza Pandemic (2012)
  - Engaging the Public in Critical Disaster Planning and Decisions Making (2013)
  - Preparedness, Response, and Recovery Considerations for Children and Families (2014) Regional Disaster Response Coordination to Support Health Outcomes (2015)

- Medical Countermeasures
  - Dispensing Medical Countermeasures for Public Health Emergencies (2008)
  - Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model (2010)
  - The Public Health Emergency Medical Countermeasures Enterprise (2010)
  - Advancing Regulatory Science for Medical Countermeasures Development (2011)
  - Enabling Rapid Response and Sustained Capability with Medical Countermeasures to Mitigate Risk of Emerging Infectious Diseases (2015)
- Research and Evaluation
  - The 2009 H1N1 Influenza Vaccination Campaign (2010)
  - The Impacts of the Affordable Care Act on Preparedness Resources and Programs (2014)
  - Research Priorities to Inform the Public Health and Medical Practice for Ebola Virus Disease – WIB (2014)

A variety of papers have been commissioned from the workshops and forums as well as products developed.

The Forum also measures the impacts of the reports it produces by monitoring the number of downloads, how the reports are being used, citations of the Forum's products, and mentions on social media to name a few. Figure 9 illustrates the number of downloads of the reports produced by the Forum.

Impacts



Users of the reports are required to type in a reason for their download. Some common responses are to gain an understanding of steps local health departments should take to be better prepared to deal with emerging diseases and as a reference for global action on emergency and disaster risk management for health in the role at WHO. The reports effect change, inspire action and inform the field.

Suzet McKinney, DrPH; BSC Member

Dr. McKinney described the Forum's recently-initiated strategic planning process. She is now the Co-Chair for the Forum on Medical and Public Health Preparedness for Catastrophic Events. The other Forum co-chair is Dr. Dan Hanfling.

One of the objectives of the Forum's strategic planning effort is to ensure the work produced meets the needs and goals of the sponsoring agencies and members. The process utilized a highly effective method that quickly formulates a plan versus being stuck in the planning and enables rapid movement to implementation. A process for reviewing the Forum's progress regularly must be in place to allow the Forum to make real-time adjustments. The desire is to focus on results, and not activities.

Figure 10 was used to guide the Forum through the strategic planning process.

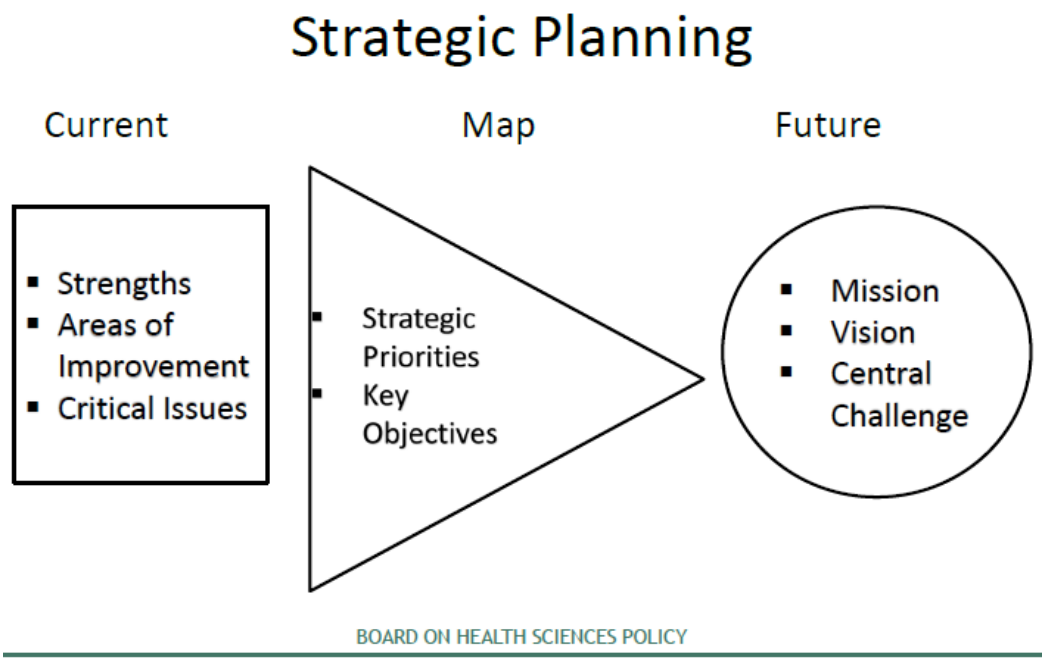


Figure 10.

The goal was to move the planning process further down the spectrum to where it should be in the future. The goals or priorities are to:

- Identify and prioritize key issues
- Achieve meaningful member engagement
- Define and leverage output
- Optimize structure, systems and processes

The Forum is seeking to answer several questions. Who is its audience? What are the goals as it relates to policy, operational applicability, national preparedness, and local/state/regional preparedness?

As a result of planning process, the map below was created to advance actionable approaches that improve preparedness (Figure 11).

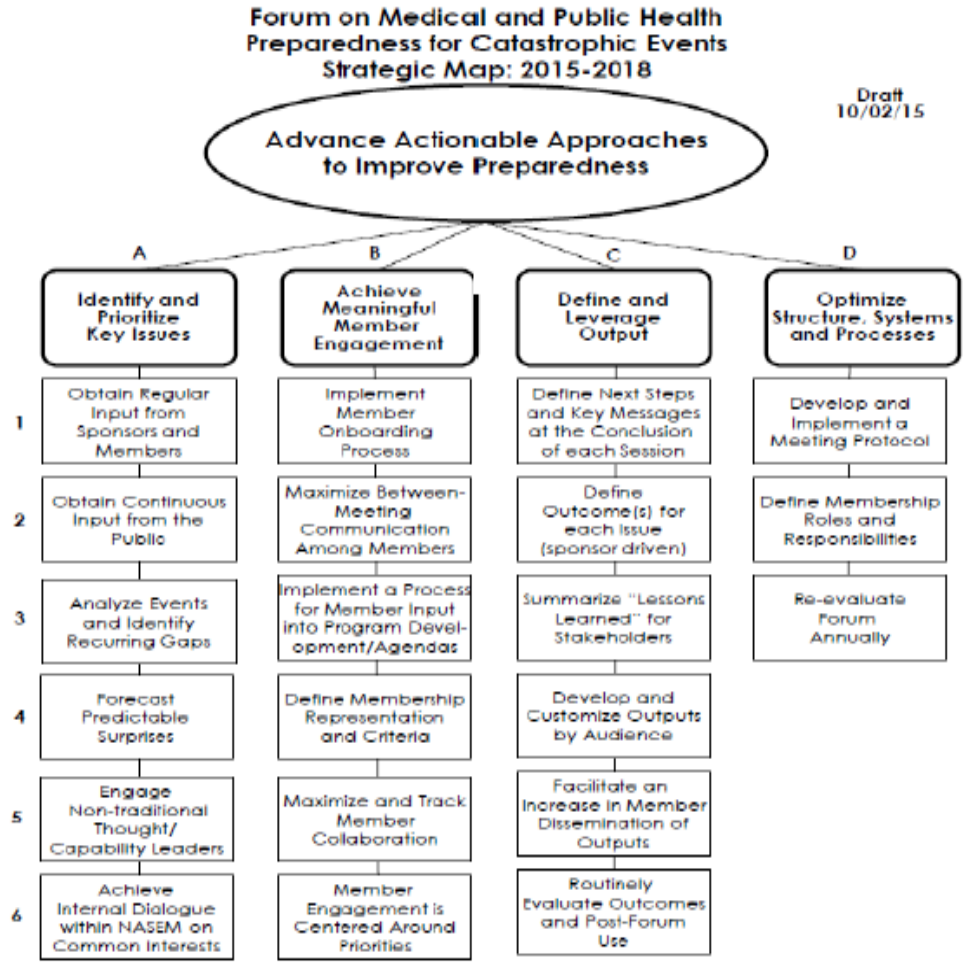


Figure 11.

Dr. McKinney would like to engage the BSC in a discussion around several opportunities. One is to help them find OPHPR priority areas that could compliment some of the Forum's priorities. There is a lot of overlap. The forum also needs to identify areas that are ripe for additional study and examine the continued challenges to national preparedness. A lot of discussion has occurred on impact of PHPR investments and how communities are benefiting from the Forum's work, and lastly, thinking about the Global Health Strategy and where can the forum conduct work and begin to see impact in global health.

After a series of clarifying questions, the following recommendation(s) were made by the BSC:

- Consider how one might show disparities and inequalities in the communities' PHPR.

- Not all communities have the capacity to implement these programs and they often have other priorities that they rank more important. It would be of value to determine implementation or uptake at the local level and how often it is happening.

- In looking at your map, the BSC can help with priority C3. I would put 5 stars to prioritize. We also need a summary of recommendations to share with the practice community and the collective lessons learned to form a way forward. This gives a touch point for the BSC.

- CDC had initiated a study on the cost of preparedness, but the methods were rudimentary. It may be useful to revisit this question to allow better characterization of the consequences of not sustaining or increasing funding to support response efforts.

- What worries me is the nature of these efforts that drive to consensus. I don't always trust it [consensus]. The problems we are looking at are so complex that the thought of a standardized method may not address the complexities and uniqueness of all events.

- Some structures we have today were designed for situations that are no longer an issue. We have to examine the system of systems and we often don't have the level of expertise to do that. Nobody is looking at how changes from generation to generation should fit together and where are the connections.

- In your analysis of the reports, agree on the top 5 or most influential efforts of the Forum's last eight years and try to understand what it was that made them useful and effective in having an impact (e.g., changing policy).

- Catastrophic response depends on where you are, so the impact and who is impacted may vary. Therefore, you may need to ensure reports address issues relevant to specific groups.

Incident Management Training and Development Program (IMTDP)

Silvia Trigoso, MPH; LO, OD, OPHPR

Jeff Bryant, Director, Division of Emergency Operations, OPHPR

Ms. Trigoso and Mr. Bryant provided information on the background and purpose of the IMTDP, its multi-phase approach, the environmental scan, and next steps for Program development and implementation.

The nature of public health response is evolving. CDC's commitment is to respond to complex public health emergencies and emerging threats and to respond quickly and effectively.

Some of the lessons learned from CDC IMS activations have helped OPHPR develop a deeper understanding of the needs for response leadership and improved processes to support success. These

lessons learned led to the development of the IMTDP. The IMTDP is intended to be an agency-wide initiative that will strengthen CDC's response capacity in collaboration and partnership with CIOs.

The goals of the IMTDP are outlined below.

- Design and implement a comprehensive and sustainable program
  - Meets CDC's IMS activation and response needs
  - Prepares response leadership
  - Develops response leadership selection process
  - Collaborate with internal and external partners
- Partnerships established
  - Task Force
  - Advisory Committee

The IMTDP methodology is intended to be comprehensive, sustainable, and support continuous improvement and include best practices, process and support, training, and exercises. A multiphase approach is being employed as the program matures. The first step was to establish a task force and advisory committee. The next step was to conduct an environmental scan, design a communication plan, and schedule a partner event. The third step was to identify the target audience, develop training, and to pilot and evaluate the training. Fourth was to commit staff and resources, develop the response leadership, and design a development program. The last step was to implement and adjust areas to optimize the process.

