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
MAY 10-11, 2017
ATLANTA, GEORGIA

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Wednesday, May 10, 2017

Welcome & Call to Order / Introductions & Opening Remarks

Thomas Inglesby, MD; Chair, OPHPR BSC

The May 2017 Board of Scientific Counselors (BSC) was called to order at 10:05 AM by Chairmen Dr. Thomas Inglesby. Each of the members of the BSC were asked to introduce themselves and their affiliated agencies/organizations.

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.

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 Report update forms should be completed and returned to Dr. Groseclose. Members were asked to identify any conflicts of interest. Dr. Inglesby is working under a grant from CDC for work related to state quarantine policy and a subcontract that is being done in conjunction with John Hopkins related to a community resilience tool, and another project related to Zika communication. Dr. Viswanath has a grant from ASPPH (CDC-funded initiative) for risk communications and preparedness. Dr. McKinney, through an appointment at the Harvard School of Public Health, is working with colleagues on a grant from ASPPH (CDC-funded initiative) in the review of the PERRC and PERLC tools. Dr. Quinlisk reported that the state of Iowa receives a multitude of grants from CDC but they are the routine types of grants that most states receive.

Dr. Redd welcomed the two new board members, Erika James and Catherine Slemp.

OPHPR 2017 Priorities and Updates

RADM Stephen C. Redd, MD; Director, OPHPR

Dr. Redd reviewed some of the topics that will be covered in the meeting. Some are carryovers from the previous meeting in December 2016.

From the opioid epidemic presentation, OPHPR is asking the BSC to think of ways that the Office can contribute to the response effort. Several states have activated to address the epidemic but at this time OPHPR is not heavily involved in the response activities.

In regard to risk management, OPHPR is attempting to identify large-scale risks and prepare for them. The BSC will hear about an Enterprise Risk Management process that was started in the prior administration. The Office wants guidance on how to ensure the process is being used to anticipate the unknown crises that may be on the horizon and the correct amount of effort is being used to reduce those risks. There will also be an update on preparing for natural disasters and on global health security.

OPHPR is still activated for the Zika virus response. Top priority is to protect pregnant women. Maintaining the focus on that population is a challenge due to the multiple facets of the disease that tend to take the attention away from the top priority. There are two efforts underway. One is to summarize and act on the lessons learned in the past year from the vector control work. OPHPR has released advice to the continental United States. Part of the plan is simplifying the recommendations for laboratory testing and clarifying zones of risk when there is local transmission. The second is to follow the pregnancies of those infected and to improve birth defect surveillance.

A low-level response effort is polio eradication. Five cases, so far, have been identified for 2017. There were only 37 cases in 2016. One of the presentations will talk about the next steps once polio is eradicated and the establishment of a system that ensures that laboratories working on polio are doing so safely. There will be a day when the final case is identified but there will be a long tail to the response, when considering vaccinations.

A few weeks ago, OPHPR participated in Gotham Shield 2017, which was a functional exercise using the fictional scenario of a terroristic detonation of a nuclear weapon on the New Jersey side of Lincoln Tunnel. A similar exercise was conducted with the Department of Defense a month ago. Some of the high-level takeaways were understanding the effects of disruptions in communications and knowing what hospitals can be communicated with particularly when it comes to using and sending medical countermeasures. Another important factor to keep in mind is depending on the scale of the event normal ways of responding may have to be altered. Discussions on what is possible if an event of abnormal scale were to occur needs to take place.

The Select Agent Program has been discussing inactivation requirements. The division is working closely with regulated entities to ensure implementation is done correctly. There's been a lot of work on staffing and reconfiguring training. The program has also experienced great progress in developing a database that will monitor the activities occurring in regulated entities.

The Division of Emergency Operations is working on exporting the global health security model, training, and advising on rapid response and emergency operations center development.

The Division of State and Local Readiness has a new five-year funding announcement that was posted in February 2017. The request for proposals was a significant lift resulting in a 150-page document. Part of this is recalibrating the program performance metrics by making them clearer and simpler.

The Division of Strategic National Stockpile is rethinking ways to accomplish the mission of the program alongside commercial supply chains.

In the future, several activities need to occur. OPHPR is trying to understand and act on feedback from the new administration. There have only been a few visitors to CDC so far from the new administration. Secretary Price announced the Reimagining Health and Human Services Initiative a week ago. This process will take place over the next six weeks and OPHPR will be heavily involved in this effort. This provides an opportunity to rethink some of the fundamental assumptions, streamline, and evaluate everyday functions.

OPHPR is continuing to support the vertical CDC program partners. This support can be seen in the nuclear detonation exercise work and our opioid epidemic response.

Interval Updates – OPHPR Division Directors

Greg Burel; Director, Division of Strategic National Stockpile

Mr. Burel provided the BSC with an update on the Strategic National Stockpile (DSNS). The division is shifting some of its thoughts on medical countermeasure (MCM) pre-positioning and thinking of ways to work closer with the commercial supply chain. The overall goal is to bridge the gaps in MCM supply and distribution.

One of the objectives is to protect the supply chain by providing time for it to ramp up in order to meet the national demands. To assist the division in its thinking it hosted workshops to discuss ways to create elasticity in the supply chain. Several agencies and organizations served as strategic contributors during the workshops. The National Advisory Committee on Children and Disasters (NACCD), National Preparedness and Response Science Board (NPRSB), and National Academies of Science, Engineering, and

Medicine (NASEM) served in an advisory capacity. McKesson, Cardinal, and Owens and Minor provided non-acute and acute care distributor perspectives. SemperMed shared challenges and capacity within the glove market.

The Healthcare Industry Distributors Association (HIDA) and DSNS hosted its 2nd Annual HIDA/DSNS Workshop, which focused on bridging response gaps during public health emergencies, as well as developing medical countermeasure playbooks that identify materiel stock-keeping units (SKU). The division also participated in an information sharing session with the International Safety Equipment Association (ISEA) to discuss surge capacity and market availability of additional personal protective equipment like N95 respirators, gowns, and face shields. DSNS has also worked with the Department of Defense (DoD) and the Food and Drug Administration (FDA) on an emergency use authorization for the Rafa auto-injectors. This will relieve some pressure while a permanent solution is sought. Lastly, 760 of 1364 (56%) cache sites are now accepting CHEMPACK drop shipment.

