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
DECEMBER 14-15, 2016
ATLANTA, GEORGIA

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Wednesday, December 14, 2016

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

Dr. Inglesby called the Board of Scientific Counselors (BSC) Meeting to order at 10:04 AM and began with opening remarks. After all the events over the last few years that CDC has taken part in and the incoming of a new presidential administration, Dr. Inglesby felt it will be an interesting time for CDC and the country in regards to the trajectory of preparedness going forward.

He also welcomed two new members to the BSC. Dr. Alonzo Plough, Vice President of Research, Evaluation, Learning and Chief Science Officer for the Robert Wood Johnson Foundation and Dr. Brent Pawlecki, Chief Health Officer for the Goodyear Corporation. Regretfully, Dr. Carol North and Ruth Bernheim will be retiring from the board at the conclusion of the meeting.

Dr. Inglesby concluded his comments by thanking OPHPR leaders and staff for convening and planning the meeting.

Roll Call & Review of FACA Conflict of Interest
Samuel Groseclose, DVM, MPH; Associate Director for Science, OPHPR and Designated Federal Official, OPHPR BSC

Dr. Groseclose conducted roll call and quorum was present. OPHPR leadership, BSC Members, Ex Officio Members, and Liaison Representatives were instructed to introduce themselves and their agencies. 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 was maintained. The meeting was led by Dr. Inglesby, the BSC Chair. Discussions and deliberations were among BSC Members, Ex Officio Members, and Liaison Representatives. Voting is conducted only among the BSC and Ex Officio Members. 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 Updates forms should be completed and returned to Dr. Groseclose prior to the meeting's end. Members were asked to identify any conflicts of interest. Dr. Inglesby's organization has CDC grants related to a Zika communications grant and the Ebola response, which are funded by CDC. He also works as a coinvestigator on an effort that studies community function after disasters, which also is funded by CDC. Vish Viswanath has an ASPPH preparedness grant. Suzet McKinney has a faculty appointment at the Harvard School of Public Health, which has a grant to correlate the Preparedness and Emergency Response Research Centers (PERRC) and Preparedness and Emergency Response Learning Centers (PERLC) project. She makes contributions to that effort.

OPHPR 2016 Priorities

OPHPR Updates from April 2016 BSC Meeting
RADM Stephen C. Redd, MD; Director, OPHPR

Looking back at 2016, the incidents that happened in terms of emergency response could not have been foreseen. In April, events like Zika and Flint, MI were still ongoing. The Ebola virus epidemic was winding down, and polio eradication was somewhat in the background. Every division played a role in the response efforts. The DEO has been continuously activated for two and a half years. DSLR has become an emergency response

program with its State and Local Coordination Taskforce. The SNS played a substantial role by sending federal medical stations to West Africa and ensuring the availability of personal protective medical equipment to hospitals that may see Ebola in the United States. SNS brought to bear contracting expertise to facilitate shipping of Zika Prevention Kits and vector control. The Select Agent Program is doing a lot of work in Zika with imports permits.

Dr. Redd highlighted further accomplishments seen by divisions. The Select Agent Program continues to maintain the record of community transmission or exposure of any registered toxin. Substantial work has been completed to increase transparency in the program. Three reports were released: 90-Day Report, a report on accomplishments, and the annual report. The annual report gave a good description of the program and its purpose. A new director, Dr. Sam Edwin, has also been appointed to DSAT. And lastly, a final rule has been created. This has been a two-year project. The document is being submitted to the Secretary for signage.

The DEO is continuing to improve processes, which will increase efficiency and effectiveness. The DEO is exploring the model used for big activations. It is being used as a hub supporting staff participating remotely in responses. This model is also being explored for global efforts. In Cameroon, response times for activations have been reduced significantly from months to weeks to now hours. A global rapid response team structure is being explored. The goal is to strengthen global emergency management programs and work closely with the Center for Global Health to ensure success.

For DSLR, the Operational Readiness Review (ORR) was conducted for 487 jurisdictions over a two-year period to assess the state and local levels' ability to respond in the case of an emergency, particularly as it relates to the dispersing of medical countermeasures. The information gathered will be used to improve their processes.

OPHPR is in the late stage of development of a new PHEP cooperative agreement funding opportunity. Work is also being conducted that will put a focus on the national surveillance strategy, improvements to the laboratory response efforts, and issues related to environmental health. In the spring, a similar process to the 90-day review was completed with DSLR experts to improve the Public Health Emergency Preparedness (PHEP) program.

For SNS, the shift is to expand beyond buying, storing, and shipping items to looking for more efficient ways to accomplish its work. Also, the division is seeking help from the National Academies of Science, Engineering, and Medicine. A presentation may be given in future meetings to report on the progress made using the feedback received.

Dr. Redd is looking forward to explaining OPHPR's role to the new administration. The presidential transition team has decided to be briefed on certain issues and emergency response was one of those requested. The team was very well informed and asked additional questions. They were given a synopsis of what has and has not been accomplished in emergency preparedness since the Bush Administration.

OPHPR will continue to work on early and effective responses. There are some emergencies that OPHPR will know they have to prepare for but it must also be prepared for threats that may not happen, like bioterrorism. And lastly, with events like Ebola and Zika, the focus in these cases is to be able to respond even if events are not expected. Incident manager training can help with that, as well as translating plans from other planning efforts.

Recommendations/Comments from the BSC:

- Appreciated the document that was put together by OPHPR in response to comments and recommendations given by the BSC. It was very helpful and useful because it allows the Board to see how its comments influence the work.

Interval Updates – OPHPR Division Directors
Chris Kosmos, RN, BSN, MS; Director, Division of State and Local Readiness

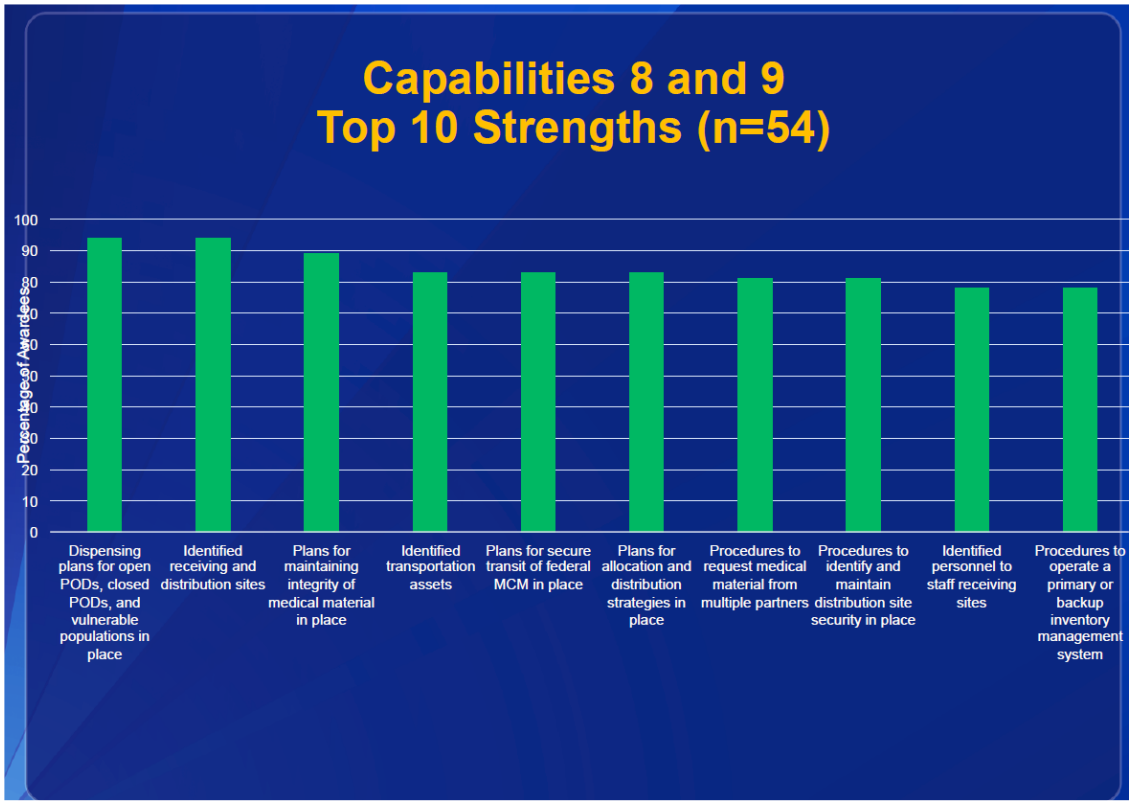
Ms. Kosmos began her presentation reviewing the accomplishments and success stories attained by DSLR in the last six months. It was noticed early in the Zika response that Puerto Rico was experiencing challenges when trying to stand up an emergency operation model. Through a new model for supporting state/territorial staffing needs, DSLR utilized staffing contracts for rapid deployment of DSLR field staff. This was found to be an efficient method because it provided consistent staffing. The division also worked closely with DSNS to find creative solutions for getting Zika Prevention Kits (ZPK) on the ground for distribution. A two-part, needs-based strategy for funding was also employed. This new targeted format allows DSLR to respond based on the needs of the jurisdiction.

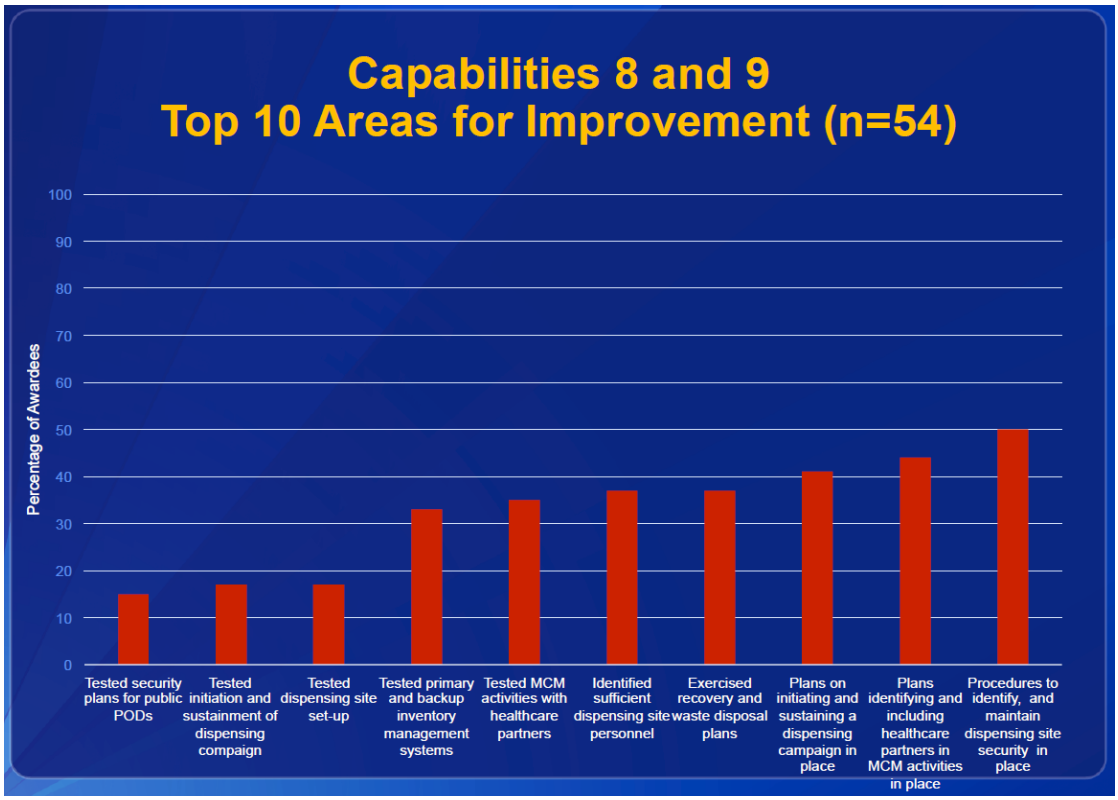
DSLR also worked with CIOs to conduct a PHEP Program Review. The review yielded 17 overarching recommendations for improving the impact of the PHEP program and improving cross-CDC collaboration. A medical countermeasures (MCM) Operational Readiness Review (ORR) was also conducted across all 62 funded jurisdictions. From this review there were many lessons learned.

Another DSLR goal was to build on the work for MCM planning and response. The MCM ORR tool was developed in conjunction with national partner associations and representatives' input from 19 state and local PHEP jurisdictions. The tool will create a standard for state/local/territorial MCM planning and response. It will also improve state/local/territorial operational readiness for a large-scale MCM mission by assessing a jurisdiction's MCM plans for specific content and ability to execute its plans. The tool can also be used to identify operational gaps and develop strategies to address gaps by designing evidence-based technical assistance strategies and addressing policy issues.

Between 2015 and 2016, there were 487 MCM ORRs conducted. Of those, 132 MCM ORRs were conducted by CDC and included 50 states, 4 directly funded localities, 8 territories and freely associated states, and 70 local planning jurisdictions. Another 355 MCM ORRs were conducted by awardees at local planning jurisdictions. Awardee-level data focused on states and 4 directly funded localities focused on PHEP capabilities 8 and 9, which address MCM dispensing and distribution. DSLR will work with states and local jurisdictions to address the identified gaps.

Below are examples of the results obtained from the review. The first figure shows the top 10 strengths for Capabilities 8 and 9, while the second figure addresses the 10 areas for improvement for those same capabilities.





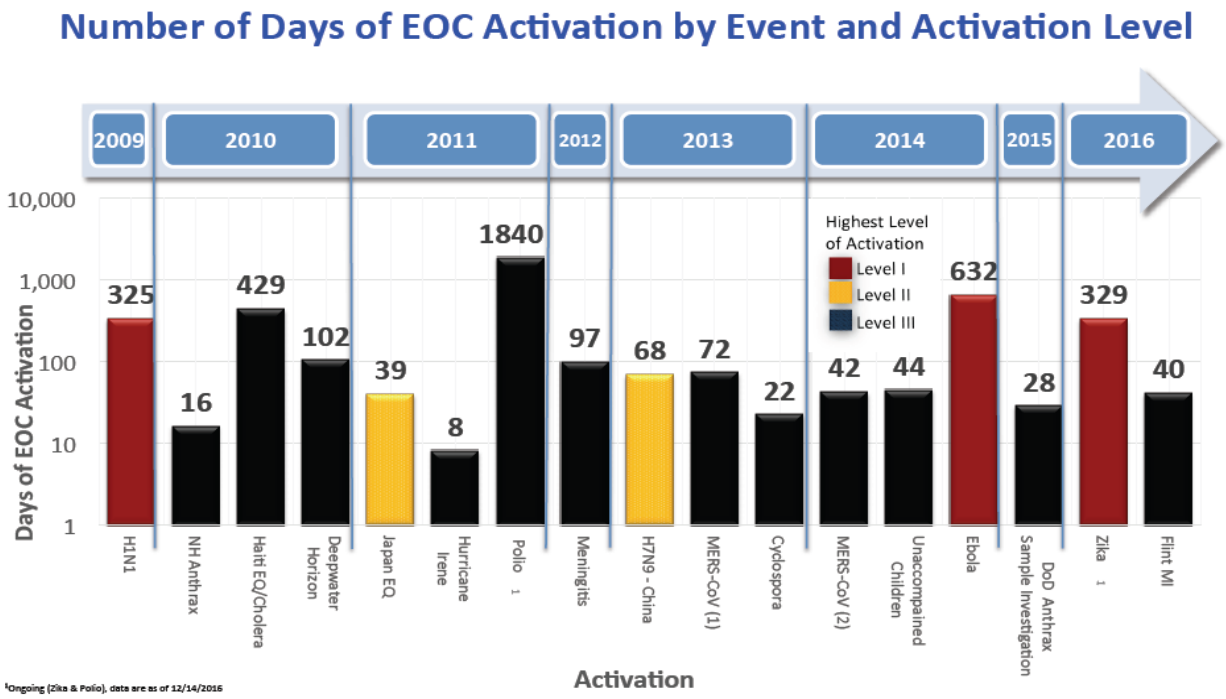
DSLR will use MCM ORR data analysis to inform program improvement and funding decisions. This will be an analysis of the 10 largest cities to determine readiness and gaps in high-risk population centers. DSLR will quantify the staffing gaps (types and numbers) at the state/local level and consider possible federal solutions to staffing shortages. The division will also continue to make progress on developing a "one-stop-shop" guidance for state and local planners for all MCMs within the SNS.