Ms. Trigoso gave the Board a more in-depth review of the environmental scan, which included an external scan utilizing detailed interviews with external partners familiar with incident management and an internal scan consisting of comprehensive interviews with senior CDC incident response leadership.

A summary of the findings were shared with the Board:

Best Practice: Purposeful Structure
- Deep Roster Bench
- Supports Experiential Training
- Consistent and Predictable

Agreements
- Pre-Roster
- Formalize Roster Methods
- Prepare all Rostered
- Use Structure to support training opportunities
- Seamless Staffing and Improve Transitions

Best Practice: Competitive Selection

- Establish formal selection process
- Formalize response leadership role in job descriptions
- Proven mature and flexible leadership capabilities

Agreements

- Selection based on competitive criteria
- Standardize selection process
- Include role in job descriptions/PMAP
- Career Paths

Best Practice: Comprehensive Training Program

- Role-specific training
- Formalize selection and recognition
- Training model based on career continuum

Agreements

- Response leadership training is different than IMS structure
- NIMS training does not provide role-specific leadership training
- Sequential and comprehensive training program/experience for all levels of response leadership
- Competitive selection process
- Formal recognition

The overall barriers identified include: leadership and agency commitment; resistance to change; development of program policies/requirements; perceived value of training; and CIO autonomy and authorities.

Several recommendations also surfaced as a result of the comprehensive process.
Purposeful Structure

Formalize roster method

- Pre-roster all response leadership
- Include role in job description
- Deployment duration minimum & maximum

Improve transition from program to IMS activation

- Implement process to transfer institutional knowledge for situational awareness
- Assign advisor to on-board leadership
- Establish process for rotations utilizing time limits and rosters
- Establish liaison process with OD

Implement structure and process to provide experiential and progressive training

- Experiential training opportunities
-
- 2. Training continuum and requirements

Competitive Selection

Selection criteria and process

- Include criteria in job descriptions
- Use as recruitment measure

Expand response leadership cadre

- Expand capacity at all levels

Career path and progression

- Provide incentives
- Formalize recognition of excellence
- Build strong alumni

Comprehensive Training Program

Competency-Based Curriculum

- Best Practices/Evidence Based
- Continuum of Training for All Career Levels

Alumni Community

- Faculty
- Community of Practice
- Advance Career Progression

Recognition of Excellence

- Formal Recognition
- Evaluation

CDC has been continuously activated since December of 2011, so putting the program together in the middle of the Ebola response has been challenging, but it is an opportune time to push this effort forward because of the organizational value that can be garnered.

After a series of clarifying questions, the following recommendation(s) were made by the BSC:

- Clearly other agencies would benefit from this. Determine how you can generalize the curriculum so that other partners can utilize the products developed. [The Division asked the Board to please suggest partners the Divisions should be talking to.]

- FEMA has an incident management course, where they take a number of people from an organization and put them through weeklong incident management training. It is a combination of lecture and scenario exercises. Perhaps some of CDC's incident managers could partake in training like this.

- Think about how you can utilize planned exercises and training events that happen across the U.S. to develop or pilot Program components. Utilizing some of the experiences from those individuals can be leveraged.

- There is not always a good self-identity that "I don't have the right skills to be a good IMS manager." There are sometimes junior people who are interested and able to acquire the requisite incident management leadership skills.

- In addition, your scientific expert or political leader isn't always the best incident manager. Everybody has to understand basic incident management and their role in the structure. FEMA does a reasonable job of training. The best training when it includes people on various levels of the public health system: fed, state, and local. Consider what is happening at the state and local levels with public health and build in expertise from other responder groups.

- Figure a way to incentivize some of the "additional duties as assigned" to increase participation. There may be opportunities for joint experiences outside the CDC that will look good on the résumé and could be beneficial because of the expertise garnered.

Mental and Behavioral Health and Community Disasters

Carol North, MD; BSC Member

Eric Carbone, MBA, PhD; Director, ERPO, OSPHP, OPHPR

Drs. North and Carbone provided a brief presentation on mental and behavioral health during community disasters. Dr. North recapped some of the mental and behavioral health issues discussed during the March 2015 BSC meeting. The goal of mental health response following a community disaster is to bring the necessary interventions and services to the community. To determine exactly what the needs are, a framework with three major parts can be used: case identification, choosing the proper intervention, and lastly actually delivering the intervention and the services. Another important objective of community assessment is determining how many resources will be needed as well as developing and testing plans to deliver them. Mental health should also be included in the emergency response efforts from beginning to end and sometimes past the event.

Mental health consequences of disasters are very prevalent and sometimes more common than physical injuries. Therefore, some of the key concepts to remember are that mental health is crosscutting, but the coverage can be spotty. There can be role issues when determining what the exact role of public health at the local level is and in addressing mental health issues during and after a response. There's a lack of integration and coordination between mental health and public health. Mental health is often organizationally separated. Coordination, although better at the state level, is very fragmented at the community level. APRH has made progress in improving the presence of mental health at the federal level but more work is needed.

The BSC was asked to address the following questions:

1. Based on the problem and possible public health roles and actions, what should OPHPR be doing to address mental and behavioral health issues associated with disasters and public health emergencies?

2. What role should state and local public health departments play to assure that mental/behavioral health issues in the community are addressed during emergency response and recovery?

3. How should the public health sector interact with the healthcare sector to assure that mental/behavioral health issues in the community are addressed during emergency response and recovery?

4. Are there public health research questions associated with this issue – if so, what are they?

Board recommendations:

- Even though localities vary in their needs, there are some standard practices that should be shared broadly to address this area.

- The level of resources available to address mental/behavioral health and service coordination are all over the map. There is a limit to how much the federal level can do to change that.

- Colorado has had many lessons learned when it comes to mass shootings. One of the lessons learned is that we did not have good partnerships with victim's assistance programs managed by law enforcement. So, we have come up with disciplines for our ESF-8 plan and attempted to clarify the roles of law enforcement versus those of community behavioral health partners, for example. We are looking at ways to sustain our model at the local level.

- SAMHSA funds available to help. There is a real opportunity to do good studies after mass shootings and the range of behavioral health response. It's different state-to-state. That might make a difference in people's thinking.

- The communities I work with may get some help but as soon as the recovery begins, post disaster, the resources are no longer available and this really effects those who are at a low economic level.

- Stress can impact the comprehension of risk messages. So we need to consider the role mental health services could play in stress reduction or improved risk communication.

- Most people get their mental services from shelters. Organizations and staff that support shelters are not often included in PHPR efforts. I would recommend talking to states that do a good job incorporating those entities.

Preparedness Updates from Liaison Representatives

Association of Public Health Laboratories (APHL)

- The lack of commercial companies that will ship select agents has affected laboratories. There is one company that will ship the agents, but unfortunately they don't have coverage for all the necessary geographic areas. This is becoming costly and alternatives are being sought out.
- APHL stood up a biosafety and biosecurity committee in light of the laboratory events that have occurred. The goal is to strengthen the biosafety and biosecurity programs. One objective is to hire safety officers that have expertise in assisting clinical laboratories and providing tools. This committee has been working with CDC's Epidemiology and Laboratory Capacity (ELC) Program.

Association of State & Territorial Health Officials (ASTHO)

- Paul Jarris is leaving ASTHO to work for the March of Dimes. Recently, he's had the opportunity to talk about his time with ASTHO and indicated that preparedness will continue to be a priority for ASTHO. It was rewarding to hear this and it shows that ASTHO will continue to treat preparedness as a priority even with its successor.

- Last week was the annual ASTHO meeting and the policy committees convened. They laid out their priorities for the year in those meetings and ways to improve work plans. Some of the priorities include having a response funds, developing a PHPR business case, and creating a "doctrine" like a MOU for state and local coordination around major disaster and incident response. When the report is finalized, it will be shared with the BSC for comments.

Council of State & Territorial Epidemiologists (CSTE)

- CSTE was funded for Disaster Epi, via NCEH ($50-60,000 per year), and is working on Mental Health and Recovery. Conducted a workshop on indicator development and how to do surveys. A "Disaster Epi Portfolio" is on the CSTE website.

- In the last 3 years, OPHPR has funded (~$100,000 per year) with CSTE embedded in EOC, often on conference calls. This was very effective for Ebola response, and improving communications with State and Local PH with the result of better coordination with CDC and non-profit organizations.

National Association of County & City Health Officials (NACCHO)

- Some of the priorities for next year include developing evidence-based metrics for PHPR, ongoing promotion of all-hazards preparedness, strengthening workforce development for responses, and strengthening community resiliency. The desire is to increase the preparedness and response capacity, expand project Public Health Ready, support information exchange, and create greater awareness of preparedness planning, and the mitigation response, and recovery resource needs for large urban jurisdictions.

- NACCHO is also examining best PHPR practices that can be shared among jurisdictions with an emphasis on issues unique to rural and frontier counties.

- NACCHO is supporting CDC in some of the Ebola efforts. This includes co-hosting with ASTHO an in-progress review of the public health system's domestic Ebola response.

- Looking to building capacity in the Medical Reserve Corps network for volunteer management and improving collaboration between ASPR and local health departments to foster national health security.

- Ensure continued integration of public health, emergency management, and other disciplines to make sure good systems are in place, as well as enhancing risk communications capacity.

- Reviewing best practices for medical countermeasures response.

Tribal Epidemiological Centers (TEC)

- TECs assist tribal communities to improve public health capacity to collect and use data for decision-making, as well as work on policy systems and environmental changes within tribal communities.
-
- TECs assist with community assessments and helps with acquiring accreditation.

- Current TECs serve 34 tribes and 4 urban Indian health programs,

- TECs are working is to improve data quality for population health monitoring and improve visibility of community health data.

- TECs are also working on several funding and partnership issues. The states often use tribal community data to validate and justify funding, but rarely does funding get down to the levels of the tribes. Direct funding of tribes seems to be a way of overcoming this challenge and is an area being explored.

- CDC was asked by the tribes to channel issues for tribal consideration to CDC's Tribal Advisory Committee, a formal consultation body coordinated by OSTLTS.

- The California TEC was just funded by the Robert Wood Johnson Foundation to conduct a two-year project to understand how tribes are approaching cross-jurisdictional concerns and this is related to preparedness.

Public Comment Period / Day's Recap / Adjourn (Day 1)

Thomas Inglesby, MD; Chair, OPHPR BSC

No public comments.

After housekeeping notes were given, Day 1 of the meeting was adjourned.

Adjourn

Thursday, October 8, 2015

Welcome & Call to Order/ Roll Call & Review of FACA Conflict of Interest (Day 2)
Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby called the meeting to order at 8:50 AM.

Roll Call & Review of FACA Conflict of Interest
Samuel Groseclose, DVM, MPH; ADS, OPHPR and DFO, OPHPR BSC

Dr. Groseclose performed the roll call and quorum was present.