Training and outreach also continues to occur. DSNS has worked with the Division of Emergency Operations (DEO) on the Global Health Security Agenda's MCM Action Package. MCM workshops have occurred in Cameroon, during October 2016, and in Kenya, during March 2017. In Atlanta, MCM training also took place in March of 2017 for the Public Health Emergency Management Fellows. State, local, tribal and territorial partner training was also provided:

- Introduction to SNS Operations 78 Attendees
- Receiving, Shipping, and Storing (RSS) Course 28 Attendees
- On Line RSS Course 213 Attendees
- CHEMPACK Webinars 965 Attendees
- Introduction to SNS Webinar 498 Attendees

DSNS is looking to revamp the training material and will hold new training classes. In the future, the goal is to include more private sector partners as well. Furthermore, some exercise planning and/or participation took place in Virginia, Dallas, Houston, Philadelphia and Pittsburgh.

The division also attended the 2017 Preparedness Summit. Some of the SNS sessions included: "Not All Responses Are the Same: Contrasting Anthrax and Influenza"; "Building Elasticity into the Medical Supply Chain in Emergency Public Health Preparedness and Response"; "A Demonstration of REALOPT and Toursolver Optimization for Medical Countermeasure Planners"; "Be Ready with the Inventory Management and Tracking System (IMATS) and Countermeasure and Response Administration (CRA)"; "Medical Countermeasures (MCM) Link Workshop: Linking You Directly to CDC"; "MCM Program Information for Public Health Professionals". In addition, DSNS' abstracts were accepted for the International Association of Emergency Managers (IAEM).

DSNS hosted nine webinars for the Inventory Management and Tracking System (IMATS) and implemented the system in two new jurisdictions, Vermont and Toledo-Lucas County. Some of the memoranda of agreement for MCM distribution have been updated in the District of Columbia, Virginia, Newark/Jersey City, Philadelphia, Pittsburgh, and New York City (a plan for forward deployment of MCMs is in final CDC legal review). In addition, more precise timelines have been developed for the delivery of products.

Communications has also improved for the division. SNS promoted the stockpile's training on the Public Health Matters blog, which was shared by Johns Hopkins' Health Security Headlines and Kaiser Daily Global Health Policy Report. Within two weeks, the page garnered 500 views. The division has also published a responder story on the stockpile's Zika efforts on http://www.cdc.gov/about/24-7/cdcresponders-zika/snsr.html and the main CDC social media outlets. On Instagram, 38,000 individuals were reached and there were 317 engaged users who liked, shared or commented. Through Facebook, there were 35,000 users, with approximately 300 users engaging in conversation. And from Twitter, 24,000 users were reached with 198 engaged. In addition, the public-facing SNS website on www.CDC.gov/phpr/stockpile/index.htm has been totally redesigned. In March of 2017, the website received 8,600 views. Other opportunities to publish are also being explored.

Mr. Burel ended his presentation with a few goals and challenges for the division. There is a need to align requirements to stable funding to ensure SNS capabilities are maintained. Another objective is to improve the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which includes an increased role for state and local representatives. Lastly, the division plans to improve technical assistance and communication to state and local partners by ensuring the right training, information, and guidance is available before and during a response.

Recommendation/Comments:

- It would be useful to have good data that tracks back to the MCM stakeholders' efforts that funding supports and sustains. This may be something to keep in mind while doing the refresher training.

- When we discuss workforce training and its effectiveness, we need to understand penetrance of training. Of the eligible workforce that needs to receive training "X", what % received training?

- Given all the aspects of a responses, it may not be a bad idea for CDC to mandate who receives products first versus working the regular supply and demand scenario.

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

The main charge of the Division of Select Agents and Toxins (DSAT) is to ensure select agents work is conducted in a safe and secure manner. Dr. Edwin's presentation focused on new regulations for inactivation of select agents and Federal Select Agent Program information system changes.

Bacillus cereus Biovar *anthracis* has been added to the Human and Health Services (HHS) list of select agents and toxins as a Tier 1 agent. The interim final rule was published in September 2016 and became effective on October 14, 2016. The final rule was then published on April 12, 2017. The final rules to the HHS/USDA amendments to the select agent regulations (SAR) were published on
January 19, 2017. It became effective on March 21, 2017.

The Select Agent Regulation (SAR) amendments include changes to the toxin permissible limits and the addition of specific requirements that must be followed for the inactivation of select agents. It also contains new provisions to the biosafety sections and some clarifications to the regulatory language regarding security, training, incident response, and records. There have been no changes made to the list of select agents and toxins.

To assistant with compliance, multiple efforts are occurring to help registered entities comply with the regulations. In response to the inadvertent shipment of live *Bacillus anthracis*, FSAP has added regulatory requirements regarding inactivation. Entities must confirm their inactivation or select agent removal procedures in-house through viability testing. The guidance on how to develop and validate procedures and protocols, and confirm inactivation or select agent removal was developed and can be found at https://www.selectagents.gov/irg-intro.html.

New regulations state that select agents and toxins that meet any of the following criteria are excluded from the requirements:

- Section 3 (d) (4): A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol.
- Section 3 (d) (5): Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

In addition, new regulations include new definitions, as it pertains to inactivation. Validated inactivation procedure means a procedure, whose efficacy is confirmed by data generated from a viability testing protocol to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render

any nucleic acids that can produce infectious forms of any select virus non-infectious for future use. The viability testing protocol means a protocol to confirm the [in-house] validated inactivation procedure by demonstrating the material is free of all viable select agent.

The eFSAP Information System is transitioning to a new secure information system that will contain select agent program information from all registered entities (DSAT + AgSAS). System development is well underway and the initial transition to the new system for first group of entities will begin in May. Following the initial launch, the system will roll out to the remaining FSAP registered entities and will also incorporate the Import Permit Program into the system (eIPP) later this year. Several benefits will come from using the system such as:

- Secure, web based, user interface (portal)
- Reduced paperwork
- Increased ease of validating and submitting information
- Reduced processing time for requests
- Increased efficiency
- Searchable database; will provide immediate, real-time information on who has what select agents, and where

External partners are anxiously awaiting the new system.