Recommendations/Comments to DSLR:

- In Executive Order 13527, FEMA was charged with developing regional MCM plans to support state and local officials, particularly around large urban cities. The FEMA National Advisory Council examined that work to see if it was useful and highlighted gaps that have yet to be resolved. Along with that, recommendations were made this past summer that will be helpful to DSLR. One of the recommendations was that FEMA regional support plans should undergo the CDC MCM ORR review. The Council also recommended working with the federal executive boards (FEB) around large cities. Recommendations were made to FEMA to do work with the FEBs and lean on some expertise at CDC to help FEBs understand the importance of their collaboration with their state and local counterparts to develop close pods. Regarding staffing and the ability of federal staff to be able to augment state and local resources, there was a recommendation made to FEMA to engage DSLR, ASPR and OPM to look at the feasibility of a policy around engagement of federal staff to assist with the staffing burden that states and locals have highlighted.
- Employers know how to talk to their employees and how to reach them. They have motivation to keep them healthy and well at work. So, find ways of engaging the employers and their worker populations. Employers can help DSLR identify what populations will need during an emergency.

Jeff Bryant, MS, MSS; Director, Division of Emergency Operations (DEO)

Mr. Bryant began his presentation with a chart showing the events for which the EOC has been activated (from 2009 to 2016; see figure below).



Polio Eradication: In Nigeria, there have been 34 cases of polio for the year, which is less than half of what was seen in 2015. So much progress has been made. There are only three countries now affected by polio: Afghanistan, Pakistan, and Nigeria. Recently, surveillance has been able to occur in the Borno States, Nigeria and genetic sequencing showed the strains seen were very close to those seen in 2011 in the same area. Now, CDC has staff in Chad, Cameroon and Nigeria working on a regional basis to conduct aggressive vaccination campaigns.

The following figure illustrates the CDC Zika response by "the numbers".

2,236	Total CDC Staff in response 116,203 person days since activation
1,033	Total Zika CDC Deployments
502	CDC Deployments to Puerto Rico
3	CERT deployed to UT, FL, TX 55 total deployments
147,861	Specimens, 69,803 Trioplex, 90,943 MAC-ELISA, processed by CDC Labs
238	Guidance documents, publications, abstracts, etc. sent through clearance
25,407	CDC Info Zika inquiries answered
199	*Epi-X* Media Tracking reports posted, and 8 HAN messages distributed
6,113	Total posts on social media
> 2.9 B	Total Twitter reach
> 18M	Total Facebook reach
> 75M	Cumulative views on the Zika website
13,500	ZPK's distributed to Puerto Rico
25,168	ZPK's distributed in total
60	Travel Health Notices posted (49 in the Americas)
46	MMWR early releases published
9	Clinical Outreach and Communication Activity (COCA) calls
25	Epidemiological Studies ongoing (12-Puerto Rico, 4-International, 9-CONUS

There has been a lot of success experienced in the global health security efforts for FY16. Data show that the DEO is exceeding its targets in four areas: initial engagement with ministries of health, identifying EOC facilities, training staff, and conducting exercises/responses. Six countries activated their EOCs on their own eleven times for public health events, e.g., infectious disease outbreaks.

CDC also has public health emergency management fellowships for two cohorts. The programs are four months long. They are for senior health officials to learn how to run an emergency management program. Last year's first cohort graduated in early June. Upon finishing training on Friday, one of the graduates was leading a response in Cameroon on the following Tuesday. FY17 is fully funded for global health security activities; therefore, DEO will continue its work in this area over the next 9 months.

DEO is conducting some public health emergency management research:

The first research project, "Persuasive Communication about Risks from and Responses to Zika" is a mixed methods study examining dissemination and uptake of risk communication messages and development of communication strategies for at-risk populations during an emergency response. The data examined comes from health department websites; news media coverage; and knowledge, attitudes, and values regarding Zika from providers, practitioners and the public. The results will be used to inform planning and implementation of emergency risk communication initiatives in future responses.

The second project, "Effective Communication in Public Health Emergencies: Developing Community-Centered Tools for People with Special Health Care Needs" will examine disaster communication needs of three select high-risk populations: children with special healthcare needs, individuals with autism spectrum disorder, and individuals with Amyotrophic Lateral Sclerosis (ALS). The results will be translated into specific communication tools for these and similarly affected populations in the event of a disaster.

The "Incident Management: Recognizing Best Practices for Training and Exercising for Public Health Emergency Management" study intends to identify best practices for training and exercises that promote or enhance public health emergency management workforce competencies. Researchers will examine current literature in multiple fields and disciplines, interview practitioners, and conduct field observations of training and exercises in multiple jurisdictions. The outcomes of this study will be used to improve emergency management training for state and local public health emergency response leaders and practitioners, Incident Management Training and Development Program (IMTDP), and Global Health Security Agenda (GHSA).

Lastly, the "CDC Emergency Risk Communication Outcomes Measures Development and Assessment" project will develop, operationalize, and evaluate measures to assess the quality, effectiveness, and impact of CDC emergency risk communication messages to targeted populations and the general population. The study will examine multiple potential methodologies and data sources for any given response. The end product will be used to recommend strategies to evaluate CDC emergency risk communications during and subsequent to an emergency response.

DEO has finished the final Ebola after action reports. OPHPR has 87 tasks that have come out of that report. Themes of those tasks include the following:

- Response funding and emergency acquisition
- Data collection and information sharing agreements
- Specific training and checklists/protocols
- Staff recruitment and deployment duration
- Response research agenda
- Responder safety, health and recognition

Seven workgroups will be convened in 2017 to work through the themes identified to make a stronger nucleus for emergency response.

Recommendations/Comments to DEO:

- Make a distinction between precluded (i.e., prevented) and avoided events. Precluded events are those that cannot be allowed to happen, like a nuclear plant meltdown. Avoided events have a probability of occurring and funding should be available to respond as best you can. A lot of the responses, like Zika, are precluded but they have to be treated as if they were avoided events. It would be interesting to see historically what stakeholders determined to be precluded versus avoided events and document the different strategies used for those events, both for prevention and response. Precluded events do not lend themselves to the use of cost–benefit analyses, but with avoided events you can rank funding options. Is this a useful dichotomization of emergency events for communication strategy?

- Conduct more studies to understand in a risk/threat-specific context what effective risk communication and engagement actually mean and to what extent the risk communication engages vulnerable populations and actions that would be taken. There needs to be specificity about the relationship of vulnerability and the specific threat content.

- ASPR has some data coming from Centers for Medicare and Medicaid Services that may help enhance your research for vulnerable populations, specifically those with special medical equipment or healthcare needs.

- As you do your studies, consider conducting a landscape review to determine what is already known about a topic being considered for study and exploit available data/information before developing a new study design.

- There are two ways of thinking of vulnerable populations with regards to risk communication and information access (communication inequality). There are groups who are exposed to this information but have barriers to accessing information and those who may process the information but are unable to act on the information. Widen the definition of vulnerable populations and think through influence of personal risk relative to delivery of information.

- From a jurisdictional perspective, assure that the whole issue of translating science into practice is considered. The challenge with communication at the jurisdictional level is getting to those we believe need the information the most or have to take specific action. This year the Zika message has been very difficult, and the contextual pieces were blocked out by the election. Those should probably be studied on how to overcome that barrier going forward. And lastly, ASTHO completely agrees with revisiting the emergency response funding approach.

Samuel S. Edwin, Ph.D., Director, Division of Select Agents and Toxins

Dr. Edwin began his presentation by outlining some of the achievements made by DSAT. He prefaced his comments by acknowledging that many of the accomplishments were realized under Dr. Dan Sosin's leadership and that Dr. Sosin continues to provide guidance.

There have been two accomplishments regarding publications. One is the publication of the Interim Final Rule, which adds Bacillus cereus biovar anthracis to the HHS list of select agents and toxins. This was made effective on October 14, 2016. In addition, there was the release of the first-ever annual report of aggregate program data for the Federal Select Agent Program (FSAP).

The division is furthering program activities, such as:

- Categorization of violations along a spectrum of severity, with enforcement options
- Began DSAT report card pilot with severity scoring in order to accompany inspection reports
- Supported independent peer-to-peer sharing forum for the select agent community through American Biological Safety Association (ABSA) International.
- Other accomplishments include the implementation of individual-based security risk assessments (SRA), which allows individuals with a current, approved SRA completed at one entity to move to another entity without the individual having to undergo a second SRA. Also, revisions to APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) are being made along with accompanying guidance to better capture information on reports of theft/loss/release. Lastly, on December 6-8, 2016, there was an in-person training workshop conducted for Responsible Officials.

These accomplishments were achieved while still conducting the daily routine functions of the division to ensure the safety and security of work with potentially dangerous biological agents and toxins. As of December 2, 2016, the DSAT has conducted 141 inspections, year-to-date and approved 1,945 amendments. For the Import Permit Program, there have been 53 inspections, year-to-date. There were 2,224 import permit application received and 1,861 approved.

Several priorities have been set going forward which include inactivation of select agents and the development, implementation, and refinement of a new electronic information system for the FSAP. DSAT will also continue filling vacancies and devise ways to retain qualified inspectors.

The nature of the work will cause continuous evolution of the program's responsibilities and challenges. In addition to the activities conducted thus far, it is critical that DSAT continues to improve the program, with an increased emphasis on risk-based inspections and prepare to overcome technological/science-based challenges, such as sequence-based classification of agents and synthetic genomics.

Recommendation/Comments to DSAT:

- It would be interesting to have a slide or two that illustrates the way the different divisions of OPHPR interact. How do they function differently with regards to monitoring and response so that an overall map is created? Divisions are coming together more and more to address the needs of emergency response; so, it would be interesting to see the interactions between the divisions in those events. Then some type of comparative analysis can be conducted to gain an overall systems view of the interactions – similarities and differences and by phase (preparedness, response, recovery). Efficiencies and opportunities might be identified.

- It is great to see some of the FSAP updates and the progress made to address recommendations made by registered entities. APHL and public health labs have had a concern previously about a lack of communication and engagement on the FSAP practices and activities. I recommend that you continue to look for ways to engage the registered entities in order to keep the select agent registered entities informed and maintain their engagement with the FSAP.

Greg Burel; Director, Division of Strategic National Stockpile

Mr. Burel provided the BSC with an overview of accomplishments DSNS has attained since last spring.

In response to the recommendation to increase collaboration and partnerships, DSNS is working in combination with the National Association of Chain Drug Stores (NACDS) to deliver prevention messaging and to produce a strong parallel distribution capacity at no cost. With the Healthcare Industry Distributors Association (HIDA), DSNS aided in the identification of acceptable substitutions and commercial availability. It also developed education strategies for key supply chain actors to decrease poor crisis purchase decisions. In conjunction with the General Service Administration (GSA), the division added to the disaster response schedules for three ZPK configurations. Lastly with the Department of Defense, a Mutual Support Agreement was created, which is currently in Department of Defense clearance. This agreement will facilitate more effective sharing of resources in either a military or civilian response.

DSNS exercised broad authorities and capabilities andcreated an innovative way of responding to emergencies through contracting. Through this new process, the division has implemented two short-term vector control contracts, one of which included residential spraying services for 3,801 indoor and 4,476 outdoor areas. There were 53 task orders completed over three months. DSNS has also awarded long-term contracts for vector control activities to prevent the spread of Zika.

DSNS contributed to the CDC's GHSA MCM Action Package and hosted three MCM in-nation Workshops for Ethiopia, Uganda, and Cameroon. There will be more to follow. The Divisioin worked with the World Bank and the World Food Program to examine pandemic supplies that might be needed. It will put nations in a position to be self-sufficient and better prepared.

To address the recommendation of the creation of an operational management and financial strategy, the division containerized 1.6 Million doses of MCMs. This action has improved delivery times by three hours and has yielded a 99.67% inventory accuracy rate with no losses due to the current Good Manufacturing Practices (GMP) failures. DSNS has migrated from the Solaris Operating System to the virtualized Linux, which has reduced costs by utilizing a smaller hardware footprint and streamlining the management of systems. This results in a better shared architecture for all the DSNS systems. As a result of these accomplishments, Greg Burel, Director, DSNS, accepted the Service to America Medal in Management Excellence on behalf of the division.

Mr. Burel ended his presentation with a few challenges that DSNS is still working to overcome. The division is looking to align requirements to stabilize funding in an effort to ensure the SNS capabilities are maintained. Another goal is to improve the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) process, which will include an increased role for state and local representatives. Lastly, DSNS plans to improve technical assistance and communication to state and local partners to ensure the appropriate training, information, and guidance is available before and during a response.

Recommendation/Comments to DSNS:

- What is DSNS doing to access information on STLT MCM inventories?
- Has OPHPR provided hands-on training for MCM distribution and monitoring? Will this be a future option for STLT health departments?
- SNS responsibilities have expanded. How do you put bounds around responsibilities? Where to start and stop?
- How can the SNS do more with less? What can the market provide? How to bridge between materiel in the SNS, what the market can provide, and the "gap" in need?

Update - OPHPR Policy Agenda
Kathryn Gallagher; Associate Director, Office of Policy, Planning & Evaluation, OPHPR

Ms. Gallagher touched on three areas, two of which were requested by the BSC at the last meeting: public and private partnerships and the development of congressional champions. The third area is on transition planning.

With Congress, more proactive outreach is occurring. The more members of Congress that come to CDC, hear and see its work, read the success stories, priorities, and challenges, the more we will see natural champions develop. Partners are being solicited to identify champions that they are currently working with in hopes that CDC may work in tandem. In the last six months, seven congressional members visited CDC; they toured the EOC and received a separate briefing from OPHPR. The downside to these meetings is conversations tend to lean more towards the specific response being attended to versus addressing OPHPR's foundational programs and examples of work from the OPHPR divisions and programs. Progress is continuing to be made in integrating those stories into the tours.

Many of the Congressional briefings for members' offices have also focused on Zika. This is a great opportunity, as well, to brief Congress on what is happening in the response and also the needs of the OPHPR. The desire is to shift the focus of the briefings from the issues of the day to the daily activities of the divisions. There have been two individual briefings where Dr. Redd represented OPHPR. Additionally, meetings with the House Homeland Security Committee, Senate Health, Education, Labor and Pensions (HELP) Committee, Senate Homeland Security, and Governor Affairs Committee have occurred along with three in-district briefings. These engagements provided opportunities to connect with constituents and highlight the work of OPHPR.

There have been a substantial number of briefings with congressional staff; sixteen in the last six months. Some briefings were conducted by OD leadership and division directors and some by OPHPR to introduce new office staff to the work conducted by OPHPR. The divisions' work that is connected to the global health agenda was included in the briefings to broaden interest.

Over the past six months, there have been some special congressional briefings organized by others. OPHPR participated in the Senate Sergeant of Arms Preparedness Briefing, where agencies come together to brief members, staff, and partners on their work. Last week, the CDC's 70th anniversary briefing occurred where each of CDC's national centers were present to talk about their priorities, projects, and work that's occurring. This effort afforded the opportunity to network and have casual conversations about their work.