Day 2 began with a follow-up conversation that began at the March 2015 BSC meeting regarding the measurement of the impact of PHPR program investments at the federal and STLT levels.

Strategic Priorities and Planning, Outcomes, and Impact Measures

PHPR Strategic Planning
Bob Ruiz, MPA; Deputy Director, OPHPR

Originally, OPHPR strategic planning was to begin in 2014, but the Ebola response delayed the process until early February 2015. The strategic planning session in February lasted a day and half. The leadership gathered to determine ways to move forward in the planning.

The Director's three priorities were articulated: respond quickly and effectively to global public health emergencies; maximize our preparedness for impact and results through our investments; and continuously improve our efficiency and effectiveness with internal and external partners. Seven action plans were developed that aligned with the Director's critical priorities, and the IMPACT Project was initiated. The last part of the planning was to ensure progress toward the objectives. To accomplish this goal, monthly tracking is conducted plus a check-in with facilitators.

There are seven action plans are as follows:

- A2: Develop portfolio of resources for timely responses
- A3: Create comprehensive communication strategy
- A4: Revise AAR process
- B1: Increase preparedness systems uptake
- B2: Develop capable workforce at state and local level
- B3: Improve state incident & information management*
- C3: Create comprehensive partner strategy

A dashboard was developed to track the action plan. It is housed on a SharePoint site available to leadership and all of OPHPR.

Looking ahead, OPHPR is tying all of this work together: the Director's Priorities, action plans, and the IMPACT project. It will continue to monitor progress and remove obstacles to achieving outcomes.

The office will also survey the landscape to focus in on 2-3 priority activities in the policy and partnership arenas.

Impact Measurement in Preparedness and Response

Angela Schwartz, MBA; OPHPR Strategy and Innovation Officer

Dr. Redd asked OPHPR to focus on three areas for the OPHPR impact measurement initiative: activities that yield some quick impact results, quick results that address one or more the priorities outlined, and identification of long-term indicators that can be measured across the OPHPR programs and investments. What external and internal stakeholders care about, how to balance those areas that are within OPHPR's span, places where OPHPR's success is dependent upon others, and DSLR's PHEP activities -- all have an influence on impact.

Ms. Schwartz covered the process that OPHPR is undertaking for impact measurement, provided an update on the IMPACT Project's status since the last BSC meeting, demo-ed the dashboard with latest measures, and discussed the latest measures.

In March 2015, OPHPR spoke to the BSC about the declining funding environment, which necessitated OPHPR to be positioned to demonstrate and effectively communicate its progress and impact on health security. It was determined that performance measures and other accountability methods are not capturing the scope of OPHPR's impact and value to public health preparedness nor demonstrating meaningful evidence of progress towards outcomes. There is a need for a coordinated roadmap for leveraging OPHPR performance information that aligned partnerships, research, investment decisions, and communications, as well as a need for integration of outcomes. Reflecting on ongoing strategic planning and evaluation efforts was also beneficial. The BSC provided feedback on outcomes, measured direction, visualization, etc., and OPHPR did its thinking around the BSC's feedback.

The next steps for the IMPACT Project are as follows:

- Incorporate Steering Committee feedback (from 9/25/15 discussion)
- Finalize Division outcomes and measures and data sources
- Finalize internal version of IMPACT indicator dashboard
- Transition operational management of Project to OPPE
- Consider additional work beginning in November 2015:
  - External version of dashboard with communications strategy
  - Stories for the measures to tangibly demonstrate impact
  - Gaps analysis, etc.

PHEP Review and Impact Project

Chris Kosmos, RN, BSN, MS; Director, Division of State and Local Readiness, OPHPR

Ms. Kosmos' portion of the presentation covered PHEP program background and context, the PHEP Impact Project, and the Pre-9/11 to Post-9/11 view of PHEP Program impact, which uses a retrospective approach to inform future direction.

The PHEP Cooperative Agreement supports all-hazards preparedness nationwide. It is formula-based (noncompetitive), providing more than $10 billion as of fiscal year 2015, with $612 million awarded for fiscal year 2015 funding. There are 62 awardees, which are comprised of 50 states, four localities, and eight U.S, territories and freely associated states.

Measuring impact has been a challenge, but DSLR has developed some key indicators that quantify and effectively communicate PHEP impact, specifically development and sustainment of state and local public health emergency response systems activated during a response. The IMPACT project will accomplish the following:

- Refine analysis of awardee data on preparedness improvements;
- Develop state-specific success stories;
- Use modeling to quantify health impact of improvements;
- Develop communication products; and
- Inform future evaluation strategy

Before the OPHPR Impact strategy began, OPHPR convened a stakeholder meeting to obtain input on CDC's strategy for describing and measuring PHEP impact. There was participation from ASTHO Directors of Public Health Preparedness (DPHP) Executive Committee and a small number of other PHEP directors as well as participation from partners, including NACCHO, TFAH, and APHL. The task was to come up with a sort of unified elevator speech that was consistent across all the agencies for describing impact.

Post-9/11, OPHPR, via the PHEP Program, developed public health emergency management systems in all 50 states, created response-ready state and local health departments, and developed a cadre of credible experts in public health emergency preparedness and response at state and local levels.

Another impact of the PHEP was to protect the health and safety of a community. For this, OPHPR developed a national capability to rapidly distribute and dispense lifesaving medical countermeasures to the public. It was also instrumental in developing national laboratory (LRN-B, LRN-C) and epidemiologic /surveillance systems.

Figure 12 illustrates the percentage of public health emergency response systems funded by the PHEP Cooperative Agreement. It illustrates that when PHEP funding goes down, the public health capabilities to respond to emergencies are negatively impacted. Some jurisdictions' PHPR activities are funded 100% by the PHEP Cooperative Agreement.

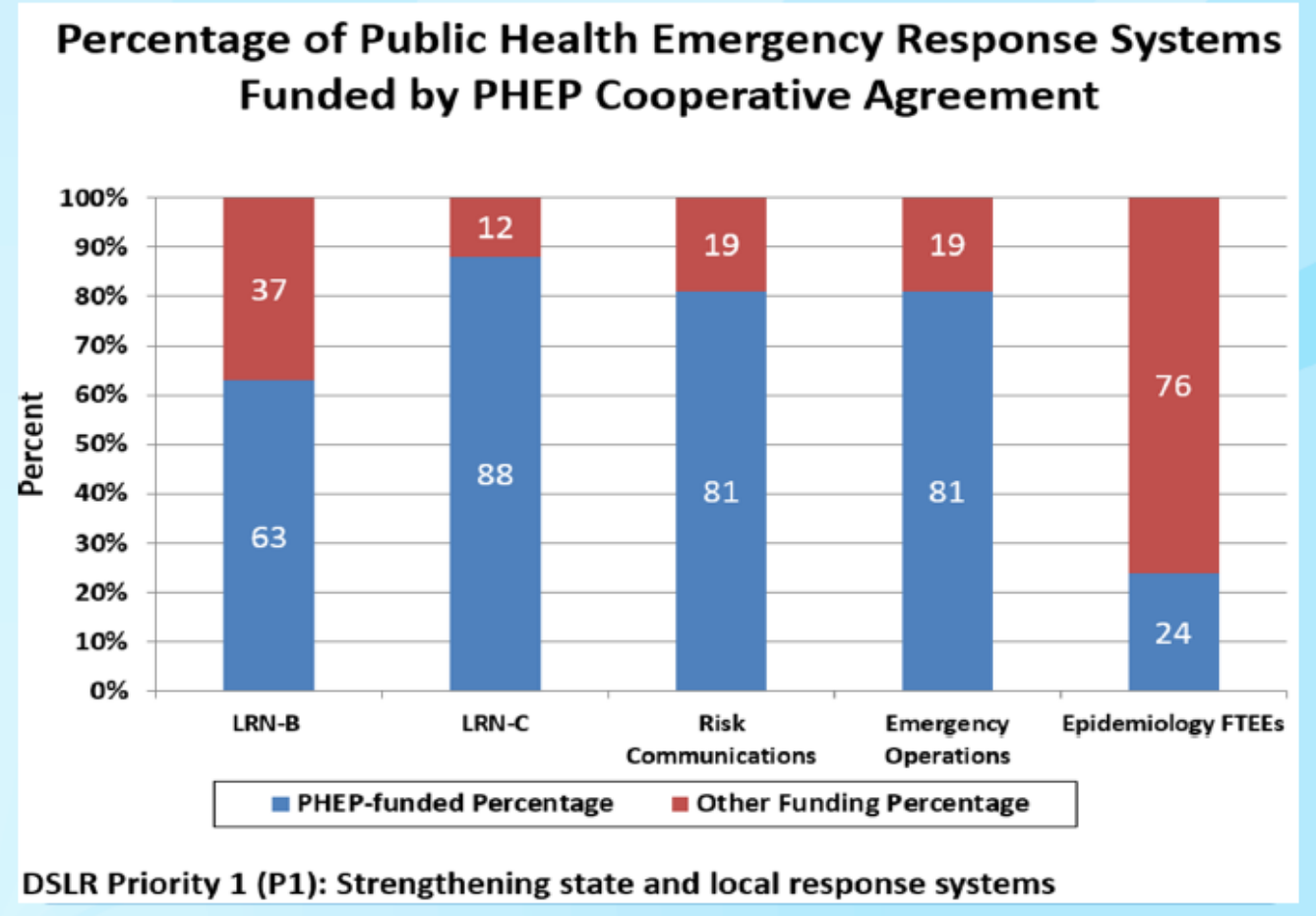


Figure 12.

Measuring and evaluating the awardees' benchmarks as indicated by program indicators and examining gap assessments did not prove to tell a compelling story. After some thinking, we determined that the impact of the PHEP Program and federal PHPR funding could be better illustrated by clearly describing the public health system capabilities prior to the $10 billion PHEP investment (as a baseline). Incorporating baseline data from where preparedness started pre-9/11 and comparing it to current benchmarks would illustrate how far preparedness had come and justify the importance of ensuring that sufficient funding is made available to continue to make improvements.

Figures 13 and 14 provide some snapshots of progress made comparing pre-9/11 to 2012.

