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

SUMMARY REPORT / RECORD OF THE PROCEEDINGS
APRIL 11-12, 2016
ATLANTA, GEORGIA

Table of Contents

Monday, April 11, 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 10:05 AM. After welcoming those in attendance, he started the meeting by thanking OPHPR for the vast amount of work undertaken to prepare for the meeting. He felt the agenda was very compelling with lots of opportunities for exchanging ideas.

He also thanked OPHPR for gaining answers to additional questions from the BSC that arose since the last meeting. He felt it was a productive new mechanism to address questions that were not able to be touched upon due to time constraints at the last meeting. Reactions to comments received from OPHPR will be addressed in this meeting as well.

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 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 form should be completed and returned. Members were asked to identify any conflicts of interest. Dr. Tom Inglesby has research grants and contracts in the areas of hospital and emergency preparedness, Ebola, Hurricane Sandy preparedness and community resilience, but was not sure if those would qualify as conflicts of interest. Dr. Viswanath has a grant through the Association of Schools and Programs of Public Health (ASPPH) on emergency preparedness. No other conflicts of interest were indicated.

The Board was updated on changes to its membership. Two new members were welcomed to the Board: Dr. Dawn Wooley and Ms. Rita Kelliher, Liaison Representative for ASPPH. Members were informed that Dr. Sally Phillips is now representing Assistant

Secretary for Preparedness and Response (ASPR). Richard Reed has resigned due to his transition to a new job outside the U.S. OPHPR thanks Mr. Reed for his service to the Board. There are two current vacancies and packages are being reviewed by Health and Human Services (HHS). It is anticipated there will be three more vacancies by the end of the calendar year. Packages for those positions are being prepared as well. Members were asked to submit recommendations of individuals to fill those positions.

Several observers and CDC staff attended the meeting and provided introductions.

OPHPR 2016 Priorities

OPHPR Updates from October 2015 BSC Meeting
RADM Stephen C. Redd, MD; Director, OPHPR

Dr. Redd outlined the issues that OPHPR is currently working on as well as the tasks they would like to accomplish.   There are three priorities. Two are related to response: 1) to respond as close to perfect as possible when activated, and 2) ensure we are prepared to respond to future emergency events, while always improving OPHPR's practices. The third priority is to work through partnerships.

As it relates to response, about a month ago, CDC was activated for four responses, which is record breaking. Polio eradication efforts have been an ongoing response effort for several years and total eradication is quickly approaching, but a barrier to achieving this goal are cases where the vaccine reverts and causes paralysis. Research continues to overcome this challenge.

OPHPR is assisting HHS and our National Center for Environmental Health with the response to contaminated water in Flint, Michigan. ASPR/HHS is the lead federal agency for the response. The issue has proven to be the most complicated response so far. CDC's role is to study the science in lead poisoning. What makes the work challenging is the coordination of the different levels of government.

Ebola has been CDC's longest activation, now over 630 days. There is no longer widespread transmission but there have been cases, which are usually caused by sexual transmission. CDC has completed intense work in Guinea and Liberia, which is a benefit. Work will probably continue in these countries for some time. Lessons are still being learned as well as ways to avoid an outbreak like Ebola in the future.

The Zika response has resulted in almost all Centers/Institutes/Offices (CIOs) of CDC working together on a response effort. It has caused collaboration between divisions that have never worked together. Similar to Flint, MI, the populations most affected are those of lower socioeconomic status.

He also reviewed some other activities that are occurring that will help to improve OPHPR's response efforts. The after action reviews are being used to identify areas of

improvements. Incident manager training will ensure that persons leading a response are better equipped. A couple of weeks ago a "dress rehearsal" exercise was completed for the Incident Manager role.

For the Global Health Security Agenda, there are two specific areas being examined. The first is the Joint External Evaluation, which is an internal domestic assessment. It defines the U.S.' capabilities to respond. In late May, a separate group will do an external evaluation as well. A score will be given. The plan is to have a three to five year reevaluation in the future. The second is the emergency operation center development (facility and systems). Over the next one to five years, CDC will be working in 17 Phase I countries. A timeline has not been established for the 15 Phase II countries and a few other selected countries.

Medical countermeasures (MCM) work includes discovering new ways to ensure product is delivered in a timely manner during an event or response. There's been enormous progress in evaluating state and local capabilities through the Operation Readiness Review. More information on impact measures were to be covered in a presentation later in the agenda.

The Select Agent Program was undergoing a 90-day review in late October 2015. Since that time, a progress report has been published on the 90-day review and the work that has occurred has been impressive. The Select Agent Program is more of a preventive program versus the other programs of OPHPR which are to detect and respond or respond and prepare to respond more effectively.

OPHPR has worked to improve its partnership efforts by ensuring that it responds as a unified entity. Partnerships will strengthen the team camaraderie and effectiveness during responses. The various leaders that have come to OPHPR have afforded the office to garner different perspectives and further enhance its processes.

OPHPR also continues to work on its partnership with the U.S. Food and Drug Administration (FDA) and ASPR. Dr. Reed recently visited the FDA and identified more areas where CDC and FDA can collaborate. The office has also worked with the Department of Defense (DoD) and the Department of Homeland Security (DHS) through the Office of Health Affairs and the Federal Emergency Management Agency (FEMA). These interactions have helped the office gain a better understanding of the cultures of other agencies.

In the private sector, with both Ebola and Zika, there has been substantial engagement mainly through the CDC Foundation. The Ebola response highlighted how critical the private sector contributions were, particularly at the beginning of the response, when there was no funding. Some of those same contributions are now occurring with Zika or in other cases where funding is not available.

Interval Updates – OPHPR Division Directors

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

The DEO was built on a model that assumed occasional response activities with time in between each response for process improvement. Since the world has changed significantly, DEO has had to renovate its processes. Due to the increasing number of activations, there has been considerable revamping of structures, processes, and practices.

As indicated by Dr. Redd the four responses that have run concurrently in 2016 have been Ebola, the polio eradication campaign, Zika, and the Flint, MI water crisis. The security situation in Afghanistan and Pakistan remains tenuous. In the last six months, in some areas of Pakistan, the polio eradication vaccination clinics and campaigns have been soft terrorist targets by militant factions. This has become a barrier to responding to polio in Pakistan and Afghanistan.

The Flint, MI water crisis is politically, socially, and economically charged. The expectation is to garner lessons at all government levels. One of the early lessons learned was the need for state and local public health departments as well as state and local emergency management agencies to know how to respond in the traditional Stafford Act fashion. He suggested putting structures together for a non-Stafford Act response as close to those that state and local government are familiar with to ensure better responses in the future.

There have been some recent issues to arise with Ebola within past few days. There was a patient who came into the United States and thought to be linked to current outbreaks in Liberia and Guinea. Thankfully, this individual tested EBD negative and tested positive for malaria. There are 50 CDC staff that still remain in Africa so significant support continues to be provided.

The Zika response has proven to be an unusual one for CDC. There's no certainty as to how long the response efforts will continue. The vector cannot be eradicated globally or in pockets where there is active transmission; therefore, it is an issue that DEO will probably work on for months to come.

Because so many activations happened simultaneously, DEO had to set up an emergency operations center (EOC) at its Chamblee Campus in a conference room. It took five hours to transform the designated space, which includes 30 work stations. There have been six full-time DEO staff assigned to support the activities. The expansion will also allow key chief information officers (CIO) to remain on the main campus. This is another example of DEO's alternate response model, which had been utilized twice in 2015.

There are three new DEO teams that were institutionalized due to lessons learned. The Medical Investigations Team and the Deployment Risk Mitigation Unit (DRMU) were

formed due to lessons learned during in the Ebola response. The third team is the Incident Management Training and Development Program.

At this time, the majority of calls taken by the Medical Investigations Team pertain to Zika but there are still some calls regarding Ebola and persons under investigation. The team is multidisciplinary and shifted seamlessly from Ebola to Zika response. The chart below is raw count process chart, but it illustrates event-based encounters, not the multiple follow-up calls required to gain resolution.
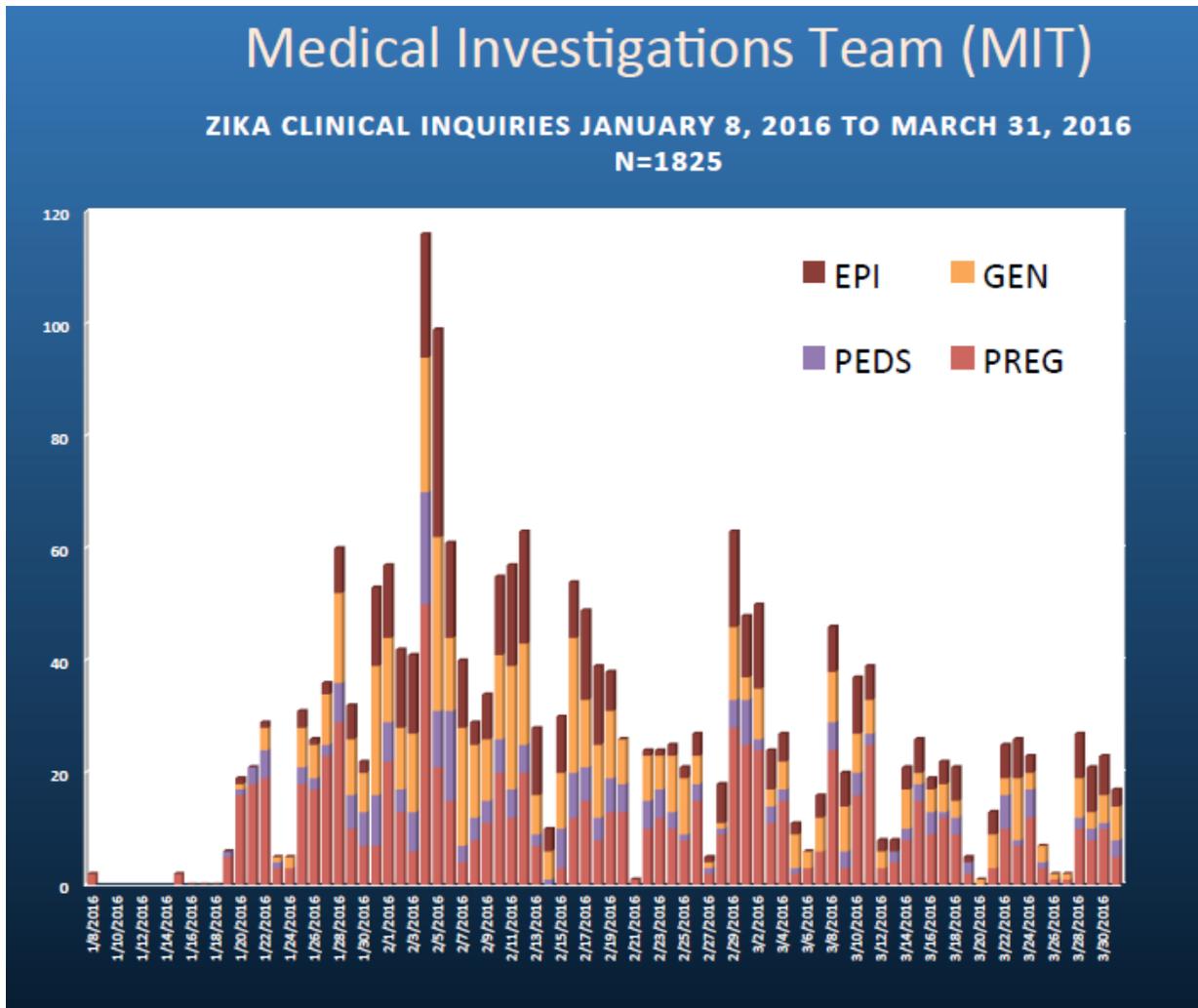
Figure 1: Zika Clinical Inquiries January 8, 2016 to March 31, 2016.

The Incident Manager Training and Development Team is still in its infancy. The Module 1 Curriculum was delivered on March 22, 2016 to selected senior CDC leaders for vetting. The curriculum pertains to how to start Incident Management System (IMS) response efforts. Real-time polling allowed DEO to gain instant feedback on the module. Three questions were asked around the following statements:

1. I feel more confident in my ability to start a CDC IMS response
2. Training materials and the case study were appropriate to teach key concepts
3. Module content will be relevant to future CDC response roles

To statement one, 88% said that they agreed and 8% said that they strongly agreed. To statement two, 38% agreed and 62% strongly agreed. To statement three, 49% strongly agreed, 38% agreed, and 13% were neutral.

Module 2 is being created. The curriculum will teach crisis leadership decision making. The intent is to pilot the module in June 2016.

The DRMU monitors Zika deployed staff on issues such as fatigue and stress to ensure the safety, welfare, and effectiveness of deployed staff. Response Evaluation teams have been embedded in each primary taskforce to assist in contributing to the work of the taskforce as well as evaluating the processes. They also help to build rapport and put context around observations. The goal is to take after action reports to a higher level compared to past responses. Gaining access to process evaluation findings during a response paints a real-time story of an activation and allows mid-course correction.

Recommendations from the BSC to the DEO were as follows:
➢ In the Flint, MI water crisis, the public has been complaining for some time about water quality issues but were not taken seriously. I suggest creating a mechanism for incorporating complaints and feedback from the public and ways to take those issues and present to the agencies that can help address the concerns.
➢ Consider taking incident managers who are not currently involved in a response and let them participate in a state level response to further sharpen their skills.
➢ It would be helpful to tabulate lessons learned via the type of incident. Then determine the mechanisms within the organization that can compile those lessons and follow up with the degree of implementation.
➢ Use model organizing devices to determine where the organization is overall, what is being done well and what needs to improve and assign a systematic score.

Dan Sosin, MD, MPH; Acting Director, Division of Select Agents and Toxins

In the past six months, there have been a number of important activities within DSAT. The division has undergone an internal review at CDC and two White House reviews. It has prepared and published the Notice of Proposed Rulemaking for the biennial review of the select agents and toxins list. The division has also issued policies and guidance as well as convened subject matter experts (SME) and spent 9 months working with interagency toxin experts to address how DSAT oversees toxin safety and security. This work led to changes seen in the Notice of Propose Rulemaking, which may play out in the final rule this fall. All of these activities were completed, while conducting daily routine functions of the division to ensure the safety and security of work with potentially dangerous biological agents and toxins.

At the close of 2015, 251 FSAP entities registered with HHS/CDC. DSAT conducted 167 select agent inspections of the 251 entities. It has also conducted 34 import permit inspections, and issued 1,899 import permits.

Year to date, through April 1, 2016, DSAT's Select Agent program now has 250 entities registered. It has received 2 new entity applications and withdrawal requests from 3 entities, which tend to be public health labs, who are no longer able to maintain the requirements. DSAT has also conducted 39 inspections, which included 15 announced and 24 unannounced.

The Import Permit Program has processed 728 permits and approved 633 permits. This includes 74 permits that were expedited for the Zika virus. It has also conducted 11 announced inspections.

In terms of enforcement/registration actions in the past six months, there were no applications denied or revoked as it pertains to administrative actions and one registration suspended. Moreover, there have been no referrals to HHS IG. There were four referrals to FBI pertaining to inventory discrepancies and shipping related issues or occasional whistleblower incidents. In those incidents, the FBI found no criminal intent.

DSAT is using the Corrective Action Plan (CAP) approach more frequently. Currently, three entities have completed a CAP, and six entities are currently participating in the program.

In October 2015, three sets of reviews and recommendations were released, all designed to strengthen the federal government's biosafety and biosecurity practices and oversight. One was an internal CDC 90-day review. The other two were federal-level reports ordered by the White House: the federal advisory panel, Report of the Federal Experts Security Advisory Panel (FESAP) and external experts, Fast Track Action Committee on Select Agent Regulations (FTAC-SAR).

DSAT has identified four areas to place emphasis on: improving entity oversight, including facility inspections and inspection reporting; improving customer service; improving incident response; and increasing transparency and engagement. Below are key achievements made to each of the areas:

- ➢ Oversight/Inspection Process
  - o Enhanced training to departures from practice requiring most judgment
  - o Tracking timeliness - intent to release annual reports
  - o Issuing interim inspection reports
  - o Auditing inspection reports
  - o Developing clear and consistent standard language
  - o Studying violations to align with risk and consequences
  - o Spectrum of severity for violations and enforcements
  - o Piloting risk scoring of inspections

- o Commissioned study on biosafety risk assessment and alternative regulatory models
- o Convening experts regarding high-risk procedures
- o Addressing inventory control concerns/clarifying policies

- ➢ Customer Service
    - o Regulatory interpretations
    - o Comment period preceding issuance of new policy
    - o Inspection feedback survey
    - o Dispute resolution process for inspection reports
    - o Regulatory Officer training
    - o Improving and enhancing guidance documents
    - o New electronic information system in development queue

- ➢ Incident Response
    - o Emergency operations/ensure adequate response capabilities
    - o Form 3 update to clarify theft/loss/release reporting requirements
    - o Reporting results and clarifying terminology

- ➢ Public Transparency and Engagement
    - o Annual public report (aggregate data)
    - o Deliberative security review process for information release
    - o International engagement to encourage related programs
    - o Supporting routine information-sharing among peers

A suggestion was given in the last presentation to find ways to take public concerns more seriously. When it comes to select agents and toxins, there is an area of unfamiliarity, which causes fear and apprehension not only about the agents and toxins themselves but also those charged to work with them. This is a challenge and DSAT welcomed the Board's perspectives on ways to communicate more effectively to society in that regard.

Recommendations from the BSC to DSAT were as follows:
- ➢ In addition to tasking law enforcement to be the holders of the select agent entity list, cleared personnel from health departments should be added. In addition, the FDA has a model for executing confidentiality agreements and possibly this model could be considered for CDC as well.
- ➢ Organizations that want to gauge advancement have a timeline with measures of what it is doing well and not doing well. In each area of concern, determine what has been proven the most difficult to implement and goes furthest against the standard operating procedures. These indicators should be presented in future meetings.

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

Ms. Kosmos' presentation focused on DSLR's accomplishments, key challenges, and overarching strategic activities moving forward. DSLR desires to frame the PHEP program impact as a set of key accomplishments that have occurred since 9/11. This will allow OPHPR to begin to speak in one voice and chart a path forward that supports key activities of state and local public health.

To accomplish this goal, DSLR has worked closely with the Association of State and Territorial Health Officials (ASTHO) to categorize accomplishments since 9/11. Six accomplishments were identified and they are as follows:

➢ Established state and local public health emergency management expertise and trained first responders to mitigate the health effects of public health threats.
➢ Instituted public health emergency management structures in all 50 states and selected local and territorial public health departments capable of leading or supporting public health responses.
➢ Sustained a nationwide system capable of rapidly distributing and dispensing lifesaving medications and emergency medical supplies to the public.
➢ Maintained nationwide laboratory and epidemiologic surveillance systems capable of faster detection and identification of public health threats.
➢ Strengthened the ability of our nation's communities to prepare for, withstand, and recover from public health threats.
➢ Integrated public health in emergency responses and, in collaboration with partners, leads and coordinates the public health and healthcare sectors.

A communication strategy has been developed called Speak with One Voice. In the strategy, PHEP program accomplishments will be packaged for various audiences. A toolkit website, which will be launched next month at the National Association of County and City Health Officials (NACCHO) Preparedness Summit, and other products are in development. Below is a graphic that communicates the intent of the strategy.
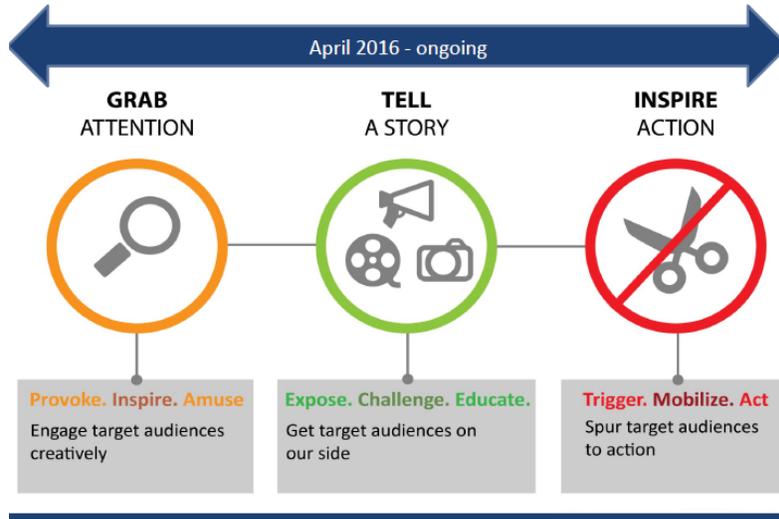
Figure 2: Speak with One Voice Strategy.