Two hearings have occurred in the last six months. Dr. Redd testified before the Senate Homeland Security and Government Affairs Committee on the federal government's preparedness for both naturally-occurring and intentionally-caused biological threats. Dr. Sosin testified before the House, Energy, and Commerce Oversight Investigation Subcommittee on bio research labs and inactivation of dangerous pathogens.

In the next six months, SMEs, scientists, and program specialists will be trained on how to communicate the work they do to Congress. The first training will be in January and this will be an annual training. This can also provide an extra level of context and interest and help Congress and others to better understand OPHPR's work and why it should be supported.

Ms. Gallagher is starting to work with PHEP and ASPR to identify some directors who can tell their stories on the Hill and have the ability to brief Congress on their work. This work is starting and will continue to develop. The division is also finding ways to provide technical assistance to offices as they ramp up their work to reauthorize Pandemic and All-Hazards Preparedness Act (PAHPA) and address gaps and opportunities.

In the last meeting the BSC asked OPHPR to look at its partnerships focusing on social media and how it could harness more capabilities and use that platform to identify more partners and make some actionable decisions. Project Operation Dragon Fire (ODF) is directed at that very issue and brings together a range of public and private partners to examine transitional data sources, social media data, and conduct analysis. This work yielded two case studies. OPHPR intends to identify one of the ODF partner organizations to pick up the work and develop a final product(s). OPHPR is talking to the CDC Foundation for more ways to look at this complex issue.

With the Science Office, OPHPR funded an 18-month research project with Price Waterhouse Coopers to look at public-private partnerships. The Partnerships Team and the Science Office are working together with Price Waterhouse Coopers to review current evidence from socioeconomic and behavioral sciences in public policy. There will be interviews and surveys utilized to gather additional information about perceptions and needs in the community. Over the next year and a half, data will be collected for analysis to determine priorities for the future. Traditional partnership work continues with regular meetings with the DC Partner Group, which has expanded. Individual meetings have been increased with each of the organizations to talk about common issues and concerns and how OPHPR can expand its work.

With regards to transition planning, CDC has contributed to the official process. OPHPR has played a role and provided briefing materials to the transition teams. OPHPR is awaiting questions from the teams. Materials are also being developed to describe OPHPR's priority issues in a way that is accessible to new individuals coming to OPHPR. Issue briefs are being developed in collaboration with the Communications Office.

Most of the work occurring presently is around learning about the individuals coming to the new administration and their priorities to find areas of common interest.

Ms. Gallagher solicited input from the board in two areas:

- What should OPHPR be thinking about and preparing for related to the transition in the administration?
- What are the gaps and opportunities OPHPR should be considering with regards to PAHPA reauthorization?

Recommendations/Comments to OPHPR's Policy Agenda:

- How do you generate policy support? Or investigate policy preference? Determine a way to increase public support and increase public sentiment on the demand side. CDC may not be able to do this but board members can assist. Board members should consider ways to influence public sentiment that will support OPHPR's work. The board and partners should play with different ways of framing language that will cause the public to be responsive and think of how the demand side can influence the policy side.

- Thinking about the culture of health is critical to this discussion. Build cultural awareness of what health "is". Focus on health being attained and maintained first. Build capacity through all individuals and determine how we all can attribute to healthiness. It's a tough message and is probably generational.

- The National Public Health Security Index (NPHSI) affords an independent, objective way to put public health preparedness in its broadest context. The Index paints a larger picture of what it takes to be prepared as a society, as well as, the measures that speak to resilience. I think the Index is a good vehicle to help put OPHPR's work into a broader context.

- I like that you all have had congress members come and tour the CDC because that is a key first step to gaining support. What's lacking in the public health community is a defined and definite plan about how to change the hearts and minds of individuals. People respond to fear and maybe you should align communication to some of the military activities that occur and convey a "what happens if" type of message. A marketing plan may be needed to determine ways to connect with the public and stakeholders on an emotional basis in order to get the message across.

- When preparing the new administration, remember the indigenous communities, specifically tribal communities and nations. Often times, they are not included in the preparedness and response discussions. Given their rurality and lack of funding available from the states, they are often not prepared to respond to emergencies.

- Recommend as much as possible, when policies are being formed around preparedness and response, to include the end users of in the discussions. There's a large gap in understanding how policy will be implemented and used by the end users in the states and districts.

- In the Department of Defense when the term public health comes up, there's some allusion to HHS being the party responsible and that Department of Defense supports those efforts. In reality, the Department of Defense and other agencies are the recipients of a good public health system. All benefit from a good public health system. I do not believe that message is being articulated.

- Congress is concerned with problems that may occur on their watch. When communicating talk about the problems that your program solves as opposed to issues. This may be helpful when talking to those on the Hill.

- Information has to be presented by trusted sources who can tell effective narratives. Getting the public on board is more critical than ever. Rethink who are trusted authorities for the persons with whom we want to communicate.

There are unintended consequences associated with public health policy decisions. Has there been an examination of the risks and benefits of policy decisions, specifically those that are relevant for preparedness and response?

CDC Surveillance Strategy Support for Preparedness and Response
Chesley Richards, MD, MPH; CDC Deputy Director for Public Health Scientific Services and Director, Office of Public Health Scientific Services

Dr. Richard's presentation focused on U.S. domestic public health surveillance activities, primarily using human health and healthcare data. It also touched on the broader aspects of public health surveillance, which encompasses U.S. domestic and global, health data and non-health data, such as environmental and social determinants, as well as human data and non-human data, such as those from animal, plant, and microbes.

Surveillance is a foundational data activity in public health. Timely, high quality, actionable data are central to fulfilling the 10 essential functions of public health, which include:

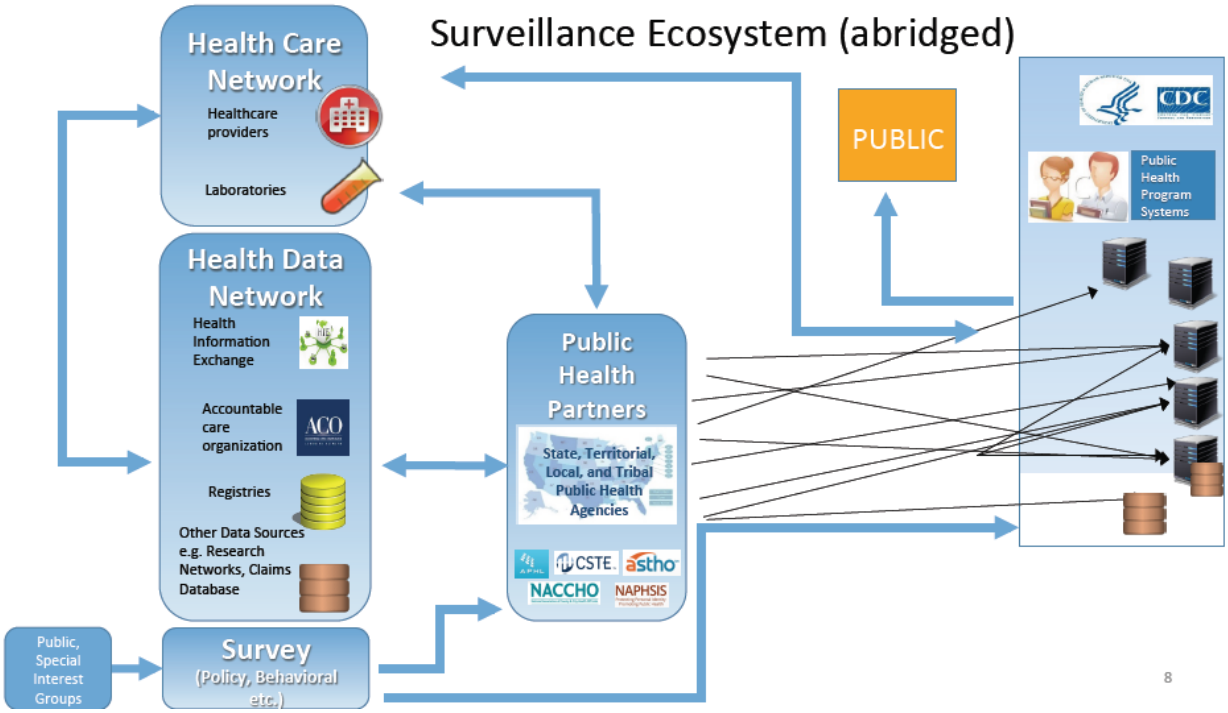
- Monitor health
- Diagnose and investigate
- Inform, educate, and empower
- Mobilize community partnerships
- Develop policies
- Enforce laws
- Link to/provide care, assure competent workforce
- Evaluate

This is done through a cyclical process of assessment, policy development, and assurance.

Dr. Chesley provided some examples of where public health surveillance has been employed. It is utilized in emerging issues, like Zika, Ebola, pandemic influenza, prescription drug overdose, and microbial resistant infections to discover information on new cases, transmission, and affected geography. Surveillance is also used for monitoring infections or exposures requiring local intervention, like HIV, STDs, healthcare-associated infections, and foodborne and waterborne illnesses, which require follow-up, case management, and local accountability. It's used to monitor chronic conditions, such as diabetes, heart disease, and cancer in order to make policy, interventions, and coordinate with healthcare entities. It's used to track health statistics like deaths and births, and can be used to monitor behaviors like tobacco and alcohol usage, physical activity, and immunization.

The CDC's surveillance work includes 5 to 11 percent of active CDC workforce. About 32 to 55 percent of extramural grant funds have a surveillance component and 18 to 21 percent of IT system capital planning dollars are devoted to surveillance.

An abridged diagram of the surveillance ecosystem was provided.



Several challenges have been realized in the surveillance ecosystem, such as proliferation. There are greater than 120 surveillance systems or activities occurring at CDC, which causes complications. Siloed surveillance activities cause problems with interconnections, interdependencies, and cause efficiencies to be unrealized. There is slow adoption of new technologies and an insufficient workforce with the right skills in the right places. Another barrier is the emerging health information policies in electronic health records and meaningful use standards, as well as, interoperability requirements.

Some of the policy drivers for enhancements to the CDC surveillance systems are being spearheaded by the White House. The Congressional FY 2015 budget language requires CDC to develop a timeline for a cloud-based and flexible IT public health data reporting platform for CDC programs. The Council of State and Territorial Epidemiologists (CSTE) and other partners have asked CDC to evaluate which data elements are truly needed for surveillance and to coordinate across CDC programs to harmonize and standardize data elements. Moreover, the CDC Director and Advisory Committee to Director charged the Office of Public Health Scientific Services (OPHSS) to lead the CDC surveillance strategy.

Upon coming into his position in 2013, Dr. Richards was given the charge to create a 90-day surveillance strategy. The goals set were to improve surveillance data availability and timeliness; make effective use of emerging information technology; retire redundant surveillance systems; and maximize performance. The three practical objectives that OPHSS has tried to address are reducing burden on the states; improving performance inside CDC; and improving value back to states. The vision of the surveillance strategy is to create effective systems with the right data and information; the right persons, time and format; effective public health action; and efficient systems. This is a cyclical process.

Several activities and initiatives have occurred since 2014. Activities include the Surveillance Leadership Board, CDC Health Information Innovation Consortium, HIT Policy Committee (FACA) representation, and the Strategic Health IT Vendor Forum. Initiatives undertaken since 2014 were as follows:

- Mortality statistics—electronic death reporting
- Lab reporting—electronic lab reporting
- Syndromic surveillance—visualization and analytics
- Notifiable diseases—electronic reporting from state health departments to CDC

Additional information regarding these activities and initiatives can be found at CDC Surveillance Strategy.

Electronic Mortality Reporting (EMR) comes from information collected from death certificates. The data informs the death reporting for the nation and historically has been an annual report. The National Center for Health Statistics (NCHS) and other leaders at CDC, like Dr. Sosin, suggested utilizing this process as a surveillance system to monitor deaths as they are occurring. Between 2010-2011, approximately 10% of all death reports were received by NCHS in ten days. With investments that have come from not only CDC and NCHS but also the Patient Centered Outcomes Research Trust Fund, electronic health record projects have been designed along with state registrars. This has resulted in a steady increase in the number of death reports received by NCHS in the 10-day window. For 2016, it is almost 50%.

The goal for jurisdictions is to try to obtain 80% of death records electronically within a state. At least 25 states can obtain this goal. There are 20 that are fairly close to meeting the metric. There are about 8 or 9 states that cannot get any of their records submitted. Special effort is being put into those states to overcome the legal and/or logistical barriers to reporting.

One of the outcomes is reducing redundant systems. As of October, the flu program is retiring the 122 cities mortality reporting system for flu and pneumonia and will use the NCHS data. This will reduce work burden on the cities. But, there is still a significant ways to go in mortality reporting. Other challenges that have to be resolved are drug overdose reporting challenges.

The National Notifiable Disease Surveillance System (NNDSS) is a system that collects data on over 90 reportable conditions in the states that the states have agreed to report to CDC. The system was built on a software standard built in 1990 and it has been modernized successfully.

The goal was to implement one data exchange standard for case notifications to improve NNDSS timeliness, efficiency and data quality. Several successes were highlighted and they were as follows:

- Message Validation, Processing and Provisioning System (MVPS)
    - Processing and provisioning data for 49% of notifiable conditions
  - Implemented functionality on 12/2/16
  - Includes all 7 hepititides and 52 other conditions
  - Pilot testing ensured that health departments could implement the messages
  - Technical assistance prepared 12 states, covering >25% of the US population, to send data
  - Allows CDC programs access to all data as soon as it is received
- New arboviral disease message incorporated data for Zika surveillance
  - Allows jurisdictions to automate transmission of data for all 29 notifiable arboviral conditions
- Message Mapping Guides are standards-based
  - Health Level 7 (HL7) format; use Logical Observation Identifiers Names and Codes (LOINC), Systemized Nomenclature of Medicine (SNOMED) and other vocabularies used in health care
  - The same core elements are used for basic surveillance data for all conditions

- Message Mapping Guides are in development for >19 additional conditions
  - Four are ready for pilot testing with health departments
  - A planned guide will simplify reporting by allowing health departments to send data to both NNDSS and FoodNET using one message
  - With the initial set of guides, they will cover >90% of reportable conditions and >95% of cases
- Message Evaluation and Testing Service (METS) allows health departments to test messages as they prepare to send data
- NNDSS Modernization Initiative (NMI) Technical Assistance and Training Resource Center provides "one-stop shopping" for jurisdictions preparing to send the new HL7 based messages

After 9/11 and the anthrax attacks, there was a need for better situational awareness nationally. Syndromic surveillance was used to answer the call. It was initially titled the BioSense Program. It was mainly CDC-centric and focused on bioterrorism. It had a large analytic team and there was limited hospital coverage. In 2008, it was renamed BioSense 2.0 and the shift was to technology. It was stakeholder-driven with limited functionality, but hospital coverage had increased. As of 2014, it was renamed to the National Syndromic Surveillance Program (NSSP). The program is now community-focused and utilizes user-preferred tools. There are expanding data sources and functionality and hospital coverage continues to increase.

NSSP is a collaboration among public health agencies and partners for timely exchange of syndromic data to improve the nation's situational awareness and responsiveness to hazardous events and disease outbreaks. Features of the program include the BioSense Platform, which allows for data flow and storage as well as provides tools and services for data management and analysis. There is also a community of practice which facilitates collaborations between CDC, jurisdictions, public health partners and enables funding and capacity building in state and local jurisdictions. It also features the Syndromic Surveillance messaging guide and the Community of Practice Portal, which offer "one stop shop" types of capabilities.

Other strategies for surveillance are needed to address several areas such as funding for states, informatics workforce, development of a CDC surveillance data platform with shared services, and electronic case reporting (eCR) for notifiable diseases from clinical providers to state health departments.