Future priorities for DSAT include a continued focus on routine program functions, like inspections, amendments, import permits, etc., to ensure the safety and security of work with potentially dangerous biological agents and toxins. Another priority is the continued focus on the implementation of amended select agent regulations, including inactivation provisions. Inspector training and the development, implementation, and refinement of eFSAP will continue to be priorities going forward. Responsible officials/alternate responsible officials training will begin in November on eFSAP and agent inactivation. Lastly, the publication of the 2016 Annual Report of the Federal Select Agent Program is to come.

Recommendation/Comments:

- In a future BSC session, it would be helpful to understand the cross-connections and impacts of the division's actions on other parts of OPHPR. Describe and share lessons learned from those interactions. It is not always clear how the activities in one division can impact another, positively and/or negatively, and therefore it is difficult to determine what advantages could be realized from division interactions. Also highlight how division roles and responsibilities impact OPHPR-wide messaging and communication.

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

Ms. Kosmos' provided an update on the recently-published 2017-2022 Hospital Preparedness Program (HPP)-Public Health Emergency Preparedness (PHEP) Funding Opportunity Announcement (FOA), new content and updated capabilities, as well as, the Medical Countermeasure Operational Readiness Review.

In the last six months, DSLR has focused on messaging, outreach and education. One of the goals is to develop clear and compelling messages about the impact of the PHEP Program on state and local preparedness and response efforts. Secondly, the division desires to clearly articulate the role of public health in ensuring the health and safety of the community during a public health emergency. Another goal is to develop an outreach and education strategy that can educate key decision-makers and allow DSLR to speak in a unified voice.

In December of 2016, the PHEP Impact Project Steering Committee was created. The committee's purpose is to coordinate the public health preparedness community's communication and advocacy efforts. It is comprised of three groups. The Executive Group is charged with providing overarching guidance and direction related to PHEP Impact Project activities. The Communication Workgroup has the duty to provide direction and oversight on communication activities, while the Policy & Partnership Workgroup gives direction and oversight on policy activities and partnership outreach.

The committee's vision is to protect America's health, safety, and security by ensuring the sustainability of the CDC's PHEP Program via financial and policy efforts. The goals of the committee are as follows:

- Develop a band of stakeholders and partners that can carry the PHEP Program's messages
- Create clear and action oriented materials that articulate the contribution to state and local public health and the importance of the PHEP Program
- Distribute marketing materials to its stakeholders or "champions" in order to increase dissemination

An Awardee Partner Meeting was held on February 28, 2017 to accomplish several objectives: develop a strategic project plan for 2017; determine short-term deliverables; and set milestones for the Communications and Policy & Partnership Workgroups. Attendees for the meeting included PHEP awardees, local preparedness directors, Association of State & Territorial Health Officials (ASTHO), National Association of County & City Health Officials (NACCHO), and Oak Ridge Associated Universities (ORAU) representatives. Thirty jurisdictions from around the country are willing to be trained on how to effectively communicate and deliver messages to their congressional leadership. The work groups developed compelling one-pagers that jurisdictions can use with the flexibility to modify the communication to address their unique needs.

DSLR has also developed and released the 2017-2022 HPP-PHEP FOA. DSLR is on day 472 for activation of the State Coordination Task Force for Zika Response. It is managing multiple funding streams through seven grant processes. This equates to a little more than 400 applications/awards, such as the PHEP Budget Period 4 (FY 2015), PHEP Budget Period 5 (FY 2016), PHEP BP5 $44.25 million funding reduction and replenishment, PHEP/Ebola I/II, and PHPR Zika I/II.

The PHEP Capabilities have been around since 2011 and are in need of a refreshing. The capabilities guidance is being updated from lessons learned through CDC partnerships. State and locals will be given the chance to weigh in on the guidance. The update will occur in three phases. During Phase 1, DSLR will collect input from subject matter experts and develop a working draft of updated content. This will take place between February 2017 and June 2017. In Phase 2, the division will mobilize work groups aligned to domains/capabilities, review working draft, and revise content as needed. This phase is expected to begin in July 2017 to September 2017. The last part of the process, Phase 3, will include vetting working draft, finalize updated content, conduct formal clearance, and the release of the final document. This will take place from October 2017 to February 2018.

There were some MCM planning improvements that occurred from 2015 to 2016. DSLR implemented a new evaluation tool to assess readiness for large MCM responses. Last year was the kickoff year for the review. The process included questionnaires and site visit to assess the ability to distribute and dispense medical countermeasures. DSLR along with its state partners assessed 487 state, local, and territorial public health departments. This number included 62 PHEP awardee jurisdictions and 425 Cities Readiness Initiative local planning jurisdictions. The review results indicated that MCM plans are relatively mature at the state and local level. DSLR provided education on what elements should be a part of the plan to make it successful.

Ms. Kosmos presented several maps related to MCM dispensing and distribution. The map of MCM dispensing operational plans for open points of dispensing shows that the majority of states are in the advanced stage of planning, while the remaining states have either established plans or intermediate plans. Only two states are in the early stage. The map of MCM dispensing adverse event reporting shows a majority of states has advanced reporting and an almost even number of the remaining states has established or intermediate reporting. Eight states are in the early stage of reporting. MCM distribution exercised transportation security plans are where major gaps have been identified across the country. The map below illustrates the distribution for the U.S.