In regards to state and local MCM planning, the goal is to improve capacity and capability to warehouse, store, distribute, and dispense medical countermeasures. In order to achieve this goal, DSLR is conducting state and local readiness assessments, providing targeted technical assistance, and placing medical countermeasure experts in the field. The DSLR MCM Operational Readiness Review process is now underway, and is collecting baseline data in approximately 500 state, local, and territorial jurisdictions across the nation. The reviews should provide a clearer readiness snapshot for these jurisdictions.

To improve operations, DSLR has undergone several organizational changes. One is the formation of the Capacity Building Branch, which is tasked with generating technical assistance strategies. Areas of particular concern are healthcare system response and public health system improvements. This branch is led by Dr. John Beltrami.

The Emergency Management Unit has also been formed to coordinate DSLR's response role. Once the EOC is activated, DSLR transitions into the State Coordination Taskforce, while also conducting its normal DSLR activities. This taskforce has been continuously activated since the Ebola response. There are four staff members on the Emergency Management Unit and they have been helping to lead the Global Health Security Agenda/Joint External Evaluation Independent Assessment.

Dr. Ernest Smith is the MCM Senior Clinician. His role is to develop state and local operational guidance for SNS assets.

Lastly, the Program Coordination Office is implementing the Public Health Emergency Preparedness (PHEP) program review recommendations. In this capacity, the office has completed development of new PHEP requirements for the FY 2016 continuation guidance, developed project plan for informatics field assignee pilot, and coordinated

work group activities to design new PHEP requirements for the FY 2017 funding opportunity announcement. This office is led by Mr. Todd Talbert.

There are many challenges, or opportunities. One is to maintain program momentum while in response mode. During the 2014 Ebola response 160 DSLR staff members assisted with response efforts; a total of 94,673 hours were dedicated to the response between July 9, 2014 and March 31, 2016. In the 2016 Zika Virus response, there have been 84 DSLR staff dedicated to the effort. Their total hours devoted to the response between January 22 and April 6 was 15,022.

An ongoing challenge is funding. Even though there has been an increase in DSLR participation for various events, there has not been an increase in funding. DSLR continues to try to advance state and local preparedness progress despite the $44.25 million PHEP funding reduction.

Some of the activities for DSLR moving forward are to design a next generation PHEP program for the new PHEP funding opportunity announcement for 2017-2022. The division will work with CDC programs to develop targets for informatics, epidemiology and surveillance, laboratory testing, and healthcare system response. Lastly, DSLR will continue to build its state and local MCM planning portfolio.

Recommendations from the BSC to DSLR were as follows:
  ➢ A suggested mechanism to deal with malicious employees, whose aim is to cause damage to the system, is to form an internal "assassin" team, who would think about all the bad things that can happen to your system. This is similar to those methods employed for counteracting computer hackers. The team can comprise PhD experts and the average staff member – all trusted individuals that have been thoroughly vetted. The biggest benefit is they've already thought of the unthinkable.

Greg Burel; Director, Division of Strategic National Stockpile

Mr. Burel provided an update on work completed with the Strategic National Stockpile (SNS). SNS is working with the National Academy of Medicine. A standing committee has been created to provide advice to CDC regarding stockpile distribution. Several meetings and a workshop have taken place to discuss opportunities for future collaborations. Mr. Burel recognized that SNS' roles have shifted to an all-hazards approach in the case of responses. In previous meetings with the BSC, SNS asked for suggestions on how to move to a supply chain process and an update will be provided as to their progress on this modification.

There have also been conversations with IOM regarding ways to align biodefense programs to maximize collaboration. SNS is assessing if it is in the right place, working with the appropriate parties, and determining long-term impacts.

In its collaboration with DSLR, SNS has been asked to be more responsive in several areas. One of the areas he highlighted was advance shipping notice. When SNS begins to move product, DSLR would like specific information on numbers of pallets, lot numbers, trucks delivering the products, etc. New York is particularly interested so they have been made the first partner in this endeavor.

SNS has had its first tabletop with its partner, the Biomedical Advanced Research and Development Authority (BARDA), to look at vendor managed inventory (VMI) contracts. Right now, Neupogen is the focus. The partner would like to make operational use of the countermeasures but is weighing the risks of holding product in one particular location, which could be subject to malicious attacks or catastrophic weather events. The exercise was very productive and the focus will now be shifted to a more full scale exercise with some of the VMI holders of products to discover other capabilities and examine ways to mitigate risk around lessening product availability to a smaller amount of locations.

Since the last BSC meeting, SNS has moved the discussion to becoming a supply chain partner. SNS assets are valued at over $7 billion and continue to increase; therefore, there is continuous concern around managing its inventory. It has also been asked to engage in more response needs. SNS is a specialty distributor of medications not available in other outlets and has the ability to influence the supply chain. The ability to influence comes from the products shipped or brought in to help augment its work, replace supply chain in crisis situations, influence what the supply chain does long-term, and how it manufactures, stores, and maintains product.

The Health Industry Distributors Association (HIDA) represents various distributors of pharmaceutical and medical device products. SNS connected with HIDA around Ebola and is planning some tabletop exercises to determine ways for integrating HIDA into response efforts. In the Zika response, SNS was able to reach out to some of HIDA's partners to determine unique ways to handle distribution in Puerto Rico.

SNS continues to work with other industries. The State Department, DoD's Defense Logistic Agencies and others have joined together to determine methods for making homogenous countermeasures for specific events, which will increase strategic buy-in power capability.

The division is also working with the Center for Global Health on the Global Health Security Initiative (GHSI). Countermeasures funded by the Center for Global Health were sent to Ethiopia but the country wasn't prepared to handle cold chain storage of products. Therefore, on the GHSI front, SNS has held workshops on increasing ability to manage products.

SNS has also worked with Rx Response to do webinars that will help states and locals increase their understanding of supply chain and how the division fits in the supply chain cycle. There will be feedback collected from viewers as to the effectiveness of these

efforts on the April 15th webinar. The hope is that this venture will also help in shifting SNS into a supply chain mechanism.

The division worked recently with National Association of Chain Drug Stores to discuss collaboration efforts on the Zika responses. The initial engagement was beneficial and more discussions will occur going forward in becoming partners on other types of responses.

Recently the division has come across some issues that do not fit necessarily in its domain space but they are complementary of other endeavors that it has undertaken. The division is working with CDC at the larger level to determine ways to do work on behalf of CDC for initiatives that accompany the work of SNS, though not technically within its roles and responsibilities.

Mr. Burel said there is also a problem with manufacturing of chemical nerve agent auto injectors in the United States. The Defense Logistics Agency (DLA) is now working with SNS to find different forms of procurement that will fix shortages. More information will be provided on this effort in the next update to the Board.

Recommendations from the BSC to SNS were as follows:
  ➢ There are a lot of gaps at the state and local level around MCM. As DSLR is working on the next PHEP Cooperative Agreement and identifying priority areas, there needs to be strong consideration to identifying best practices among states and locals for MCM distribution and dispensing because they are very different. The best practices should be validated, evaluated, and proven to be best practices. It should be a requirement in the PHEP for states and locals to adopt certain practices. Otherwise, varying gaps will continue to exist. These best practices can be ones that CDC has developed as well as state and locals.
  ➢ For science diplomacy and true international purposes, it seems like OPHPR has a lot to give internationally and more can be completed beyond the Global Health Security Agenda umbrella.

Update on OPHPR Office of the Director
Finance and Budget, Recent Human Resource Efforts, Employee Viewpoint Survey and Action Plan, Information Technology & Communications Portfolio

The afternoon session began with a panel presentation by the following:
  ➢ Bob Ruiz; MPA; Deputy Director, OPHPR
  ➢ Jill Smith; Associate Director for Communication (Acting), OPHPR
  ➢ Jeannie Fox Craig, MHR; Management Officer, OPHPR
  ➢ Dan Tuten, MS; Associate Director, Information Resources, OPHPR
  ➢ Allison Herrington, MPA; Public Health Analyst, OPHPR

Several areas were highlighted pertaining to the current state of OPHPR. OPHPR funding is stable with minor increases to DSAT, PHEP, and DSNS in fiscal year 2016. However, reprogramming is still a concern, which can have a significant impact on the budget. The mission is growing and staff needs are increasing. Communications is improving and OPHPR continues to reach more communities through modern channels. In addition, the IT portfolio needs greater attention, centralization, and modernization, which will require significant capital. Lastly, the organizational atmosphere is good but there is room for improvement.

Several slides were presented related to the OPHPR budget. Funding has been relatively level. Below is a graph that illustrates the funding to OPHPR since its enactment in 2012 to the fiscal year 2017 President's Budget. The second slide shows the segmentation of the funding for fiscal year 2016. The total budget for 2016 is $1,304,872,481. A large portion of the budget, 49%, was used to support the PHEP, $638,822,263. The last pie chart explains the division of funding to PHPR and the National Centers by organization.
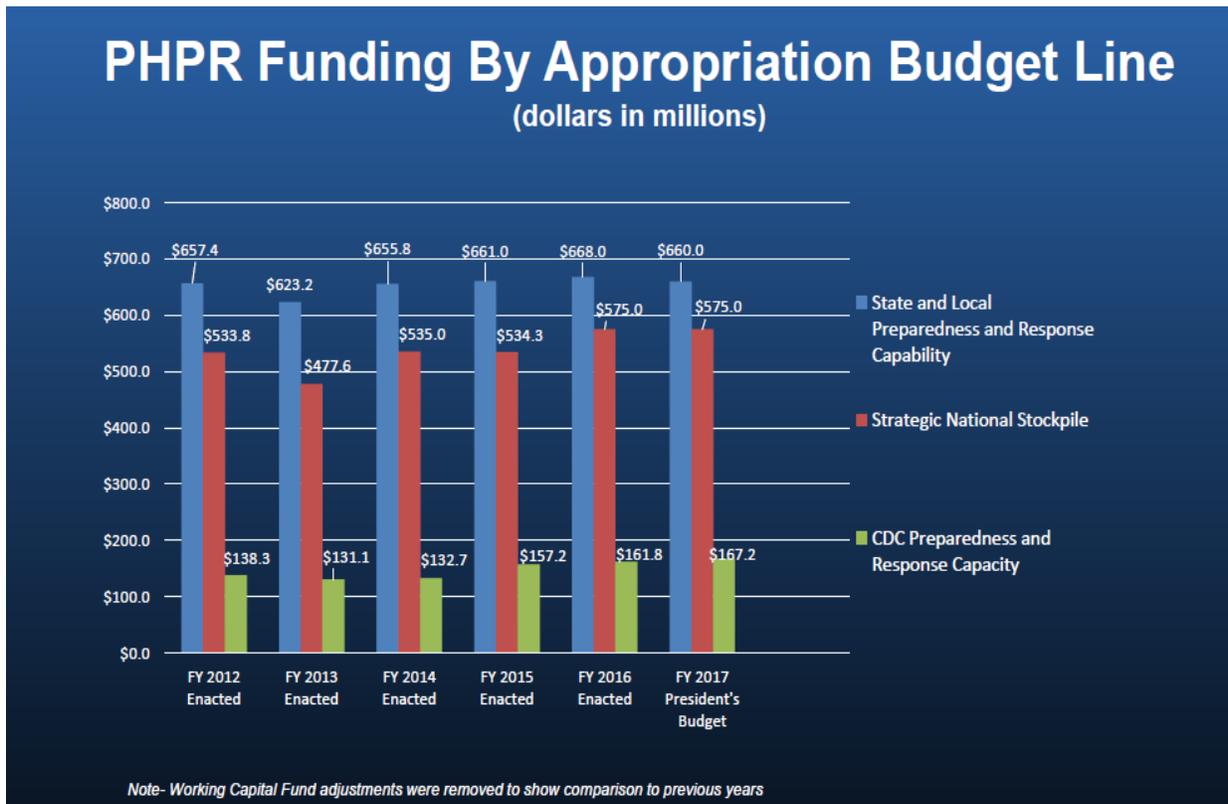

Figure 3: Funding by Appropriation.
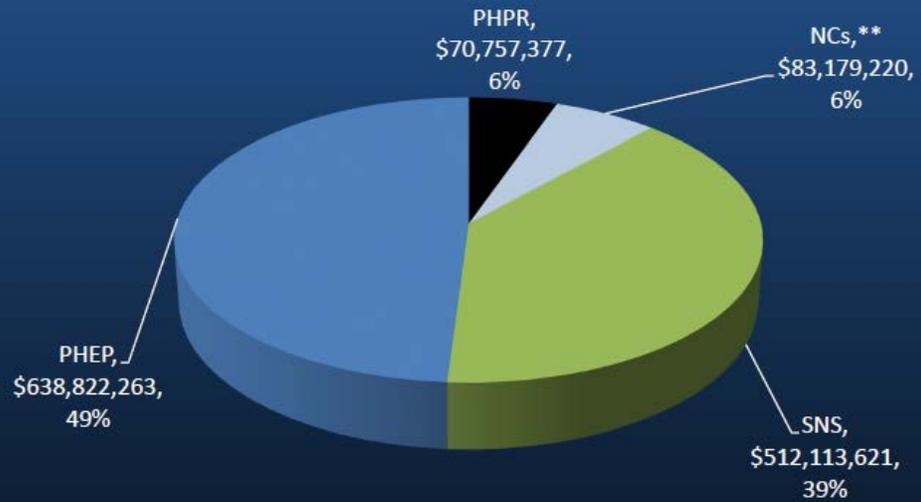
Figure 4: PHPR 2016 Total Funding.
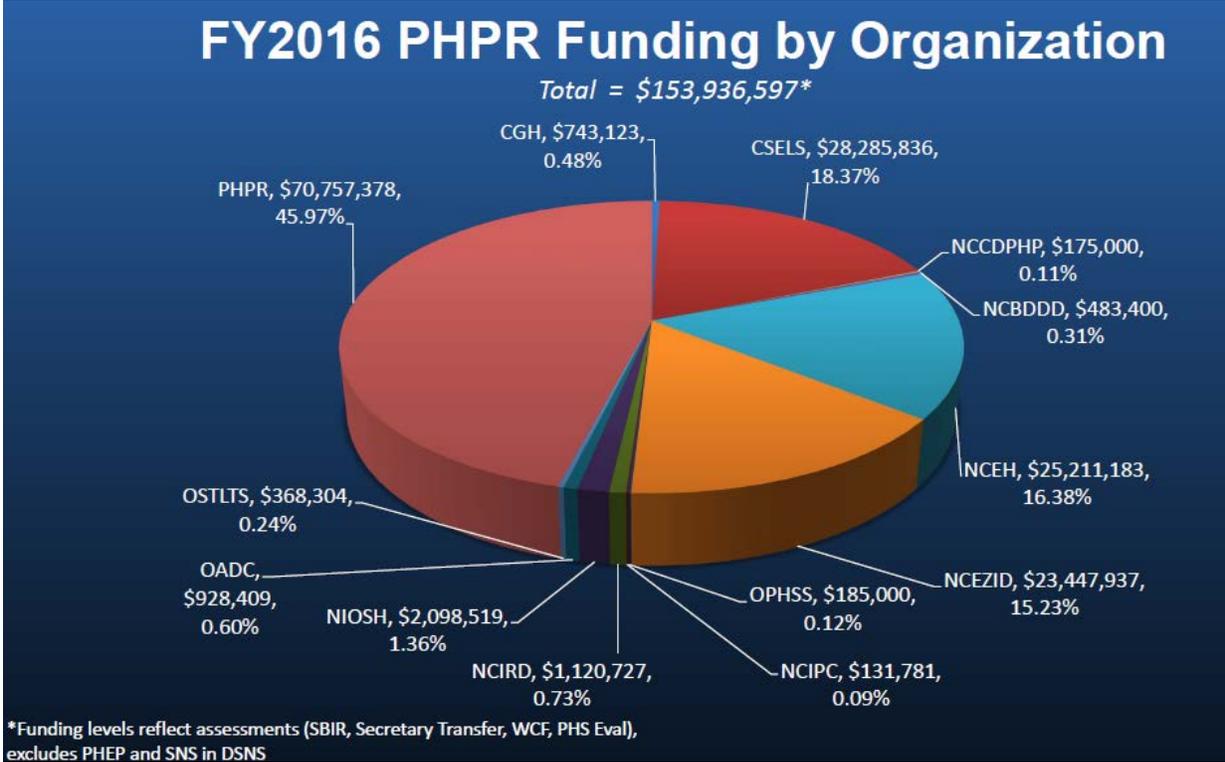
Figure 5: PHPR Funding by Organization for 2016.

Information technology investments: OPHPR utilizes a two-year planning cycle and is currently planning for fiscal year 2018. Investment analysis takes into consideration the alignment to programmatic missions as well the operating efficiencies in the system. Even if an area is aligned with the mission, if an area is not showing impact, funding may be withdrawn and reinvested in another field. Three areas have been deemed highest priority. The primary system for the Select Agents Program over the next few years will undergo modernization. The Strategic National Stockpile's resource system needs to continue to modernize to keep up with current requirements. Lastly, there are a number of extramural IT investments, which are a part of the PHEP grant.

OPHPR's IT program budget makes up 3% of the overall budget to the program. This is in line with industry standards, which normally average 2.5% for public and nonprofit organizations, 5% for healthcare, and 3% for the industries overall. The largest portion of the IT portfolio is laboratory regulation and quality assurance, with the next largest being emergency response support. Internal IT investments are $13,865,048.00 and extramural IT investments, $26,747,000.00.Other components of the portfolio are information systems planning, development, operations, and maintenance; knowledge management and library services; shared informatics services; and risk and emergency communication.

The next topic discussed was **communications**. OPHPR utilizes several channels for communications. Below is a list of the many conduits employed.

- Communication Projects and Campaigns: Ex. Ready Wrigley Prepares for Earthquakes
- Digital and Social Media: Ex. Public Health Matters blog, @CDCemergency
- News Media/Issues Management Planning & Response
- Website, graphics, and video
- Emergency Response - Communication Support: Ex. Ebola communication-infographics & illustrations
- OPHPR Internal Communications Support

Several mini campaigns have been created to engage and educate the public as well as garner creditability. Social media has also been instrumental in connecting CDC to the public. It has one the largest Twitter accounts in the federal government with 1.73 million followers (@CDCemergency). CDC's Facebook account has almost 90,000 followers. There is also a Public Health Matters Blog, which allows OPHPR to showcase it work. There are 45,000 subscribers to the blog.

During activations and emergencies, OPHPR's Communications Office is able to supplement work occurring in the DEO. Communication expertise and surge support are offered in the form of graphics/infographics, the web, social media, and news media responses. OPHPR digital and social media channels are also utilized to inform the public during activations and emergencies. In 2014, the Ebola Twitter Chat was employed. It requires tremendous efforts to gather subject matter experts and talking points, as well as provide Q&A.

Several internal communications are also provided to help divisions learn about each other and the work that is occurring across CDC. Below is a list of internal platforms utilized.
- The Connector Employee Newsletter
- Intranet/SharePoint
- Director's Walk Arounds
- Director's 20 LIVE
- All-Hands Meetings

The Communications Office mission is to increase connectivity to achieve the CDC mission.

The BSC was also informed on a new endeavor to OPHPR. **Operation Dragon Fire** (ODF) is a new technology to OPHPR that will deliver better information to response decisions makers during a disaster. It provides a means to blend and analyze new data sources, such as social media and business data, with traditional data sources.

Operation Dragon Fire is currently in product development and is collaborating with many different organizations across the country to establish a blueprint and create viable products, which will demonstrate the usefulness of the system. Product features are a result of feedback collected from nongovernmental organizations, Voluntary Organizations Active in Disaster (VOAD), local government, and public health. All

software coding is performed by volunteers, who were recruited from "Hack-a-thons" and nongovernmental organizations that focus on technology volunteerism.

On April 14, there will be a live test in San Mateo, CA of the system with the County EMS and on May 24 a virtual test at the National VOAD Conference in Minneapolis, MN. In September 2016, the system will transition to an owner, who will build out the entire technology ecosystem. The owner's name has yet to be announced.

An update was also provided on the **2015 Employee Viewpoint Survey** (EVS) Results. In 2015, OPHPR achieved an 82% response rate on the EVS, with across the board increased participation in the divisions. OPHPR outperformed the HHS participation goal by 12 points and increased 14 points compared to the 2014 results. Overall positive responses increased by three percentage points, to 67%, which is just below the CDC average of 68%. This increase reversed a three-year decline, which started in 2012.