The Surveillance Strategy Workforce Plan will address several critical areas. The plan provides or facilitates a focused, relevant inventory of available trainings in informatics in two broad categories: general and specialized. It also affords tools and material support for front-line managers to assess and track training of staff in informatics competencies. Moreover, it offers and promotes use of assessment and tracking tools for systems and process improvement. The plan will engage fellows in developing or adapting tools and trainings, which facilitate their use, and align INFO-AID assistance to meet strategic goals of CDC, CIOs, and state, tribal, local, or territorial (STLT) health departments (HD). Lastly, the plan facilitates peer-to-peer learning through sponsorship and technical assistance for problem-oriented learning communities.

CDC sponsors two informatics training programs currently. The Public Health Informatics Fellowship Program, or PHIFP, is a two-year fellowship for CDC CIOs. The program enrolls eight to ten fellows per year. This program is dependent on CIO funding for fellows' salary and benefits. Strengthening Health Systems through Interprofessional Education or SHINE is an Applied Public Health Informatics Fellowship (APHIF) and is a one-year fellowship for STLT HDs. Participants in the course are graduates from academic informatics programs. There is an Informatics Training in Place Program (iTIPP), which is a one-year fellowship for current STLT HD non-informatics staff.

There's a big demand for public health informatics. Below is a list of some of the areas where public informatics is needed:

- Center for Global Health
  - 3-5 fellows per year past two years
  - International fellows (iTIPP)
- STLT HDs
  - Informatics for Epidemiologists (CSTE identified need)
    - Changing data sources and analytic methods
  - General (Enterprise) Informaticians
    - Develop business tools for leadership
    - Set HD informatics strategy and inform investment
  - Population Health Informaticians (Public Health 3.0)
    - Health systems and all payer claims data
    - Disparate data sources: schools, census, pharmacy, retail, CMS, all payor claims

Near term plans for the informatics programs is to have more cross collaboration between fellowships and provide shared curriculum and training resources between CDC and Field programs. Also in the plan is to reevaluate the current curriculum and recruitment goals. To aid in sustainability, there is a plan to seek new sources of funding and recruit more CDC mentors for the programs.

The surveillance data platform represents a new opportunity to achieve essential outcomes. The project will provide common, cloud-based services to enable efficient exchange and use of data for effective public health action by CDC and its partners. The platform will deliver shared services that provide measurable value to multiple surveillance programs and external partners. There are three desired outcomes.

1. CDC improves public health outcomes through agility and shared services.
2. CDC reduces reporting burden on states and partners.
3. CDC complies with directives from Congress and CDC Director to develop a shared cloud-based platform.

The future direction for OPHSS as it relates to informatics is to enhance cybersecurity, especially with new data sources and approaches. There are plans to enhance the use of standards and harmonization of data for routine data transfer and to increase interoperability. The intent is to make processes where individuals will not be forced to standardize but to make systems so appealing that it will cause them to want to utilize the system. As it relates to automation, there will be machine-to-machine data transfer, with appropriate security. New approaches and tools are being developed for advanced analytics, natural language processing, machine learning, and cloud computing. System approaches will support the incorporation of center/program based innovations to provide greater availability to CDC programs and external stakeholders/partners.

There is a Meaningful Use of electronic health records requirement coming in 2018 that will require clinicians to certify the ability to send case reports to public health organizations. CDC galvanized state and local health departments to coordinate together to work on eCR. The PHEP program is aligned with the eCR goal by providing data in real time to decision makers. As a result, a national coalition of vendors, healthcare systems, and public health organizations have come together to work on eCR. The Office of the National Coordinator for Health Information Technology published the Connecting Health and Care for the Nation. The document identified several key principles of interoperability. OPHSS is aligning its work with the principals in the plan.

The work is doable and it is a start to accomplishing the goals. Lastly, it is not overly complicated. It has been found to be very attractive to the vendors and health systems working with CDC.

OPHSS is also working on a "Digital Bridge" initiative. The vision is to design a bidirectional information exchange between health care and public health. The initial focus will be to collaboratively develop an interoperable, multi-jurisdictional approach for eCR that is consistent, nationwide, and sustainable. The governance body will be led by Robert Wood Johnson Foundation with equal representation from public health, health care delivery systems, and electronic health record vendors. There are initial implementation projects of a standard technical framework in five sites to be completed by December 2017.

Dr. Richards asked for feedback regarding surveillance strategy activities and emergency preparedness and response surveillance needs:

- Opportunities to better coordinate and collaborate
- Areas not addressed that would benefit preparedness and response
- Alternate approaches

Recommendations/Comments to OPHSS:

- Having more robust surveillance information on the other non-clinical or non-disease-associated contextual factors of risk and equity that relate to preparedness capabilities would better represent capabilities and capacities and are important to understand systemically and nationally. It is also important to understand regional response differences and associated characteristics. Access to this information might be accomplished through partnerships.

- Pay attention to data inputs and the definitions around them because it will affect the quality of data. For death certificates, for example, the standard default was cardiac arrest when data was unknown.

- Please continue to remove surveillance system silos. Much of the data now is not actionable but descriptive. Please continue moving more towards actionable data. Consider the opioid addiction crisis as a possible case study and hone in on it to improve our understanding of critical information for action.

- At the local and state levels, there is a need for more support from CDC on how to get hospital systems to report good data. A national perspective would be helpful to tell the stories and best practices so that locals and states can get to the next level.

- Expert interpreters are needed in the field who can offer multiple interpretations or a single set of variables that are sufficient to encompass interpretation of any data. Every quantitative system has always demanded some kind of qualitative, complementary system of interpreters who have multiple interpretations to make sense of the data. Quantitative data alone cannot do it.

- Public health departments feel that they don't have the resources - analytics, databases, or staff - to harness the data needed from electronic health records. So, it's going to be a challenge for them in the beginning. Another problem is language. Surveillance is a term that can have different definitions. I don't know if it's a good idea to imagine a unifying field theory of surveillance. It could be that in the long run different language would help. For customers and funders, it might be useful to disaggregate the term and be more specific.

- Local health departments would like assistance making the case for collection of quality syndromic surveillance data.

- STLT informatics capacity/capability are limited; additional expertise is needed. STLTs would benefit from more information on resources needed to build and sustain STLT's ability to manage increasing types and volumes of health-related data.

OPHPR's Practice-Based Research Agenda
Samuel Groseclose, DVM, MPH; Associate Director for Science, OPHPR and Designated Federal Official, OPHPR BSC

The purpose of the presentation was to provide a background on OPHPR's research experience; orient the board on its research agenda development process; and seek input on the research agenda.

In the 2006 PAHPA, the Secretary said that the CDC shall "define the existing knowledge base for public health preparedness and response systems; establish a research agenda based on Federal, State, local, and tribal public health preparedness priorities…and conduct public health systems research that is consistent with the agenda…" OPHPR, then known as Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), requested the Institute of Medicine to identify research priorities. The priorities were as follows:

- Enhancing usefulness of training
- Improving risk communications
- Creating sustainable public health preparedness and response systems
- Generating metrics for effectiveness and efficiency

From that effort, nine PERRCs were created and funded by research grants to schools of public health. Their work resulted in the completion of 34 distinct research projects, over 200 publications, and over 95 policy and practice tools, including models. There were many faculty and students trained in areas of preparedness and response research. The 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) did not mention research programs based at schools of public health. Language regarding research was mainly associated with countermeasures development, or Biomedical Advanced Research and Development Authority (BARDA). The PERRC had been funded off and on for FY14 through FY16. Congress no longer earmarked funds for PERRCs, but appropriations continued to include approximately $8 million each year for Academic Centers for Public Health Preparedness

In hindsight, the grant mechanism for the PERRC Program provided CDC limited opportunities to influence the research. The Extramural Research Program Office and research activities operated largely in isolation from OPHPR Divisions. PERRCs had insufficient engagement with the practice community and limited time to implement strong translation components. OPHPR has not established structures to support translation of research.

Since the PERRC Program ended, FY15 Academic Center funds supported translation and evaluation of select PERRC and PERLC products; this initiative will end mid FY17. The Office of Applied Research (OAR) summarized key PERRC and Hurricane Sandy Recovery research program findings for an indexed set of reports for OPHPR project officer or SME use.

In FY16, research contracts were awarded. The aim is to fund research that supports the work of OPHPR's Divisions, as well as state and local partners. In the Broad Agency Announcement (BAA) the government solicits brief concept papers for consideration. These will be three-year research contracts. All qualified offerors include, but are not limited to, schools of public health. OPHPR awarded seven contracts, totaling $8.4 million, to private and public sector organizations and universities.

Several benefits were realized from this approach. Topics are based on priorities identified by state and local preparedness directors, CDC SMEs, and input from divisions. The BAA mechanism allows for an expedited process. OPHPR reviews concept papers for merit and interest to program needs and invite formal proposals at their discretion. The contract mechanism gives CDC more control over project timelines, milestones, and outcomes. OPHPR scientists can directly collaborate on the projects and CDC owns all data and deliverables. The offerors are strongly encouraged to partner with health departments and other organizations.

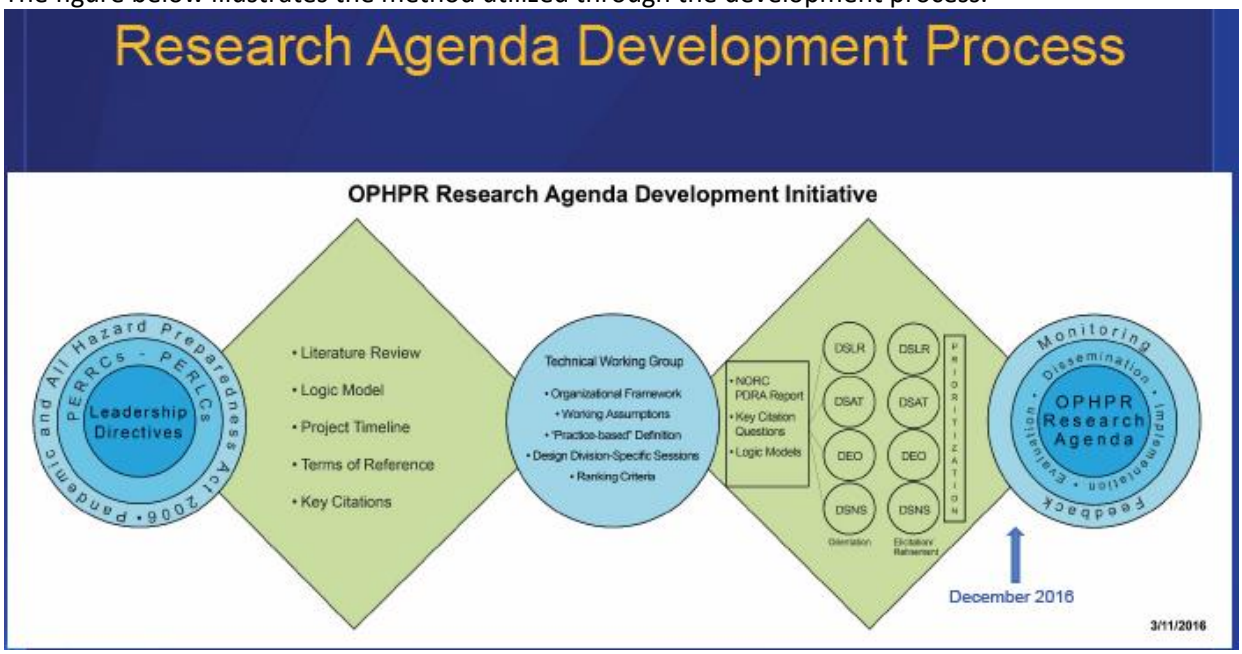
Phase 1 of the practice-based research agenda development was the State/Local Public Health Practice-Driven Research Priorities Project. This project surveyed of all State PHEP Directors and over 100 local preparedness officials, followed by focus groups and three expert panel sessions. It identified priority research topics for the field, based on the framework of the 15 capabilities. The final report was received in February 2016. A higher information need was reported more often for local PHEP programs versus the states and there are different information needs reported among the locals and states. Our STLT colleagues were challenged to articulate focused research questions.

In Phase 2, a systematic process was employed to gather input from OPHPR divisions to identify and prioritize research questions that would guide funding and resource allocation for OPHPR. A technical working group was used to define the process and to use practice-driven priorities as a starting point. Also, division logic models were reviewed to inform the development.

The research agenda will help to do several things. It will be used to develop high quality information to address gaps in OPHPR Divisions' preparedness, response, and recovery practice knowledge. It also will guide the direction and development of new projects, as well as research questions. Lastly, the agenda will serve as a roadmap for stakeholders to be aware of OPHPR's focus and provide an opportunity to partner on future priorities. However, the agenda will not address administrative and regulatory processes associated with conducting research or collecting information (e.g., OMB PRA or Human Subject Protections) or funding.

The target audience for the agenda is primarily the OPHPR divisions, who will commit to answer research questions as well as to support dissemination and translation of findings to practice. The secondary target audiences are STLT HDs and other public health system partners, such as healthcare and emergency management.

The figure below illustrates the method utilized through the development process.



Working assumptions for the agenda are as follows:

- Research agenda will be a prioritized agenda.
- Research agenda will be limited to a timeframe of 1 – 2 years.
- Research agenda may include applied scientific, operational, evaluation, and implementation research questions.
- Research agenda will avoid duplication of efforts by other CIOs (e.g., not antimicrobial resistance, global health security, advanced molecular diagnostics).
- Research agenda will be inclusive of all hazards.
- Research agenda will allow for innovative research.
- OPHPR does not expect to accomplish everything on the research agenda (before revisiting priorities).
- Success of research will be based on performance improvement and new knowledge gained rather than on achievement of expected research outcomes.

Several next steps have been identified. The first step is to validate what the topic or question represents. Is it a true knowledge gap? Or, a knowledge dissemination shortfall or knowledge translation deficit? The division needs to further specify research questions and obtain division, BSC, and partner feedback on the draft research agenda. Next steps are also to use research questions to guide OPHPR's activities and investments and to implement an OPHPR strategy for translation of research to practice. Lastly, OPHPR will implement a research evaluation strategy.

Dale Rose, PhD, MS; Associate Director for Science, Division of Emergency Operations, OPHPR

Dr. Rose's presentation laid out some priority areas and the assumptions associated with the priorities. The priority research areas of interest include the following:

- Incident management
  - Defining outcomes and most critical elements
  - Identifying predictors of / barriers to success
  - Determining (cost-) effective training modalities
- Emergency risk communication
  - Defining outcomes of interest
- Establishing feasible assessment methods across responses
  - Identifying preferred communication modalities for various populations / contexts
- Responder health and well-being
  - Identifying predictors of adverse / desired outcomes

Some assumptions have been made with regard to the research. Specific, operationalizable research questions will follow from the high-level questions put forward by DEO. The future research can produce generalizable findings for the practice community or address CDC-specific needs. These areas attempt to address high priority gaps in evidence inside emergency preparedness/response.

Some examples of high level research questions are listed below:

- What are the characteristics of an effective incident management system?
- Which elements of an incident management system should be prioritized for capacity building in low resource environments?
- Do public health agencies implement evidence-based risk communication practices and messages during emergencies?
- What individual, system, or organizational factors enhance, protect or adversely impact health or well-being of public health staff deployed as part of an emergency response?

Bryan Shelby, MSPH, PhD; Deputy Associate Director for Science, DSAT

Dr. Shelby covered one of the topics related to considerations for the research agenda due to time constraints. Given DSAT's unique role as a regulator, how should DSAT approach getting the answers to these questions as the research would have to be conducted by regulated entities?