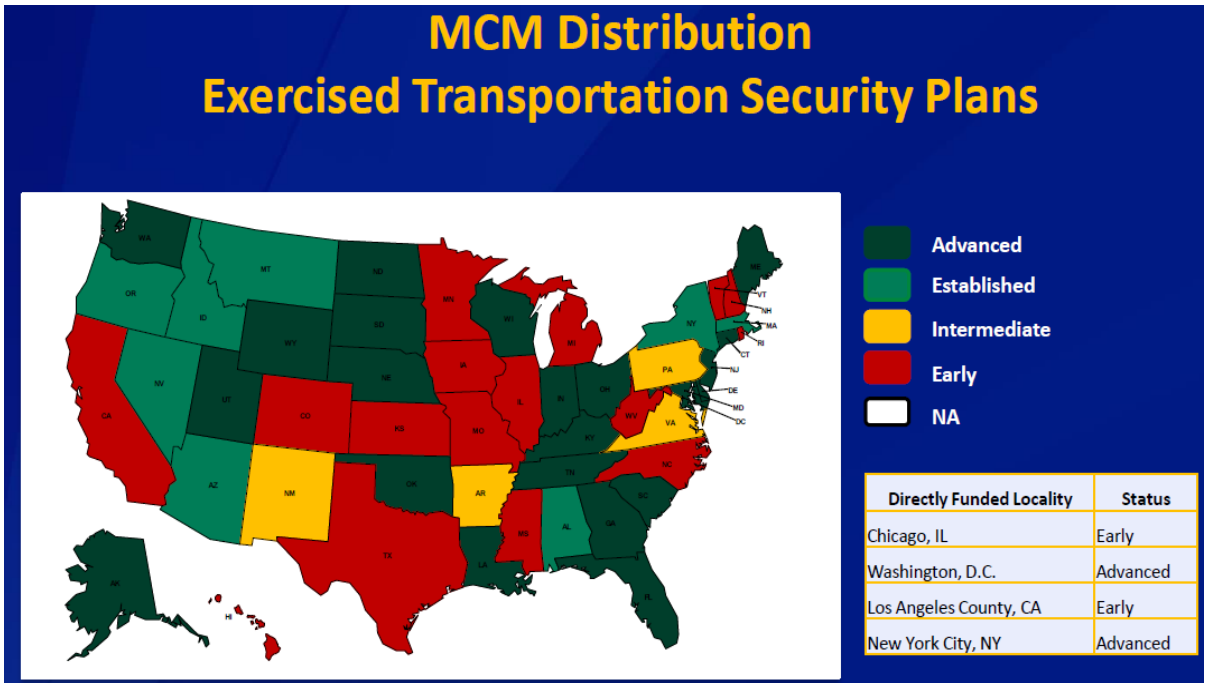

Figure 1. MCM Distribution Exercised Transportation Security Plans

Ms. Kosmos ended her presentation with some of the challenges and opportunities for DSLR going forward. They are as follows:

- Prepare for and deploy refined MCM ORR process: enhanced for ease of use and more consistency of application.
- Refine how we look at readiness and expand ORR beyond MCM to all capabilities
- Refresh 15 public health preparedness capabilities
- Prepare for an uncertain future regarding budgets, staffing, and resources.
- Streamline awardee grants management processes
- Enhance partnerships

Recommendations/Comments:

- Intertwine the communications from the Index and those of DSLR. With the pledge to do more with messaging around the National Health Security Preparedness Index (NHSPI), it would be nice to intertwine the messages of the Index with DSLR's communication strategies.

- Help colleagues to understand that the NHSPI is a tool that can help them. Many colleagues don't recognize the direct alignment of the Index to the PHP capabilities. Refine or point out where they intersect so this will change their thinking.

- Explore response fatigue, the cause, and what resilience look like. The health system may provide lessons and be a resource.

- Given all the good work that is being done, sustainability is critical, so focus on how to sustain PHEP efforts in light of budget uncertainty.

- Go back and look at the outcomes of the communication plans. How effective were our response communications? Did they vary by purpose of the communication or by audience? This type of evaluation should help in the development of desired program performance metrics and achieve the impact that can be realized.

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

Mr. Bryant presented the work of DEO in four categories: emergency response, incident management training (for senior leaders likely to lead a CDC emergency response), efforts in global health security, and risk management. Two of these categories were discussed in today's briefing and the remaining two topics were covered on day two of the meeting.

In the past, Zika outbreaks were occurring in Africa, Southeast Asia, and the Pacific Islands. Now, active Zika transmission is happening in many countries and territories located in the Americas, as well as, the Commonwealth of Puerto Rico, U.S. Virgin Islands, Miami-Dade, FL, and Brownsville, TX. The current priority areas for Zika are laboratory diagnostics, clinical services, vector management, best practices, and the response phase. DEO is now in the phase of identifying best practices and detecting areas for improvement.

There is a tension that exists. Limited-term staff have been on response continuously since early in the Zika epidemic. The work they are performing is critical and needs to continue, but there are fiscal realities that will surface in five months. The challenge is to identify ways to transition the work to match the lower-resourced environment and continue to respond effectively.

One of the best practices realized from the Zika response comes from the Pregnancy and Birth Defects Rapid Response Network. The process can be applied to future responses. Below is an illustration of the network's processes.

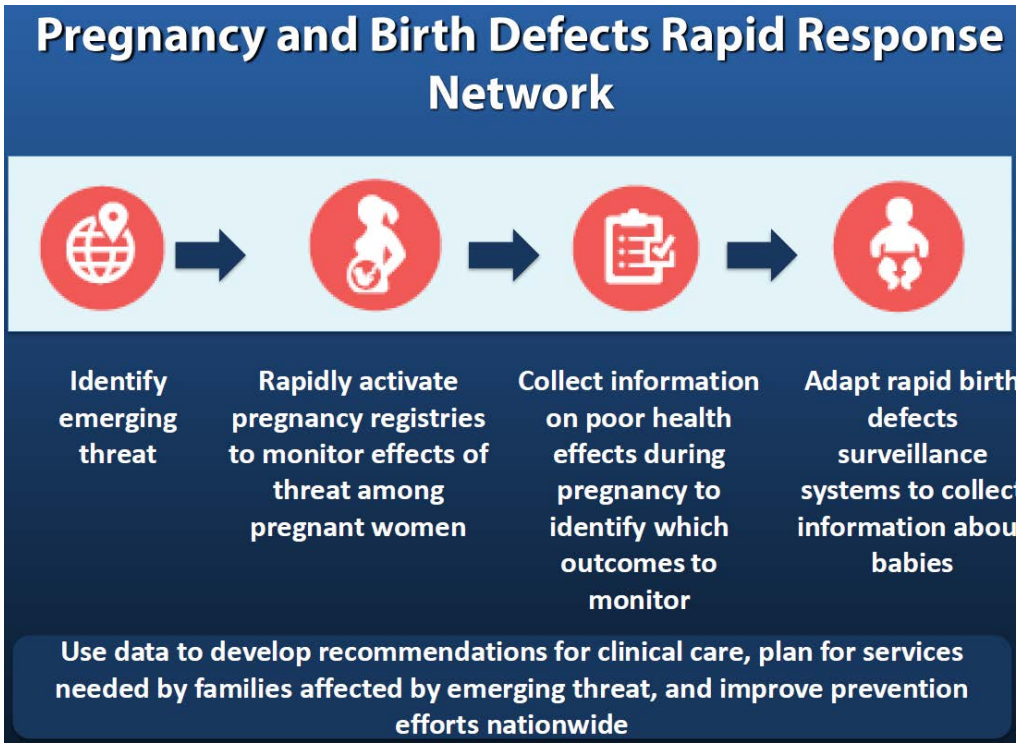

Figure 2. Pregnancy and Birth Defects Rapid Response Network

In order to be truly effective, a pregnancy registry had to be developed and used going forward to monitor long-term sequelae and provide surveillance data on mothers and babies affected by Zika. The data garnered can be used to inform clinical guidance and the development of further protective measures.