The Employee Engagement Index (EEI) is generated based on responses to 15 EVS items that measure employee perception of leadership, supervisors, and intrinsic work experience. OPHPR reported a four-point gain in 2015 on EEI positive responses and outpaced the CDC-wide gain of two percentage points.

The Results Oriented Performance Culture Index is generated based on responses to 13 items measuring employee perception of performance management, appraisals, and recognition. Results showed 60% positive responses –equivalent to the CDC agency-wide response. The goal is to be at or above 65%.

Additionally, there are some opportunities for improvement. In OPHPR, 30% of respondents said they are planning to leave for another job within one year. This exceeds the CDC average by 12 percentage points. Responses from these same employees were considerably lower on key indexes. OPHPR is analyzing the data to gain more insight. This may require activities such as focus groups to determine more in-depth reasons for dissatisfaction.

A Five-Year Action Plan was designed, in collaboration with approximately 30 staff members across OPHPR, to further improve EVS scores. The plan was constructed using data from 2012 to 2014. Below is a flow chart that illustrates the plan and its three main goals: enhance the performance plan program; improve the recognition program; and improve processes for attending professional development training. Several activities have been recommended to address each goal.
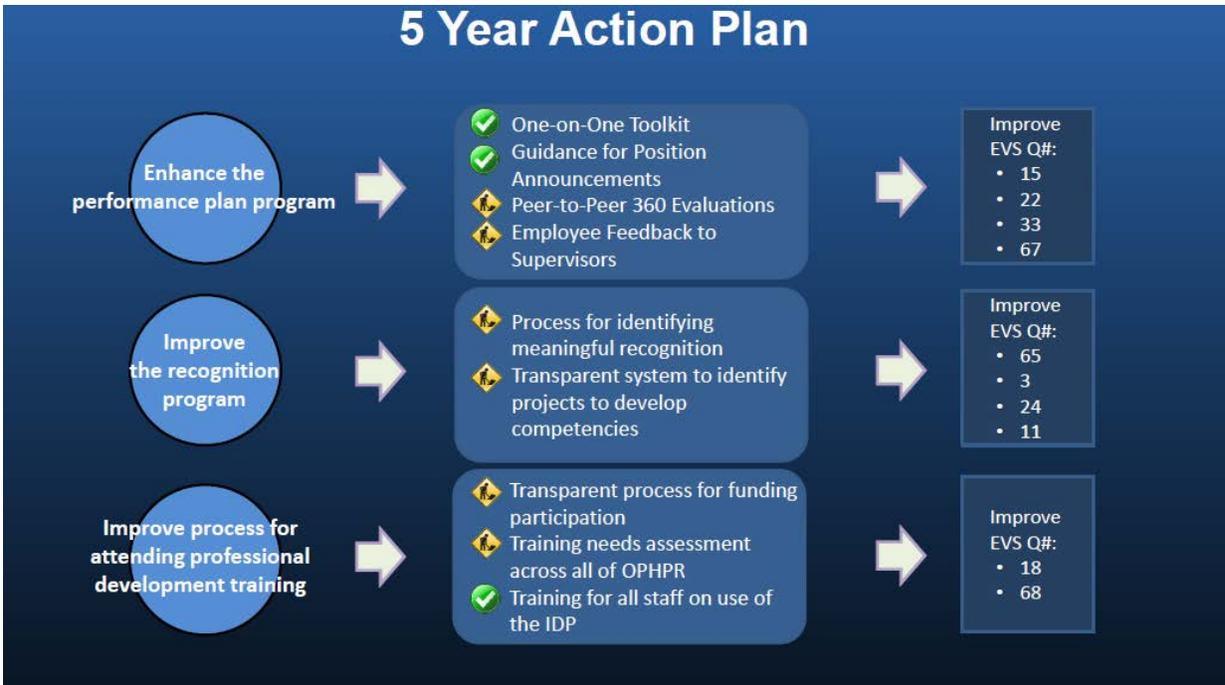
Figure 6: OPHPR 5-Year Action Plan.

Also shared in the presentation was the **Strategic Human Capital Management Plan** and its processes. Below is the Talent Strategy Model utilized for the plan. The model should allow a more granular level of understanding concerning the needs of employees and of the organization. DSAT was the subject of this first review.
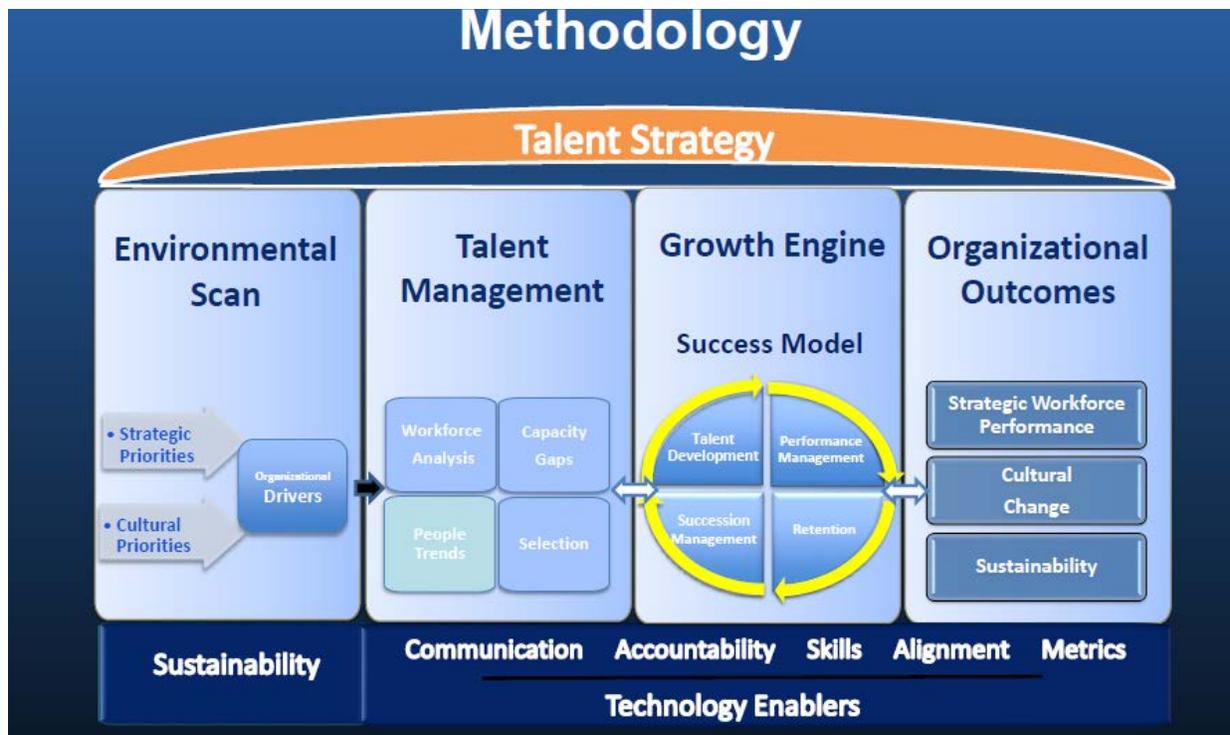
Figure 7: Talent Strategy Model.

The first step in utilizing the model is to determine workforce demographics. DSAT workforce data show that the workforce is diverse by race and ethnicity, gender, disability, and generations, but more recruitment and hiring of Hispanics needs to occur.

The next step was to look at the DSAT Operations Branch GS-403 Microbiologist series. During the environmental scan and interviews, several questions arose regarding grade levels. Therefore, grade level assessments were conducted across the federal government as a whole, CDC, and the Operations Branch. Results indicated that GS-13 positions and higher account for a smaller share of total positions in the Operations Branch, compared to CDC and federal government workforces

In the analysis of educational attainment, the Operations Branch outpaces the federal government average in the 403 occupational series. Approximately 86% of the Operations Branch employees have attained at least a master's degree, compared to 66% of the 403 series nationwide.

The analysis also examined the organization's inspection workload. The purpose was to ensure the correct formula was in place to determine days spent in the field on lab inspections and the appropriate number of staff needed to conduct different numbers of lab inspections per time period. The model was based on number of inspections per year, reasonable number of days for an inspector to work in the field, the number of skilled staff available, and the number of staff members needed to meet different numbers and types of inspections. Below are the models for an 18-month and 12-month cycles.

Figure 8: DSAT Talent Strategy, 18-Month Cycle.

Figure 9: DSAT Talent Strategy, 12-Month Cycle.

Results indicate that the Operations Branch would need seven or twenty-seven more inspection staff, if using the 18-month cycle or 12-month cycle model, respectively. Twenty-seven more staff members will cost the agency anywhere from $2.2 million to $2.3 million per year. This further underscores the need for an increase in DSAT's funding to meet the inspection burden/need.

In summary, OPHPR has clear direction and committed leadership across the Center. Its finances are stable but growth will require careful monitoring. The mission is expanding; therefore, prioritization will be key. Communications are improving but pre-messaging strategies and a broader reach are needed. The IT portfolio is a critical investment under review, and OPHPR will continue work on its organizational climate.

Recommendations to OPHPR from the BSC were as follows:
- ➢ For those individuals who indicated that they were leaving CDC, you should ask the question what would be required or have to change, if anything, to make them stay at CDC.
- ➢ Work on career paths for all employees so if a particular job is not a good fit, the employee could possibly find a position in another part of CDC.

> ➢ Do not try to obtain 100% retention of employees because there are some employees who are beneficial to the agency and should be retained, while other employees should not be retained.

Updates - OPHPR Policy Agenda/Budget Planning/Impact Measurement Initiative

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

Ms. Kathy Gallagher updated the BSC on the IMPACT Project, OPHPR Policy Strategy, Partnership Strategy agenda, and the present state of the budget and congressional interactions.

At the last BSC meeting, several presentations were made around the **IMPACT Project** and the BSC's recommendations were used to structure future efforts, particularly on how to integrate supplementary work. In-depth thought and discussion were undertaken to choose measures to demonstrate preparedness investments; align overarching priorities to IMPACT measures; and create a Dashboard to serve as a tool for decision-making. Additional deliberation was given to determining which tiles in the Dashboard would require greater focus and how to refine the measures in order to better track progress towards goals. For now, the project is used for internal management and prioritization. Creating a public-facing portion to the IMPACT Project may be created in the future.

Below is screenshot of the Dashboard displaying the 2016 OPHPR Strategic Priorities. The red tiles are areas where human and financial resources should be focused to make progress. A couple of tiles do not have a measure identified. Appropriate data is being collected to effectively track those measures. This is an iterative process, so changes may be forthcoming.
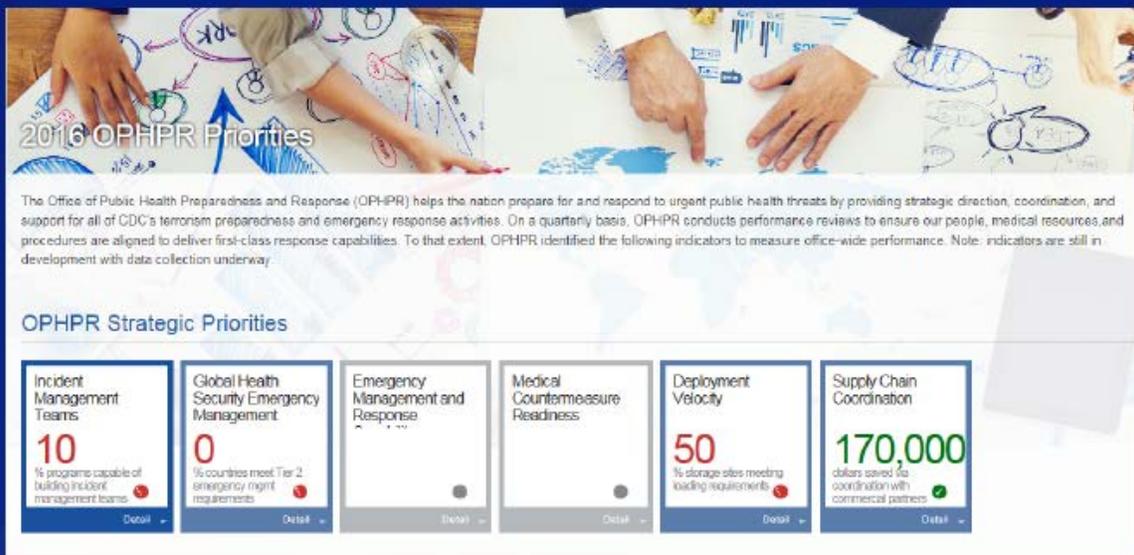
Figure 10: Example of Dashboard for OD.

The Dashboard also includes a breakdown for each division.   Each division has anywhere from six to eight tiles, which are the high priority key measures for that division. Clicking on each of the tiles will provide a more granular explanation of the measure.

Next steps for the IMPACT Project include continuing to collaborate on final measures. A steering committee will convene to further discuss the project. Interim reports towards the goals will be completed for those areas where data is collected either once a year or every 18 months. Going forward the IMPACT measures will be incorporated into daily operations. Efforts will also consist of developing strategies to address program gaps in order to bring about improvements.   OPHPR will also communicate progress to its stakeholders.

Below is OPPE's **framework used to create policy strategies and priorities** and link them to the appropriate audiences.

Figure 11: OPHPR Outcomes and Priorities through IMPACT.

From here, plans are made to work with decision makers to implement the initiatives prescribed. There are some criteria that must be fulfilled before selecting priorities, like strategic importance, feasibility, and time sensitivity. Using the congressional calendar, OPHPR identifies opportunities for reaching out to partners on Capitol Hill. These engagements are tracked on a timeline.

Work continues for developing a **partnership strategy**. Partnerships inform CDC in several ways.

> ➤ What capacities and programs are needed domestically and globally for health security
> ➤ How to measure and evaluate programs
> ➤ What systems can be better coordinated for improved responses

OPHPR works with partners to coordinate outreach efforts and strategic communications. OPHPR is developing a full partnership strategy that will include measures for evaluating partnerships.

OPHPR builds its partner relationships through quarterly meetings, monthly communications, and offsite meetings as needed. It coordinates communications using mechanisms like the strategic messaging for Preparedness Month and for response actions. OPHPR also listens to its partners to gain better understanding of gaps or to gleam best practices. Partnerships also provide a platform for sharing program updates and progress, such as budget, policy, or program issues and successes.

As it relates to congressional interaction, there has been more proactive outreach since October to congressional leaders. There were 24 congressional briefings and over half of those were proactive. The goal is to increase that trend going forward and develop relationships from those interactions and sustain them going forward. OPHPR will also continue to respond to inquiries from congressional members. There has also been significant engagements with the Government Accountability Office (GAO) and the division has participated in investigations with the Office of the Inspector General (OIG).

The figures below provide the BSC a snapshot of the FY 2016 budget appropriation and the 2017 President's budget. The fiscal year 2017 budget maintained most of the increases seen in 2016. OPHPR will soon begin work on the 2018 budget. New to the budget will be a funding request for continued support of response efforts related to the Zika epidemic.

Budget Update
Public Health Preparedness and Response

(Dollars in millions)	FY 2016 Appropriation	FY 2017 President's Budget
State and Local Preparedness and Response Capability	$668.200	$660.00
CDC Preparedness and Response Capability	$161.800	$167.166
Strategic National Stockpile	$575.00	$575.00
TOTAL	$1, 405.000	$1, 402.166

Figure 12: PHPR's Budget Update.

Figure 13: Budget Update on Zika Response Funding.

Recommendations from the BSC were as follows:
  ➢ OPHPR should identify champions on the Hill who will help to further its work. Ms. Rita Kelliher with the Association of Schools and Programs of Public Health (ASPPH) volunteered to facilitate some connections in Washington, DC.
  ➢ More partnerships should be formed with the private sector, particularly around areas such as social media and other application program interface issues. Once partnerships are made, determine mechanisms to sustain the relationship.

Update on National Health Security Preparedness Index (NHSPI) and CoPE-WELL, a community resilience index

Glen Mays, PhD, MPH; NHSPI Program Management Office, University of Kentucky

The NHSPI, overall, was designed to increase awareness and understanding of preparedness as a shared responsibility of multiple sectors in government and society.

The Index was created to do the following:
  ➢ Identify strengths and vulnerabilities
  ➢ Track progress
  ➢ Encourage coordination & collaboration
  ➢ Facilitate planning & policy development
  ➢ Support benchmarking & quality improvement
  ➢ Drive research & development

On April 26, 2016, the third revision to the Index will be released. It will contain six domains and 19 subdomains. From the previous versions of the Index, 65% of the measures were retained, 12% were re-specified, and 8 new measures were added,

resulting in a total of 134 measures. Ninety percent of the retained measures have updated data from the second release.

The structure of the Index has remained, for the most part, consistent. Below is the current structure.

Current Index Structure

Overall Index Score					
Health Security Surveillance	Community Planning & Engagement	Incident & Information Management	Healthcare Delivery	Countermeasure Management	Environmental & Occupational Health
Health Surveillance & Epidemiological Investigation	Cross-Sector / Community Collaboration	Incident Management & Multi-Agency Coordination	Prehospital Care	Medical Materiel Management, Distribution, & Dispensing	Food & Water Security
Biological Monitoring & Laboratory Testing	Children & Other At-Risk Populations	Emergency Public Information & Warning	Inpatient Care	Countermeasure Utilization & Effectiveness	Environmental Monitoring
	Management of Volunteers during Emergencies	Legal & Administrative	Long-Term Care	Non-Pharmaceutical Intervention	
	Social Capital & Cohesion		Mental & Behavioral Healthcare		
			Home Care		

PREPARE☑

Figure 14: Current Index Structure.

Several methodological enhancements have occurred to the Index in 2016. One is consolidation, which reduced the number of correlated, redundant and noisy measures. Composition has been expanded to include social, environmental, and economic indicators of preparedness and resiliency. Improvements have also been made to the computation structure. For grouping and weighting, empirical methods are utilized to ensure internal consistency and discriminating power. Scaling has been enhanced to reflect distributional properties of the data. The Index can be used for comparisons to address accuracy and uncertainty and for trending by applying new methods or measures retrospectively.

Furthermore, the measure set has been changed. There were 42 measures eliminated due to poor data periodicity (i.e., infrequent data updates) for over three years and 29 measures eliminated due to poor construct validity. There was a need to re-specify 22 measures to improve construct validity and eight new measures were added. As a result the Index has much higher construct validity.

Below is an illustration of the current Index structure and methodology utilized. The next slide summarizes the weight structure and provides the capability constructs.


Figure 15: Index Structure and Methodology.

Figure 16: Index Delphi Weights & Foundational Capabilities.

Preliminary results from the Index show national preparedness trending upward in most functional areas during 2013-15, except in environmental health and healthcare delivery. Preparedness improved in most states during 2013-15, but significant geographic differences remain. Improvements in preparedness occurred across the U.S. in both above-average and below-average states. However, some below-average states continued to lose ground. Lastly, gaps in preparedness between the highest and lowest states are large and persistent, and they have increased in environmental health and in healthcare delivery. This may shed some light on health equity issues.

There are several caveats and cautions that must be considered when interpreting the results of the Index. There are imperfect measures, some latent constructs (i.e., theoretical in nature; they cannot be observed directly and, therefore, cannot be measured directly either), and possible missing capabilities. Another factor to consider is the timing and accuracy of underlying data sources.

The Index is now in the state preview period. The 2016 Index, when released, can be viewed at www.nhspi.org. National convening to showcase the uses of the Index will begin in the fall of 2016. ASPR, CDC, National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Healthy People 2020 (i.e., the data sources for many of the measures incorporated into the Index) will continue to

incorporate advances in measurements. However, there will be a need for additional analysis to fully understand causes and consequences of the changes made.

Recommendations from the BSC were as follows:

➢ It would be nice if there was a single index that would measure threats of preparedness, but the problem is there cannot be one single index to do that. There needs to be at least two indices that utilize very different formulations. Events, for example, that have occurred in Paris, Brussels and San Bernardino or whatever is happening in the current political climate are variables that should be included in the Index because those variables have the potential to directly affect preparedness efforts in the United States. Weights, variables, even construct validities do not have a single notion. People often provide a behavioral explanation of a phenomenon versus a technical one. You should identify the fuzziest variables and put aside constructs.