One of DSAT's research questions is: "What criteria should be required to ensure entities have inactivated select agents effectively? What types of evidence are necessary to determine the inactivation effectiveness?" The current FSAP policy does not require entities to demonstrate in-house validation of inactivation except for Bacillus anthracis and B. cereus biovar anthracis. In May 2015, FSAP learned that improperly inactivated B. anthracis samples were distributed to domestic and foreign laboratories that were not equipped or registered to possess viable B. anthracis. As a result, FSAP issued a policy outlining the requirement for validation of inactivation methods and viability testing procedures for vegetative and spore preparations of B. anthracis and B. cereus biovar anthracis. FSAP has been asked to develop regulations and guidance to ensure inactivation methodologies of all select agents are validated and effective.

The challenges surrounding inactivation are in identifying prescriptive requirements as described in the FSAP inactivated B. anthracis and B. cereus biovar anthracis policy for all 58 replicating select agents regulated by FSAP. Currently, every inactivation method requires intensive SME input and continual review.

Another challenge is identifying the statistical rigor needed for every inactivation method. Validating the effectiveness of inactivation procedures is complicated and may require assistance of a statistician who may not be available to many entities. The number of replicates needed to statistically validate the inactivation procedure may be beyond the resource capacities of many entities. In addition, making guidance for entities that is helpful and applicable to all select agents and inactivation methods is a challenge, as well as identifying inactivation methods that can effectively render viral genomes non-infectious.

The overarching goal as it pertains to inactivation is to develop guidance on principles and procedures to validate BSAT inactivation methods to ensure effective inactivation. Guidance should be applicable to all select agents, types of entities, and inactivation methods.

The board was given several questions to deliberate on. They were as follows:

- What methods might we use to improve our ability to move from a description of a practice-relevant information gap to a well-specified and "answerable" research question?
- What are your recommendations regarding how we specify the topics or questions properly for our stakeholders and the research community?
- Should we provide contextual information that describes how we arrived at the question and why it needs to be answered now?
- What information should be available (or what research methods should be used) to increase the likelihood that practice-relevant information is generated?
- How should we describe and "market" our practice-based knowledge gaps and research questions in order to increase the likelihood that the research community and our partners contribute to the generation of practice-based evidence?
- From which external stakeholders, would you recommend that we seek input as we finalize our practice-driven research questions?

In addition to all presenters, Tina Bhavsar, PharmD (Health Scientist, Science Team, Division of Strategic National Stockpile) and Theresa Smith, MD, MPH (Associate Director for Science, Division of State and Local Readiness) helped to answer the board's questions.

Recommendations/Comments for OPHPR's Research Agenda:

- You should determine the mental maps which are qualitative, not necessarily quantitative, and encompass mitigation efforts, which is one of the best ways to learn about a system. It's not just studying it theoretically but changing it for the better.

- Consider generating key questions pre-event and establish process to send CDC researchers or EIS officers to do risk communications research, for example, during a response and ask some prepared questions to gain knowledge on motivating factors that influence action. States would love to have this type of information.

- There is concern that the negative RNA viral genomes are not regulated. There is an issue of the safety of the copy DNA if the viral genome replication is defective. Viral vector systems are being made for the viruses. NIH does have a guidance document for the complementary DNA (cDNA) and is making case by case allowance for labs to work with the full-length cDNA as low as biosafety level II, which is more a biosecurity issue than biosafety. So, the concern is about recombination; there's a lack of data on recombination rates or mutation rates for these viruses. I would recommend regulating those genomes and I would recommend research on recombination and mutation for those viruses.

- An interesting question is what kind of organizations or agencies implement successfully? What are the organizational characteristics that make for successful implementation and what are the barriers and facilitators? Those questions will be very helpful. You can also make a difference in rapid ascertainment studies. This is where you need a place for practitioners and researchers to be embedded so research can be done quickly. Think about how the embedding can happen. Also, consider a rapid research network that can be activated immediately to fill these studies and analyze the data.

- CDC had a program called the Academic Public Health Department which allowed the public health department and academic center to be connected for essential learning between practitioners and researchers. Learn from that history and think about this as not just encouraging partnerships but funding practice research partnerships. Secondly is dissemination. Have a dissemination pathway that writes in language that is applicable and gets to people on the ground and be stronger about connecting practice and academia. Do research on what is effective response management that begins to look at some of the best and some of the constraints of classic Incident Command System (ICS) management structure, National Incident Management (NIM) structure. Probe for case studies to see how many agencies in real response alter to be more effective in those local context with their partners.

- How much of your research agenda includes behavioral research or investigates the behavior of the public and responders during preparedness, response, and recovery? This is very important and should be translated.

- While probing the practice community, be very careful because the academic community is ready to dive in, but the practice community can be overwhelmed with responses like Zika, Ebola, etc. Implement standards around how the probing will occur. The research agenda should also inform the capabilities. For uptake and acceptance by stakeholders, the research should focus on highly complex issues that cannot be solved or resolved by practitioners in the field but where the field experience can help to refine questions and the areas of study. Look at deployments where CDC is deploying its staff and the presence of DSLR staff that are in the field. Those deployments will offer information on hard to resolve problems that practitioners are encountering. Another is intricacies associated with converting adult medications to pediatric doses. Research can be effective for areas like that.

- Be sure to involve the intended audience while formulating your research questions.
- We need research on how to get the answers out to the practice community so that they can act on it

Preparedness Updates from Liaison Representatives

Association of Public Health Laboratories (APHL)

APHL stood up the Biosafety and Biosecurity Committee to help improve and enhance biosafety and biosecurity in laboratories. A number of different activities have occurred in that regard. Funding has come through the Epidemiology and Laboratory Capacity (ELC) Program. One safety officer in each state as well as some larger jurisdictions was hired to help enhance biosafety and biosecurity in the public health labs as well as in clinical laboratories. There are very few people with this background so training is essential. Documents have been created to help with risk assessments, checklist for site visits, and workshops have been held.

A "twinning" program has been instituted for new biosafety officers who want additional expertise. They are paired up with another biosafety officer that is more seasoned to learn biosafety practices and procedures. The listserv has proven to be a beneficial tool for biosafety officers. The amount of interaction is unbelievable. It is interactive and engaging. It was striking to find out that so many public health laboratories did not have a dedicated biosafety officer.

Zika testing is going to be a sustained effort. CSTE is working with CDC to push out laboratory guidance that has been continually updated over the last year and it continues to provide webinars for public health and clinical laboratories. IT is a struggle and getting sustained funding is hugely beneficial. In New York, 10,000 patients have been tested and finding resources to support that testing is a struggle.

Association of State & Territorial Health Officials (ASTHO)

ASTHO is expanding capacity on Zika prevention and control efforts, thanks to grants and cooperative agreements through CDC. ASTHO has five specific project awards from CDC. An ASTHO Zika Taskforce was stood up to provide real-time input from users. The agencies have learned to have top questions on Zika with simple answers. In conjunction with consultants, those questions were created for Zika and are continually updated on the website. There has been collaboration with Harvard University's Opinion Research Program to conduct public opinion polls. Work is being conducted in the Caribbean to provide direct public health and clinician staff support. Two weeks ago, ASTHO planned and conducted an in-progress review for the Puerto Rico Department of Health. There will be a similar in-progress review for the continental United States.

ASTHO has prepared a preparedness policy. Four top priorities were identified and one of those is public health emergency capacity funding. Alignment in messaging is crucial. A focus on critical infrastructure fragility was included as well as cybersecurity and public health emergency response workforce preparedness. The fourth area is in mass violence.

Work is being conducted for the presidential transition. Alignment messaging will be important. Reaching out to Congress is critical. ASTHO has signed on to Trust for America's Health Blueprint for a Healthier America 2016 policy priorities for the next administration and Congress. The agency will work on a chapter of the Public Health and Healthcare System: Being Prepared for Emergencies.

Through the cooperative agreement with the CDC, ASTHO leads the National Alliance for Radiation Readiness, which is comprised of 16 public health entities. There will be a traveler's screening guidance released on lessons learned.

ASTHO released a Health impact assessment (HIA) report building on the CSTE template for the public and practitioner. This allowed for transparency.

*Council of State & Territorial Epidemiologists (*CSTE)

CSTE is supporting the establishment of a permanent public health emergency fund, which is needed particularly for unpredictable emergency events. It continues to put effort in the National Health Preparedness Index to determine ways to use it on a practical level.

One of the great successes during the Ebola response was seeing health-associated infections being brought into an emergency response effort. CSTE encourages CDC to continue the movement to push general involvement and improvement of infection control within the healthcare environment. Currently, the dentistry area is being included in this regard.

There's been some discussions with public health preparedness leaders. CSTE is in favor of broadening the use of PHEP funds to include electronic disease reporting and electronic data systems. There have been challenges to using these systems to improve the health of constituents.

There are some general preparedness activities ongoing to help states respond to natural disasters. Zika has caused expansion of activities such as traveler health, which is not an area that has been explored in depth. Preparing travelers before they go on their expeditions and putting together traveling monitoring programs are a necessary expertise.

National Association of County & City Health Officials (NACCHO)

Related to preparedness priorities, NACCHO has been:

- supporting local health departments with the Zika response
- conveying critical work that local public health is working on in coordination with federal agencies and the public,
- looking at assessing vector control competency and
- facilitating local input on CDC guidance and strategies.

The association also provided talking points for local officials who were addressing the PHEP redirection of funds. They have worked with CDC on vector control capability and on developing a more comprehensive understanding of mosquito surveillance and control activities across the U.S. over the next six months.

NACCHO is supporting the strengthening of the public health preparedness workforce development. It is implementing the third iteration of its Roadmap to Ready Program. CDC funded NACCHO to support local public health agencies in a demonstration project to increase administrative preparedness capabilities at the local level.

The association is also looking at improving the efficiency and efficacy of MCM utilization at the local level and is working with CDC and SNS, local health departments and other partners to institute national programs such as Flu on Call and Flu Med Finder. Pharmacies are also being incorporated into the preparedness response arena.

NACCHO prepared a policy statement advocating for adequate stockpiling and distribution of antivirals to meet time and resources needed for pandemic influenza and has partnered with SNS to provide information and feedback about MCM planning considerations for large scale antibiotic responses. The agency is also working on

a draft policy statement related to healthcare coalitions and the importance of understanding the structures and authorities in place at the state and local level.

Tribal Epidemiological Centers (TEC)

TEC were established in 1996 under the Indian Healthcare Improvement Act which was reauthorized in 2010 and given public health authority. TEC are established through a cooperative agreement with the Indian Health Services and representatives' areas match those of the Indian Health Service areas. Each area is different and serves various tribes with diverse emergency response capabilities and needs. Preparedness and emergency response capability remains a required public health objective that is required. Members are sent to outbreak trainings but thankfully have not been activated. In consultation with tribal health directors, the issue that constantly surfaces is funding for preparedness and emergency response to help with training and education. Tribes receive funding through states but it does not provide the infrastructure needed for a tribal nation to handle emerging crises.

Public Comment Period / Day's Recap / Adjourn (Day 1)
Thomas Inglesby, MD; Chair, OPHPR BSC

No public comments.

After reviewing housekeeping notes, the meeting was adjourned at 5:17 PM.

Thursday, December 15, 2016

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

The second day of the December 2016 BSC Meeting was called to order by Dr. Inglesby at 8:35 AM.

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

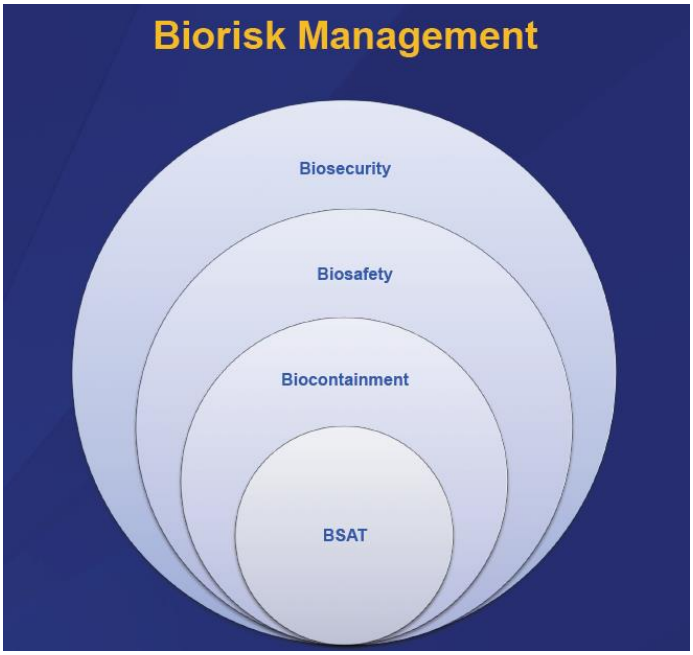
Dr. Groseclose conducted roll call and quorum was present.

DSAT Biosafety and Biosecurity Regulations
Samuel S. Edwin, PhD; Director, Division of Select Agents and Toxins

Dr. Edwin began by giving a brief overview of the FSAP and providing some core definitions. The select agent regulations (SAR) require individuals, private and public organizations, academic institutions, and government agencies in the U.S. to register with the FSAP before they can lawfully possess and use biological select agents and toxins (BSAT). Implementation of these regulations is delegated to the CDC, DSAT for HHS and to the Animal and Plant Health Inspection Service's (APHIS) Agriculture Select Agent Services (AgSAS) for the United States Department of Agriculture (USDA). The DSAT and AgSAS operate as the FSAP to coordinate the regulation of BSAT.

There are several terms that are commonly used in the program. BSAT are biological select agents and toxins that have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. Biosafety is a combination of practices, procedures and equipment that ensure safety of employees, public, and the environment from BSAT used in the laboratory. Biosecurity are measures taken to protect BSAT from unauthorized access, theft, loss or release. Lastly, biocontainment consists of laboratory design, engineering controls, and safety and security equipment to keep the laboratorian safe and contain BSAT within the laboratory.

If illustrated, biorisk management would look like the diagram below.



BSAT biorisk management work is risk management that involves collaborative effort between scientific researchers, responsible officials (ROs), and biosafety and security professionals to identify safety and security hazards associated with biocontainment research activities, conduct appropriate assessments, and formulate appropriate mitigation measures to reduce risk.

A biosafety and biosecurity statement was issued by the White House in 2015. The statement defines what biosafety should be as it relates to select agents. It states, "A national biosafety and biosecurity system is paramount to protecting the Nation's health, ability to conduct the highest quality research, national defense, and upholding public trust as the Federal government works to develop better means to prevent, detect and respond to infectious disease threats around the world."

There are multiple groups within the federal government that took a look at biosafety and biosecurity. The program reviews followed high-profile laboratory incidents involving select agents and toxins that occurred at federally regulated laboratories. Multiple groups within the federal government took a closer look at the biosafety and security practices involved in the conduct and oversight of this critical work. The scope of the reviews, at the national level, addressed FSAP and beyond.

For the FSAP Program there were three sets of reviews in October 2015 and recommendations were released. These reviews were designed to strengthen the federal government's biosafety and biosecurity practices and oversight. One was the Internal CDC 90-day review. The remaining two were federal-level reports ordered by the White House. There was the federal advisory panel, Report of the Federal Experts Security Advisory Panel (FESAP), and the external experts, Fast Track Action Committee on Select Agent Regulations (FTAC-SAR). The primary emphasis of the reviews was to improve entity oversight including facility inspections and inspection reporting; advance customer service and incident response; and increase transparency and engagement. Some of these activities were being conducted already but needed improvements.

The CDC Director ordered a 90-day review in the summer of 2015 to examine FSAP and make recommendations to improve the CDC's select agent and toxin regulatory program. The resulting report produced

recommendations in three main areas: inspections, incident reporting, and transparency and public understanding.

Below are the ten recommendations as well as the activities that have occurred to address the concerns in the 90-day review.

- Recommendation 1: Reduce variability between inspectors
  - Update: Identified regulatory departures requiring higher judgment and that result in increased variability between inspectors; training is in progress. Also, initiated internal quarterly inspection report audits to assess clarity and consistency of reports.