The inaugural response leadership cohort of OPHPR's Incident Management Training and Development Program (IMTDP) was held Monday, May 8, 2017. Seventeen agencies were involved in development of the training. Out of the past 526 response leaders at CDC since 2009, only 372 (71%) are still available. Nineteen percent of the total CDC workforce is eligible to retire in one year. This presents a great potential for loss of experience and knowledge. The inaugural Cohort launch targeted 15 to 20 senior leaders for training as incident and deputy-incident managers.

After the first IMTDP session, cohort members were asked two questions. Question 1: Now that you've participated in Module 1, how likely are you to utilize what you learned today in your future response leader role? Out of 15 respondents, 11 (73%) said, "I am very likely to utilize what I learned today in my future response leader role" and 4 (27%) said, "I already know when and how I will utilize what I learned today in my future response leader role". Question 2: Now that you've participated in Module 1, how able are you to put what you've learned into practice when starting a CDC IMS activation? Again, out of 15 respondents, 8 (53%) said, "I will need more hands-on experience to be fully competent at starting a CDC IMS activation" and 7 (47%) said, "I am able to start a CDC IMS activation at a fully-competent level".

Currently, all response staff has to split time between their regular job roles and the DEO. DEO is seeking solutions for managing expectations and setting realistic outcomes. One of the goals in 2016 was to identify four or five things that partners can look to CDC to manage in a response.

DEO just completed active support for the exercise, Gotham Shield 2017. The goal of the program is to aid prevention, protection, response, and recovery activities for a rad/nuke event. The priorities are to update the CDC Rad/Nuke emergency response plan annex, finalize the Nuke/Rad IM structure, revisit the MCM requirements, and develop pre- and post-incident public health messaging.

Mr. Bryant also reported that the Department of Energy is currently leading a response in Washington State at the Hanford Nuclear Waste Site. The effort is being supported by the Environmental Protection Agency (EPA). At this time, there have been no requests made for CDC assistance. Furthermore, there have been no reports of physical injury, human exposure, or contamination. The Radiation Studies Branch, National Center for Environmental Health is in close coordination with the Department of Energy. In addition, the Agency for Toxic Substances and Disease Registry (ATSDR) and HHS Region X regional emergency coordinators are monitoring the processes.

DEO is providing assistance in response to a couple of emerging threats. One is the opioid overdose epidemic. Since 1999, opioid prescriptions have quadrupled. The number of deaths attributed to drug overdose continues to increase in the U.S. Approximately a half a million people have died from overdoses between 2000 and 2015.

The second threat is the H7N9 virus. Currently, the risk to the public's health is low, but the virus has pandemic potential. Pandemic preparedness actions to respond to this virus include surveillance, vaccine development, genetic analysis, and susceptibility testing. CDC is coordinating with clinical and public health labs to conduct influenza surveillance. Any novel influenza A virus that is suspected as being H7N9 will be sent to a CDC confirmatory testing facility.

Lastly, at last week's Preparedness Summit, there were numerous descriptions of processes, structures, and products that will be beneficial to responses activities. These items need to be added to the literature. Therefore, publishing is also one of the priority areas for DEO in both 2017 and 2018.

Recommendations/Comments:

- Be strategic in how you deliver messages to avoid message fatigue.

- Publishing can be a fantastic mechanism for translating research findings into actions and can be used as a nontraditional method for internal and external marketing.

- Have a more specific characterization of the request in terms of messaging, audiences and outcomes, and your expectations. Providing a more specific characterization of your desired outcomes will assist the Board to in providing more advice.

- Ponder what the critical infrastructure, processes, are and expertise needed to respond to whatever comes. State and local health departments often don't know what public health emergency will occur next. Focusing on specific issues/hazards takes away from thinking about the common infrastructure needs for response in general. It would be helpful to understand and development "fundamental" capacities and capabilities.

- After action reports are a retrospective, not prospective, tool; therefore after action reports are helpful, but insufficient for strategic planning.

- There's a contrast between what CDC does in a response compared to other agencies who are involved in responses, like FEMA, for example. When communicating to Congress, portray CDC as the agency that provides support and expertise throughout the response and continues until recovery, unlike agencies like FEMA who are in and out. CDC is there from the initial response and throughout recovery.

- Some business entities have a meeting a couple of times a month with diverse industries to talk about risk management and their processes. Using this process can probably yield a list of several unthinkable or worst-case scenarios and allow the division to expand its thinking.

- Utilize stakeholder maps that point out the interests or areas of importance for each stakeholder. This can help recognize the range of stakeholder issues that have to be addressed/considered.

Biological Agent Containment Working Group – Rationale and Proposed Tasks

RADM Stephen C. Redd, MD; Director, OPHPR

The presentations during this session were intended to provide information that will help the BSC determine whether to recommend the creation of a Biological Agent

Containment Working Group. Two things have led to the desire to form the workgroup. Through internal discussions it was determined that DSAT needed additional advice around what should that program really be doing and should OPHPR move from a list-based regulatory program to something else.

In addition, OPHPR has assumed responsibility for polio containment activities. Part of the requirement for doing this function is to have an external group provide input and oversight. So, the workgroup will help to fulfill that requirement.

Christye Brown, PhD, MPH, Senior Public Health Advisor, Polio Containment Activity, OPHPR

Dr. Brown introduced the new Biological Agent Containment Working Group (BACWG) concept and reviewed the terms of reference recommended for the BACWG. OPHPR is seeking guidance and recommendations to support its responsibilities in the oversight of OPHPR efforts to improve and ensure biosafety and pathogen security. OPHPR would like to use the mechanism of a working group of the BSC to provide this input.