➢ Even when there is confidence in the measures, what is missing is causality. It is the duty of the preparedness community to determine the root of the issue.

➢ More consideration should be given to the concepts that are embodied and not immediate reflection on the numbers. The Index, unfortunately, has become all about the numbers. The focus should be on the domains and subdomains, which was meant to be the primary focus when the Index was constructed.

➢ Although the Index offers numbers to assessment preparedness, there is still a need to continue identifying gaps.

➢ Peer training, where higher scoring locations can help lower scoring locations in sharing expertise, should be considered.

Any additional recommendations and comments should be sent to Drs. Inglesby, Mays, Redd.

Jonathan Links, PhD; Professor and Vice Provost, Johns Hopkins University

Dr. Links presented the CoPE-Well Project. He has worked also on the Index but noted CoPE-WELL and the Index are very different in their origin and charge. The Index came with a charge, which was fairly straining, that would lead eventually to a score for preparedness fairly quickly. CoPE-WELL has a research charge without boundaries or preconditions.

The motivation for developing CoPE-WELL is to increase community resilience. Inspiration for the project can be tied to the White House Presidential Policy Directive 8 given on March 30, 2011. It stated, "Resilience refers to the ability to adapt to changing conditions and withstand and rapidly recover from disruption due to emergencies." Resilience literature typically focuses on recovery. The challenge of increasing national resilience is widely recognized. Moreover, defining what makes a community resilient has been difficult to determine. Therefore, understanding what interventions can improve community resilience has been difficult.

CoPE-WELL was intended as a strategy and planning tool that can bring communities together to build resilience. It is also a vehicle to help communities develop their own frameworks and datasets to track over time and across their jurisdictions. The project was not, however, intended to be a crisis management dashboard.

Three terms are important in the CoPE-WELL Project: resistance, recovery, and resilience. Several graphs regarding community functioning over time were presented. The graphs illustrated the difference between resilience and recovery. It is important to distinguish between the two concepts because both are important elements of resilience, but, the things communities can do to build resilience are not necessarily the things that they do to improve recovery. In the CoPE-WELL model, resistance is driven by the factors that modify the event's effects on the community. Recovery is driven by different factors which replenish community functioning. Building resilience, thus, requires conscious decision-making around the differences between resistance and recovery. Below is the CoPE-WELL conceptual model.
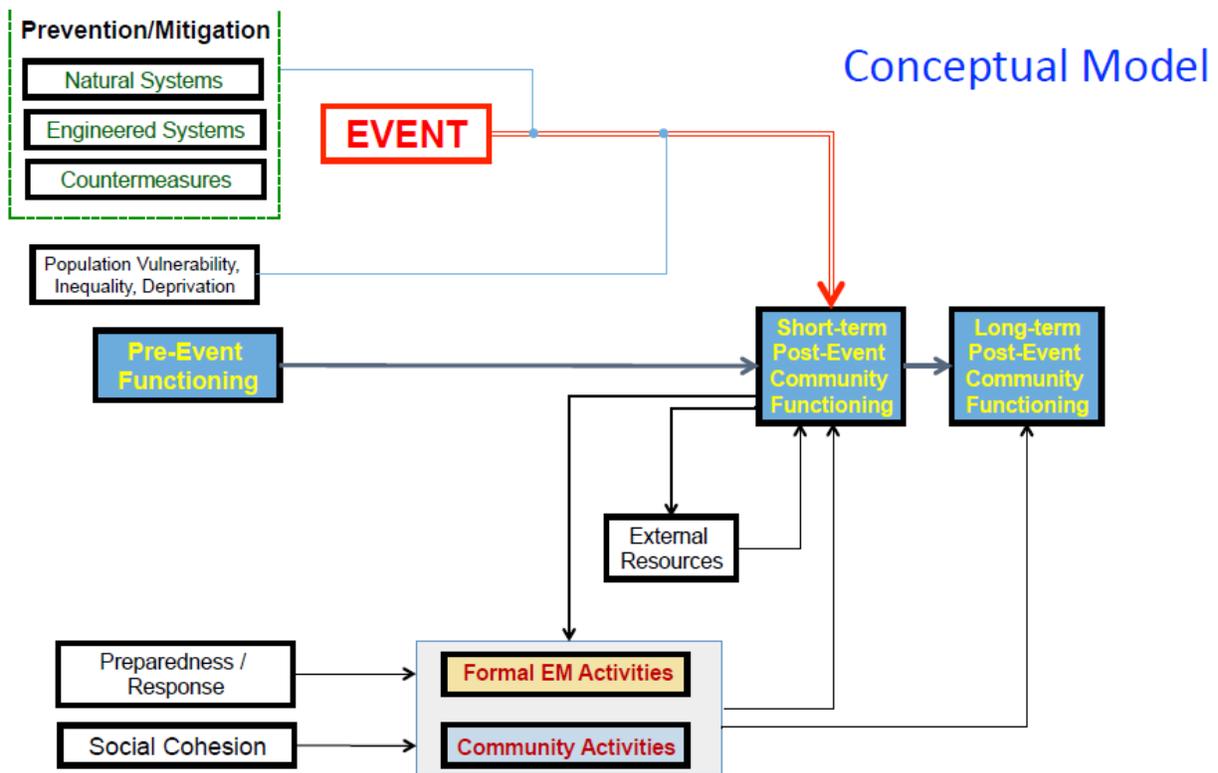
Figure 17: CoPE-WELL Conceptual Model.

CoPE-WELL's computational model is based on a system dynamics model – a dynamic model that reflects how the components, which themselves reflect capabilities and capacities, interact with each other. In a system dynamic model, the explanations of why things occur within the system are contained within the structure of the system itself. Equally as important is the non-linear nature of the model which accounts for the fact that complex systems change as conditions change. The various resources, actions, and other elements and their influence within the system become stronger or weaker

over the course of time. This ability to handle complexity and nonlinearity is critical to studying how communities resist adverse impacts and how they adapt and recover function over time. A linear, static model cannot possibly represent the complex, time-dependent interactions that occur in the real world.

Below is an illustration of CoPE-WELL's System Dynamics Model as well as the complex math used to create the model.

Figure 18:   CoPE-WELL System Dynamics Model.

The Math Behind the Model
(just so you know it exists)

Event damage rate $= \text{Event}_t \cdot (\text{PM}_0 + \text{PVID}_0)/2$

CF depletion rate $= \alpha \cdot \text{CF}_t \cdot \text{Event damage rate}$

SC flow rate $= \text{CF}_t \cdot \text{SC}_t \cdot (\text{CF}_0 - \text{CF}_t)$

PR flow rate $= \text{PR}_t \cdot (\text{CF}_0 - \text{CF}_t)$

ER flow rate $= \text{ER}_t \cdot (\text{CF}_0 - \text{CF}_t)$

CF replenish rate $=$ SC flow rate $+$ PR flow rate $+$ ER flow rate

If natural event:
$$\text{Event}_t = \text{Event}_0 \cdot k \cdot \exp(-k \cdot t)$$

If pandemic event:
$$\text{Event}_t = \text{Event}_0 \cdot \frac{1}{\sqrt{2\pi\sigma^2}} \cdot \exp\left(\frac{-(t-\tau)^2}{2\sigma^2}\right)$$

- t: time
- τ: event peak time
- σ: event spread

$$\frac{d\text{SC}}{dt} = - \text{SC flow rate}$$

$$\frac{d\text{PR}}{dt} = - \text{PR flow rate}$$

$$\frac{d\text{ER}}{dt} = - \text{ER flow rate}$$

$$\frac{d\text{CF}}{dt} = - \text{CF depletion rate} + \text{CF replenish rate}$$
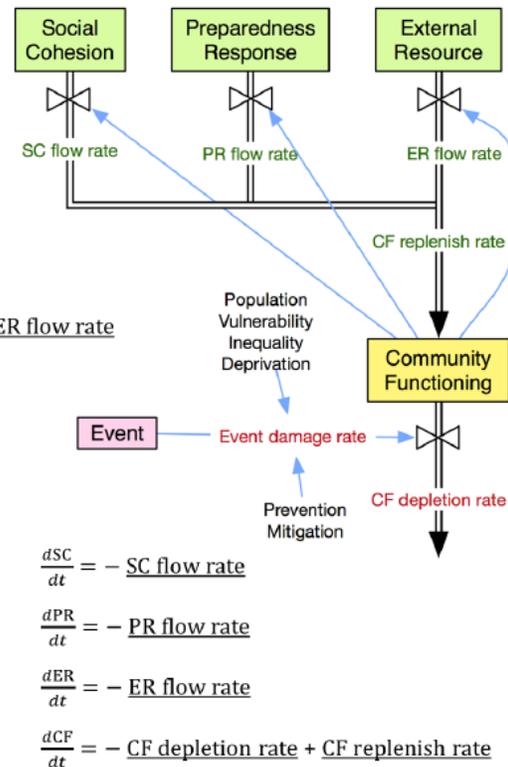
Figure 19: Math Behind the Model.

Dr. Links shared a series of slides of U.S. maps which illustrated how CoPE-WELL projects resiliency using different data types, such as: individual measurement data to observe the percentage of children with single parents and domain-level data to estimate population vulnerability, inequality deprivation, and social cohesion. He also displayed how the tool can be used for county support to assist in predicting the influence of various interventions on community functioning after an event. An example can be seen in the diagram below.

Predicting Influence of Various Interventions on Community Functioning Post-Event (User Interactive Interface)
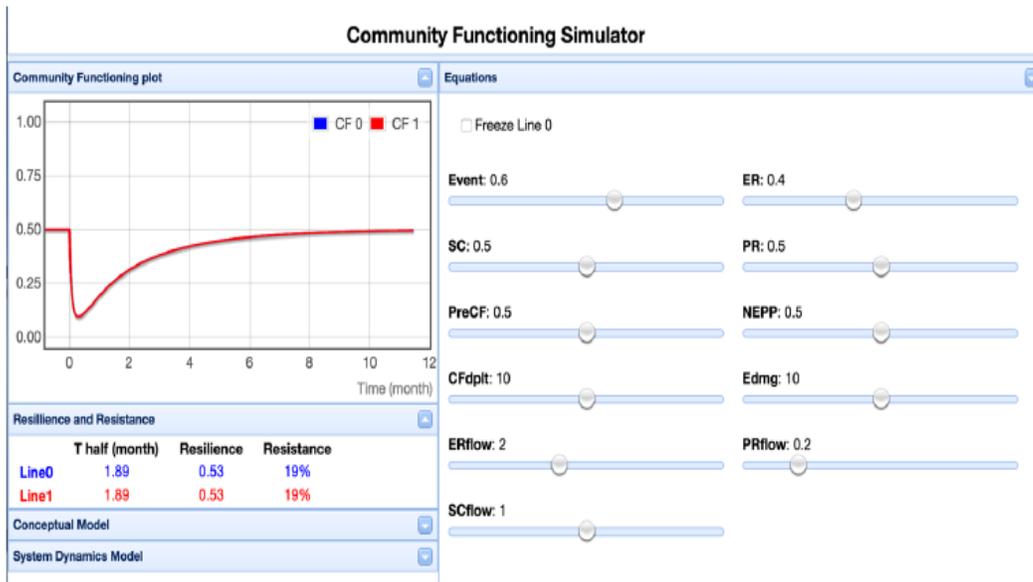
Figure 20: Predicting Influence of Various Interventions on Community Functioning Post-Event.

A project is currently underway in New York utilizing the CoPE-WELL Model as a part of ASPR's Post-Sandy Reconstruction Project. Dr. Links highlighted three types of data utilized for the project. One data source was geoscale data from the 42 United Hospital funded areas. They also utilized measures available only for New York City. This data was chosen because it was more directly related to the domains of interest. The model also employed New York City-specific values for the measures. As a result, CoPE-WELL was able to predict resilience for New York City function at one year post-event.

CoPE-WELL can be used for framing high-level policy discussions about resilience. It can also be utilized for predicting how much community functioning might be affected by a disaster, and the time it might take for community functioning to rebound to pre-disaster levels. The tool can evaluate, in the context of planning, the potential effects of various pre-, peri-, and post-event interventions on community resilience, in a given community. It can be employed for supporting and sparking cross-sector dialogue, leading to a greater understanding of what influences disaster resilience or for engaging communities in strengthening resilience together. Lastly, it can drive the science of resilience by identifying critical unanswered questions.

The biggest challenge to using CoPE-WELL is finding measures at the county level. A possible solution would be to utilize local self-assessment data based on a standard rubric. Dr. Links suggested some possible steps to follow to overcome the challenge.

1. Use a standardized, expert-developed, self-evaluation rubric that allows local communities, through facilitated cross sector discussion, to code themselves for each domain in the model. Describe domains on a simple 1-4 scale.
2. Input estimated values into the model.
3. Run model to obtain results estimating resistance, recovery and overall resilience of the community.
4. Use to advance understanding of what influences resilience and drive dialogue around how it might be strengthened locally.

CoPE-WELL will be presented at the April 2016 Preparedness Summit. Developers are in the process of gathering explicit feedback from stakeholders and considering additional partnerships at the local level to develop a standardized rating rubric. Developers are also preparing a paper for publication as another way of gaining feedback and input.

Dr. Links closed his presentation by posing several questions to the BSC.
➢ What questions / thoughts does this presentation raise for you?
➢ Does the CoPE-WELL conceptual and computational model resonate with you? Are we missing anything?
➢ What potential current uses outlined are most valuable to you?
➢ What does our difficulty in identifying reasonable county level indicators for domains and subdomains suggest we need moving forward? How might this be addressed -- short / longer term?
➢ What reaction / how much interest would you anticipate in the model? How is it best shared / with whom?

Recommendations from the BSC were as follows:
➢ There is an opportunity to connect to local data currently being acquired through community health assessments and efforts to complete population health improvement at local, regional, and state levels. With the development of the recent measurement tools, it is now time to shift the conversation to connecting the tools to the community, who can then lead the charge for understanding and improving their communities. Best results in efforts are seen when the government supports local activity and brings information or even collects information together that can be used for the community's benefit. The real value is the conversation and the support that occur in the local communities. Dr. Levine offered her help in this respect.
➢ Leverage community and federally-led efforts into a "one-team" approach so that multiple organizations are collaborating and coordinating their activities and not over-tasking the community.
➢ It is "easy" to make a model but the real issue is to ensure that you have modeled resilience correctly. Are the right measures being utilized to obtain resilience estimates? Perform a post-hoc analysis examining disasters in a couple of regions and try to predict the resiliency of the community and see if model predicts the same results.

- One of the biggest components for building a model is not just the math but working backwards to readily identify the different assumptions. The model becomes a concrete way to work back to the "fuzzy stuff," which is hard for people to express. If you are fortunate to have several models, it is possible to coalesce, but only after the conflict between the models are resolved to bring about a hybrid model. But you cannot get to the hybrid model that different stakeholders will adopt if you can't get an understanding of why each of the stakeholders see the world differently. To believe that a consensus model will work for all stakeholders only annoys them because they will believe that their point of view is not being understood and they will disengage from the conversation.
- It would be interesting to perform a case study of Hurricane Sandy versus Hurricane Katrina and apply the CoPE-WELL Model to both situations to derive some interesting concepts.
- When talking about community functioning, one concept for consideration is how the functioning accounts for those who are out of the mainstream and public structure in the community. A suggestion would be to measure political inequality. Another component the data may not capture is the power of the community and the leadership in the community.
- To gain a better understanding of the communities that may be overlooked, examine the 1995 heat wave incident in Chicago where over 750 deaths occurred. The vast majority of those individuals were socially isolated and were not even linked into their neighbors.

Preparedness Updates from Liaison Representatives
Association of Public Health Laboratories (APHL)
Christina Egan, PhD, CBSP

APHL is actively engaged in three endeavors. One pertains to select agents. APHL members provided comments and a response to proposed changes in the Select Agent Rule. APHL members have been pleased with the level of engagement within the last several months. Suggestions and comments from APHL are intended to improve efficiency and communication in regulated labs. APHL's comments have also helped DSAT update its forms.

Another endeavor is in the biosafety realm. Since 2014, many safety issues were uncovered. Gaps are being addressed and assistance is being provided to labs to ensure biosafety. Staff has provided a good amount of training and tools so that labs can train others in their jurisdiction. APHL has also worked with several of its senior level members to discuss issues with Capitol Hill on changes made in biosafety.

Lastly, APHL has worked diligently with the labs on Zika testing. In collaboration with CDC, they have provided guidance to the public health and clinical laboratories on Zika testing and developed tools, like risk assessment, for labs to use. Florida and New York have received a tremendous amount of samples for testing. Two assays have been approved for public health labs for Zika testing, but they are not automated, therefore,

causing delays in turnaround time. APHL is working with the Laboratory Response Network (LRN) and other subject matter expert laboratories to find solutions.

Association of State & Territorial Health Officials (ASTHO)
Marissa Levine, MD, MPH

Dr. Levine covered five areas. One is the National Homeland Security Consortium. ASTHO is a charter member and was able to contribute to the drafting of the 2016 National Issues Brief, which will inform Homeland Security related discussions. Funding for the consortium comes through DHS for public and private sectors to coalesce efforts and perspectives about how best to protect America. Topics will include cyber security, critical infrastructure protection, various natural threats, and many others related to public health. ASTHO will share the report with the BSC once completed.

ASTHO in partnership with CDC and the Keystone Policy Center launched a web-based toolkit called Improving our Access to Electronic Health Records during Outbreaks of Healthcare Associated Infections. The aim is to help health agencies improve information exchange with healthcare facilities for outbreak investigations. It includes best practices, lessons learned, and tools.

In another collaboration with CDC, ASTHO is supporting state and territorial health agencies to eliminate healthcare-associated infections and protect patients across healthcare settings. This arose out of experiences with Ebola. Dr. Levine distributed a one-pager to members of the BSC that contained more details.

ASTHO continues to work closely with the National Emergency Management Association and the National Governors Association to strengthen the connections between public health, Homeland Security, and emergency management. One of NEMA's members recently oriented new state health officials. The ASTHO-NEMA Joint Policy Workgroup is convening and has expanded to include NACCHO and the NGA's homeland security advisors.

ASTHO has served as the administrator for the National Alliance for Radiation Readiness. This is a coalition of 16 public health entities and one of the key products is a clearinghouse which can be found at www.radiationready.org. Two products that will become available are guidance for traveler screening at ports of entry following an international radiation event and an anti-neutropenics distribution framework for jurisdictions.

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

CSTE has been working on Zika and other key areas in the last three months. Zika response activities for CSTE started in January. A National Zika Conference Call with CSTE, CDC, and the International Society for Disease Surveillance occurred. The

purpose was to examine situational awareness and to discuss state and local jurisdictional needs and concerns in an effort to improve bidirectional communication.

An ad hoc Zika working group was also convened. It is comprised of surveillance and vector-borne disease subject matter experts to provide feedback to CDC on guidance documents and discuss pressing issues. They will continue to meet weekly.

In February 2016, the CSTE board put together an interim position statement called Zika Virus Disease and Congenital Zika Virus Infection Interim Case Definition to add Zika infection to the National Notifiable Disease List. It includes standard criteria for case classification of viral disease and explicitly adds Zika to the notifiable conditions.

Also, in February 2016, CSTE's Vector Borne Diseases Subcommittee Chair, Dr. Carina Blackmore, represented CSTE at the National Academies of Science Engineering and Medicine in Washington, DC during the Zika Virus Rapid Research Workshop.

In March 2016, the CSTE National Office activated after-hours on-call staff scheduling to provide after-hour capacity to respond to any emergency or urgent preparedness related matters. CSTE continues to coordinate National Zika Calls with CDC's EOC and other health care partners to ensure consistent and timely communications with its stakeholders. It also coordinates the collection of feedback on critical guidance documents.

In addition, CSTE is still deploying individuals to West Africa to help with the Ebola response.

National Association of County & City Health Officials (NACCHO)
Michele Askenazi, MPH, CHS

NACCHO is determining ways to recover and restore from the recent decline in PHEP funding, which has had a significant impact on local and public health agencies. In coordination with CDC, ASTHO, APHL and CSTE, NACCHO is characterizing the impact and reallocation of those funds. They have disseminated templates to all local public health agencies, asking that letters be sent to local officials to communicate the direct impact of reduced funding to response efforts.