PHEP: National Snapshot of Progress Before 9/11 to Present (2012)

Public Health Preparedness Capability	Before 9/11	Current Status (2012)
Emergency Operations: ICS structure with preassigned roles in place	5%	100%
Emergency Operations: Ability to notify and mobilize staff/ emergency communications systems in place	20%	98%
Emergency Operations: Operational response plans complete	22%	95%
Epi/Lab: Platform to share electronic laboratory reporting	22%	95%

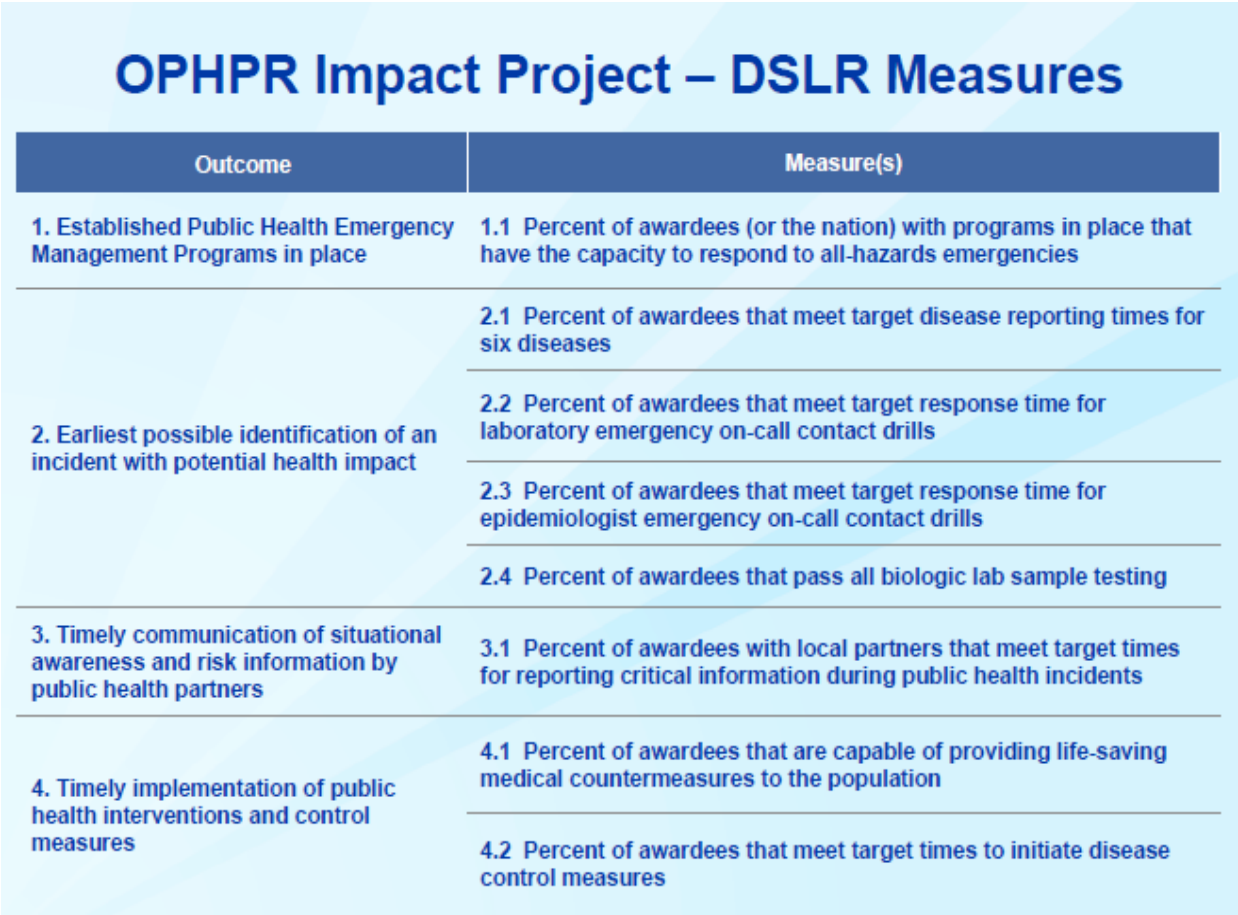
Figure 13

PHEP: National Snapshot of Progress Before 9/11 to Present (2012)

Public Health Preparedness Capability	Before 9/11	Current Status (2012)
Medical Countermeasures: Sufficient storage/distribution capability	0%	98%
Medical Countermeasures: Inventory management system	2%	92%
Medical Countermeasures: Pre-identified points of dispensing sites	2%	100%
Medical Countermeasure: Plans developed	2%	100%

Figure 14.

Figure 15 provides examples of DSLR outcomes and measures.



OPHPR Impact Project – DSLR Measures

Outcome	Measure(s)
1. Established Public Health Emergency Management Programs in place	1.1 Percent of awardees (or the nation) with programs in place that have the capacity to respond to all-hazards emergencies
2. Earliest possible identification of an incident with potential health impact	2.1 Percent of awardees that meet target disease reporting times for six diseases
	2.2 Percent of awardees that meet target response time for laboratory emergency on-call contact drills
	2.3 Percent of awardees that meet target response time for epidemiologist emergency on-call contact drills
	2.4 Percent of awardees that pass all biologic lab sample testing
3. Timely communication of situational awareness and risk information by public health partners	3.1 Percent of awardees with local partners that meet target times for reporting critical information during public health incidents
4. Timely implementation of public health interventions and control measures	4.1 Percent of awardees that are capable of providing life-saving medical countermeasures to the population
	4.2 Percent of awardees that meet target times to initiate disease control measures

Figure 15.

BSC Recommendations:

- You are spot on and when you match your indicators with stories; it's very power when talking to congressional leaders. The numbers will help but to have true impact tied to the stories is compelling.

- Consider monitoring the same metrics with a tribal focus.

- What comes mind is the greater frequency of these reemerging diseases and other threats that are on the horizon that we have not made much progress on. It's critical to tie these measures very close to the MCM Operational Readiness tool to ensure the jurisdictions have operational capacity.

Ms. Schwartz demonstrated the IMPACT project dashboard through a series of screenshots. Each of the four Divisions will be included on the dashboard selections. Using DSNS as an example, the screenshot below was shared (Figure 16).

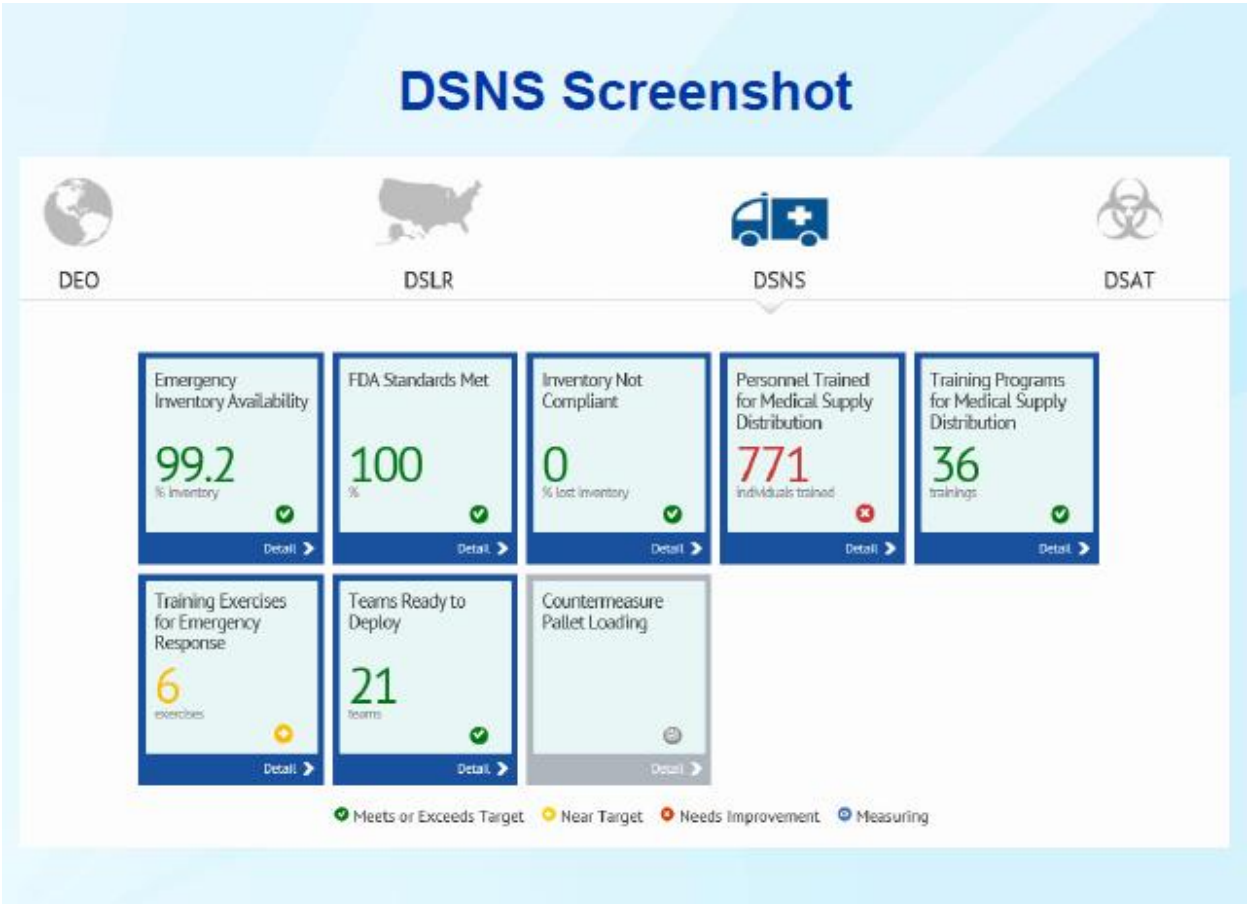


Figure 16.

The squares on the dashboard are called “tiles” and each Division has between 8 to 10 tiles available. Only a few words can be used to describe each of the tiles, but the desire is for the wording to be so enticing that the user feels compelled to click it for more information. This will cause the dashboard to open a plethora of in-depth details, videos, and stories regarding the subject of the tile. The colors of the metrics indicate how the Division is progressing for the metric. Green implies exceeding targets. Yellow is “meeting expectations”, and red is “needs improvement”. Tiles in grey mean either discussions regarding the metric are ongoing or the Division is awaiting more data.

Recommendations from the discussion:

- Development of the measures will present a challenge to DSLR and OPHPR. The taxpayers may start to ask questions about the amount of money spent on preparedness and the progress seen thus far, but I applaud the effort and encourage you to move forward in your work.

- Exercises of PHPR capabilities that are going to be most critical for DSNS are those that work through the entire MCM distribution process. They are most critical and will allow the program

to measure, not just its capability, but the effectiveness of the enterprise capability and how it translates to operational readiness at the state and local level.

- How well are DSNS and DSLR able to help jurisdictions understand the concept of an MCM push package? Jurisdictions that have a lot of staff turnover have individuals who have not dealt with a push package. In Chicago, a recent exercise mobilized a push package for training purposes to exercise "real-world" conditions.

- It would be useful to know the difference between what you require for the country in the SNS and what is available in the SNS. If the number is always the same then it's not a useful tile, but otherwise it would be useful to add.

- A possible tile is how quickly the DEO was able to deploy a requested individual for response.

- Another potential measure is, what percentage of CDC's experts requested were able to be activated within a given period of time?

- There is no good system for reporting lab occupational exposures. HHS is working within the federal government but outside the federal government is a different matter. I don't think the systems are in place outside the federal government. Discussions are occurring but efforts are ad hoc at present.

- It would be useful to know how many registered labs DSAT has "touched" in a specified period of time?

- If there is any kind of risk stratification process for lab activities, knowing the number of labs doing higher risk work and the number of inspections conducted for those entities would be useful.