The charge of the Biological Agent Containment Working Group (BACWG), if enacted, is to provide advice and guidance to the OPHPR BSC regarding biological select agents (BSAT), importation of infectious materials, and containment of polioviruses.

The BACWG will be co-chaired by two BSC members and have a total membership of 6 to 7 members. The members will come from disciplines such as microbiology, molecular biology, virology, biosafety, biosecurity, physics, chemistry, bioinformatics, state public health departments, academic research and clinical institutions, and private and commercial entities working with relevant infectious materials. The directors of Division of Select Agents and Toxins and Poliovirus Containment Activity (PCA) will serve as CDC co-leads. Federal laboratory stakeholders will be invited to participate as appropriate.

The reporting will include minutes of the working group meetings, which will be submitted to the OPHPR BSC. The BACWG co-chairs will present meeting summaries to the full OPHPR BSC for deliberation, discussion, and/or decision. Any approved recommendations will be included in the OPHPR BSC Annual Report.

Today's session presentations will provide an overview from the Polio Containment Activity and DSAT regarding their rationale for establishing the working group. After those presentations the Board will deliberate and consider whether to approve the charge to form the BACWG. After this meeting, there will be a determination made of working group membership and, once convened, the working group will determine its tasks and timelines.

Alison Mawle, PhD; Polio Containment Activity

Dr. Mawle provided a high-level overview of the Polio Containment Activity. She began by describing the poliovirus. The virus is a single-strand RNA genome and contains 7,500 nucleotides. There are three types of poliovirus: PV1, PV2, and PV3. Two vaccines exist for the poliovirus, Salk and Sabin. Salk is inactivated (IPV) and is given as an intramuscular vaccine. There is no mucosal immunity, and it can't revert. Sabin contains live attenuated (OPV) and is given orally. There is mucosal immunity, and it can revert as vaccine-associated paralytic polio (VAPP) and vaccine-derived poliovirus (VDPV). The oral vaccine was discontinued in the U.S. in 2000.

The PV2 has not been seen since 1999 and was officially declared eradicated by World Health Organization (WHO) in September of 2015. It was decided to reduce the risk of VDPV2 emergence and the reversion of vaccine strains to neurovirulent phenotype (VAPP). In April 2016, the decision was made to synchronize the global switch from trivalent OPV to bivalent OPV. The recommendation was made to include a minimum of one dose IPV in schedule to provide PV2 immunity. Since the eradication, PV2 has been classified as "exotic".

WHO's Global Action Plan, known as GAPIII, intends "…to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use." It is this part of the plan that the BSC is being solicited for advice.

There are three phases of the Global Action Plan. The activities of Phase 1 are inventory, destruction, and preparation for poliovirus type 2 containment. Phase 2 is the poliovirus type 2 containment period. And lastly, Phase 3 will be the final poliovirus containment. The Poliovirus Containment Activity is currently in Phase 2.

PV2 materials include infectious materials or virus isolates that are known to contain WPV2, VDPV2, or Sabin 2. Potential infectious materials are more complicated. In these cases, the presence of poliovirus is unknown but collected in a place and time where poliovirus was circulating or OPV was used, and storage consistent with maintaining infectivity. These include stool and respiratory specimens. Although the focus is on PV2, these definitions are also relevant for PV 1 and 3 after complete eradication.

There are three steps to containment. The first is to destroy and document autoclaving and incineration. The second step is to contain. This process includes establishing entities, called Polio-Essential Facility (PEF) in which poliovirus is only worked on in a certified-containment space. The last step is to transfer materials to a polio-essential facility. In Phase 2, PV2 may only be handled in certified PEFs.

The WHO Containment Certification Scheme describes the implementation, audit process and certification process under GAP III. The scheme was endorsed by the

Strategic Advisory Group of Experts (SAGE; principal advisory group to WHO for vaccines and immunization) in October 2016. Certification is against the biorisk management standard laid out in GAP III, annex 2 (16 elements) and applies to infectious materials and potentially infectious materials. The certification is a joint, lengthy, process between the National Authority for Containment (NAC) and WHO. The process is estimated to take about a year. The country sets the rules in light of their different governing infrastructure requirements but WHO can counter a country's rules and ask for modifications.

There are 16 technical requirements for containment in essential facilities:

- Biorisk management system
- Risk assessment
- Poliovirus inventory and information
- General safety
- Personnel and competency
- Good microbiological technique
- Clothing and personal protective equipment
- Human factors
- Healthcare
- Emergency response and contingency planning
- Accident/incident investigation
- Facility physical requirements
- Equipment and maintenance
- Decontamination, disinfection, and sterilization
- Transport procedures
- Security

CDC needs advice and input on the risk assessment portion.

As far as progress to date in the U.S., in December 2015, there was the appointment of a National Polio Containment Coordinator, the initiation of a U.S. survey, and the establishment of the National Containment Committee. In December 2016, approval was given for the establishment of Polio Containment Activity at CDC. And, in January 2017, Polio Containment Activity was stood up in OPHPR.

The PCA's mandate is to be the functional arm of the National Authority for Containment. It is responsible for implementation of the Containment Certification Scheme (CCS) for GAP III implementation. The PCA is located at CDC due to significant scientific expertise in poliovirus, eradication, and laboratory containment. It is situated within the Office of Public Health Preparedness and Response to separate CCS implementation organizationally from CDC's polio program.

In the last four months, several activities have taken place. Three representatives attended the WHO auditor training in February 2017. The PCA has also developed audit materials, an audit tracking database, and the application to become a PEF. Outreach has begun to potential PEFs identified by the survey. Survey activities continue. There have also been interactions with WHO, Pan American Health Organization (PAHO), and WHO Regional Collaborating Centers (RCC).

The role of the BACWG will be to provide an external review of the PCA audit process, as well as, advice and input on risk assessment methodologies.

Recommendations/Comments:

- Look at recent crises that are seemingly unrelated to current issue under consideration and ask the "ridiculous and unorthodox" questions. For example, what did we learn from the Volkswagen or Wells Fargo crises that pertain to what is happening in OPHPR? Rattle and shake up the world view and cause thinking around things that haven't been considered in anyway before. When doing risk management, thinking has to be done systemically.

- Always consider, as part of future deliberations, the scenario of needing to ramp up vaccine development and distribution and immunization efforts in a world in which polio is eradicated, but reemerges unexpectedly.