A few major objectives are being undertaken by NACCHO, which include the following:
- ➢ Increasing preparedness and response capacity through workgroups that have been created (Preparedness Policy Advisory, Incident Management, Medical Countermeasures, Preparedness Planning Outcomes and Measurement, Risk Communication and Information Sharing, Surge Management, and Preparedness Committee)
- ➢ Providing a unified point of engagement between the PHEP and HPP directors to help provide consistency in information sharing.
- ➢ Developing tools related to how the PHEP, MCMORR and public health accreditation align.

> ➢ Increasing medical countermeasure capabilities in order to develop strategies that strengthen preparedness.

There is an effort being undertaken regarding public health law and the Public Health Law Workgroup. NACCHO is issuing briefs on legal topics that impact those at the local level.

Lastly, the Big Cities Preparedness Collaborative has expanded and is now under NACCHO's facilitation. It is comprised of 22 local health departments representing large urban jurisdictions. The group exchanges information regarding emergency preparedness and response and will meet at the NACCHO Preparedness Summit 2016 to discuss the current state of PHEP and how it can provide information to CDC regarding the priority areas and funding.

Tribal Epidemiological Centers (TEC)
Kristen Hill, MSHSA

Ms. Hill has recently met with several state and tribal representatives to gain an understanding of how tribes are faring in terms of preparedness.

Additional discussions with Homeland Security, the DoD's Bureau of Indian Affairs, and Indian Health Services indicate that they all have pieces of the preparedness puzzle, but the process is uncoordinated overall. She would like to find resources to study preparedness for tribal groups. The National Congress of American Indians in 2015 passed a resolution for Congress to appropriate a small amount of funds to study preparedness in the tribal community.

Secondly, she talked about tribal epidemiological centers, which are unique. They are attempting to build local tribal capacity to collect and use data to manage their community's population health needs. The TEC system is in its 20th year. They will be writing for their next five year cooperative agreement. She urged federal partners to look at tribal epidemiological centers as significant partners because of the amount of trust they have garnered in their community and for their understanding of tribal processes.

Associations of Schools and Programs of Public Health (ASPPH)
Rita Kelliher, MSPH

Ms. Kelliher highlighted several projects. ASPPH recently completed a study to assess the use of competencies among Council on Education for Public Health (CEPH)-accredited schools and programs of public health and with state and local governmental public health agencies. The purpose of the study was to examine competencies developed by CDC-funded Preparedness Emergency Response Learning Centers (PERLC) and the master's levels public health preparedness and response competency set. The project highlighted the uses of the competency models and barriers to usage.

A second project reviewed how the competency models were used in developing training and to examine the preparedness needs and gaps in training of state and local public health practitioners. Trainings were created in collaboration with ASTHO and NACCHO. Results found that the core competency model is not generally used by training managers anymore. Many did not know about the model before being interviewed. When the competency models were first featured, they were thoroughly showcased. Now, knowledge of the models has begun to dissipate, particularly in the case of turnover in which the models were not shared with new hires. The lesson learned is when models are instituted, a sustainability plan should also be developed to ensure ongoing usage. A paper is forthcoming on ways to enhance core competencies. Updates to the competency model are being considered.

ASPPH is also serving as a coordinating center for a newly funded OPHPR initiative, which focuses on translation, application, and evaluation of research products and training developed by the CDC-funded PERLC and Preparedness and Emergency Response Research Centers (PERRC) to improve public health preparedness and response practices, policies, and programs. The project, which is composed of three subprojects, will lead to improved public health practice and enhanced health security by providing workforce development opportunities in public health practice settings. Nine awards were recently granted. Work on this project began in January 2016.

The Association was also asked to report on efforts that schools are undertaking around Ebola and Zika. A couple of schools found women who are pregnant or considering becoming pregnant in the next 12 months are not aware of key facts regarding the Zika Virus. This further emphasizes the need for communication and education.

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

No public comments.

Day 1 of the meeting was adjourned at 5:11 PM.

Tuesday, April 12, 2016

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

Dr. Inglesby called Day 2 of the Board of Scientific Counselors to order at 8:32 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.

Zika Response Activities

The morning session began with a panel presentation on CDC's Zika response:

- ➢ Beth Bell, MD, MPH; Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
- ➢ Greg Burel; Director, Division of Strategic National Stockpile, OPHPR
- ➢ Dan Sosin, MD, MPH; Acting Director, Division of Select Agents and Toxins, OPHPR
- ➢ Chris Kosmos, RN, BSN, MS; Director, Division of State and Local Readiness, OPHPR
- ➢ Jeff Bryant, MS, MSS; Director, Division of Emergency Operations, OPHPR

Beth Bell, MD, MPH

Dr. Bell first presented to the BSC a high-level summary on the Zika Virus epidemiology. The virus is a Flavivirus, closely related to dengue, yellow fever, Japanese encephalitis, and West Nile viruses; transmission is by the Aedes aegypti mosquito. There is increasing evidence of a link between Zika virus infection and microcephaly, which is a devastating birth defect. CDC is investigating a range of additional adverse birth outcomes. More than thirty countries and territories have reported local transmission of the virus and much is still unknown, so research is ongoing.

On January 22, 2016, CDC activated its Emergency Operations Center to respond to the Zika Virus. On February 1, 2016, the World Health Organization (WHO) declared Zika a Public Health Emergency of International Concern (PHEIC) due to clusters of microcephaly and other neurological disorders in some areas affected by Zika. Later, on February 8, 2016, CDC elevated its EOC activation to a Level 1, which is the highest level of response reserved for critical emergencies. Currently, there are over 1,000 CDC staff working on the response.

Surveillance activities include monitoring and reporting cases of Zika in the U.S. and its territories. The Zika Active Pregnancy Surveillance System is being used in Puerto Rico. Vector surveillance and control efforts include providing guidance for vector surveillance before and during mosquito season and supporting mosquito control programs, both in the U.S. and around the world.

The U.S. Zika Pregnancy Registry was designed to learn more about effects of Zika virus infection during pregnancy and about growth and development of babies whose mothers had Zika while pregnant. Collaboration is occurring with state, tribal, local, and territorial health departments to collect information about the Zika virus infection during pregnancy and at birth. The data collected through this registry will inform updated recommendations. It is important to follow infants who appear to be normal at birth to see if there are any other effects that might manifest in the future.

CDC has worked with FDA to establish Emergency Use Authorizations (EUA) for the Zika diagnostic tests developed at CDC. The tests are being distributed to state and local laboratories. CDC is also working with BARDA to expand diagnostic testing capacity.

On the international front, CDC is coordinating response with Pan American Health Organization (PAHO) and regional partners and providing technical assistance to PAHO, WHO, and affected countries. The agency is also actively engaged in Brazil, Colombia, and other countries in the Americas.

In this response more than past responses, field research is pivotal to learning how to control the virus. Therefore, CDC is conducting studies to learn more about the link between Zika and microcephaly and GBS. This includes collaborating with Colombia to monitor pregnancy outcomes in women with Zika virus and with Brazil to study the link between Zika with microcephaly and the possibility of a link between Zika and GBS. CDC is also examining how long the Zika virus stays in semen, urine, and breast-milk.

Outreach and education efforts include:
➢ Educating the public about Zika, including women of reproductive age and their partners
➢ Providing guidance to travelers and Americans living in areas with current outbreaks
➢ Creating and distributing Zika Prevention Kits for affected US territories
➢ Supporting state and local response to Zika virus
    o Providing information and tools needed for preparedness and response
    o Hosted Zika Action Plan (ZAP) Summit on April 1

Planning guidance has been created for the states. The phased risk-based plan is a support tool for states to consider a phased response to the Zika virus. It includes actions to be considered upon laboratory confirmation of the first locally acquired case of Zika virus infection in their state. Vector control is an accompanying guidance to the

phased risk-based plan. Communications planning provides states with resources to develop adapted communication strategies for their state.

Guidance is also being provided to clinicians. CDC is reaching out to clinicians to provide guidance and recommendations for preventing Zika, including MMWR guidance, Health Alert Network outreach, Clinician Outreach and Communication Activity (COCA) services, and partner organizations. CDC is continually updating guidance with new information as it becomes available.

Greg Burel; Director, Division of Strategic National Stockpile

Authorities codified in 42 U.S.Code, 247d directs the HHS Secretary to maintain a national repository of antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical equipment and supplies, the Strategic National Stockpile. For Zika, there is no appropriate pharmaceutical intervention. Therefore DSNS and NCEZID are trying to locate items that would be useful to deploy to assist in the response.

The authorities are very broad. It was determined that the SNS can enter into contracts for the vector control needed because it protects the health of the United States. Two 90-day urgent and compelling requirement contracts have been entered to do vector control in the outlying areas of the United States, e.g., U.S. Virgin Island, Puerto Rico, Guam, and American Samoa. The contracts went to two separate vendors, one in Puerto Rico and one to Vector Disease Control International in Arkansas.

Included in the contracts is the capability to do residual spraying in both interior and exterior areas of residences, hospitals, schools, other public buildings and public places, vacant lots, and so on. Also included was the ability to do aerial spraying of pesticides to kill both adult mosquitoes and their larvae. The maximum limitation on one of the contracts is $5 million and the other is being raised to $10 million.

SNS has also worked on the Zika prevention kits (ZPK; which include items that will reduce an individual's risk of getting Zika) and deployed them to areas of need. This effort required work with the CDC Foundation, who has acquired a number of kits as donated products from a variety of sources. Surge staff and SNS warehouses were utilized to disperse the kits. Roughly 5,000 have been shipped and another 25,000 more will be disseminated in the next few weeks. This may be an ongoing effort.

The Zika virus response has placed the SNS in areas it has not been engaged in previously, like hazardous material management. This has caused the division to reexamine its shipping and storage mechanisms. Lessons learned through this process will continue to inform SNS on areas that should be modified in the future.

Lastly, the SNS has provided basic laboratory supplies to areas where they were scarce.

Dan Sosin, MD, MPH; Acting Director, Division of Select Agents and Toxins

Dr. Sosin talked about the Import Permit Program. There have been roughly 1,900 imports in 2015 associated with approximately 30 inspections. A small portion of the entities that import are undergoing an inspection that is distinct from the biosecurity mandate included in the Select Agent Regulations. It was determined that CDC should be knowledgeable about the entities that are importing infectious agents in addition to specified Select Agents. The agency is now employing biosafety oversight inspection processes. It is required that entities have biosafety measures that are commensurate with the hazards posed by the agent or the material consistent with the Select Agent Program.

Associated with Zika, there have been 93 permits issued since 2000. In 2015 and 2016, there were 16 and 74 permits issued, respectively. As requests are entered, DSAT is providing 24-hour turnaround to ensure there is no delay to moving samples into the United States for research and surveillance.

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

Ms. Kosmos updated the BSC on the role of the State Coordination Taskforce. When not in a response, the taskforce is responsible for ensuring readiness of the U.S. public health system. In a response, it works in partnership with other team leads and taskforce leads in CDC's Incident Command System to guarantee the readiness of the public health system.

Every response has its unique challenges. In the case of Zika, one is funding. Funding sources have been pulled together to address the critical needs of the response. Creative mechanisms have had to be employed to secure funding, and in-depth thinking is occurring around how to continue work if funding is not available.

Without new funds in place, problems in the islands and places that have ongoing transmission continue to be a perplexing issue. DSLR is determining ways to staff, ensure vector control and vector surveillance, assure there are people in the pipeline with ZPKs, and that the U.S. Virgin Islands has lab equipment. In conjunction with SNS, a "lab in a box" concept was designed, which can be deployed to areas of need. When no longer needed, it is sent back to the SNS. There has been discussion of deploying staff and using contractors to also support staffing needs moving forward.

Furthermore, Zika response efforts have been taken very seriously in the Continental U.S. A lack of funding has not stopped state and local jurisdictions from being proactive, engaged, and completing impressive planning. The Zika Summit was convened for state and local public health entities to learn more about Zika. The engagement allowed DSLR to gain a greater understanding of the level of planning occurring at the state and local level. DSLR will facilitate connections to subject matter experts to assist in planning. Follow-up conversations will occur on any changes to their planning efforts.

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

The DEO is the platform used to respond to public health emergencies and threats. There have been over 1,000 staff members utilized for the Zika response at only two and half months into the activation. At the peak of Ebola, 240 staff were deployed internationally. There are currently 35 people in West Africa responding to Ebola. In Puerto Rico, the DEO is at the peak of deployment with 60 staff members deployed and a few other staff members are deployed to Colombia, Brazil, American Samoa, Republic of the Marshall Islands, and the U.S. Virgin Islands.

The workhorse of DEO is logistics. The Logistics Team has worked every weekend for the last several years. Their primary task is to issue equipment for international travel.

The Deployment Coordination Unit ensures all travelers have their pre-deployment requirements met and provides presentations to staff on what to expect when deployed. Lessons learned from safety officers deployed during the Ebola response are being applied.

The Operations team drives the day-to-day rhythm of the EOC by setting up conference lines, meetings, and addressing administrative needs during the response. They are also deployed to countries and territories like the U.S. Virgin Islands and Puerto Rico to assist with set up of their EOC structures and operations.

The Medical Investigations Team conducts employee monitoring for those returning from deployment.

The Situational Awareness Team generates maps and links to support responses. The daily IM update slides come from this team. It is also where the Epi-X Platform is housed.

Planners are embedded in the taskforce structure to conduct evaluations during the responses. They also work with the Policy Unit on writing plans.

The Science Team helps with clearance and dissemination of scientific guidance. Dale Rose is the Associate Director for Science. Through his efforts, documents are moving through clearance faster and in a diplomatic and professional manner. The plan is to institutionalize the process he is using.

There are three areas in which the DEO looks to partner with CDC Centers, Institutes and Offices (CIOs). One is policy, which is tough for the EOC to do alone. Having a policy lead from CIOs will help facilitate the process. The second area is risk communicators. CIOs are still heavily used in the four active responses. This is another area where the DEO would like to partner with the CIOs to be leads or co-leads. The third area is the chief of staff, who guides the incident manager and deputy incident manager. This is another area where DEO would like to partner with the CIOs.

Recommendations from the BSC were as follows:

➢ In the crisis management process, do some thinking around the behavioral and mental aspects of crisis communication and wording to the public.
➢ Issues of race, class, and ethnicity are a big concern. Individuals may not be able to take advantage of the services being provided. There are segments of the population that do not necessarily plug into social media readily. Strategies should be developed and implemented to make sure that those segments are included in preparedness efforts. Community partners are a fantastic mechanism to help ensure communication is reaching those populations.
➢ Arizona developed a model for vulnerable populations called Nothing for Us Without Us. The model utilizes individuals from disenfranchised populations to inform their processes and it has proven to be very effective.
➢ As lessons are learned in Puerto Rico, continue to provide feedback. It would also be beneficial to share the public-private partnerships developed.
➢ Medical psychologists should be a part of the response team. Behavioral consequences can't be separated from the physical and medical. It would be a surprise if societal waves of depression do not follow this Zika response.

US Laboratory Response Network (LRN)

The morning's second panel presentation was given by the following individuals:
➢ Joanne Andreadis, PhD; Senior Advisor for Laboratory Preparedness, Office of the Director, OPHPR
➢ Jasmine Chaitram, MPH, MT(ASCP); Team Lead, LRN Operations, NCEZID
➢ Amy Watson, PhD; LRN-Chemical Program Coordinator, National Center for Environmental Health
➢ Todd Talbert, MA; Senior Advisor, Division of State and Local Readiness, OPHPR

Public Health Preparedness and Response is the capability of the public health system, communities, and individuals to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those in which scale, timing, or unpredictability threatens to overwhelm routine capabilities. Public health preparedness, therefore, should be dynamic and flexible, since public health threats are always present and continue to evolve.

Building a robust network requires a systems approach. The response network includes input from partnerships, the PHEP, the LRN, and the intramural portfolio.

OPHPR's Intramural Portfolio investments help to strengthen, expand, and create new response capabilities. The portfolio invests in innovative people, processes, and products to advance CDC preparedness and response to chemical, biological, radiological, and nuclear (CBRN) disasters. Before an event, the goal is to prepare and sustain the public health workforce and infrastructure to support a response. During an event, response and communication are vital. When responding, the aim is to decrease the time needed to identify an event and implement effective interventions.

Communication improves timeliness and accuracy of situational awareness and communications. The goal during recovery is to decrease the time needed to restore community health to pre-event levels.

Below is an illustration of the methodology for strengthening CDC and state and local laboratories' capabilities and capacity.
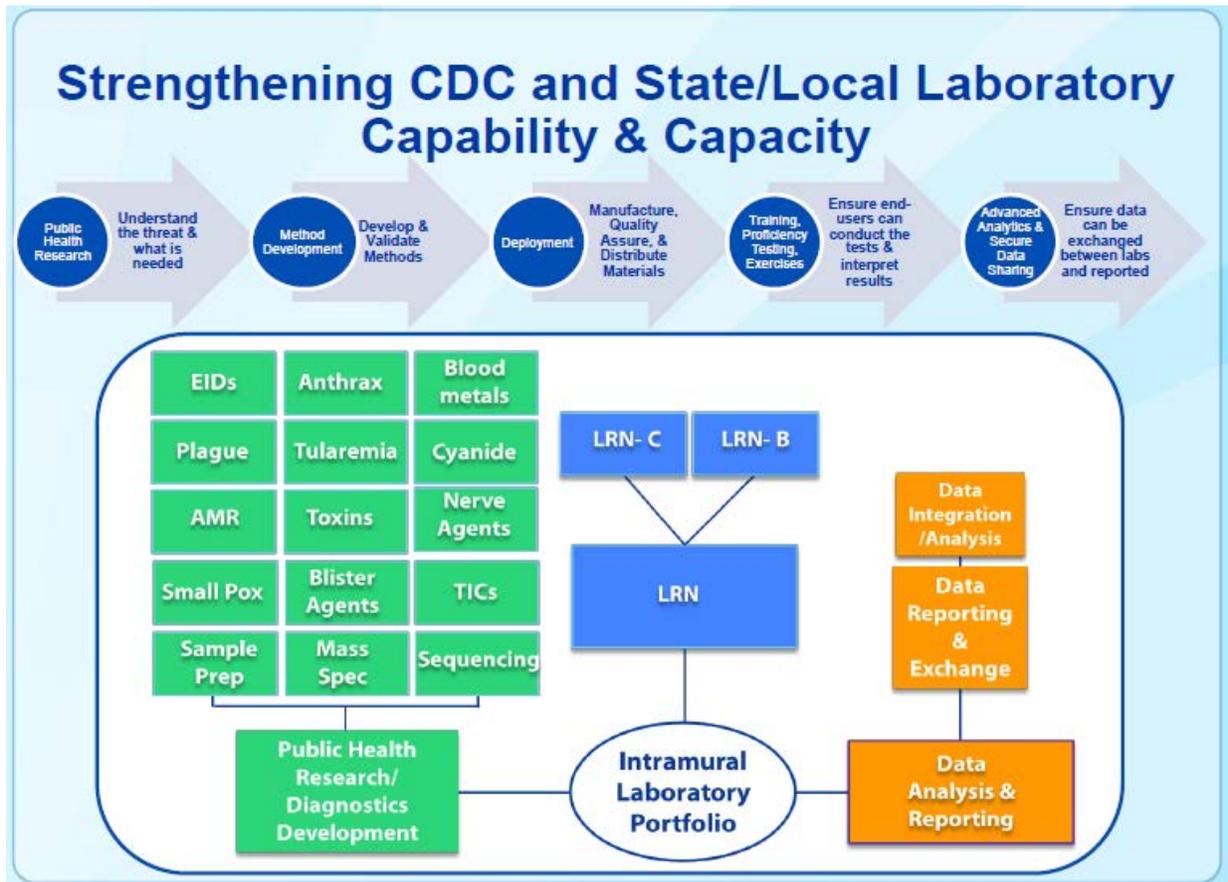
Figure 21: Methodology for Strengthening CDC and State/Local Laboratory Capability & Capacity.

The mission of the LRN Biological (LRN-B) as it relates to preparedness and response is to provide rapid laboratory response to biological and chemical threats and to inform critical decisions about public health and safety. The vision is to continually improve laboratory capacity and capability for existing and globally emerging threats. Some of its founding partners include CDC, Federal Bureau of Investigation (FBI), APHL, and the DoD.

The LRN has some challenges. In spite of the increase in emergency events, there are declining resources and expanding responsibilities. There are challenges to speed, scale, and sustainability of responses, as well as leveraging the LRN workforce and infrastructure investments for routine, state, and local activities. Another challenge can be seen in technological advances, such as synthetic biology or gain- or loss-of-function, which require the establishment of a new cadre of tools and capabilities.