- Regarding biosafety, consider a tile for no-fault reporting or near misses, which would encourage reporting and provide descriptions of real-world incidents that all could learn from. Non-punitive reporting has to be encouraged because it is another opportunity for learning.

- The biggest challenge is scale and speed to scale. Ebola and H1N1 had some great lessons learned and information there, but if the two events happened simultaneously, is OPHPR or CDC able to scale-up to meet the response needs? How quickly is OPHPR/CDC able to scale-up? Does it meet the need?

- Align Division measures as closely as possible with what is going to happen or what should happen with the partners and stakeholders. In addition, your experience can inform the efforts that are incident-specific and lead to a more standardized template.

- I heard the term "new normal" several times yesterday. Telling a compelling story of PHPR impact may require a deeper look at what is really going on during responses across the

"system", so we don't miss the elephant in the room in terms of mounting effective responses to international and domestic incidents that keep recurring as "normal" is changing front of us.

- Concerning communication, clarify what you want to do with the dashboard. Find areas to make more improvements and refinements. Indicators may improve and others may need to be added going forward.

- How are you communicating with the staff to get everyone's buy-in?

- Be sensitive to how much of this is in your control. Some indicators are not up to targets not because of your work, but as a result of the input of other partners. Try to parse out how much of the metric is dependent upon OPHPR's work and, and, for that area of responsibility, how did OPHPR do in your efforts?

- There is value in considering, "How to do less "better"?" How to simplify? How do you prioritize what less is and focus the resources you have to do that?

- If and when funding is cut, what do we do? Do we let percentages fall? Decide what capabilities and capacities are most important to maintain. It will be key to prioritize in that situation.

CDC's Intramural Preparedness and Response Portfolio

Joanne Andreadis, PhD; Laboratory Preparedness Activity, OPHPR

Dr. Andreadis provided the BSC with information on the Intramural Preparedness and Response Portfolio, highlighting the goal of portfolio management, its challenges, and how the intramural portfolio is being used to improve federal, state, and local responses to events. The portfolio focuses on core public health competencies: surveillance, epidemiology, medical countermeasures, and laboratory capabilities. OPHPR's management and oversight of the portfolio is intended to strengthen core programs, address gaps, and create new capabilities.

Public health preparedness and response is the capability of the public health system, communities, and individuals to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those in which scale, timing, or unpredictability threatens to overwhelm routine capabilities. OPHPR helps the nation prepare for and respond to urgent public health threats by providing strategic direction, coordination, and support for all of CDC's preparedness and emergency response activities. CDC establishes strategy and policies to support federal, state, and local preparedness. With regard to funding, it provides strategic management and oversight of preparedness and emergency response funding appropriated each year by Congress (~ $1.2 billion annually) to support CDC and state and local activities. CDC manages key operational and regulatory public health preparedness programs.

Figure 17 illustrates the distribution of preparedness funding for FY 2015 and the major activities supported.

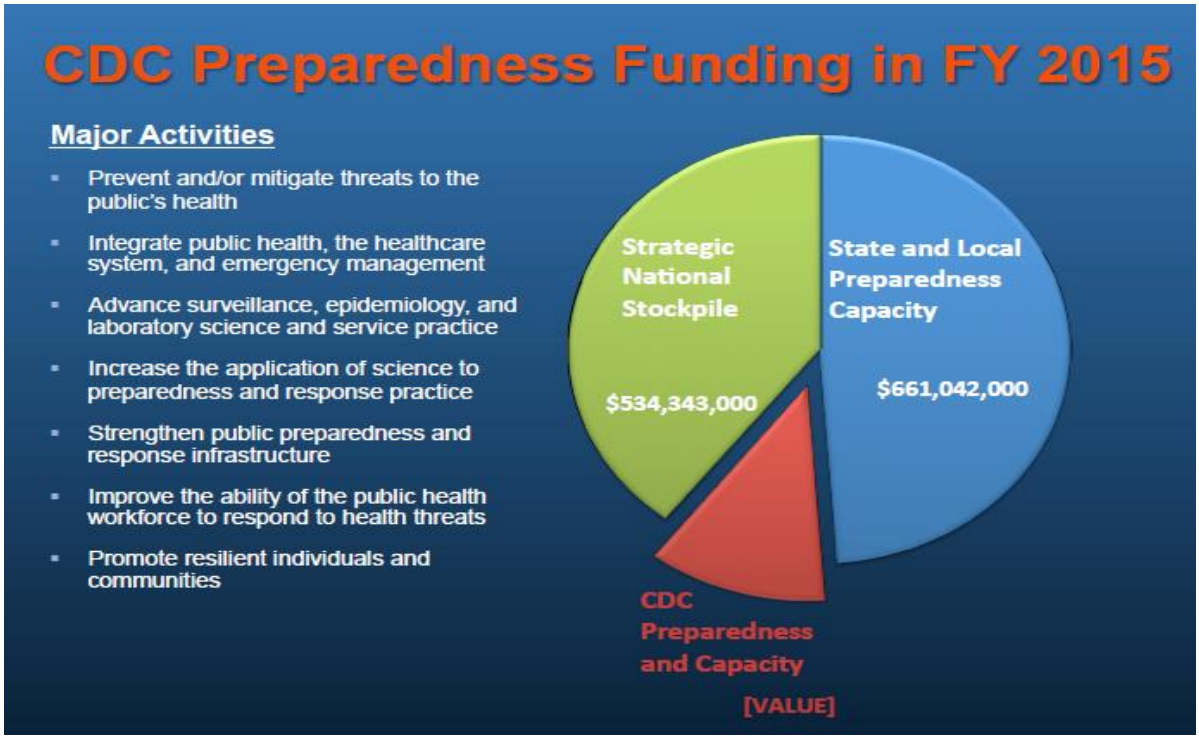


Figure 17.

When trying to determine if preparedness has reached an optimal level, it is important to remember that public health preparedness is dynamic. Threats are always present and continue to evolve. Another idea to consider are the small responses that occur every day and not just the major events.

In thinking forward, it is important to not forget past events that fundamentally set the course for how the nation prepares for and responds to bioterrorism, such as 9/11 and anthrax. Since 9/11, CDC has changed and evolved in many ways.

Figure 18 provides some examples of how U.S. PHPR has changed post- 9/11.

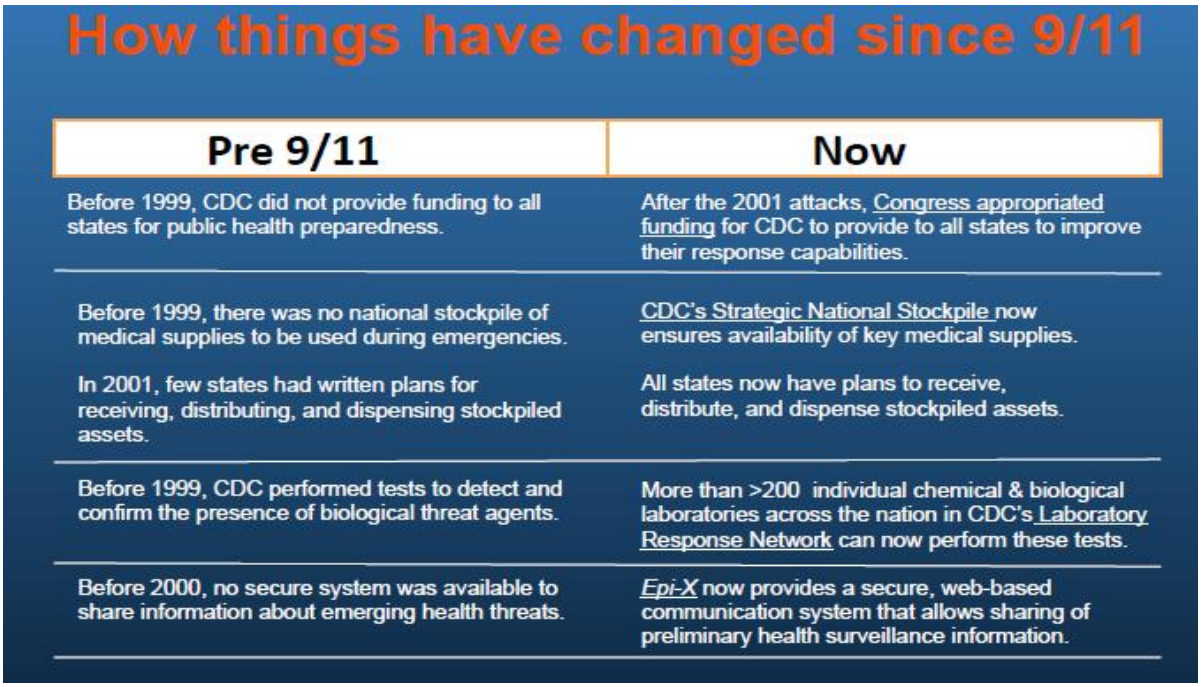


Figure 18.

Globalization increases the speed and scale that diseases spread and effective response requires transparency, scientific collaboration, adaptability, and robust networks. SARS was used as an example. In 2002, SARS emerged as an unknown virus from China's Guangdong province. Approximately, 2-3 months later, SARS was a worldwide epidemic, with 8,096 people being infected and 774 deaths occurring.

The changing environment can create unpredictable crises and alter disease patterns requiring enhanced surveillance, risk identification, and forecasting tools.

Social and political unrest also add to the burden of unanticipated threats. Social and political disruption can stress health infrastructure, creating an environment conducive to disease transmission and unanticipated access to threat agents requiring flexible response capabilities.

The future requires that OPHPR be able to evolve and adapt. It has to be proactive and not reactive. It must expand its toolbox of solutions and the tools must be adjustable and not a one size fits all approach. The office must live and breathe the 3 C's: cooperation, communication, and coordinated action and refrain from creating silos. Lastly, OPHPR must foster an environment of continuous learning, assessment, and improvement.

Concerning OPHPR's intramural portfolio, several questions were asked: Is OPHPR doing the right things? Are our investments making a difference and having impact? Are the products and information generated being used effectively? Are resources being used as efficiently as possible? In attempting to answer the questions, challenges were uncovered. A 2009 BSC report reviewing OPHPR's intramural portfolio process confirmed the challenges. A few of the findings from the report

were “a lack of a plan for how to advance CDC’s epidemiology, lab, surveillance, and medical countermeasures capabilities,” “a need to prioritize between must haves and nice to have projects,” “lack of review of 95% of the intramural portfolio,” and “a need for a more systematic process gap identification.”

In the last year and a half, our efforts to improve intramural portfolio management and oversight included collaborative (participation of SMEs from across CDC) development of a common agenda for surveillance, epidemiology, MCM, and laboratory preparedness and response activities to 1) set agency priorities, 2) inform investments, and 3) measure progress toward achieving goals. A more systematic approach for gap identification was also implemented. Portfolio oversight identified some approaches to increase the flexibility of preparedness funding to allow for more rapid progress and to enable programs to address new threats and take advantage of new opportunities. The portfolio improvement efforts strengthened partnerships within CDC.