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

Dr. Edwin shared some of the perspectives from DSAT. The FSAP regulates all entities that possess, use, or transfer biological agents or toxins that have the potential to pose a severe threat to public health and safety. The Import Permit Program regulates the importation of infectious biological agents, infectious substances, and vectors capable of causing communicable disease in humans.

The FSAP is supervised jointly by DSAT at CDC, U.S. Department of Health and Human Services and the Agriculture Select Agent Services (AgSAS) at the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA). DSAT regulates those agents that cause disease in humans, while AgSAS regulates those that can cause disease in animals and plants. DSAT and AgSAS both regulate zoonotic agents.

FSAP's key regulation functions and activities are listed below.

- Promulgates the select agent regulations
- Provides oversight of possession, use, and transfer
- Conducts inspections and approves registrations
- Approves individual access to select agents & toxins
- Receives reports of a theft, loss, or release

- Takes appropriate enforcement actions
- Serves as a resource on compliance with the regulations
- Collaborates with domestic and international partners

Advances in science and technology lead to evolving questions for the program, short- and long-term, particularly, in the area of applied biosafety. Given FSAP's unique role as a regulator, DSAT will ask for the working group's guidance around four questions related to laboratory research being conducted by regulated entities.

1. How can DSAT implement a regulatory framework around synthetic biology so that we only regulate those synthetic organisms that pose a threat to public health and safety? How can DSAT track, assess virulence and/or regulate unregulated microorganisms with select agent genes?
2. What criteria (e.g., 10^{-6} sterility assurance level) should be required to ensure entities have inactivated BSAT effectively? What types of evidence are necessary to determine the inactivation effectiveness?
3. What is the difficulty to produce infectious select agent positive-stranded viruses from genomic material? What are the biosafety and security risks if positive-stranded RNA genomic material is not regulated?
4. How can DSAT be more transparent with program data given the vulnerabilities with the release of the information?

Recommendations/Comments:

- ASPR's Biosafety and Biosecurity Division expressed appreciation for the focus OPHPR has put on biosafety and biosecurity. OPHPR's support for the standing up of a biocontainment working group reflects the desire to increase the effectiveness of the FSAP and to strengthen and improve oversight of the important work conducted with biological select agents and other infectious materials. OPHPR has worked steadfastly in collaboration with ASPR and other federal partners to implement two sets of recommendations, one from the Federal Experts Security Advisory Panel and the other from the Fast Track Action Committee on Select Agent Regulations. ASPR feels that the recommendations made by Federal Experts Security Advisory Panel (FESAP) and Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) reflect the culture of responsibility, oversight, outreach and education applied by safety research, incident reporting, material accountability, inspection processes, and regulatory changes in guidance to improve biosafety and biosecurity. The agency further believes that a biological agent containment working group builds on the significant steps taken by the CDC to enhance biosafety and biosecurity.

- Enthusiastic about your interest in identifying research priorities in biosafety and biosecurity. Secondly, the oversight for emerging risk is another issue for which there's a relatively blank reaction from the government and DSAT is the logical place to put that.

Vote was taken for the establishment of the working group and members unanimously supported its creation. Board members were solicited for membership suggestions. Dr. Wooley and Dr. Plough have agreed to be the co-chairs for the workgroup. The Liaison Representatives will come together to identify individuals from their agencies and report back to the BSC with their suggestions. Dr. Wooley asked OPHPR to think about any conflicts of interest when selecting members. Dr. Groseclose said that members will be vetted with the co-chairs before a final determination is made. Dr. Quinlisk suggested speaking with APHL for membership suggestions. Dr. Inglesby suggested Dr. Marc Lipsitch, a scientist and epidemiologist at Harvard who studies risks and biosafety issues, and Dr. Kevin Esvelt, a synthetic biology expert from MIT who has given much thought to risk management and has written extensively on scientific self-regulation. Dr. Groseclose will follow up after the meeting for more suggestions from the board.

Federal and State Perspectives on the Opioid Overdose Epidemic as a Public Health Emergency

Grant Baldwin, PhD, MPH; Director, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control

Dr. Baldwin's presented information collected from the Division of Unintentional Injury Prevention regarding the opioid epidemic. He began by presenting several maps that illustrated the increase rates of deaths in the country as a result of drug overdoses. The maps below illustrate the rates of drug overdose deaths in 2000 compared to 2015.