- Recommendation 2a: Monitor timeliness with routine analysis of inspection report data
  - Update: First annual summary was published in April 2016; ongoing efforts to look at internal timeliness underway.

- Recommendation 2b: Interim inspection reports
  - Update: Now issuing two types: 1). Routine preliminary reports that are for an entity's information only and 2). Immediate action preliminary reports that highlight serious violations needing urgent action

- Recommendation 2c: Staffing and retention plan
  - Update: Internal report completed; work to implement improvements is underway.

- Recommendation 3: Standardizing risk assessments
  - Update: An independent external group was convened to conduct this review and a report of recommendations is being finalized.

- Recommendation 4: Inspection scoring program
  - Update: Developed list of common regulatory departures found during inspections and applied a numeric severity score (1-3) to each; used to categorize the severity of an inspection and allows for comparisons. DSAT report card pilot underway.

- Recommendation 5: Enforcement options list (severity spectrum)
  - Update: Developed table of examples of regulatory departures and ordered by severity; captured enforcement options for each; shared for feedback with regulated community and others.

- Recommendation 6: Alternative enforcement models report
  - Update: An independent external group was convened to conduct review of a report of recommendations is being finalized.

- Recommendation 7: Analysis of inspection findings and risk
  - Update: Analyzing inspection findings data from 2013-2015; will inform development of a manuscript.

- Recommendation 8: Form 3 changes (reports of theft/loss/release)
  - Update: Revised the form and accompanying guidance so that incident reporting is more informative about the actual and potential risk of reported theft, loss, and release incidents; shared with the regulated community for comment and updated form is now with the Office of Management & Budget for review.

- Recommendation 9: Incorporating molecular diagnostics
  - Update: Analyses ongoing.

- Recommendation 10: Public release of inspection findings
  - Update: First annual report of FSAP program data issued in June 2016; will release on ongoing basis moving forward.

There were also two other advisory panels that made recommendations for agencies working with select agents and toxins. On July 2, 2010, President Obama signed Executive Order 13546 "Optimizing the Security of Biological Select Agents and Toxins," which created and tasked the Federal Experts Security Advisory Panel (FESAP) to address policy issues relevant to the security of BSAT. The order was re-chartered in July 2014 to evaluate approaches to enhance biosafety and biosecurity in the United States. The FESAP recommended the following:

- Recommendation 2.1: Add a specific requirement for the documentation of the drills and exercises required in sections 11 (Security), 12 (Biosafety), and 14 (Incident Response) of current SAR.
  - Update: Language addressing requirements for drills and exercises was included as part of the Notice of Proposed Rulemaking (NPRM) published in January 2016; changes are dependent upon the Final Rule.

- Recommendation 2.2: Add a specific requirement to section 15 (Training) to include how a trainee can access the HHS Office of the Inspector General (OIG) Hotline to anonymously report a safety or security concern.
  - Update: Added hotline information to FSAP website; a proposal requiring entities to provide training on how to access the hotline was also included as part of the NPRM published in January 2016; changes are dependent upon the Final Rule.

- Recommendation 2.3: Optimize guidance to address integration of the RO with entity's biosafety and biosecurity oversight committee(s).
  - Update: The RO guidance document is being updated to address integration of the RO with the entity's biosafety and biosecurity oversight committee(s).

- Recommendation 2.6: Improve guidance for biosafety plans.
  - Update: Improved guidance for biosafety plans is in development

- Recommendation 2.7: Amend guidance documents to suggest that entities consider establishing policies on maximum work hours for high containment workers.
  - Update: In April 2016, message was sent to regulated entities to communicate the importance of entities establishing policies on maximum work hours for those in high containment laboratories.

The second panel to make recommendations was the Fast Track Action Committee (FTAC) on the SAR. In order to engage a wide range of stakeholders, the National Science and Technology Council (NSTC) established a FTAC on the SAR under the Subcommittee on Biological Defense Research and Development of its Committee on Homeland and National Security. The FTAC and the White House Office of Science and Technology Policy (OSTP) convened two listening sessions for SAR stakeholders to provide individual views that inform and support the process. Their recommendations were as follows with the divisions updates included:

- Regulation Interpretations: The FTAC recommends developing a formal mechanism for issuing, publicizing, and accepting requests for interpretations of the SAR.
    - Update: FSAP developed a formal mechanism for accepting requests for interpretation of the SAR and issuing interpretations. Information about the process was communicated to the regulated community.

- Public Release of Information: The FTAC recommends that information about BSAT research, including laboratory incidents, be periodically provided to the public, and that federal BSAT laboratories adopt, to the maximum extent feasible, a policy of transparency regarding both the agents used and laboratory incidents.
    - Update: FSAP released a public report of 2015 aggregate program data in June 2016. We will continue this practice going forward.

- Sharing Best Practices: The FTAC recommends members of the regulated community establish a mechanism for sharing best practices.
    - Update: 1). FSAP entered into an agreement with American Biological Safety Association International (ABSA) to provide this service independent of the regulator; includes an online discussion forum, in-person workshop, and webinars for the regulated community to share information and best practices. FSAP will provide ongoing support as needed. 2). FSAP conducted an in-person RO training workshop December 6-8.

- Individual-based Security Risk Assessments (SRA): The FTAC recommends that in the absence of specific information indicating otherwise, individuals who have been granted access to select agents or toxins at one BSAT institution be able to move to another BSAT institution without having to wait for a new SRA.
    - Update: Implemented as of July 2016, for those with a current approved SRA, the process allows visitors, transferring personnel, and personnel who work at more than one entity to work without having to undergo an additional SRA at the second entity. This will help increase ease of ability for those in the regulated community to move among institutions.

- Emergency Situations: The FTAC recommends development of a mechanism to expedite approvals or to relax FSAP requirements in response to time-urgent emergency situations.
    - Update: HHS Biosafety and Biosecurity Council reviewed and concluded that current waiver authorities are adequate to respond to time-urgent situations; a process is in place to use if needed. FSAP will continue to be attentive for potential scenarios where current authorities might fall short.

- Inventory Control Requirements: The FTAC recommends retaining requirements to maintain inventories of samples containing BSAT, while ensuring that BSAT institutions are not requested to characterize biological agents quantitatively.
    - Update: FSAP communicated to regulated community that SAR do not require volumetric quantitative inventory controls for select biological agents, only for select toxins.

- Consistency of Inspections: The FTAC recommends development of an approach to improve the consistency of the inspection process across inspectors, inspecting agencies, and inspected sites.
    - Update: a). Rotation of entity files to ensure consistency; b). Inspection workgroup identified a list of regulatory departures requiring greater judgment leading to variability. This was used to develop inspector training plan and modules to address this concern; and c). Post-inspection surveys.

- Improve Customer Service in Communicating with Regulated Entities: The FTAC recommends improving communication before and after site inspections and improving the timeliness of inspection reports.
    - Update: Many efforts are underway in this area, including: FSAP providing RO/ARO training 6-8 Dec 2016; webcast on 8 Feb 2017 to provide guidance on regulations; redesigning National Select Agent Registry to include online portal-based entry of all registration, transfer, and theft, loss or release information for regulated community.

- Categorize Inspection Findings: The FTAC recommends developing a system to categorize findings on inspection reports.
    - Update: FSAP has developed several new initiatives and shared them with the regulated community to gather comments and feedback. These initiatives include:
        - Severity of inspection departures and enforcement actions
        - Inspection report card - DSAT pilot
        - Complexity information

- Appeals Process: The FTAC recommends expanding the appeals process for institutions to adjudicate disputed findings in inspection reports.
    - Update: FSAP developed and announced to the regulated community an informal dispute resolution process to adjudicate, through ROs, a registered entity's dispute of an inspection report finding/observation.

- International Engagement: The FTAC recommends international engagement to explore harmonization of pathogen security standards and ensure understanding of the rationale for, and implementation of, the SAR equivalent standards by collaborating foreign governments.
    - Update: DSAT supports this, as well as other global work, through its international program efforts.

- Guidance for Customs Inspectors: The FTAC recommends providing better training and guidance for customs inspectors who process BSAT shipments.
    - Update: Developed guidance for Customs and Border Protection (CBP) inspectors that process shipments of select agent and toxins coming into the U.S. to increase awareness of the applicable regulations; continue to work with CBP on implementation.

Next steps for DSAT are to continue to focus on program improvement, while maintaining routine work of the division. Some efforts are completed but many remain ongoing.

Updates will be posted online at: DSAT: Progress Towards Change.

Recommendations/Comments to DSAT:

- Pursue Recommendation 9 – Incorporating molecular diagnostics" especially with regard to viruses because their genomes can be infectious even if it's something that is not directly cultureable. Also, some of the viruses whose genomes are not directly infectious might require only one additional step to become infectious. Consider the implications of some of those nucleic acids in a sample. Consider not just focusing on virulent genes.

- APHL recommended being careful with respect to addressing molecular diagnostics in the Select Agent Regulations. Public health labs get positives by PCR but cannot isolate the organism in some circumstances. When there are outbreak investigations and numerous samples are being received, there's a big burden on the laboratories to inventory and document the samples when there may be

little to no risk, if we can't culture it. Be sure to include public health laboratories in the discussion of Select Agent Regulation changes as well.

- Look across all the various programs and activities to identify the major heuristics that people use when considering biosafety and biosecurity. Encourage looking at biosafety/biosecurity "system" and assess it systemically. What are the different assumptions the stakeholders are making about them? What are the various heuristics that people are looking for?

- Have a consistent file manager for registered entities and mix up the inspection teams.

- There is some uneasiness regarding the absence of regulation of "gain of function" for non-BSAT agents. Is there a clear and consistent way to define an agent's potential high-risk "gain of function" in order to include this risk in the SAR?

- Modified FSAP regulations have resulted in a change in lab business practice. Labs are sending more Bacillus spp. samples to public health labs to rule-out anthrax. Recommend developing a protocol to avoid this practice.

- APHL would like to discuss issues regarding SAT shipment with FSAP.

Radiation Threat Preparedness and Response

Armin Ansari, PhD, CHP; Radiation Studies Branch (RSB), Division of Environmental Hazards and Health Effects, National Center for Environmental Health

Dr. Ansari presented a portion of the efforts CDC is undertaking with regards to radiation preparedness. His presentation focused on defining radiation emergency, giving an overview of the public health response work, updating the board on activities CDC and the RSB are undertaking, and highlighting the gaps and challenges to their work.

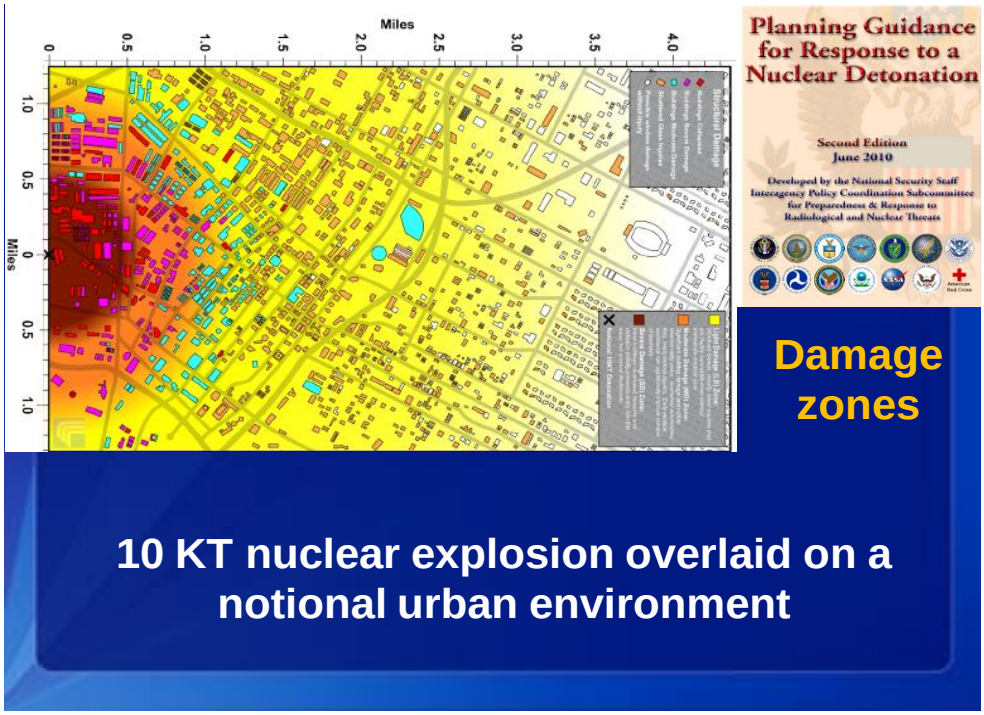
There have been quite a few past experiences of radiation-associated emergencies. He highlighted events such as Hiroshima/Nagasaki (1945), Three Mile Island (1979), Chernobyl (1986), Goiânia (1987), Tokai-mura (1999), London (2006), and Fukushima (2011). There are some generalities, but the consequences and characteristics of each differ.

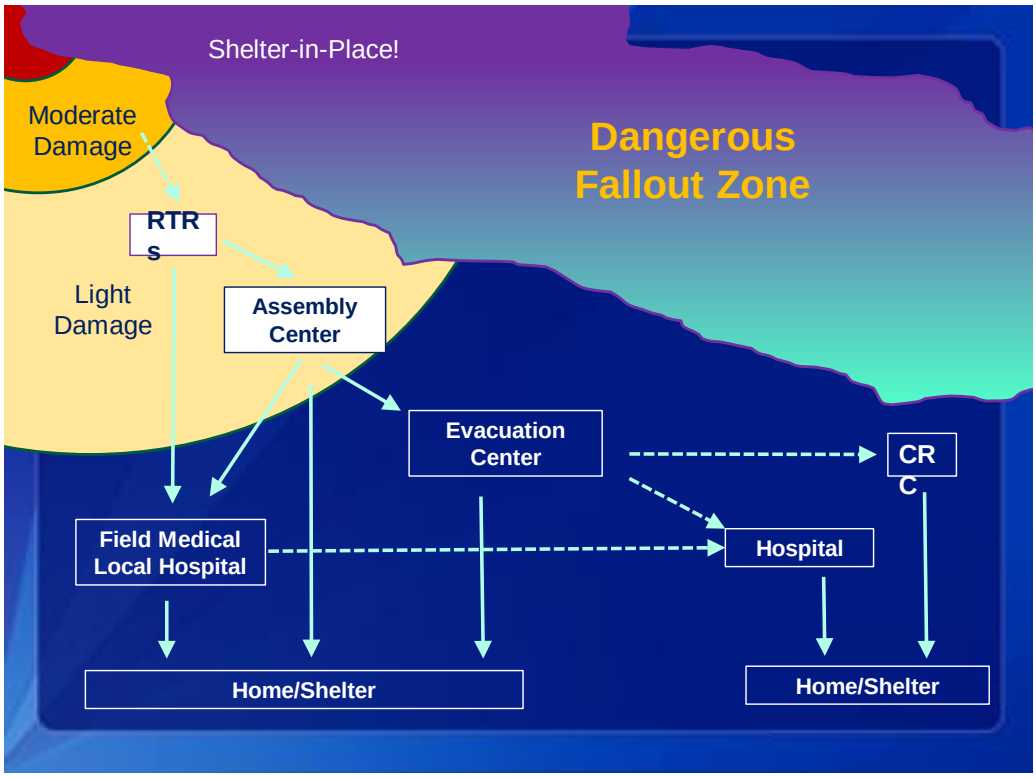
He provided two definitions utilized in chemical, biological, radiological, and nuclear (CBRN) environments. A nuclear incident involves a nuclear detonation. A radiological incident does not involve a nuclear detonation. Each causes different psychosocial issues, radiological issues, etc.