Figure 19 illustrates the logic model we developed. It is a cyclical process that should enable continuous improvement.

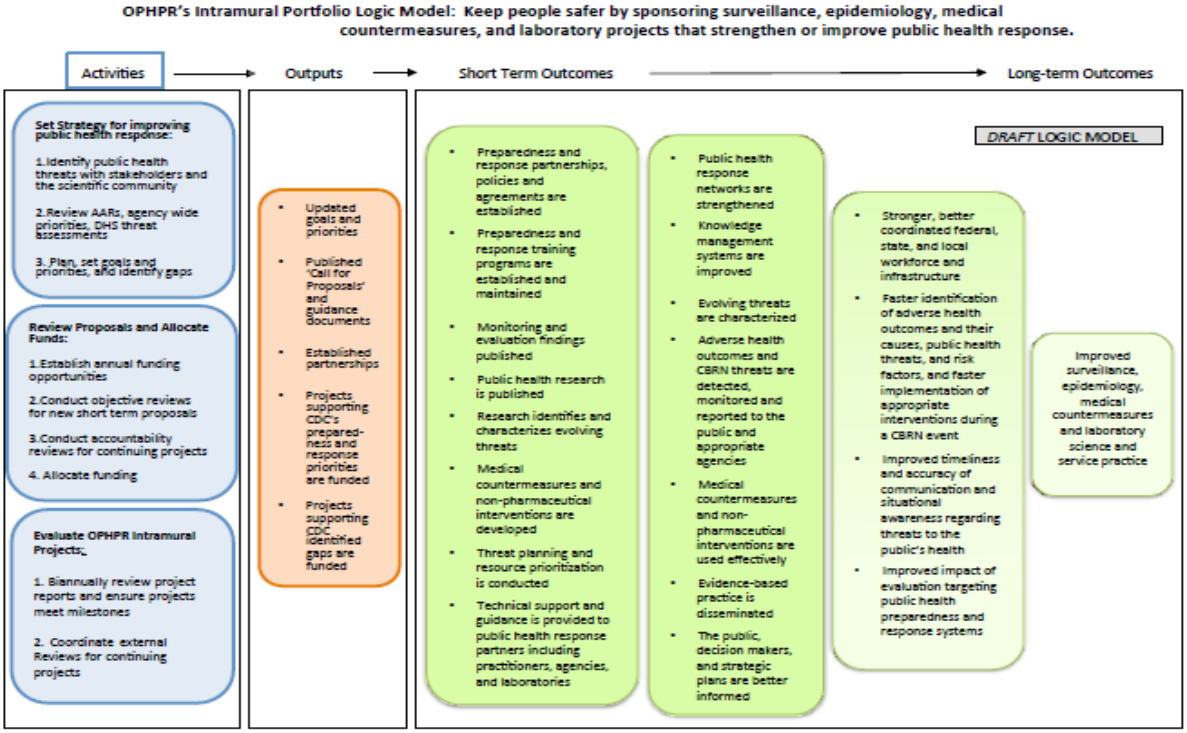


Figure 19.

In collaboration with internal and external partners, four goals were established and priority activities identified as essential to achieving each goal.

1. Preparedness - Prepare and sustain a safe and proficient, federal, state and local workforce and infrastructure to lead and manage a secure, effective, timely and coordinated public health response to priority health threats.

2. Response Timeliness - Improve timeliness in identifying causes, determining risk factors, and informing implementation of appropriate interventions for those affected by threats to the public's health.
3. Response Situational Awareness & Communication - Improve the timeliness and accuracy and effectiveness of situational awareness and communications regarding threats to the public's health and at-risk populations.
4. Response Evaluation - Improve the impact of our evaluations in support of continual improvement and resilient public health preparedness and response systems.

The Portfolio Improvement Initiative directly supports one of OPHPR's 2011 strategic plan objectives: to advance surveillance, epidemiology, and laboratory science and service practice.

OPHPR's intramural portfolio invests in innovative people, processes, and products to advance preparedness and response to CBRN threats. We have categorized intramural projects in three categories: Enterprise Systems, Threat-based capabilities, and short-term. Enterprise Systems are enterprise preparedness and response systems (e.g., LRN-B, LRN-C, EOC, BioSense, and the Select Agent Program) that are long-term, high-priority programs not specifically aligned to a threat. The Threat-Based Capabilities projects address threat-specific capabilities, such as public health research, radiological laboratory testing, and core rapid response capacity and include collaborative alignment to risk-based priorities. Lastly, the short-term (one to three years in duration) projects are research and development projects, akin to innovative pilot programs that address high-priority gaps or inefficiencies. These projects should address high priority, short-term efforts; evaluation should occur to determine how, or if, the findings from short-term projects should be disseminated and translated further.

Figures 20 and 21 illustrate some currently-funded intramural projects.


Ongoing Intramural Projects
More.. Better.. Faster…Expansion of USG laboratory methods to identify & characterize nerve agents, toxins, and radiological threats
NCEH
Replacing the Mouse Bioassay… Mass spectrometry (EndoPep MS) method to detect botulism
NCEH, NCEZID, BARDA
Data Integration, Visualization, Sharing…
DCIPHER: Data collation and integration for public health event responses
NCEZID, OPHSS, OPHPR
1 million
100
Pivoting to Address Evolving Threats…
Leveraging the LRN distribution network to improve surveillance & response
NCEZID

Figure 20.

Figure 21.

Next steps: address challenges caused by ever expanding programmatic needs that are coupled with stagnant or declining resources; continue work with federal partners to better leverage expertise and assets where there are common goals; and develop and institute metrics to determine if impact is being made.

BSC Recommendations:

- Strongly encourage you to continue to make a good case that this is money well spent. The new approach to portfolio oversight gives more opportunity for better focus.

- Think about the kind of industries that are similar and determine if there is a mechanism in place that informs what happens next in their planning and strategic process. Is there alignment across the enterprise? Are the objectives and goals achievable and worth looking at? In addition, think about the unintended consequences like finding efficiencies in these systems, but everybody loses on the funding side.

Informal Update on National Health Security Preparedness Index (NHSPI)

Jim Blumenstock, Association of State and Territorial Health Officials

The University of Kentucky and Robert Wood Johnson Foundation released draft three of the NHSPI and is retooling it from its prior version. The proposal describing their examination of the existing NHSPI and their recommendations for modifying the NHSPI is a detailed analysis of each of the indicators found in the earlier NHSPI versions. Three major concerns with the proposed revision were identified. Any recommendations for changes to the third iteration of the NHSPI will be taken into consideration, but the plan is still to release the Index to the public by the end of the calendar year.

The current approach to revision of the NHSPI is a mathematical one. The early NHSPI versions relied on face validity of some of the measures included to indicate level of capability. After reviewing indicators statistically, 86 of the indicators were recommended for exclusion from the NHSPI because they didn't pass the validity test. At this time, no one knows what the third NHSPI will look like or how to understand or explain the changes from year to year in the scores.

The second issue raised during review of the NHSPI is that of data variability. If there was no variability in values for indicators across jurisdictions, does that discount the indicator? There are 11 indicators in the NHSPI that states received high scores on with little variability. The proposal is that those 11 indicators should be removed from the NHSPI. The question is why disqualify those because everyone is getting good scores without taking in consideration the criticality and the importance of the measure.

There is also concern about marginalizing the health security "domain" for which indicators are removed. What does removal of an indicator suggest? If it is not included that could be suggesting that it's not important.

Sustainability is another concern. Just because states are getting a good score this year it doesn't mean there won't be erosion in that domain or capability in future years.

Lastly, there are recommendations to have greater emphasis on state-to-state comparisons. Although appreciated for their importance and value, with comparisons, the devil is always in the details. How good are the data? How well is the NHSPI objectively and completely presented to paint a proper picture? Previously, a conscious decision was made to not provide any data visualization that would be interpreted as a state report card or scorecard.

BSC Recommendations:

- In the sub-domains and domains, if there's a divergence in the measures and outliers are excluded, I'm not sure that it's a valid method to determine what should be excluded. I think it's worth examining further.

- Within the sub-domain, I don't think it's expected that the individual indicators go up and down together. The mathematical approach to indicator review did not consider that issue.

- Another threat is the index losing credibility in the practice community and the threat of it being seen as a burden versus a help to the community.

- Some individual measures are so critical to a response that you don't want to have any erosion.

Select Agent Incidents 2015: Lessons Learned and Issues to Consider

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

Dr. Weyant updated the BSC on three specific SAT-associated incident investigations that occurred in 2015: Tulane National Primate Research Center, Life Sciences Testing Facility, Dugway Proving Grounds, and Life Sciences Testing Facility. These investigations identified some specific issues that the Division needs help addressing. One is doing a better job of doing assessment of risk and identification of high-risk activities by the Federal Select Agent Program. Another issue is determining what inactivation of select agents really means. In the current regulations, Dr. Weyant couldn't recall the term "inactivation" being used. There is also a significant issue around Federal Select Agent Program transparency. Over the last 10 years or so the select agent database has gone from being an almost "classified" database with limited review and information release to the current situation in which stakeholders, lawmakers, and senior officials are now requesting more information about the database and institutions' work with select agents at the state and local level.

In the Tulane National Primate Research Center incident, DSAT investigated the infection of two non-human primates (NHP) in entity's breeding colony with a strain of a Tier 1 select agent used in the entity's registered select agent laboratory. The investigation was initiated in mid-December of 2014. The facility houses a breeding colony of roughly 4,000 animals in open cages. The sick animals were not quarantined in a sealed laboratory environment. This institution is located on what used to be a rice plantation, so the soil conditions are very similar to the tropical soils in which *B. pseudomallei* is found naturally. Isolates from the animals were the same as isolates found in the laboratory.

A Federal Select Agent Program (FSAP) Joint Inspection was conducted from January 21 – 23, 2015 and again February 5 – 13, 2015 and DSAT was plugged into a unified command structure. Below are the findings from the investigation.

- Failure in planning and response to accidental infection of an animal with a Tier 1 select agent;
- Failure to sufficiently contain the Tier 1 select agent from initial and subsequent release into the breeding colony population;
- Failure to execute an effective occupational health plan; and
- Failure to implement the security plan by allowing personnel to share their unique means of access into secure areas where select agents were used or stored.

The potential root cause of primate infection was failure to implement a biosafety plan with regard to the proper donning and doffing of Personal Protective Equipment (PPE). The animal care staff who worked in a registered select agent laboratory also cared for animals in the breeding colony and/or veterinary clinic, where NHPs became infected. Interviews of workers and review of video camera footage indicated widespread non-compliance with prescribed donning and doffing procedures.

To resolve the matter, all select agent work was suspended at this facility on February 11, 2015. An investigation report was issued on March 4, 2015, and a verification inspection was scheduled for the week of October 5, 2015.