Future efforts for the LRN include the expansion of USG laboratory methods to identify and characterize exposures to toxins, nerve agents, and infectious diseases. The LRN must pivot to address evolving threats by leveraging distribution and network capabilities to support surveillance and response. There is also a need to pilot new technologies to allow the LRN to standardize, integrate, analyze and better leverage existing data resources during a response.

The structure for LRN-B testing resembles a pyramid. At the top are three national laboratories which specialize in strain characterizations, select agent activity, and highly infectious biological agents. Next are the reference labs. There are roughly 130 reference labs and their task is to conduct investigation and/or referral of samples. Samples may come from public health, military, veterinary, agriculture, food, and international entities. There are more than 1,000 sentinel labs, who conduct routine diagnostic services, rule-out and referral steps in identification process. They also can test samples to determine if they should be shipped to reference or national labs for further testing.

The LRN-B Program Office provides a number of services such as:
- Assay development and deployment
- Standardized reagents and controls
- Agent-specific protocols and testing algorithms
- Restricted access website
- Training & technology transfer
- Technical site visits
- Proficiency testing
- Exercises
- 24/7 access to technical assistance
- Lab referral directory, including CDC referral
- Electronic data messaging
- Help desk

Over the years LRN-B has been instrumental in several historical events such as the 2001 Anthrax attack, the 2008 ricin incident, and the 2011 anthrax inhalation case.

LRN infrastructure provides support during emerging threats by providing real-time PCR surge capacity. There are automated DNA extraction equipment and staff trained in molecular techniques and biosafety. Existing communications and partnerships with clinical labs are present. Lastly, the laboratories have garnered extensive expertise through experiences in past and current responses such as SARS 2003, H1N1 2009, MERS 2013, Ebola 2014, and Zika 2016.

Challenges to the LRN-B include:
- Sustainability of public health laboratories
- Prioritizing assay development

- ➤ Implementing advanced technologies (e.g. sequencing)
- ➤ Maintaining electronic data exchange capabilities
- ➤ Decreasing capacity for variola virus (smallpox) testing
- ➤ Transition to next generation real-time PCR instrument

Below is an illustration of the structure of the LRN Chemical (LRN-C).
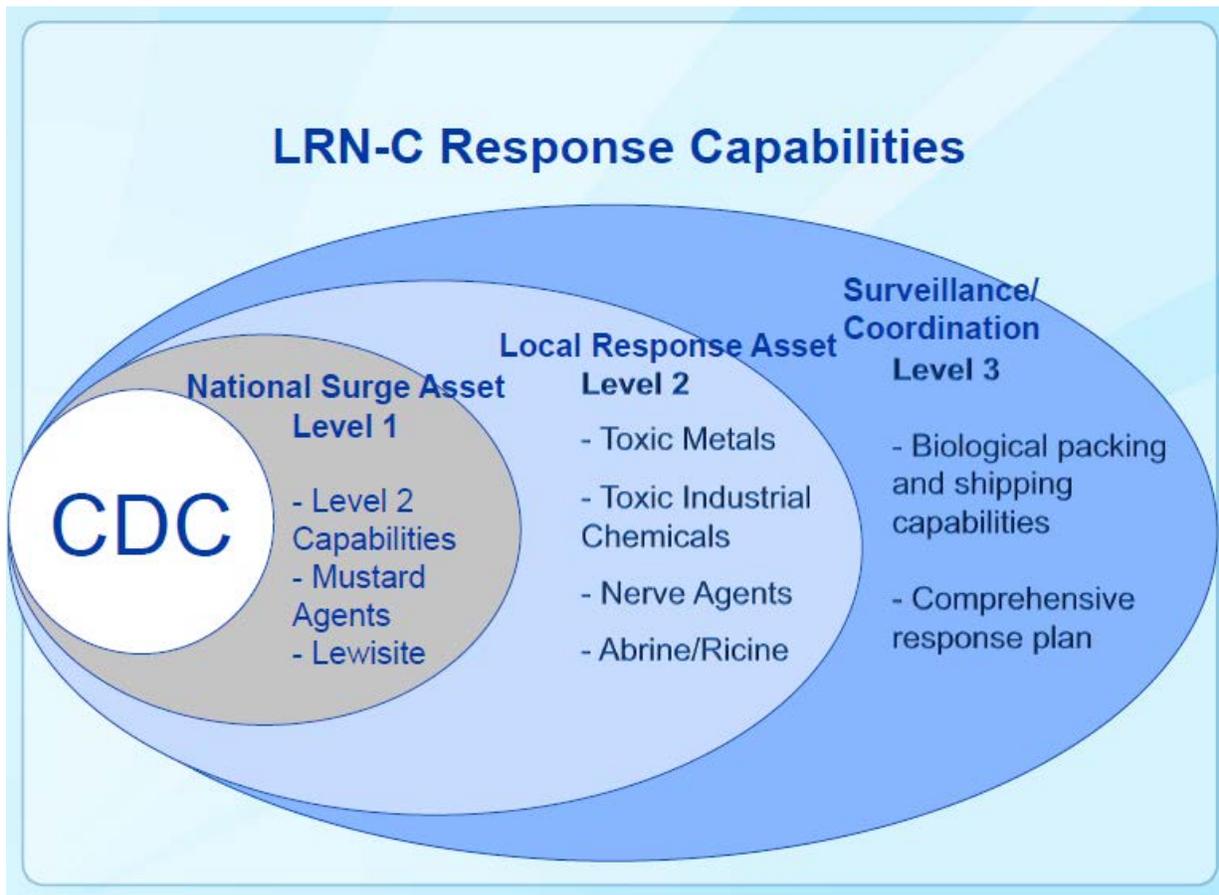
Figure 22: LRN-C Response Capabilities.

The goals of the LRN-C are to increase network capacity and capability for response to high threat chemical warfare agents and leverage network assets to address evolving public health issues. In order to achieve its goals, the LRN-C must accomplish the following objectives:
- ➤ Increase capacity for sulfur mustard exposures by 4 times
- ➤ Deploy protein adducts methods
- ➤ Inter-network marine toxins response

- ➢ Drugs of abuse
- ➢ Provide direct, open access to the network for other USG partners (e.g., FBI, FDA, EPA, DOS, etc.)
- ➢ Develop model for rapid method deployment

Below is the 5-year plan for the LRN-C going forward.
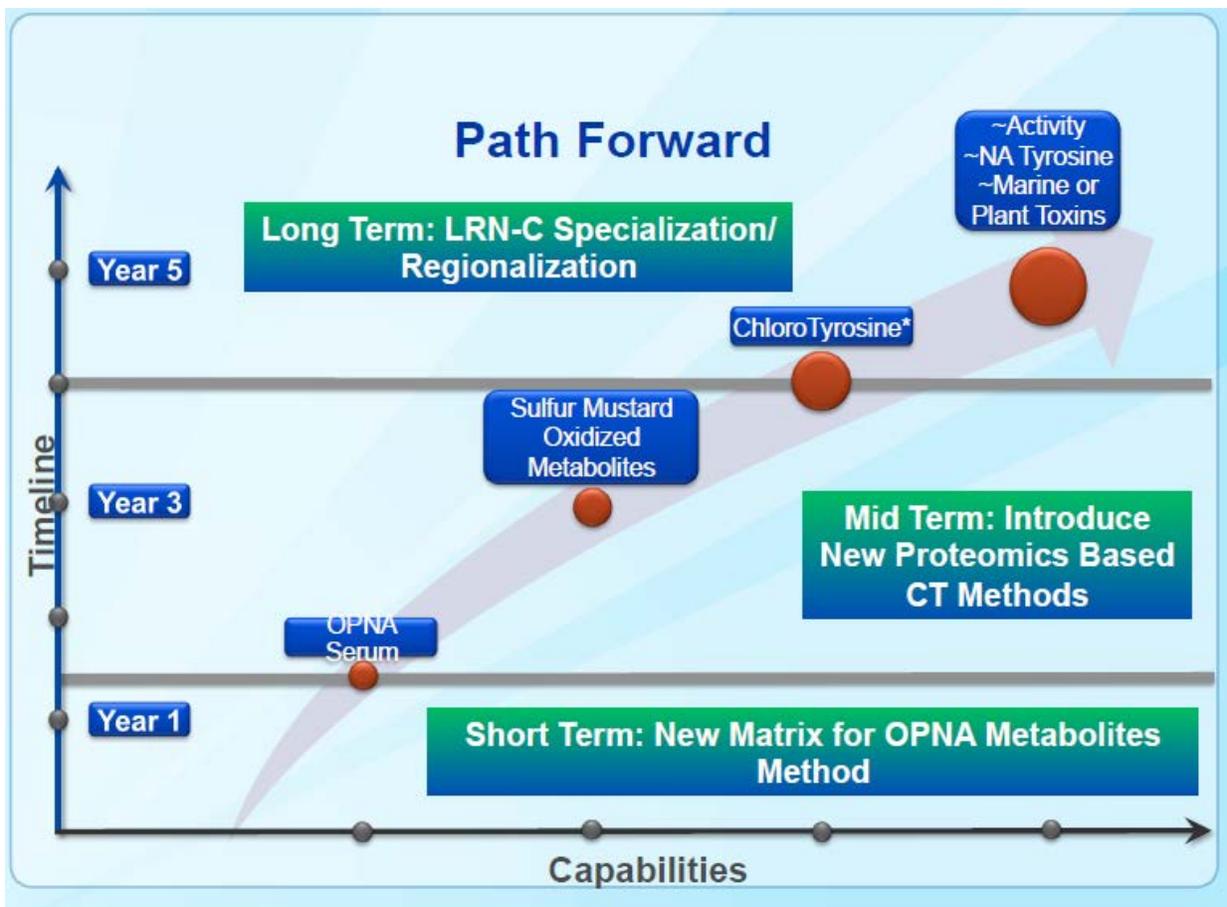
Figure 23: LRN-C's 5-Year Plan.

The LRN-C has realized some recent accomplishments. It has doubled its network capacity to detect Organophosphorus Nerve Agents (OPNA) metabolites. It is also taking part in some joint ventures like CDC-sponsored Chemical Threat Response Capacity used in numerous local public health responses in 2015-2016, like Flint, Michigan (toxic metals testing); Durango, Colorado (metals testing); Hoosick Fall, NY

(perfluorooctanoic acid biosurveillance); and numerous marine toxins responses and other local biomonitoring activities.

Challenges for the LRN-C include dynamic local and state preparedness priorities, while the preparedness budgets continue to reduce. Aging laboratory equipment is another challenge, as well as speed of deploying methods and communications.

Laboratory support is provided by the PHEP Program. The PHEP Program has established public health emergency management capability within 62 state, local, tribal, and territorial public health systems. PHEP funding supports public health laboratories' priorities, such as workforce development and staffing; outreach to sentinel laboratories and other partners; training programs; equipment procurement and maintenance; and reagents and supplies. The PHEP program was awarded $611,750,000 fiscal year 2014 to support the 15 PHEP capabilities. Of that amount, $10.3 million was allocated to 10 Level 1 chemical laboratories and nearly $80 million to public health laboratory testing. The pie charts below shows the distribution for the funding from the PHEP LRNs B and C for 2014.
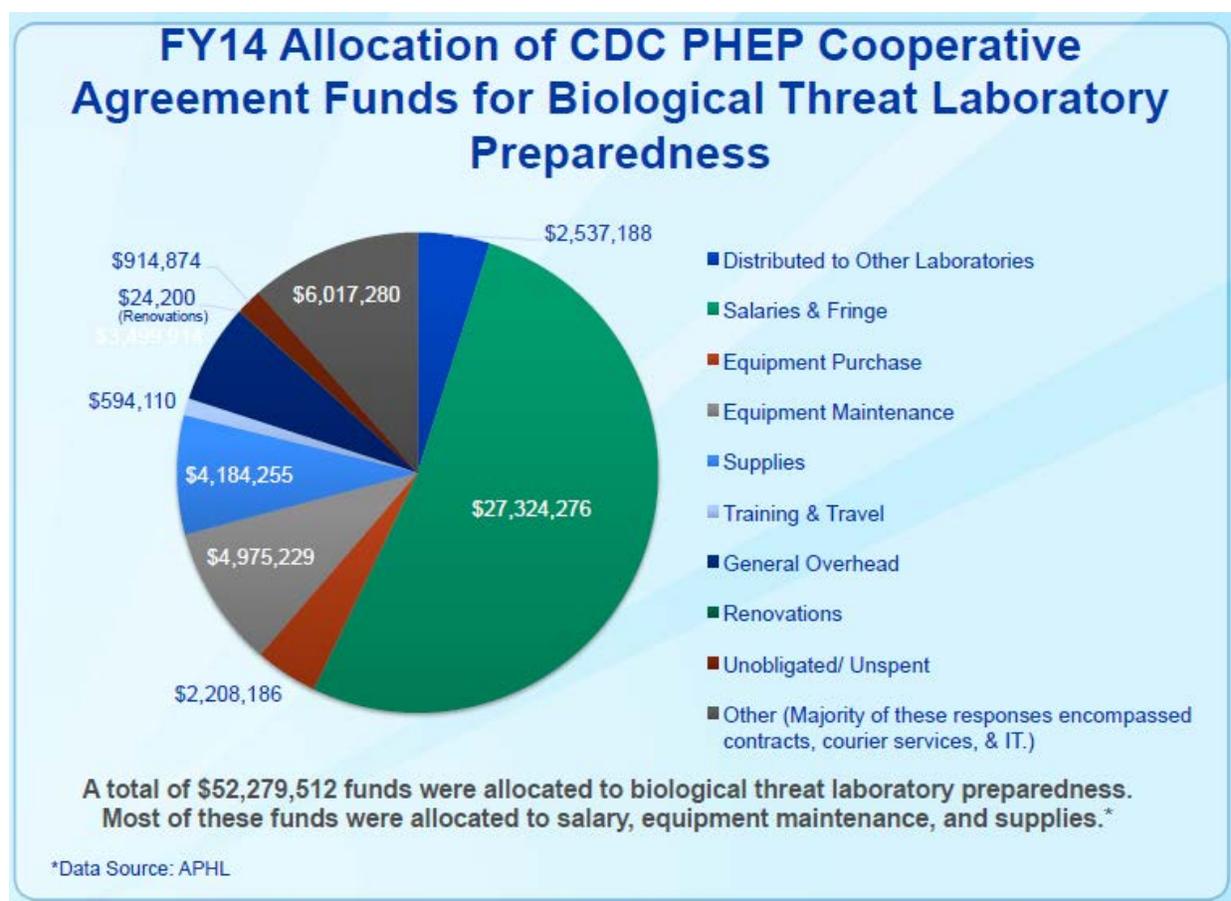
Figure 24: FY14 Allocation of CDC PHEP Cooperative Agreement Funds for Biological Threat Laboratory Preparedness.

FY14 Allocation of CDC PHEP Cooperative Agreement Funds for Chemical Threat Laboratory Preparedness

$459,263
$2,096,272
$5,000 (Renovations)
$66,000
$312,281
$2,231,046
$13,433,540
$3,173,920
$4,346,900
$847,879

- Distributed to Other Laboratories
- Salaries & Fringe
- Equipment Purchase
- Equipment Maintenance
- Supplies
- Training & Travel
- General Overhead
- Renovations
- Unobligated/ Unspent
- Other (Majority of these responses encompassed contracts, courier services, & IT.)

A total of $26,972,101 funds were allocated to chemical threat laboratory preparedness. Most of these funds were allocated to salary, equipment maintenance, and supplies.*

*Data Source: APHL

Figure 25: FY14 Allocation of CDC PHEP Cooperative Agreement Funds for Chemical Threat Laboratory Preparedness.

Several initiatives have been undertaken as a part of the PHEP laboratory capability. They are as follows:

- ➢ Prescriptive language to help prioritize awardee preparedness investments
  - o Requirement to provide a letter signed by the jurisdiction's senior health official confirming the PHEP director, epidemiology lead, and public health laboratory director provided input into work plans
- ➢ Implementing national strategies in partnership with the LRN-B Program Office
  - o Advanced and Standard laboratory capability
  - o Strategy for coverage within specially designated High Priority Areas (HPAs) considered to be at a higher risk due to population density, geographic location and other risk factors.
- ➢ The LRN-C equipment refresh initiative is largely supported by the PHEP program
  - o 2017-2018 equipment refresh requirement:
    - ▪ Purchase of ICP-MS (inductively coupled plasma mass spectrometry) to detect toxic metals
    - ▪ Estimate: $220,000 - $400,000 per lab or up to $13.4 million for the entire network.
  - o 2020 equipment refresh requirement:

- Purchase of NAM (nerve agent metabolites) instrumentation to detect NAM in people
- Estimate: $320,000-$572,600 per lab or up to $18.4 million for the entire network.

Recommendations from the BSC to the LRN were as follows:
- ➢ Work with SMEs on a risk-based assessment of the LRNs' current work. That type of assessment can probably restore some of the capabilities that have been lost.
- ➢ Before preparing for an event, the first step would be to conduct an audit of the threats and capabilities and then after recovery, of course, capture the lessons learned. Secondly, along with the technicians who are conducting the lab work, embed marketing, sales, and consumer psychologists, who think of the psychosocial impacts and how they can be addressed.
- ➢ The APHL, in partnership with the Great Lakes Tribal Epidemiological Center, has piloted a survey to tribal community health center laboratories. The results would be very informative. IHS used to be the "go-to" place for laboratory testing and information, but the landscape has changed and interactions with each of the tribal community health center laboratories is essential to gain an understanding of the tribal communities' needs.

Health, Crisis, and Risk Communication – Approaches and Considerations

Katherine Daniel, PhD; Associate Director for Communication, CDC

For CDC, all work conducted is based on the science and data; communications is no different. The social marketing triangle helps to explain the multifaceted approach to communication, in general, but can be applied for crisis communication as well. The focus is always on the "customer" and what is known about them. But, customers differ, which is a challenge. A mixed-approach must be utilized to get to the target audience.

Figure 26: The Social Marketing Triangle.

The value/cost exchange matrix uses the concepts of hug, nudge, shove, and smack. The hug from a public health perspective is something that is done for free and it makes the individuals feel good. It promotes a behavior change and is active, positive reinforcement. The nudge is where the default option is not made readily available to encourage individuals to consider other options. Shoves are where limitations are placed on behaviors and require public policy implementation, such as seatbelt laws or graduated licenses. Smacks are penalties for violating laws, like selling cigarettes to minors or CDC's smoking campaigns.

CDC and Dr. Barbara Reynolds have been working with the Crisis and Emergency Risk Communication (CERC) Manual, which is a helpful resource for crisis and emergency risk communications. There are six principles. Be first -- don't sit back until everything is known. Be right -- don't fudge, if something is unknown say that and admit any mistakes. Be credible -- this is essential for people to trust the messages (once lost it is hard to regain). Express empathy -- science organizations tend to not do that well. Empathizing with the audience's position will increase communication. Promote action -- give the audience tasks that they can do. It will give them a sense of power and will help stimulate buy-in to the message. Show respect -- don't be condescending. Be deliberate in the messaging. Think of how the message is being delivered to family members.

Swarm intelligence can be applied to emergency responses. When crisis communication needs to happen in an emergency response, swarm intelligence brings unity to the mission. It is similar to the concept that the whole is greater than its individual parts. There is a generosity of spirit and action. Everyone is there not for themselves but to help each other. In the swarm concept, everyone has a function and it's important

that everybody stays in their lane to accomplish the goals. The CDC's regular training helps people to focus on their lane. But, it is allowable to assist a person in another lane if they are in need of help. Lack of criticism is another part of the swarm intelligence theory and it means having no ego and laying no blame. There must also be a foundation of trust and relationships. Having a cadre of trusted individuals or partners that can be called upon in the middle of a crisis is valuable.

Dealing with an ambivalent audience, who is not sure what to think or have already formed an opinion, is difficult. The use of reverse psychology can be employed to reach them. For this audience, whenever a message is given they will give the counter of it. The CDC Foundation has funded some research, which means no federal dollars were spent, to work with private companies to engage politically-active and influential audiences, who are conservative-leaning. Feedback from the audience's reactions to different messages showed that this group is interested in how actions will affect Americans and how CDC is protecting the American public. So, for this audience, messaging must be modified and presented in a fashion that demonstrates that CDC is working on what they have deemed important.

Pew Research found that messages must be crafted for the media village that the audience lives in. For half of the audience, public health brings an instant negative response. When probed as to why, the response was when I hear the word "public health" I thought healthcare, and thus Obamacare, and I don't like it. In messaging, be aware of the trigger words to avoid losing the intended audience.