Radiological incidents can occur due to transportation accidents, nuclear power plant accidents, spent fuel storage leaks/spills, and lost/abandoned sources. However, nuclear incidents can be strategic nuclear weapons, which were used in the Cold War and covered a megaton range, but are not considered likely threats today. Another example of a nuclear incident is an improvised nuclear device (IND), which is typically low-yield and in the kiloton range. INDs are possible tools of terrorism because there is no warning. These devices are of utmost importance in the national surveillance scenario planning.

The immediate and massive destruction by a nuclear bomb is not caused by radiation but by the shockwave, which accounts for fifty percent of the damage. Heat makes up another 35% of the damage, leaving radiation to account for only 15% of the damage.

Dr. Ansari provided an illustration called Planning Guidance for Response to a Nuclear Detonation. The map shows a 10KT nuclear explosion overlaid on a national urban environment. Charts like the one below can be used to create an effective medical response effort to a nuclear detonation. He also presented a flow chart of where shelter-in-place areas should be utilized and the relationship of radiation triage and transport, community receptive center (CRC), hospitals, etc. should occur in planning efforts. Planning groups are currently working on these different areas.





The branch is currently utilizing a Hurricane Katrina diaspora map to do a comparison analysis. During Katrina, a vast majority of individuals dispersed to regions just outside of New Orleans. Doing an analysis similar to this can help in planning efforts so that resources are placed in the right locations.

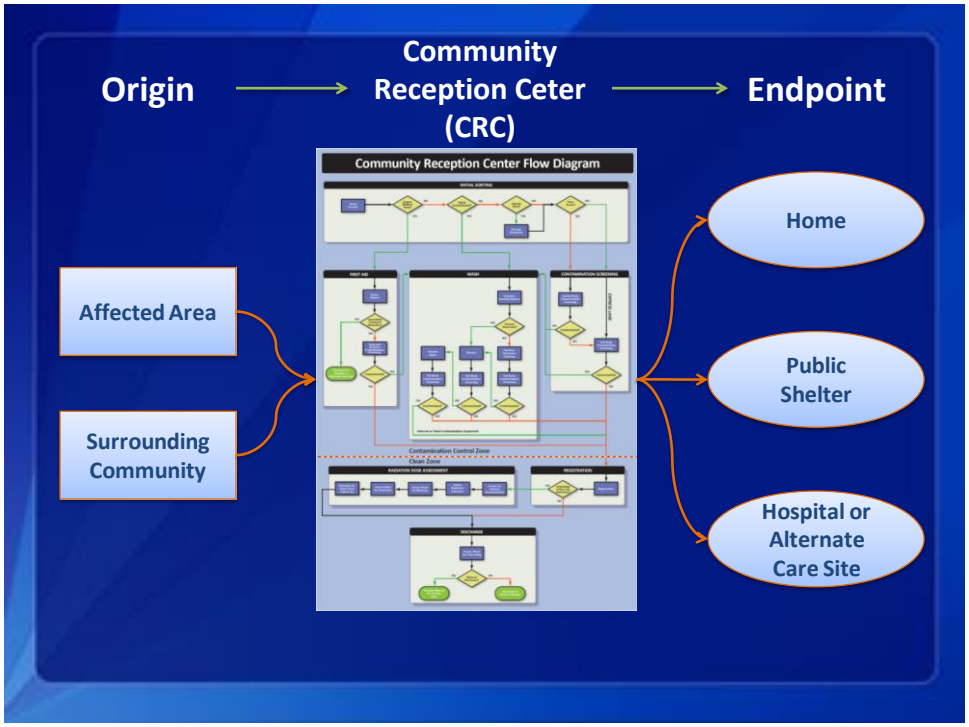
The Radiation Studies Branch (RSB) has been doing a number of key activities such as preparing guidance; formative and evaluative research; training and education; tools, technical assistance, and collaboration; and partnerships.

Population monitoring evaluates potentially-affected populations for:

- Immediate need for medical treatment (both rad and non-rad related)
- Presence of contamination on body or clothing
- Intake of radioactive materials
- Removal of external or internal contamination (decontamination)
- Radiation dose received and risk of health effects
- Long-term health effects (needs registry)

Dr. Ansari presented the difference between bioassay and biodosimetry. Bioassay is used to assess internal contamination. This is completed by NCEH in the Division of Laboratory Sciences. It utilizes a rapid, Clinical Laboratory Improvement Amendments (CLIA)-certified spot urine test for 14 priority radionuclides. The throughput and surge capacity are limited. Biodosimetry is used to assess radiation exposure utilizing the cytogenetic assay and BARDA products. The method can do 10s of thousands of samples, but staffing can be a barrier. The division has to consider infrastructure to put in place in order to respond to the demand for lab testing to characterize exposure.

The picture below explains the concept of a CRC. Pod plans were used to create a CRC. Some staff used for pods can assist for radiological events so pilots are occurring to test and observe CRC exercises for radiological events.



Tools and guidance have been created such as the Guide to Operating Public Shelters in a Radiation Emergency and the Radiogical/Nuclear Law Enforcement and Investigation guidance. Several agencies were used to inform guidance.

The branch has participated in several formative and evaluative research roundtables to obtain input from key audiences to discuss topics such as:

- Partnering with Meteorologists
- Hospital Mass Casualty Management
- Hospital Communications
- Poison Control Centers
- Psychosocial Issues
- Role of EMS
- School Preparedness

CDC conducted audience research using focus groups and individual interviews for usability testing. Research centered on the following:

- IND Message Testing (English and Spanish)
- Messaging Gaps of State/Local Partners
- Evaluation of Tool Kits
- Usability Testing of Radiation Emergencies Website
- Radiation Emergency Messaging for Nursing Women
- Evaluation of Radiation Emergency Fact Sheets
- Focus Groups on Messaging Gaps for Lay and Professional Audiences

Radiation Basics Made Simple is a module created for online training. It is the first in a series of modular trainings, which utilizes lecture-style video and interactive knowledge checks. There are eight segments: Sources of Radiation; Radioactive Decay; Measuring Radiation; Biological Effects of Radiation; Radiation Protection; Decontamination; Environmental Impact of Radioactivity; and Responding to Radiation Emergencies. Continuing education is available.

Another training module is the medical countermeasures training. It is also online and contains brief segments with animation. Continuing education credits are also available for this training.

Infographics were also audience tested for colors, diagrams and text to make sure that it resonated with the targeted group.

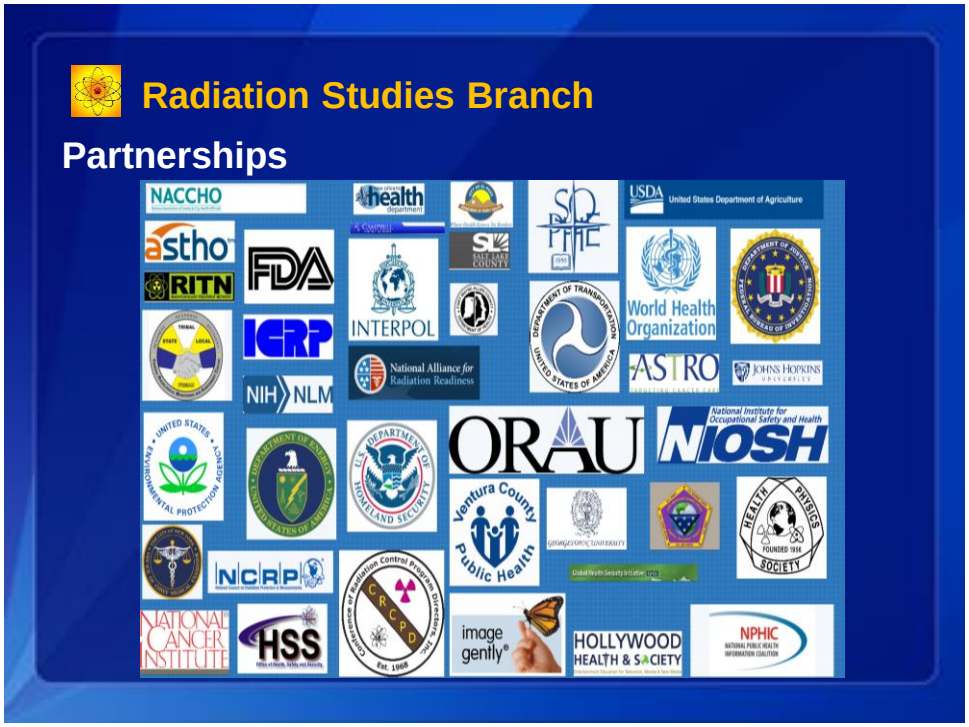
The Internal Contamination Clinical Reference tool has been created, which is an application which estimates reference concentrations of radionuclides in urine assuming intakes equal to the Clinical Decision Guide for each radionuclide. The tool uses hypothetical patient scenarios. It is available in the Apps Store and Google Play.

Some other tools are virtual CRC, RealOpt CRC, CRC-STEP, and ICAT, as well as the Resource Library. The website has over 100 tools. One of the recent ones is the Radiation Hazard Scale. This is a communication tool for the public. It has been tested with professional audiences and focus groups. The language in the paragraph descriptions was examined to make sure the meaning is clear and concise. CDC has cleared this tool and it will be released in January 2017.

The branch provided technical assistance and collaboration in the Fukushima and Polonium-210 poisoning incident. It also provides technical assistance and collaboration nationally with the National Council on Radiation Protection and Measurements (NCRP), which was chartered by Congress in 1964. The RSB staff serving on the Council to provide the Radiation Protection Guidance for the U.S. discussed medical exposures of the U.S. population and chaired the 2017 annual meeting on emergency response. Another collaboration that CDC participated in was the Conference of Radiation Control Program Directors (CRCPD). Some other partners included National Alliance for Radiation Readiness, Oak Ridge National Library, ASTHO, and NACCHO.

International technical assistance has been provided by the RSB staff who serve on the U.S. delegation to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), which was established by the UN General Assembly in 1955. The International Atomic Energy Agency (IAEA) coordinates training in the U.S. and collaborates on emergency communication projects. For the World Health Organization (WHO), the RSB worked with the Guidelines Development Group (GDG) for the revision of the WHO KI guidance and the Radiation Emergency Medical Preparedness and Assistance Network (REMPAN) Internal Contamination Working Group. Other international collaborations include INTERPOL (International Criminal Police Organization), Health Canada, and Global Health Security Initiative (GHSI).

The figure below illustrates some of the branch's partners.



Some of the internal challenges to the organization are as follows:

- Radiation/nuclear hazards require different response CONOPS than biological threats or natural disasters.
- CDC staff knowledge of radiation/nuclear hazards and response requirements is limited.
- CDC radiation/nuclear SME "bench" is shallow.
- CDC staff have been almost continuously mobilized for emergency responses over the past few years
    - Fatigue, burn-out, lack of availability to learn new skills (e.g., radiation/nuclear response).

Recommendations/Comments to RSB:

- Do not forget to partner with the business community so they can help with dissemination. Dr. Ansari asked for help partnering with the Business Executives for National Security.

- In terms of radiation threat guidance, there's a need for ongoing readiness guidance to understand more about radiation threats, maintain knowledge of the threat and response recommendations, and decide when to conduct refresher courses for responders and health care providers.

- Do not underestimate the need to and the effort required to work with local communities, states, and other stakeholders. They are going to ask who is in charge of what entities so roles and responsibilities need to be clarified.

- What's being done with respect to radiation threat preparedness for tribal communities?

- Does CDC plan and prepare for mixed CBRN-agent events/scenarios?

Incorporating Non-Federal Stakeholders into Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Decision-Making

Joanna M. Prasher, PhD; Senior Advisor for Medical Countermeasures, OPHPR
Ernest (Chip) Smith, MD, MS, MPH&TM; Associate Director for Medical Countermeasures, Division of State and Local Readiness, OPHPR

The board was asked to consider the following questions while listening to the presentation.

- Have we identified all the appropriate non-federal stakeholder groups to involve in PHEMCE decision making?
- How can we ensure sufficient representative input within and across the diverse sets of stakeholders?
- Will the types of engagements proposed most effectively and efficiently achieve the stated goals for non-federal stakeholder engagement?

The PHEMCE is a federal coordinating body established by HHS in 2006 that protects the U.S. civilian population from national health security threats through medical countermeasures. Member agencies include HHS: ASPR (as well as BARDA), CDC, FDA, NIH, DoD, DHS, VA and USDA. The group develops, produces and makes available MCMs that limit adverse health impacts and includes pharmaceutical medical interventions, such as vaccines and antimicrobials, as well as non-pharmaceuticals, like ventilators and diagnostics.

PHEMCE has several cross-cutting strategic deliverables that it is responsible for. There is the Annual PHEMCE Strategy and Implementation Plan, the SNS Annual Review, and the PHEMCE Multiyear Budget. It is also responsible for preparedness assessments and civilian MCM requirements.

CDC has a number of key roles that it plays in the PHEMCE. It provides disease-specific scientific expertise and optimizes and maintains the SNS to meet the PHEMCE's priorities. CDC also supports public health infrastructure at the federal, state and local levels to detect and effectively respond to public health emergencies. In addition, it promotes collaboration with state and local public health officials and serves as a critical link to healthcare community. Lastly, CDC develops and recommends utilization policies, including regulatory mechanisms and clinical guidance for effective MCM use.

PHEMCE has started to identify some of its critical non-federal stakeholders, like state, local, tribal, and territorial (SLTT) public health; healthcare community; emergency management; and professional and representative organizations. There are two end goals for engagement with these stakeholders. One is visibility into the PHEMCE's processes or factors considered for MCM end-users. The second goal is to incorporate non-federal partner perspectives, needs, and constraints into PHEMCE decisions on MCM stockpiling and guidance. The end-user is important to PHEMCE. They are at the frontline and inform the PHEMCE on areas such as its needs, capabilities, expectations, and plans.

When looking at engagement options, a portfolio approach is employed. The table below is an example of this approach.

Engagement Options – A Portfolio Approach

Product	Stakeholders	Engagement Type(s)
Intergovernmental consultation	State, local, tribal, & territorial (SLTT) public health departments	PHEMCE membership
Input of non-federal stakeholders into particular PHEMCE products	SLTT public health departments; professional & representative organizations; healthcare community; emergency management	Direct input/review (through existing MCM WGs or channels); tabletop exercises to validate assumptions;
Understanding of end-user goals/ needs/ capabilities	SLTT public health departments; professional & representative organizations; healthcare community; emergency management	Ongoing CDC engagements; MCM operational readiness review and analysis; technical assistance requests

OPHPR/DSLR SLTT engagements, for example, encompass routine DSLR interactions with PHEP Awardees. There are several monthly calls like the HPP-PHEP Awardee Conference Call, ASTHO Directors of Public Health Preparedness (DPHP) Conference Call, and ASTHO DPHP Executive Committee Conference Call. There is a monthly ASTHO Executive MCM Steering Committee meeting and a monthly DSLR Second Wednesday Webinar.

The DPHP Executive Committee serves as a consultative body for DSLR. DSLR provides updates and vets preliminary ideas in development on policy and programmatic issues. Members inform CDC of potential challenges with implementation and propose solutions to barriers.

Discussions center on resources and staffing shortfalls. There are some upcoming non-federal engagements planned for 2017. Below are some of the forthcoming events.

- Jan. 25 & 26, 2017: Operational Resource Guide Stakeholder Meeting
- April 2017: NACCHO Annual Preparedness Summit
- July 2017: MCM ORR Training for all awardees

Site reviews, MCM operational readiness review, assessments, and technical advice will be ongoing activities throughout 2017 as well.

The presenters gave examples of the types of feedback sought from non-federal stakeholders. Stakeholders might be asked if the PHEMCE high priority threats are in line with the concerns of communities. This will identify opportunities to leverage ongoing public health work to support intentional/emergent threat

preparedness. Input is also sought regarding scenario-based MCM needs, MCM distribution and dispensing issues, and the validity of the PHEMCE's assumptions. Another area of interest is desired drug characteristics, acquisition plans, choices around holding one versus multiple products, and storage considerations.