The incident at the Life Science Test Facility, Dugway Proving Grounds involved investigating the finding that an inactivated select agent produced viable colonies when cultivated. The early findings showed that Entity (i.e., regulated laboratory) #1 was responsible for inactivating the select agent, and Entity #2 received the select agent from entity #1. In addition, Entity #3, a registered laboratory who cultivated the material notified the EOC the evening of May 22, 2015 and DSAT was notified the same evening.

Several questions surfaced. Was the select agent not adequately inactivated by Entity #1? Did Entity #2 work with the material or distribute to any other sources? Could Entity #3 have cross-contaminated the inactivated material?

In response DSAT teams were deployed on Memorial Day, May 25, 2015. Team #1 was tasked to investigate Entity #1 and Team #2 investigated Entities #2 and 3, which were in the same geographic location.

The investigation of Entity #1 uncovered that the select agent, *Bacillus anthracis* spore suspension, was inadequately inactivated prior to shipment to other entities, which were registered and non-registered. The root causes of the this error were a failure to account for variable amounts of spores treated by irradiation in the Standard Operating Procedure and failure to validate the method used for inactivation of the *Bacillus anthracis* spore suspension using standardized control spore samples at varying concentrations.

The actions taken to correct the problem were as follows:

- Immediate suspension of all shipments of inactivated *Bacillus anthracis* preparations
- All inactivated *B. anthracis* spore suspensions must be treated as select agents
- DSAT begins immediate follow-up of all shipments of inadequately inactivated *Bacillus anthracis* preparations from entity #1
- Report issued 6/5/2015 – entity to provide biweekly updates of progress made toward resolution of departures
- Biweekly updates currently ongoing

The DSAT investigation did not identify any suspected or confirmed cases of anthrax infection in potentially exposed individuals. There are a total of 193 laboratories in all 50 states, plus three territories (Guam, The Virgin Islands and Puerto Rico), plus DC, and eight other countries (Korea, Australia, Canada, Japan, England, Italy, Germany, and Norway) that received live *B. anthracis* samples. The decontamination of laboratories has been completed in Delaware, New Jersey, Utah, Wisconsin, Texas, and Tennessee. In addition, the post-exposure prophylaxis for six domestic civilian laboratory workers was completed in July 2015.

As a consequence of this event, CDC received notification on July 17, 2015 from FedEx that they will be suspending all shipments of Select Agents. FedEx was named in the press as the courier who shipped

the sample to Korea, which caused a political firestorm. This incident may even result in similar couriers deciding to no longer ship select agents.

The third investigation was also at the Life Science Testing Facility, Dugway Proving Grounds. DSAT was notified on August 20, 2015 of positive results for *Bacillus anthracis* from environmental sampling in the Testing Facility. The Federal Select Agent Program Joint Investigation took place from August 27 – 28, 2015. The purpose of the investigation was to determine the root cause(s) of the contamination, if any contamination had occurred outside of the registered rooms or containment boundaries, and if the entity had implemented their Occupational Health Program appropriately.

Major findings from the investigation:

- Failure to develop and implement a biosafety plan commensurate with the risk of the select agent, given its intended use;
- Failure to develop procedures that were reviewed by the entity Institutional Biosafety Committee (IBC), as specified in the entity biosafety plan;
- Failure to ensure that the biosafety and containment procedures were sufficient to contain the select agents;
- Failure to report incidents that constituted a release of a select agent outside of primary containment to the entity's Responsible Official and Federal Select Agent Program;
- Failure to receive prior authorization to transfer select agents; and
- Failure to fully implement the entity's security plan.

It was determined that the root cause was the failure to ensure that the biosafety and containment procedures were sufficient to hold large volumes of *B. anthracis* spore suspensions and lyophilized material manipulated outside of primary containment leading to release of select agents outside of primary containment. Corrective action included suspension of all select agent and toxin work, which took place on August 28, 2015. A draft report of inspection violations is now pending final review.

Dr. Weyant reviewed the impacts of investigations with the BSC and presented several issues for consideration:

- How to better identify higher risk institutions/activities?
  - Better analysis of past inspection data
  - Better analysis of incidents and "near misses"
  - Better risk assessment
  - More rigorous assessment of biosafety plan implementation
- Policy and regulatory requirements for inactivation of select agents
  - Current policy for *B. anthracis*: Inactivated preparations for distribution (not waste) are considered select agents
  - What about the other BSAT?
  - Should this be codified in regulation?
  - Is there a combination of inactivation/non-viability confirmation protocols that would be acceptable for the exclusion of inactivated BSAT from regulation?
- Are the Current Select Agent Regulations and Policies sufficient for the exclusion of select agent strains?

- Test case review by Select Agent and Toxin Intragovernmental Technical Advisory Committee
- Posting of excluded strain description on national select agent website, i.e. lcr- *Y. pestis*.

- Should the Federal Select Agent Program be more transparent?
  - Inspection Reports (individual and collective)
  - Incident Reports (individual and collective)
  - Compliance and Enforcement Actions (individual and collective)

BSC Recommendations:

- Having a proactive communication plan in place would help so you are prepared to communicate effectively.

- The incident manager's ability to work with partners is critical and should continue to be a key piece in your playbook. There are some striking commonalities with environmental management: disinfection, transport, and disposal. Recognize that you can build a script for every potential scenario or threat but those are areas we also need to gain momentum.

- Whenever there's an incident, there are always two cohorts we have to communicate with from a response perspective, the affected jurisdictions and the not-yet-affected jurisdictions. This may require having different scripts to address each of the cohorts.

- Move to more openness, while continuing the same level of commitment to security, because the public has become leery at times of CDC. We don't need to lock down the names of people and institutions.

- Look at the list that we regulate and determine if it's too long and what can we do to sharpen the focus as well as lower the number of institutions that require such close study.

- Is all this research and work on SATs needed? That's not really in the purview of CDC responsibility but it may be that only a subset of this work is really necessary.

Healthcare Preparedness and Public Health Interface during Emergency Response
Harald Pietz; Deputy Director, DSLR, OPHPR
Michael Bell, MD; Deputy Director, DHQP, NCEZID
CAPT Deborah Levy, PhD; Healthcare Preparedness Activity, OPHPR

Mr. Pietz and Drs. Bell and Levy co-presented on issues related to health care and public health interactions during the Ebola response. CDC continues to activity contribute to the Ebola response. The desire is to get to a zero new cases. Several activities have taken place to work towards this goal. One of the most significant was an active monitoring program implemented across the country to identify cases coming into the United States. More than 30,000 travelers have been monitored since 2014. Continuous quality improvements were made and OPHPR, in the process, identified some needs that should be addressed. This led to guidance for a three-tiered hospital system model to safely and effectively provide different levels of Ebola screening and treatment.

Figure 22 illustrates key DSLR activities and accomplishments during the 2014 Ebola Response.

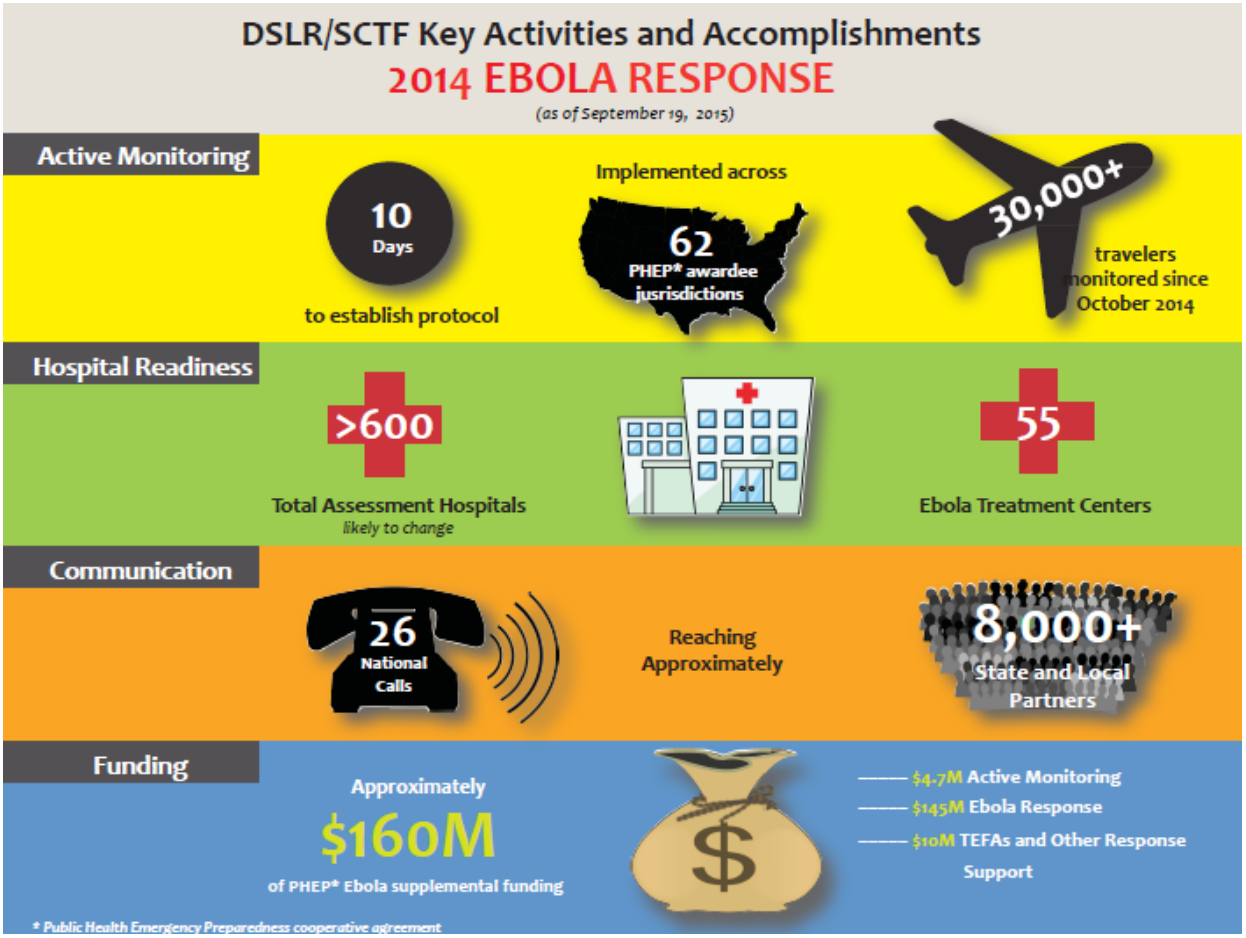


Figure 22.

The objectives of Ebola preparedness in the healthcare arena is to support prompt, safe patient identification; triage and placement; the correct use of PPE to protect personnel and patients; and effective environmental hygiene. It is also to guarantee appropriate supply management for infection control, safe handling, transport and storage of waste, and effective, sustainable training; and assure competence.

OPHPR has worked closely with the state Healthcare-Associated Infection (HAI) programs to help control Ebola infections. This was achieved by strengthening state HAI programs, accelerating state/local HAI prevention activities, providing infection control training, and supporting innovations in infection control.

For state HAI programs, the office targeted facility assessments to identify gaps in infection control and facilitated training and implementation. Another task was to improve coordination between healthcare and public health.