Uncertainty affects risks or perceived risks. When uncertainty is highest, it becomes difficult to do messaging because no one wants to be accused of misinforming. Zika is a challenge because there is a lot more to be learned, but CDC will have to become comfortable with presenting information and making decisions, even if uncertainty is still high.

Different risks have different acceptability dimensions, such as:
  ➢ Voluntary vs. involuntary
  ➢ Certain vs. uncertain
  ➢ Familiar vs. exotic
  ➢ Natural vs. manmade
  ➢ Reversible vs. permanent
  ➢ Statistical vs. anecdotal
  ➢ Fairly vs. unfairly distributed
  ➢ Affecting adults vs. children

During a crisis, when the need is constant and more than what can be provided, it is an incredible stressor. It can cause individuals to mentally "go to the basement." This was seen during the Ebola response. Survival becomes the focus. It is important to learn how to communicate effectively even if those stressors are present.

It is hard to pick one approach or strategy, but in the case of communication all of the approaches are relevant. CDC should continue to identify other relevant strategies to communication.

Ian Mitroff, PhD; OPHPR BSC Member

Dr. Mitroff and his colleagues have employed the Myers-Briggs to understand various social phenomena. People are grouped together who have the same personality type (four groups). Doing this magnifies the way each personality type looks at the world and highlights the differences among the groups. Two of the principal dimensions of the Myers-Briggs are looking at the parts or observing the whole. Neither are right nor wrong just different ways of viewing. The vertical dimensions can be analytical or technical or it can be personal or people. The result is four perceptions for every problem. This can be employed in open-ended exercises to draw out differences and it illustrates how personality gets externalized. Below is an example of the model.

The Myers-Briggs

Analytical/Technical T

	1	2	
Parts S	Details, Facts, Formulas, Here & Now	The Big Picture, Multiple Interpretations, Systems, Future Possibilities	Whole N
	4	3	
	Specific Individuals, Stories, Personal Values, Feelings	Communities, the Entire Planet, Governance, Societal Values, Politics	

Personal/People F
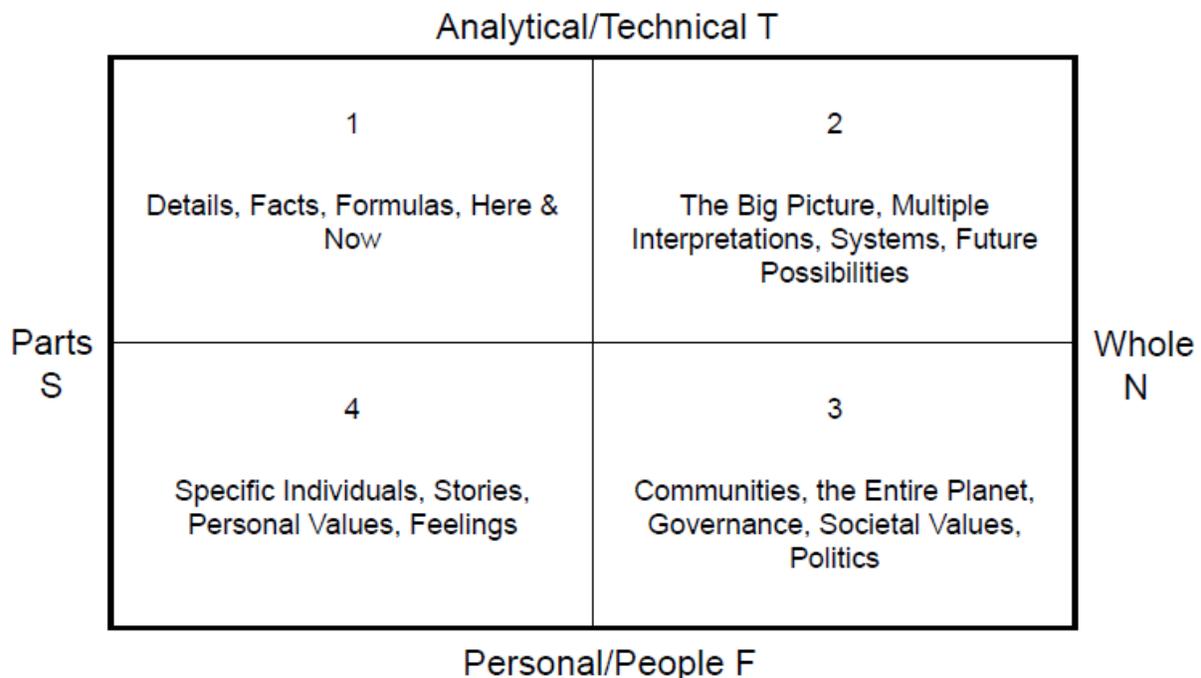
Figure 27: Myers-Briggs Model.

ST, the sensing-thinking approach, is from the expected value. This language may insult the audience because the message will not speak to the people's fears and anxieties. Rather, they feel as if they are being patronized. The NT, or intuiting approach, employs a systemic point of view. A whole system of risk is considered. NF, or intuitive feeling, speaks to the shared fears of the community. The messages are fashioned by involving the community in determining ways to address the fears. SF is sensing feeling. Messages for this audience should inform them on ways to feel safe.

Behavioral economics says people pay attention to losses versus gains. But losses in behavioral economics are measured almost solely in terms of money. When designing a robust communication system, all four quadrants of the Myers-Briggs Model must be addressed. A "blended" approach must be utilized to capture all the audiences.

This same method can be used to diagnose organizational problems. If designing a CDC for today, what would it embody for each of the four quadrants so that it may face the complexity of its work? Some organizations will take on the personality of the work it has to perform. A technical company will probably only utilize the upper quadrants. Whereas public or welfare organizations would utilize the bottom two. Using the models can point out the strengths and weakness of both.

Vish Viswanath, PhD; OPHPR BSC Member

Dr. Viswanath's presentation offered suggestions related to Zika. He focused on three questions.
1. What is the media saying about Zika?
2. What are people hearing about Zika?
3. What are people doing about it?

The media is not good at covering probability or numbers. Most media is episodic driven. So, when the media reports on crises like Zika and Ebola, it is presented as though it is a new issue with no past history. This lends to the audience a sense of crisis and the thought that health institutions have no experience addressing the crisis.

Media uses several rhetorical strategies. One is exemplars, which is where one case is used to represent a class of events. This method can lead to only a part of the story being told, which distorts risk.

Second strategy is objectivity. In this case, strategies are doubled to communicate objectivity. This method covers both sides and all the sides of the story. This happens routinely in vaccination stories.

The third strategy is using quotes. In this strategy, reporting centers around the quote of what someone has said. This is often used in newspaper headlines. The problem is that the audience will form an opinion of risk just off reading the headline and will rarely read the entire article to learn the whole story.

Another strategy is to use street interviews, where the audience listens to the opinions of others interviewed on the street and this now informs the audience's perception of risk.

How people hear the message is based on two ideas - exposure to the media and how they process the information. Exposure to the media in most cases is incidental or casual. There are others who are motivated by either a desire to gain more education

or they are being impacted in some way. Personal salience makes audiences active seekers of information.

People generally don't understand probabilities. They are much more comfortable with verbal descriptors. However, descriptors may not catch probability and can be influenced by single cases. In this situation, the audience will remember the final outcome but not the science, which again impacts the interpretation of risk.

Access and ability to process information can be affected by class, race, and ethnicity. Approaches utilized to reach disenfranchised audiences will differ. Thirty-four percent of people don't have access to internet, so access to information may be limited. The amount of stressors a person is facing in life will cause them to filter out issues that don't pertain to their day-to-day challenges. They cannot emotionally afford to add anything else to their other list of stressors.

Some suggested strategies to communication would be to understand the segmentation of the audience paying particular attention to the heterogeneity of the audience. Exemplars matter so make them strategic. Trust is critical as well as is presenting comparative risk. It is also important to understand the culture of journalism. Constantly monitor and evaluate the communication processes employed. Lastly, consult the community to determine effective ways to reach the disenfranchised and others who may not readily engage with the community.

Recommendations from the BSC were as follows:
- Every organization needs an integrator. Consider hiring engineers who are well-versed in social science; they can speak the language and know the language of the organization and can translate it effectively to the different quadrants.
- Put more effort into finding a way to do what matters and divorce some of the political aspects. Try to amplify the service that is being offered.

Medical Countermeasures Enterprise-CDC Roles and Responsibilities
Susan E. Gorman, PharmD, MS; Associate Director for Science, Division of Strategic National Stockpile, OPHPR

Dr. Gorman began the presentation with some brief remarks regarding MCMs. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) was established in 2006 by HHS to coordinate federal efforts and enhance preparedness for chemical, radiation, nuclear, pandemic influenza, and emerging infectious diseases. PHEMCE is a coordinated interagency effort that works to optimize preparedness for public health emergencies with respect to the creating, stockpiling and use of medical countermeasures. CDC is a partner in this enterprise.

It is essential to be able to deliver MCMs in times of need. State and local partners should understand how to accept MCMs, as well as their purpose and ways of

dispensing. Legal and regulatory frameworks are needed to make MCMs available and usable. This will require various partnerships at every level of government to ensure a successful response.

The presentations for this section will share some of the work accomplished in all levels of partnerships for MCMs.

Dana Meaney-Delman, MD MPH; Clinical Team Lead, Pregnancy and Birth Defects Task Force, NCEZID

The USG is committed to the research, development, and procurement of medical products to mitigate the effects of biologic threats. Under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, such medical products are defined as medical countermeasures, which are stockpiled in the SNS for public health emergencies. There is a need for clinical guidelines for appropriately diagnosis, prevention, and treatment of threat agents during public health emergencies.

CDC provides a vast amount of clinical guidelines. Lately, the desire is to standardize the process for clinical guideline development. On the national level as well as CDC, clinical guideline development is becoming increasingly standardized with a focus on a rigorous, transparent process.

Guideline requirements include:
  ➢ Defined scope and purpose
  ➢ Description of participants and competing interests
  ➢ How evidence was obtained and summarized
  ➢ Methods used to develop recommendations
  ➢ A process for reviewing and vetting the recommendations
  ➢ How the guidelines will be disseminated, evaluated and updated

In the case of bio-threat agents, there are unique challenges to developing clinical guidance. Clinical guidelines development recommendations are often more applicable for chronic disease management, and some elements may not be feasible when considering bio-threat agents. There is an absence of randomized-control trials. There is a dearth of human observational data in many instances and comparison groups may not be plentiful. There is a reliance on limited experimental animal data and animal data does not capture the necessary clinical indicators for decision-making. Among clinicians, there is also limited experience treating some bio-threat infectious diseases.

A couple of years ago, the CDC's Countermeasures Guidelines Development activity was created in partnership with the PHEMCE. The workgroup adapted concepts and objectives outlined in the OADS' "Guidelines and Recommendations: A CDC Primer" to bio-threat medical countermeasures guidelines development. The workgroup has a goal of providing a robust, systematic, transparent process to develop evidence-based clinical guidelines for countermeasure use by enhancing the USG's ability to protect and treat those affected by a bio-threat event in a manner that is acceptable to the clinical

community. The workgroup consists of CDC staff with expertise in multiple bio-threats and special populations, and who provide training on clinical guidelines development from leaders in the field to external and internal partners.

When considering the development of guidelines, the workgroup tries to answer several questions.
- Is there a public health threat that would benefit from the issuance of guidelines?
- Are there changes in the disease/threat under consideration?
    - New evidence regarding the disease?
    - Changes in available treatments and interventions?
    - Need to consider special populations
    - Changes in the target audience?
- Does CDC, with its unique position at the crossroads of public health and clinical care, have a role in developing such guidelines?

CDC looks at several things like clearly defining the specific clinical issues addressed in the guidelines and sufficiently focusing on public health impacts, ethical considerations, and existing knowledge and gaps for all relevant populations potentially impacted. Steps to developing guidelines includes creating a technical development group to define scope, target audience, key questions, resource needs, and coordinate processes. Convening a steering committee helps to guide and advise the technical development group and assist with prioritization of topics and selection of expert participants. The systematic review team collects direct and indirect evidence and the working and writing groups develop draft recommendations. Lastly, a project management group handles the administrative functions.

The Technical Development Group (TDG) is in charge of overall coordination of the guideline development process and various workgroups. The group has a variety of expertise representing multiple components of guideline development. Its members are subject matter experts whose backgrounds include threat agents, MCMs, regulatory, clinical guidance experts, systematic review methodologists, and data abstractors.

The federal steering committee serves in an advisory role by reviewing scope, goals and objectives, prioritizing topic areas and methods, and identifying of expert panel nominees for work groups and expert meetings. They attend guidance development meetings to facilitate access to unpublished relevant data that would contribute to the process. Lastly, they review draft and completed guidance recommendations.

The systematic review teams gather evidence for questions posed by TDG. One of the major challenges to maintaining a timeline for guideline development is the systematic review step. Extensive staff resources are need to comprehensively search the literature and summarize the evidence.

The working and writing groups are comprised of a combination of CDC and external experts who use clinical, research, or public health expertise in clinical guidance topics at hand and clinical expertise involving subpopulations at higher risk for adverse health

events. Subject matter experts are used to handle regulatory issues with MCM, as well as external partners from within federal, state, local government, academia, and the clinical community. CDC serves as co-lead to facilitate writing of the recommendations.

Overall, this process is a very exciting venture. CDC has refined its clinical guidance process for bio-threat agents, which is complex and time-intensive.   Evidence collection and interpretation is key. Guidelines are for a bio-threat event. Guidance and MCM recommendations may vary during an emergency.

Recommendations from the BSC are as follows:
  ➢ Be directive for algorithmic decisions, particularly for decisions that have policy ramifications and could be perceived as equity or political decisions.
  ➢ There is a knowledge gap in the understanding of the role of PHEMCE and how it fits in with the logistical capacity at the local level to distribute and dispense medial countermeasures. Identify areas where the local and state levels can be educated on logistics and nuances of the MCMs.

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

One of the capabilities is to assure a nationwide system capable of rapidly distributing and dispensing lifesaving medications and emergency medical supplies to the public during emergency responses.   The MCM ORR is the answer to assessing and enhancing that capability.

This slide below shows capabilities pre/9-11 contrasted to those of 2012 and the accomplishments realized.

CDC's MCM-Related Impact Since 9/11

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

Figure 28: CDC's MCM-Related Impact since 9/11.

From 2004 to 2015, the PHEP Program provided approximately $302 million in dedicated funding for medical countermeasure planning, with $53 million in fiscal year 2015, which accounts for approximately 9% of the total PHEP funding to fund states and 72 localities. It is intended to assure readiness across the state, including locals and tribes.

In an effort to discover ways to get to the next level of MCM planning, DSLR conducted an internal and external review to inform MCM planning. Key recommendations were to advance assessment processes to measure operational readiness through an operational readiness review (ORR), assure consistency of approach, and include stakeholders in the design process.

The MCM mission is to develop and sustain a prepared public health and healthcare system fully capable of distributing and dispensing MCMs. The MCM ORR's purpose is to improve state and local readiness for a large-scale MCM mission; evaluate quality of jurisdictional MCM plans and jurisdictional ability to execute plans; assist states in evaluating local/tribal capacity and capability; and identify operational gaps and provide technical assistance solutions.

Operational readiness is the ability to successfully execute a large-scale MCM distribution and dispensing mission. MCM ORR determines a readiness status for 90

planning and operational elements that are based on criteria outlined in CDC's preparedness capability and the four levels of readiness, which are early, intermediate, established, and advanced. The goal of the PHEP is to achieve by 2022, for all 62 PHEP jurisdictions, a status of "established" for both the planning and operational elements.

Since 2015, several activities have occurred with MCM ORR. From 2015 to 2016, CDC conducted baseline MCM ORRs and will finalize analysis of baseline data in late fall 2016. From 2016-2017, the focus will be on technical assistance to address operational gaps. CDC will publicly release 2015-2016 MCM ORR baseline data, including awardee-specific and national data. In 2017, the agency will conduct its next round of MCM ORRs.

From 2015 to 2016, 494 PHEP and CRI jurisdictions will be assessed to establish a baseline. This represents nearly 60% of the U.S. population. CDC will conduct 132 ORRs for 62 awardees and 70 local planning jurisdictions. Awardees will conduct a total of 362 ORRs across all remaining local planning jurisdictions. To date, CDC has completed 114 of the 132 site visits.

CDC has received 44 site visit feedback surveys from 23 state respondents and 21 local respondents. Preliminary feedback shows a 74% positive response rate. Respondents felt that the tool is useful for improving operational readiness. Questions in the tools are easy to understand, as well as in the guidance documentation. Additional feedback showed that 84% of respondents moderately or strongly agree that the tool is useful for program improvement; 77% favored expanding ORR to all-hazards review and not just MCM; and 77% stated ORR was a moderately or extremely challenging process.
The next steps are to continue developing a national baseline of state, local, and territorial MCM capabilities as well as DSLR organizational improvements. Other steps are to focus on training and technical assistance by providing competency training to state and local MCM coordinators; provide targeted technical assistance to states to address gaps and advance MCM capabilities; ensure states provide similar assistance to their local jurisdictions; and coordinate regional collaboration.

Additional future steps include redesigning the ORR tool based on the 2016 evaluation of baseline data and awardee feedback; work with state and local partners to vet clinical and operational guidance for SNS assets; and continue to engage in Public Health Emergency Medical Countermeasure Enterprise activities to provide state and local perspective.

The MCM Strategy will accomplish the following:
- ➢ Assure state/local guidance for all the current holdings of the SNS
  - o Develop a planning framework that serves as a coordinated "one-stop-shop" for state/local MCM planners
- ➢ Improve competency of state/local MCM Coordinators
  - o Develop MCM core competencies
  - o Develop training programs
  - o Hold states accountable to assure competency

- Develop technical assistance strategies to address gaps in state and local MCM operational readiness.

CDR Yon Yu, PharmD; Associate Director for Regulatory Affairs, NCEZID

Dr. Yu described emergency use authorizations (EUA). An EUA is authorization to use unapproved drugs, unlicensed biological productions, or unapproved/uncleared medical devices to respond to an emergency involving a chemical, biological, radiological, or nuclear agent. It is used for serious or life-threatening diseases or conditions if there is a reason to believe products may be effective; if know and potential benefits outweigh potential risk, and if there is no adequate, approved, available alternative. An EUA can be requested by anyone.

The Commissioner of the FDA may issue an EUA after HHS has declared that the circumstances justify the EUA based on one of the following determinations:
- DHS – actual or significant potential for domestic emergency involving CBRN agent
- DHS – determination of material threat (domestic or abroad)
- DOD – actual or significant potential for military emergency
- HHS – actual or potential public health emergency affecting national security or health security of US citizens abroad.

The beneficial aspect of the EUA is that it can be used for unapproved drugs or when there is no alternative. It's also instrumental when investigational requirements are difficult to meet in mass dispensing due to informed consent and institutional board reviews. In addition, it's part of the PREP Act protection.

Section 564A(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the Secretary to "create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning such product's approved, licensed, or cleared conditions of use". Such products are not considered unapproved and not adulterated or misbranded if introduced into interstate commerce during an emergency determined by the Secretary of Homeland Security, Defense, or Health and Human Services; or by a government entity, or a person acting on behalf of a government entity, in preparation for an emergency response.

Instructions must concern a disease or condition for which the product in question has been approved, licensed, or cleared by FDA. The EUA is intended to put CDC in the place of a physician who, in the face of an emergency and without other options, must decide how to use a product in a situation for which the product has been approved by FDA for a particular use, but guidance is necessary concerning how the product should be used in the context of the emergency.

The use of EUAs is consistent with CDC's traditional role and expertise in providing event-driven treatment recommendations and facilitating an emergency response.

CDC's extensive clinical treatment expertise enables the agency to serve as a proxy for an individual doctor-patient relationship to issue treatment decisions during emergency circumstances. It facilitates close integration with CDC's current, frontline role in managing SNS products for which EUI may be needed, and coordination with state and local officials about deployment and on-site experience. Lastly, EUAs capitalize on CDC's existing risk communications expertise and considerable experience developing emergency fact sheets for use of MCMs in the EUA/pre-EUA context.

In the case of the PREP Act, the Secretary of HHS may issue a declaration to provide liability immunity, except for willful misconduct, to "covered persons" and for claims causally related to development, distribution, administration, and use of "covered countermeasures". Declaration triggers compensation fund for serious physical injuries or death and covers medical benefits, lost wages, and death benefits. It is an exclusive remedy, reduced by insurance and workers' compensation. The PREP Act is different from PHE and EUA declarations.