There are some issues that will need to be resolved. The following list of concerns were provided to the board:

- Direct participation by SLTT representatives in PHEMCE bodies
  - Opportunities for intergovernmental consultation being actively explored by PHEMCE
- Gaining sufficient representative input across diverse sets of stakeholders
- Appropriate handling of procurement-sensitive information
- Balancing open discussion imperatives with the risk of divulging strategic vulnerabilities

Recommendations/Comments to OPHPR:

- Strongly recommend engaging with Professor Ed Freeman, University of Virginia. He is one of the people credited with inventing the name "stakeholder" and has written extensively about stakeholder management. He has studied different stakeholder groups and ways to include stakeholders. Another idea is to research assumptional analysis, which is a methodology for arriving at critical assumptions that different stakeholders bring to any policy perspective and is critical for identifying assumptions in which major stakeholders disagree. Also, look up strategic assumption surfacing and testing, which is a methodology that reveals the underlying assumptions of a policy or plan and helps create a map for exploring them.

- Provide opportunities to have dialogue to understand local partners' assumptions regarding MCM distribution. There are nuances there that may be lost in a time-limited assessment process or drill. Be a conduit of dialogue between state and local first responders.

- Identify the body of assumptions which most people strongly agree with and then have one prominent stakeholder from the inside or outside who disagrees or provides alternate views. Identify who your critics are for that role.

- Regarding having too many people from too many places/organizations informing the process, perhaps have a representative from DPHP Executive Committee and other groups. The representatives from key groups would have to have a broader more strategic perspective, for example, someone who understands both rural and urban issues regarding MCM.

- Think about where MCM distribution is going to happen. Don't miss the local or state leadership perspective.

- Have representatives of each major government and health care entity so you are not surprised by who is in the chain, their issues, needs, and assumptions. Map out the process of which individuals are in the chain and specify their roles and responsibilities.

- Include the person who is writing the state/local MCM distribution plan. They have a good understanding of how it should be implemented.

- Be thoughtful with respect to who is at the table. Those individuals should not always be the traditional individuals. Bring people who are not familiar with the process. They can provide interesting perspectives.

- As you are developing the target product profile be sure to have clinical and local points of view.

End-of-Term Remarks by Dr. Carol North:

A presentation was made to Dr. Carol North, who is retiring from the board. Dr. North expressed excitement about being a part of the committee and provided some closing thoughts and considerations. She asked that going forward that OPHPR include more research or conduct more research on mental health as part of the emergency and medical response efforts. She felt it was a subject that has not been explored extensively. She asked that OPHPR consider having a designated staff member or program function to ensure systematic consideration of potential relevance of mental health in every area of preparedness. Experts will be needed who can differentiate stress and psychiatric illnesses such as PTSD using full diagnostics rather than symptom screeners. Then, also, select intervention plans targeted to the results of the assessment. Be very careful in selecting experts to bring to the table. There is a lot of "silliness and nonsense" in the field. There is separate expertise in social and behavioral responses that relate to risk communication and psychosocial terrorism prevention. She suggested that OPHPR do the following:

- Review the current existing literature to help plan and guide disaster and mental health preparation and response.
- Need appropriate new research. The best research comes from embedding disaster researchers in the disaster setting.

There are some lost research opportunities. She gave an example of the Dallas County Ebola response where she was invited to help with a survey, but because of health department work on Zika, the Ebola-related work had to be put aside. There should be mechanisms put into place so that those opportunities are not lost.

Health, Crisis and Risk Communication
Katherine Daniel, PhD; Associate Director for Communication, CDC
Dana L. Pitts, MPH; Associate Director for Communication, OPHPR

This presentation was in response to questions from the BSC regarding risk communication. Three-quarters of communicators in OPHPR are found outside of the Communications Office. Communication encompasses communication basics which uses the web, metrics, products, and literacy. Dissemination takes into consideration platforms, partners, and connections. Strategic position looks at the audience, message, and relevance. Lastly, research and evaluation requires listening, testing, analyzing, and applying.

The Public Health Matters Blog is connecting and driving content beyond OPHPR. There were some specific questions that surfaced with regards to preparedness. A campaign was launched called the Power of Preparedness and took place in September 2016 during the National Preparedness Month. There were several things learned from the campaign such as:

- Preparedness connects
- Content counts
- Human interest sells
- Creativity matters
- It must work locally
- It needs to be ready when we need it

The question still to be answered is, "Is preparedness communication working when it comes time to respond?"

CDC's mission is to prevent, detect, and respond. It accomplishes its goal through a number of mechanisms such as guidance and communications; epidemiology and surveillance; global health; vector control; laboratory and diagnostics; and state and local partnerships. Communication underlies all of these components.

The world is facing a unique emergency, Zika. There are many challenges that are different from any emergency CDC has been asked to respond to in the past. Zika has caused a new wave of children being born with birth defects in U.S., Puerto Rico, and elsewhere. Vaccines are still years away for Zika. Testing is critical to understand the birth defect links better and there's much more to learn. Zika has proven to be the most complex communication challenge ever for the agency.

Building capacity requires coordinating with partners, reaching key groups, and handling the flow of information learned or received. While building, CDC has to be flexible and able to adapt while in the midst of a response. The agency cannot afford to wait until it has all of the information with accuracy, but must convey what it knows at that moment with transparency: Communications should state what is known, thoughts behind the information, and how the community should respond based on the information it has. Also, when communicating, CDC must remember that the loudest voices heard at the beginning are often not the ones that should cause the greatest concern. It's often the ones that are not heard from that should be the most critical, like vulnerable populations.

Using Zika as an example, the communication goals were as follows:

- Priority audiences
- Information access
- Help people understand Zika transmission
- Audience monitoring
- Work with partners
- Help governments respond

In an emergency response, data should be used to improve the strategy. Recommended approaches include:. Use convenient, ad-hoc info sources to learn what people know and don't know. Track message uptake and behavior change in real-time. Add or revise tactics, channels, spokespeople, and messages. Update and reinforce through channels, news media, and partners. As the response evolves and more is learned, address gaps with targeted messaging. Some of these efforts will require some external support and funding to complete.

Another suggestion for risk communication is to pinpoint gaps in the audience. Message testing has indicated that people want information from credible and trustworthy sources like healthcare providers (HCPs). For example, studies show that only 54% of survey participants got information from HCPs about Zika. Increased clinician outreach frequency and modalities after surveys showed only OB/GYNs understood the guidance, but other disciplines did not feel comfortable giving out the information.

During Ebola, it was assumed that healthcare clinicians carried the same thoughts and values as CDC when it came to Ebola. At CDC, when an epidemic hits the agency runs to aid, but that is not always the sentiment of clinicians. It was found that doctors and nurses who didn't feel they were adequately trained to deal with Ebola experienced fear, and for some, withdrawal. Therefore, it's important to continually measure the strategy for effectiveness.

Continue to check on message uptake. Real-time analysis can be instrumental. For example, 90% of individuals know Zika is spread by mosquitoes, but only 68% know Zika can be sexually transmitted. Some early results to the Zika paid-advertising campaign were shared and were as follows:

- Knowledge:
  - Exposed groups more likely to know Zika causes microcephaly (87% vs. 80%), is transmitted sexually (68% vs. 60%), and that travel advisories are in effect (64% vs. 60%)
- Actions:
  - Exposed groups report they are more likely to take action, e.g., cover up, and remove standing water
- Outcomes:
  - Fewer pregnant women infected in early targeted areas (3.5%) than in later targeted areas (7.6%)

The government feels that when there is fear it has failed to adequately communicate, but actually fear is natural and can be used to aid communication. The goal is to not allow people to panic. Take the fears and channel them into protective action, which gives society a sense of control and empowerment to protect themselves and others. Fear cannot be exterminated. The steps to take in crisis and emergency risk communication are to be first, be right, be credible, express empathy, promote action, and show respect.

The importance of engaging the community cannot be overstated. Engage the community before it leads to rumors, misinformation, or distrust. Communities can be very helpful in risk communication but often are overlooked in the communication strategy. Communication strategies should include individuals at all kinds of levels in the community. For some communities, it's not what is said but what is heard. In these cases, the community may have to do its own work to fix this situation. If CDC being a part of the communication causes distrust, it may need to remove any of its branding just to ensure that the message is communicated and uptake occurs.

Media can be a challenge to communication. Everyone lives in a media village. Thanks to technological advances, when a person clicks on a media outlet, from then on, the media provided is tailored to the individual. As a result, people may think they are receiving limited types of information because other perspectives are being left out of the information they have been provided.

Another problem is "fake news". This is increasingly being seen on social media. It can cause some challenges to CDC if they are quoted in one of these stories and cited incorrectly. It's important that CDC gets the facts out quickly to counteract the effects of fake news. Communication has to be an investment and supported in the system to be effective.

The presentation ended with action questions to the board. From the discussions over the last two days, what are one or two things OPHPR can do now to field-test ideas and its funding opportunities around communication?

Recommendations/Comments to Communications:

- There are a group of people in this country who are not a part of the larger media communication ecosystem. These people don't use the internet. This falls under information segregation. The assumption is that they have cell phones but even the cell phones can become disconnected or their hardware is very outdated. So, access to information and the process of accessing the information can be a barrier. These groups need to be studied. They are called "hard to reach" but should be thought of as "the hardly reached." This is an area of research that is worthy of investment, and this group is disproportionately challenged with other issues.

- Another issue is utility and reach. To reach a larger audience, what can be conceptualized without losing the utility of the message? What is the quota limit of the message that must be adhered to and what part can be changed to tailor it to different audiences?

- A lot of the ability to know who your stakeholders are could be found in data from your databases.

- Some healthcare providers become irritated by patients who came in knowing more than them about their condition and how to test for their condition. So, how do we efficiently give information out to the healthcare providers and ahead of the public? It would be nice to have some help in research in that regard.

- Rally resources to connect people and efforts on approaches that make the most sense. Focus on at risk populations through vehicles that work for that audience, like the faith community, social organizations, and neighborhoods so that you can reach a more granular level.

- Zika coverage is everywhere. Communicating with creativity is important. The zombie apocalypse preparedness campaign from CDC was very effective at gaining people's attention. Perhaps you could employ more campaigns like the zombie apocalypse to other emerging health threats.

- There is a misunderstanding of what public health is. Be sure to keep restating the overall value of public health, what it is, and what it isn't in your communication strategies.

- It would be helpful to document the communication efforts around vector control and spraying for mosquitoes in Puerto Rico. What were the communication objectives? How were they addressed? What worked? What might be improved?

Public Comment Period

There were two individuals who had comments for the public comment period. Sandy Steiner is the Scientific Clearance Official for the OPHPR. She expressed comments to Dr. Edwin regarding the dissemination of the annual report. In addition to having it posted on the website, consider releasing the information as an MMWR supplement every year to increase dissemination and transparency of the program's work. The second comment was for the PHEMCE. The advisory committee being built is from the ground up. There are some models that were utilized in the past that should be considered. She highlighted the Advisory Committee for Immunization Practices. Their model, in terms of rigor, is very good and allows for presentation of evidence-base, review of the data, voting, and recommendations. This may be something that can be pursued in the future. Another suggestion is to use the model that BARDA uses with the FDA for biological and new drugs that come to the market. Their system is more closed and focused but it does allow external SMEs to contribute to the committee's work.

Vincent Hill, from CDC'sss Waterborne Disease Prevention Branch, has worked on water-related emergency preparedness. Crisis and risk communication have been a huge part of those efforts. The branch is currently responding to an outbreak around shigellosis so risk communication is critical to its work. The branch has been funded by PHPR to complete a project focused on developing risk communication tools around water emergencies for local and state partners. He asked that the division continue to work on practical tools that help local and state stakeholders. It also is important to maintain technical expertise and capacity around water emergency preparedness and improve communication channels.

Meeting Recap & Evaluations, Action Items & Future Agenda
Samuel Groseclose, DVM, MPH; Associate Director for Science, OPHPR

The board utilized a new process to capture immediate evaluation responses before closing comments were given.

RADM Stephen C. Redd, MD; Director, OPHPR

Dr. Redd thanked everyone for their participation. The input will continue to help CDC improve its work. He encouraged continued input on every aspect of the meeting, including logistics. He also expressed agreement at Dr. North's comment and will find new ways to bring the mental health work more into the area of emergency preparedness. The work to follow is critical and OPHPR will continue to hone in on recommendations put forward from the board. Dr. Redd promised to provide a high-level turn around on the main takeaways of the meeting and looks forward to more meetings and interactions with the board.

Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby observed that the last few years the engagement has increased and those who host the meeting are assuring the BSC that core issues are being brought to the board. He asked that the board be specific in its observations, recommendations, and reflections. He suggested that more time should be left for discussions going forward and emphasized the importance of pre-reading the material so that there will be enriching discussions.

With no other comments, the meeting was adjourned at 2:47 PM.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the December 14-15, 2016 meeting of the OPHPR BSC are accurate and complete.

February 7, 2017 _____/S/_____

Date 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 – December 14-15, 2016

NAME	AFFILIATION	DAY 1 (December 14, 2016)	DAY 2 (December 15, 2016)
Inglesby, Thomas	Chair and SGE	In person	In person
Brandeau, Margaret	SGE	In person	In person
Bernheim, Ruth	SGE	Phone	Phone
Mitroff, Ian	SGE	Phone	Phone
McKinney, Suzet	SGE	In person	In person
North, Carol	SGE	In person	In person
Wooley, Dawn	SGE	In person	In person
Viswanath, Kasisomayajula	SGE	In person	In person
Alonzo Plough	SGE	In person	In person
Brent Pawlecki	SGE	In person	In person
Bradley Dickerson, DHS	Ex Officio	In person	In person
Jack Herrmann, DHHS	Ex Officio	In person	In person
Wireman, Jodi, DoD	Ex Officio	In person	In person
Christina Egan (APHL)	Liaison	In person	In person
Christina Pacheco (TEC)	Liaison	In person	In person
Marissa Levine (ASTHO)	Liaison	In person	In person
Michele Askenazi (NACCHO)	Liaison	In person	In person
Patricia Quinlisk (CSTE)	Liaison	In person	In person

APPENDIX C: ACRONYMS

AAR After Action Report
ABSA American Biological Safety Association
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
CONOPS Concept of Operations
CRC Community Reception Center
CRCPD Conference of Radiation Control Program Directors
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
DRMU Deployment Risk Mitigation Unit
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
FESAP Federal Experts Security Advisory Panel
FOA Funding Opportunity Announcement
FRO Financial Resources Office (CDC)
FSAP Federal Select Agent Program
FTAC Fast Track Action Committee (on Select Agent Regulations)
GAO Government Accountability Office
HCW Healthcare Worker
HIT Health Information Technolog**y**
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
NASEM National Academy of Science, Engineering, and Medicine
NCEH National Center for Environmental Health
NCEZID National Center for Emerging and Zoonotic Infectious Disease
NCHS National Center for Health Statistics
NCIRD National Center for Immunization and Respiratory Diseases
NIHB National Indian Health Board
NIH National Institutes for Health
NSSP National Syndromic Surveillance Program
NSTC National Science and Technology Council
OAR Office of Applied Research (OPHPR)
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)
OSTP Office of Science and Technology Policy
PAHO Pan American Health Organization
PAHPA Pandemic and All-Hazards Preparedness Act (PL 109-417)
PERRC Preparedness and Emergency Response Research Center
PHEP Public Health Emergency Preparedness
PHPR Public Health Preparedness and Response
RO Registered Official
SAR Select Agent Regulations
SGE Special Government Employee
SRA Security risk assessment
STLT State, Tribal, Local or Territorial
TEC Tribal Epidemiological Center
TFAH Trust for America's Health