For state and local prevention activities, OPHPR modeled state policies for implementation of infection control and provided technical assistance to state HAI programs, hospitals and other healthcare facilities. The office offered infection control training that was Ebola-specific using a standardized

infection control curricula based on CDC guidelines. OPHPR also looks to revisit risk-assessment in infection control in the future.

There have been innovations in infection control related to research. There are still challenges with infection control equipment. More improvements are being made to increase adherence to usage. There are also some novel interventions to come, which will prevent pathogen transmission in healthcare settings.

To determine the readiness of the Ebola-designated facilities there will be on-site assessments of all designated Ebola assessment hospitals and identification of gaps in preparedness. OPHPR will address gaps through consultation/training using CDC- based resources; develop mitigation plan with facility with follow-up to confirm that gaps are addressed.

CDC technical assistance to the state health departments listed below.

- REP (Rapid Ebola Preparedness) - Oct 2014-Jan 2015
  - Ebola treatment centers
  - 21 states plus D.C.
  - 81 facilities
- Ebola readiness assessment hospital visits
  - 17 states
  - 39 facilities through September 2015
  - About 15 more state visits scheduled Oct-Dec, 2015

The 11 Ebola Assessment Hospital Minimum Capability Domains are:

- Facility Infrastructure
- Waste Management
- Patient Transport
- Worker Safety
- Laboratory Safety and Testing
- Environmental Services
- Staffing
- Clinical Management
- Training
- Operations Coordination
- PPE

Challenges have been observed related to some of the domains such as:

- Infrastructure
  - Care spaces interfere with movement of HCW providing care
  - Lack of adequate PPE doffing space
- Staffing
  - Inadequate # of trained staff available for 96 hours of care
  - Unrealistic shift durations in full PPE
- PPE
  - Supply chain improved, but variability in protocols for use

- Variation in sources, personal preferences, experience
- Inconsistent local expertise to train HCWs

- Training
  - Competency is labor intensive to establish and maintain
  - Perception that training resources and opportunities are limited
- Waste management
  - Highly variable local regulations
  - Hauling and disposal of solid waste
  - Flushing of human waste into sewage systems
  - Solutions exist but can be expensive and/or cumbersome
- Occupational health
  - Optimal monitoring protocols for patient care staff
  - Coordination of monitoring with health department
- Environmental cleaning and disinfection
  - Overuse/misuse (e.g., spraying on personnel) of bleach products
  - Implementation of terminal cleaning protocols
- Clinical management
  - Protocols for special populations (e.g., children)
  - Appropriate use of invasive (high-risk) procedures

Early in the Ebola response, the model utilized for response was similar to our approach to influenza outbreak response because of all of the previous experience garnered from pandemic influenza event. As part of that model, OPHPR collaborated on the development of various checklists with other agencies such as ASPR regarding healthcare facilities and healthcare providers. The office was tasked with providing technical assistance to healthcare providers from non-hospital sectors, like EMS, clinics, pharmacies, home health as well as state and local public health, and hospital entities regarding exercises and drills. CDC teams also provided guidance for active and direct active monitoring.

The office also has aided in the development of the mechanism for Emory and University of Nebraska Medical Center hospitals to assist with the development of training material for the response and supported communications including Clinician Outreach and Communication Activity (COCA) calls and took part in partner webinars.

Efforts were initially focused on the international front, but when the domestic incidents occurred, it was noticed that some alterations to the response model needed to be made to address the domestic outbreak. Various sectors of the healthcare delivery system began requesting information that OPHPR did not have.

Armed with a better understanding of Ebola, the State Coordination Task force collaborated with ASPR to create a hospital-tiered strategy and developed the EMS/9--1--1 guidance in partnership with DOT, DHS, and HHS/ASPR entitled the “Interim Guidance for Emergency Medical Services (EMS) Systems and 9--1--1 Public Safety Answering Points (PSAPs) for Management of Patients with Known or Suspected Ebola Virus Disease in the United States.” Also in partnership with ASPR, DOT, DHS and other key stakeholders, the concept of an Operations Planning Template was developed for the management of persons under investigation (PUI) and Ebola patients, and supporting discussion and exercise guides.

OPHPR is also a member of a White House interagency workgroup, which is developing guidance that can be used by the states for handling Ebola and other Category A infectious wastes. The subgroups of this effort include planning, communications, research, and review of ETC plans. The expectations from the White House is that waste planning should seek local options from cradle to grave.

OPHPR is also supporting several training efforts: HHS/ASPR- and CDC-funded National Ebola Training and Education Center (NETEC) and NIEHS- and CDC-funded Worker Training Program (WTP) for Ebola Biosafety and Infectious Disease Response Training.

OPHPR continues to work with partners to address gaps associated with EMS and patient transport:

- Coordinate State and local EMS planning for PPE
  - May need help procuring appropriate medical equipment rather than relying on HAZMAT gear
  - Should practice donning and doffing with the healthcare facility using their method instead of HAZMAT procedures
- Plan transport to regional or state ETCs
  - Coordinate among state public health, local EMS, hospitals, and law enforcement
  - Long distances could require fuel, a change of provider, and additional stops
- Provide clear direction on where to dispose of or store waste
- Include EMS in all exercises from tabletop to full scale
- Document and practice ambulance terminal cleaning process
- Secure the site selected for locked ambulance until released and cleaned

BSC Recommendations

- Take the lessons learned and tools developed from the Ebola response and build upon them going forward in our next response.

- Recommend having tabletop exercises that include a vast array of responders and stakeholders at different levels of government to work through response scenarios.

- A “kitchen cabinet” should be created, which includes a small set of local and state partners who are readily available and are preassembled. They serve as a reality/pulse check unit that can help with resolution of major policy decisions, and implementation suggestions. This may need to be piloted to create the right balance of engagement.

- Determine what the intersection between public health and public safety is and how we fit them together, locate the gaps, and leverage capacity across the whole of community. There are a lot interesting parallels between H1N1 and the Ebola response, but Ebola went beyond it. It is an example of multiple sectors working across the economy. Perhaps there’s some pre-scripting that can be done since we’ve had these two incidences, which can start to inform what the “new normal” will look like.

- The clinical community seems to respond to clinical leaders so involvement of nursing leaders from professional societies and clinical leaders from the clinical societies may be beneficial.

- State and local health departments can help the clinical community on everything that happens outside of institutional walls. Clinicians are less likely to listen to those outside their institution or profession telling them what to do in their environment.

Public Comment Period (Day 2)

No public comments.

Meeting Recap & Evaluations, Action Items & Future Agenda

RADM Stephen C. Redd, MD, Director, OPHPR

Dr. Redd thanked everyone for coming and providing such rich dialogue and solid recommendations. They will be summarized and at the very minimum OPHPR will report back to the BSC at the next meeting how the advice has been used. A couple of areas that Dr. Redd noted for further discussion were on the global health security agenda implementation and risk communications, which is essential to the work OPHPR does.

Dr. Redd posed several questions for consideration: What should OPHPR be funding within CDC? Where do you draw the boundaries? What is it that OPHPR is trying to get better at? Is it really to be sure that for overwhelming problems CDC is 100% ready? Alternatively, is it much more about the smaller responses, with the expectation that it can put everything together for the big events?

Dr. Redd would also like to schedule a call midway between the next meetings to provide a progress report.

Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby reminded the Board that members have been given an open invitation to provide additional reflections to OPHPR on the issues raised over the past two days. For any additional considerations, the Board was encouraged to contact OPHPR and share their thoughts.

He also thanked the BSC for a great meeting and being so engaging and the CDC staff for its hospitality and for coordinating the meeting.

Samuel Groseclose, DVM, MPH; Associate Director for Science, OPHPR

Dr. Groseclose closed the meeting by thanking the BSC for coming and assisting OPHPR in thinking through its activities. He also thanked the staff and contractors for putting together a productive meeting. Ms. Brown will be in touch regarding the next call and meeting.

With the conclusion of all comments, the meeting was adjourned.

Meeting Adjournment
With no other comments, the meeting was adjourned by the Board Chair.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the October 7-8, 2015 meeting of the OPHPR BSC are accurate and complete.

X

Thomas V. Inglesby, MD
Chair, Board of Scientific Counselors, OPHPR

APPENDIX A: OPHPR BSC MEMBERSHIP ROSTER

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APPENDIX B: BSC MEMBER ATTENDANCE ROSTER

BSC Meeting Attendance Roster
Atlanta, GA – October 7-8, 2015

NAME	AFFILIATION	DAY 1 (OCTOBER 7, 2015)	DAY 2 (OCTOBER 8, 2015)
Inglesby, Thomas	Chair and SGE	In person	In person
Bernheim, Ruth	SGE	Absent	Phone
Brandeau, Margaret	SGE	Absent	Absent
Mitroff, Ian	SGE	In person	Absent
McKinney, Suzet	SGE	In person	In person
North, Carol	SGE	In person	In person
Reed, Richard	SGE	In person	In person
Viswanath, Kasisomayajula	SGE	In person	In person
Phillips, Sally, DHS	Ex Officio	In person	In person
Kaplowitz, Lisa, HHS	Ex Officio	In person	In person
Wireman, Jodi, DoD	Ex Officio	In person	In person
Curran, James (ASPPH)	Liaison	Absent	Absent
Egan, Christina (APHL)	Liaison	Phone	Phone
Hill, Kristin (TEC)	Liaison	In person	In person
Blumenstock, Jim (ASTHO)	Liaison	In person	In person
Askenazi, Michele (NACCHO)	Liaison	In person	In person
Quinlisk, Patricia (CSTE)	Liaison	Phone	Phone

APPENDIX C: ACRONYMS

AAR After Action Report
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
ASPPH Association of Schools and Programs of Public Health
ASPR Assistant Secretary for Preparedness and Response (HHS)
ASTHO Association of State and Territorial Health Officers
BSAT Biological Select Agents and Toxins
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
DOT Department of Transportation
DPHP Directors of Public Health Preparedness
DSAT Division of Select Agents and Toxins (CDC)
DSLR Division of State and Local Readiness (CDC)
DSNS Division of Strategic National Stockpile (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
GAO Government Accountability Office
FRO Financial Resources Office (CDC)
HCW Healthcare Worker
HPA Healthcare Preparedness Activity (CDC)
HPP Hospital Preparedness Program
HHS US Department of Health and Human Services
IHR International Health Regulations
IOM Institute of Medicine
IT Information Technology
LO Learning Office (CDC)
LRN Laboratory Response Network
LRN-B Laboratory Response Network Biological
LRN-C Laboratory Response Network Chemical
MASO Management Analysis and Services Office (CDC)
MCM Medical Countermeasure
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)
OIG Office of the Inspector General
OPHPR Office of Public Health Preparedness and Response (CDC)
OPPE Office of Policy, Planning, and Evaluation (CDC)
ORR Operational Readiness Review
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
PHPR Public Health Preparedness and Response
SGE Special Government Employee
SLTT State, Local, Tribal, and Territorial
TEC Tribal Epidemiological Center
TFAH Trust for America's Health