Those protected by the PREP Act include the following:
- Covered persons"
  - Manufacturers
  - Distributors
  - State, local government, tribal government, others who supervise or administer countermeasure programs, including private sector
  - Licensed health professionals and others identified by the Secretary (volunteers)
  - Officials, agents, employees of all of the above
  - United States
- Countermeasure recipients

It protects manufacture, development, testing, distribution, administration, or use of "covered countermeasures". Covered Countermeasures include drugs, biological products, devices that are approved, licensed, or cleared, covered by EUA or EUI, qualified Pandemic or epidemic product, security countermeasures, and other emergency authorities.

Declaration contents include the following:
- Categories of diseases, health conditions, or health threats
- Effective time period
- Population to receive countermeasure
- Geographic area of administration and use
- Limitations on distribution
  - Federal awards and activities
  - Authority Having Jurisdiction
- Additional qualified persons
  - Individuals acting under an EUA
  - Individuals acting under Authority Having Jurisdiction

Current PREP Act declarations have been published in the Federal Register for Pandemic influenza countermeasures, Ebola virus therapeutics, Ebola virus vaccines, Anthrax countermeasures, Smallpox countermeasures, Botulism countermeasures, and acute radiation syndrome countermeasures. They can be viewed at www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) included key provisions to enhance medical countermeasures development, deployment and emergency use of medical countermeasures. It amended the Emergency Use Authorization (EUA) authority (FD&C Act §564) and establish new Emergency Use Authorities (FD&C Act §564A and 505-1). **Mass Dispensing** allows mass dispensing of approved MCMs, during an actual CBRNE event, without an individual prescription if permitted under State law or in accordance with an order issued by the Secretary. **Shelf-Life Extension** expressly authorizes FDA to extend the shelf life of expired or expiring MCMs; products with extended expiry will not be deemed unapproved, adulterated, or misbranded. **Emergency Use Instructions** permits a designated HHS official to create and issue, and others to disseminate, emergency use instructions concerning FDA-approved conditions of use. The **cGMP Waiver** permits authorization of deviations from otherwise applicable current Good Manufacturing Practices (cGMP) requirements. The **REMS Waiver** expands authority to waive Risk Evaluation and Mitigation Strategies (REMS) to cover any element based on scenarios giving rise to an emergency use.

Emergency Use Instructions authorize the issuance of Emergency Use Instructions for FDA-approved, licensed, or cleared products concerning their approved conditions of use in an emergency or potential emergency. They are intended to inform healthcare providers during emergency and individuals to whom an "eligible product" is to be administered. EUIs provide information regarding event-driven prevention and treatment of a disease or condition for which the MCM has been approved, licensed, or cleared by FDA in the face of an emergency. They facilitate MCM use without violating FD&C Act and provide legal protection for MCM use in a non-medical model or non-traditional way.

CDC is the agency chosen to utilize EUIs because it is a lead agency during a public health response and provides prevention and treatment recommendations during public health emergencies. CDC has relationships with state, local health officials and clinical sector and manages SNS assets. Also, it has risk communication expertise. The FDA advocated for CDC since FDA's traditionally narrow interpretation of "approved use" may pose obstacles in optimizing the flexibility intended with EUI.

The table highlights specific examples that distinguish an EUA from an EUI.

Contrasting an EUA versus an EUI

EUA	EUI
Applies to unapproved MCM or unapproved use of an approved MCM (off-label use)	Applies only to approved MCM concerning "approved conditions of use:
FDA reviews and authorizes	CDC develops and issues
Eligible for PREP Act coverage	Eligible for PREP Act coverage

The delegation of EUI authority to CDC necessitated internal discussions to assess interpretation, applicability and implementation of EUI. To help define CDC's EUI score, it formed an EUI Work Group in June 2014 to define CDC's interpretation of EUI scope; formulate criteria for EUI; outline procedures for evaluating MCMs including specific considerations involved in the decision to pursue EUI; and create a framework for developing, clearing, issuing and communicating CDC-generated EUI.

Several EUI activities have taken place at CDC. CDC conducted a review of SNS formulary to determine eligible of MCMs for EUI development. It has defined essential elements and template for EUI and created CDC EUA-EUI Concept of Operations. The agency has developed EUI MOU with FDA and internal and external website materials. Furthermore, CDC completed the initial EUI Fact Sheets for Doxycycline and ciprofloxacin for anthrax post-exposure prophylaxis.

This is a schematic view of EUI decision flow.

## CDC's Emergency Use Instructions (EUI) Decisional Flow
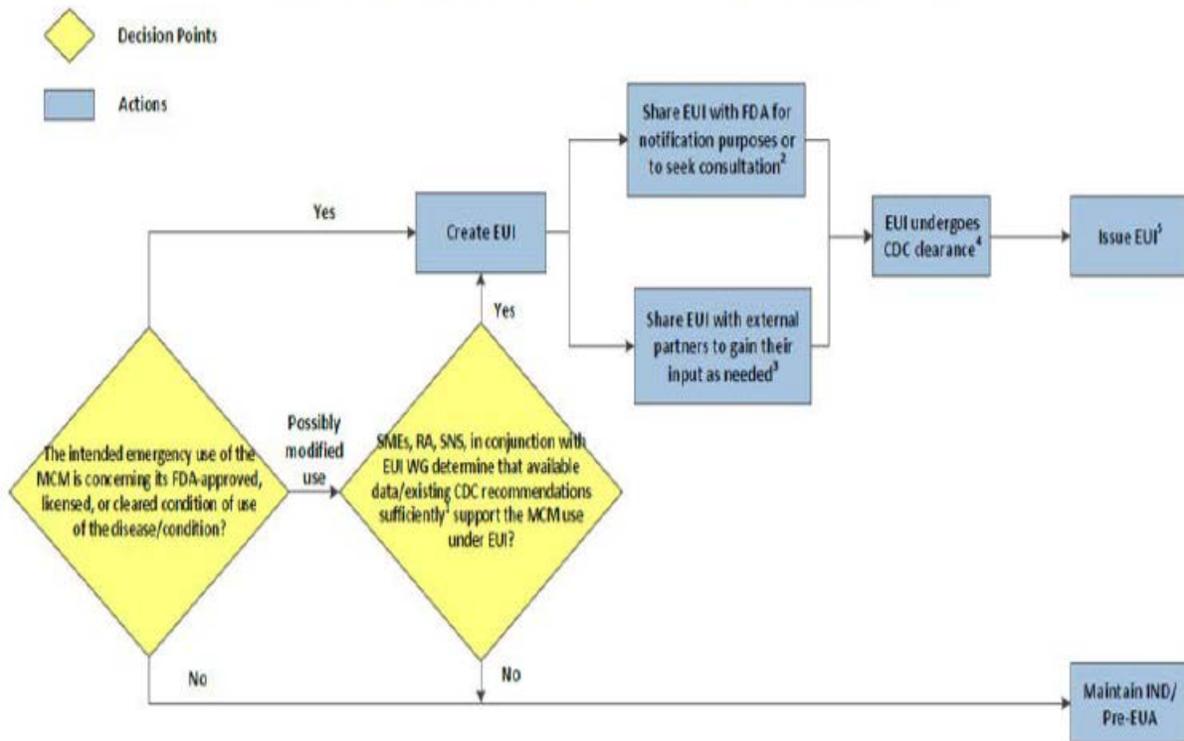
Figure 29: CDC's Emergency Use Instructions Decisional Flow Chart.

Steps to the EUI Decisional Process includes the following:
- ➢ Identify stockpiled-MCMs that meet the prerequisite criteria
  - o FDA-approved, licensed, or cleared and
  - o Intended use concerns the MCM's FDA-approved, licensed, or cleared indication
- ➢ Decision to develop and issue EUI will be based on:
  - o Emergency use necessitates instructions and information that deviate from approved labeling, standard clinical practice, and/or standard medical modality (e.g., individual prescription within the patient-clinician relationship)
  - o Availability of relevant data/information to assess risk versus benefits
  - o Any existing CDC recommendations
- ➢ CDC may recommend consideration of an Investigational New Drug/Investigational Device Exemption (IND/IDE) or EUA if emergency use of MCM would present risks for which no data or inadequate information is available to support its use under EUI.

A framework for coordination and consultation between the two agencies to support CDC's authority to create and issue EUI for eligible MCMs has been created. The MOU outlines CDC as the lead agency with authority to determine, create, issue, and disseminate EUI. It provides an option for CDC to consult with FDA and establishes mechanism for FDA to share any data relevant to CDC's determination and creation of

69

EUI. The MOU outlines criteria for development of EUI and provides means for CDC to notify the appropriate parties when final EUI are available.

Dissemination plans for issued-EUI include web posting of authorized EUI materials once "issued" pre-emergency-posted on password-protected CDC JOIN SharePoint for sharing with public health partners and during emergency–posted EUI information and materials on CDC JOIN SharePoint. Question and answers are also being developed regarding emergency use of MCMs for state and local public health partners given the "new" EUI and "familiarity" with EUA.

MCMs and materials ready for initial EUI include:
  ➢ Ciprofloxacin EUI for Health Care Professionals (HCP): inhalation anthrax post-exposure prophylaxis (PEP)
  ➢ Ciprofloxacin EUI for Recipients: inhalation anthrax PEP
  ➢ Doxycycline EUI for HCP: inhalation anthrax PEP
  ➢ Doxycycline EUI for Recipients: inhalation anthrax PEP
  ➢ Doxycycline Crushing Instructions Pamphlet
  ➢ Doxycycline Crushing Instructions Video

  ➢ Additional MCM being considered for EUI are as follows:
  ➢ Pandemic influenza MCMs in the SNS
  ➢ Modified Neupogen dosing regimen and titration for radiation-induced myelosuppression
  ➢ Pediatric dosing instructions for botulism antitoxin
  ➢ Modified ciprofloxacin dosing instructions for plague
  ➢ Anthrax Vaccine for PEP of adults > 64 years of age
  ➢ Event-specific EUIs for stockpiled approved-MCMs

Recommendations from the BSC were as follows:
  ➢ It would be helpful to have EUI authority guidance and aspects that support it at CDC to help streamline processes during events.
  ➢ Colleagues at the local level would like to see mass vaccination exercises that meet the same criteria, objectives, processes, locations and flows that CDC is using for its pods.

Remarks from the CDC Director
Thomas R. Frieden, MD, MPH; Director, CDC and Administrator, ATSDR

Dr. Frieden joined the BSC via the phone. He began by thanking the members for their time, input, and recommendations. He is eager to hear the Board's perspectives related to Zika, which he says is the most difficult response that he has taken part in, and it emphasizes the importance of OPHPR to aiding in the response.

He is hoping that Congress will approve the proposed supplemental funding. It is critical to mounting a robust response.

The Zika response is also part of the Global Health Security Agenda. Efforts that are undertaken now will influence the progress going forward. Global health security is essentially preparedness around the world. CDC's role in that is building capacity and specific capabilities in areas like managing epidemiology, communications, and surveillance. OPHPR is increasingly transitioning into this role.

One concept he wanted to convey was the thought of **mainstreaming preparedness**. In some programs and jurisdictions, preparedness is still a problem and doesn't enrich the day-to-day functioning of programs. In order to be maximally effective, preparedness must be mainstreamed. Some preparedness activities are structurally strengthening other parts of the public health response. Crises are becoming more frequent and longer and OPHPR is adding more activities to its workload. Dr. Frieden intends to promote mainstreaming preparedness as the new normal.

Public Comment Period

No public comments.

Meeting Recap & Evaluations, Action Items & Future Agenda
RADM Stephen C. Redd, MD; Director, OPHPR

OPHPR is trying to eliminate seams in its work. The office plans to continue to support the theme of working as a team. There are more significant partners that will be invited to the next meeting.

Dr. Redd is considering adding a session on vulnerable populations to the next meeting, since it was a topic that arose several times during the meeting. A lot of time is spent on physiological vulnerabilities of children, the elder, and pregnant women, but there's another domain he believes we are missing that should addressed. Dr. Levine suggested we apply an equity lens on the work and lend more perspectives. Dr. Quinlisk would like OPHPR to provide examples of collaborations that helped to close the seams in OPHPR's processes.

OPHPR leadership will report back to BSC on processes that have been developed as a result of the recommendations.

Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby said he was impressed with the work occurring, which is garnering more attention. He is appreciative of all the work completed since the last meeting based on the recommendations the BSC made. He expressed gratitude to the BSC for coming to share their expertise. He also thanked the CDC leadership and staff for planning a successful meeting.

Meeting Adjourn - With no further comments, the meeting was adjourned at 3:30 PM.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the April 11-12, 2016 meeting of the OPHPR BSC are accurate and complete.

6/27/2016
_____
Date

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

APPENDIX A: OPHPR BSC MEMBERSHIP ROSTER

Designated Federal Official
Samuel L. Groseclose, DVM, MPH
Associate Director for Science, OPHPR
Centers for Disease Control and Prevention
Atlanta, GA
slg0@cdc.gov

Chair
Thomas Inglesby, M.D.
Director and CEO, UPMC Center for Health Security
Term: 2/29/2016 – 9/30/2019
tinglesby@upmc.edu

Special Government Employees

Ruth G. Bernheim, J.D., M.P.H.
Chair, Department of Public Health Services and William Hobson
Associate Professor of Information Sciences
University of Virginia School of Medicine
Charlottesville, Virginia
Term: 11/20/2012 -9/30/2016
rg3r@virginia.edu

Margaret L. Brandeau, Ph.D.
Coleman F. Fung Professor, School of Engineering
Department of Management Science and Engineering
Stanford University
Stanford, CA
Term: 3/1/2016 - 9/30/2019
brandeau@stanford.edu

Suzet McKinney, Dr.P.H., M.P.H.
Executive Director, Illinois Medical District Commission
Chicago, IL
Term: 9/30/2013 – 9/30/2017
SMcKinney@medicaldistrict.org

Ian I. Mitroff, Ph.D.
Adjunct Professor, College of Environmental Design and
Research Associate, Center for Catastrophic Risk Management
Haas School of Business, University of California, Berkeley
Oakland, California
Term: 11/20/2012 -9/30/2016
ianmitroff@earthlink.net

Carol S. North, M.D., M.P.E.
Professor of Psychiatry and Director, Division of Trauma and Disaster
The University of Texas Southwestern Medical Center
Dallas, Texas
Term: 11/20/2012 -9/30/2016
carol.north@utsouthwestern.edu

Kasisomayajula Viswanath, Ph.D., M.A., M.C.J.
Associate Professor, Department of Social and Behavioral Sciences
Harvard School of Public Health
Boston, Massachusetts
Term: 8/13/2014 – 9/30/2018
vish_viswanath@dfci.harvard.edu

Dawn P. Wooley, Ph.D.
Associate Professor of Virology
Wright State University
Dayton, OH
Term: 3/2/2016 – 9/30/2018
dawn.wooley@wright.edu

Department of Health and Human Services

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health & Human Services
Washington, DC
Nicole.Lurie@hhs.gov

Alternate - Sally Phillips, R.N., Ph.D.
Deputy Assistant Secretary for Policy, Office of the ASPR
US Department of Health and Human Services
Washington, DC
Sally.phillips@hhs.gov

Department of Defense

Jody R. Wireman, Ph.D., M.S.P.H., M.P.A., CIH
DABT HQ NORAD-USNORTHCOM
Director, SG Force Health Protection
Peterson AFB, CO
jody.r.wireman.civ@mail.mil

Alternate - Eric Sergienko M.D., M.P.H.
Captain, Medical Corps, US Navy
DoD Liaison to CDC
Atlanta, GA
byy3@cdc.gov

Department of Homeland Security

Kathryn Brinsfield, M.D., M.P.H.
Assistant Secretary for Health Affairs and
Chief Medical Officer
Department of Homeland Security
Washington, DC
kathryn.brinsfield@hq.dhs.gov

Liaison Representatives

Michele Askenazi, MPH, CHES
National Association of County and City Health Officials (NACCHO)
Director, Emergency Preparedness and Response, Tri-County Health Department
Greenwood Village, CO
maskenazi@tchd.org

James Curran, M.D., M.P.H.
Association of Schools and Programs of Public Health (ASPPH)
Dean, Rollins School of Public Health
Emory University
Atlanta, GA
jcurran@emory.edu

Christina Egan, Ph.D., CBSP
Association of Public Health Laboratories (APHL)
Chief, Biodefense Laboratory, Wadsworth Center
New York State Department of Health
Albany, NY
christina.egan@health.ny.gov

Kristin Hill, M.S.H.S.A.
Tribal Epidemiological Centers (TEC)
Director, Great Lakes Inter-Tribal Epidemiology Center
Lac du Flambeau, WI
khill@glitc.org

Marissa Levine, M.D., M.P.H.
Commissioner, Virginia Department of Health
Association of State and Territorial Health Officials (ASTHO)
Richmond, VA
marissa.levine@vdh.virginia.gov

Patricia Quinlisk, M.D., M.P.H.
Council of State and Territorial Epidemiologists (CSTE)
Medical Director and State Epidemiologist
Iowa Department of Public Health
Des Moines, IA
patricia.quinlisk@idph.iowa.gov

APPENDIX B: BSC MEMBER ATTENDANCE ROSTER

BSC Meeting Attendance Roster
Atlanta, GA – April 11-12, 2016

NAME	AFFILIATION	DAY 1 (APRIL 11, 2016)	DAY 2 (APRIL 12, 2016)
Inglesby, Thomas	Chair and SGE	In person	In person
Bernheim, Ruth	SGE	Phone	Phone
Brandeau, Margaret	SGE	In person	In person
Mitroff, Ian	SGE	In person	Absent
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
Phillips, Sally, HHS	Ex Officio	Phone	Phone
Brinsfield, Kathy, DHS	Ex Officio	Phone	Phone
Wireman, Jodi, DoD	Ex Officio	In person	In person
Kelliher, Rita (ASPPH)	Liaison	In person	In person
Egan, Christina (APHL)	Liaison	Phone	Phone
Hill, Kristin (TEC)	Liaison	In person	In person
Levine, Marissa (ASTHO)	Liaison	In person	In person
Askenazi, Michele (NACCHO)	Liaison	In person	In person
Quinlisk, Patricia (CSTE)	Liaison	In person	In person

APPENDIX C: ACRONYMS

AAR After Action Report
AMT Anthrax Management Team
APHL Association of Public Health Laboratories
ARRA/HITECH American Recovery and Reinvestment Act/Health Information Technology for Economic and Clinical Health Act
ASPPH Association of Schools and Programs of Public Health
ASPR Assistant Secretary for Preparedness and Response (HHS)
ASTHO Association of State and Territorial Health Officers
BSAT Biological Select Agents and Toxins
BSC Board of Scientific Counselors
CDC Centers for Disease Control and Prevention
CEFO Career Epidemiology Field Officer
CSTE Council of State and Territorial Epidemiologists
DEO Division of Emergency Operations (CDC)
DHS US Department of Homeland Security
DoD Department of Defense
DOT Department of Transportation
DPHP Directors of Public Health Preparedness
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
FOA Funding Opportunity Announcement
GAO Government Accountability Office
FRO Financial Resources Office (CDC)
HCW Healthcare Worker
HPA Healthcare Preparedness Activity (CDC)
HPP Hospital Preparedness Program
HHS US Department of Health and Human Services
IHR International Health Regulations
IOM Institute of Medicine
IT Information Technology
LO Learning Office (CDC)
LRN Laboratory Response Network
LRN-B Laboratory Response Network Biological
LRN-C Laboratory Response Network Chemical
MASO Management Analysis and Services Office (CDC)

MCM Medical Countermeasure
NACCHO National Association of County and City Health Officials
NCEH National Center for Environmental Health
NCEZID National Center for Emerging and Zoonotic Infectious Disease
NCIRD National Center for Immunization and Respiratory Diseases
NIHB National Indian Health Board
NIH National Institutes for Health
OD Office of the Director
OID Office of Infectious Diseases (CDC)
OIG Office of the Inspector General
OPHPR Office of Public Health Preparedness and Response (CDC)
OPPE Office of Policy, Planning, and Evaluation (CDC)
ORR Operational Readiness Review
OSPHP Office of Science and Public Health Practice (CDC)
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
SGE Special Government Employee
SLTT State, Local, Tribal, and Territorial
TEC Tribal Epidemiological Center
TFAH Trust for America's Health