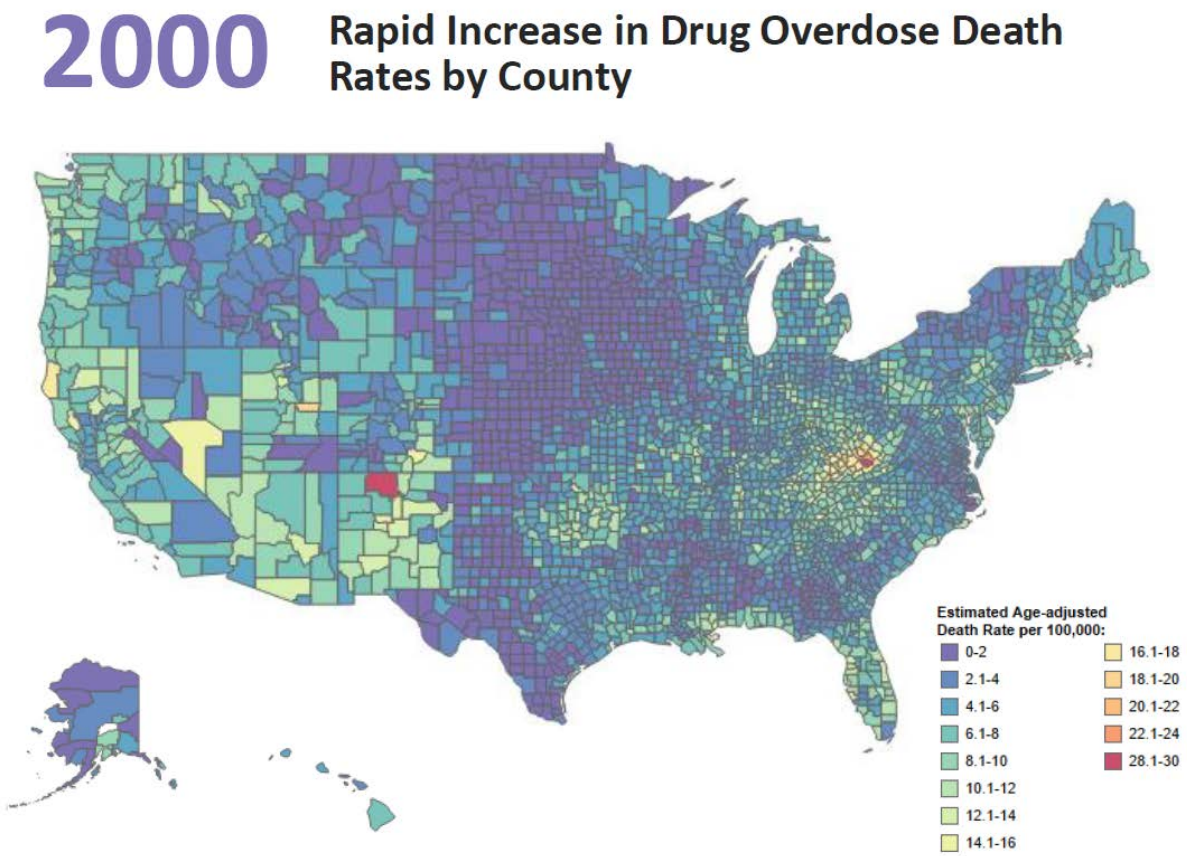

Figure 3. 2000 Rapid Increase in Drug Overdose Death Rates by County

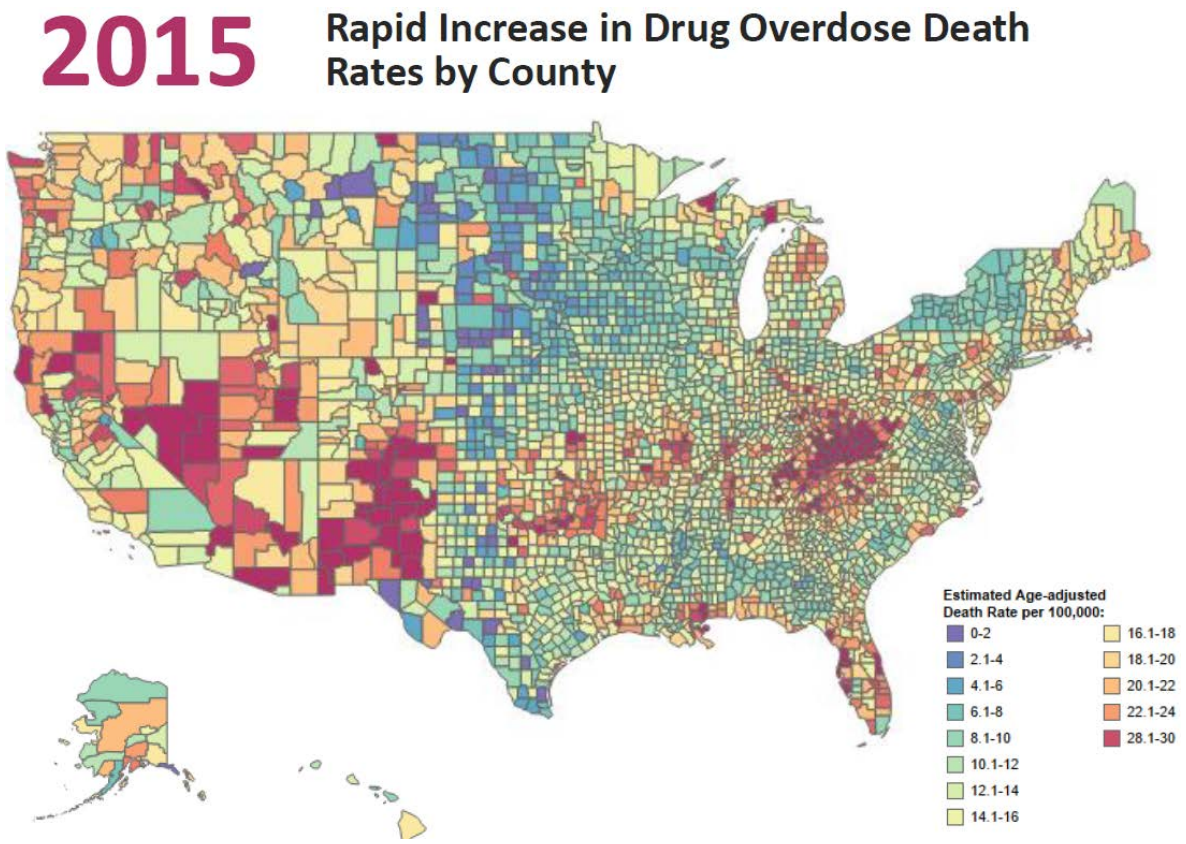

Figure 4. 2015 Rapid Increase in Drug Overdose Death Rates by County

Drug overdose deaths are at an all-time high. He reported that in some communities access to heroin is as easy as ordering a pizza. He described the epidemic in waves. Wave 1 deals with prescription opioids. Over 183,000 people have died from prescription opioids since 1999. Natural and semi-synthetic opioid death rates have increased four-fold from 1999 to 2011 and methadone death rates increased six-fold from 1999 to 2007. Wave 2 is heroin use. Over 70,000 people have died from heroin since 2010. Heroin death rate has increased over four-fold since 2010. And Wave 3 is due to synthetic opioids, most likely Fentanyl. Deaths from synthetic opioids excluding methadone increased from approximately 3,100 in 2013 to over 9,500 in 2015. Synthetic opioid death rates, excluding methadone, have tripled in two years. The rise in Fentanyl use is due to its low cost; therefore, it is more profitable for drug traffickers. It's also being used to lace other drugs such as marijuana as well.

The impact of the epidemic on states is evolving and getting worst. West Virginia has seen the worst burden followed by New Hampshire, Kentucky, Ohio, and Rhode Island.

The division has identified two groups of people to target in order to counteract the epidemic. Group one is composed of those that are addicted or dependent. For those individuals, access to services is of most importance. The second group is those who are at risk for addiction or dependence. For those individuals, protection from dangerous drugs is the goal. Last year at the Rx Summit, Dr. Frieden reported on a technical package to stop the opioid epidemic. The components of the package include the following:

- Improve prescribing for pain
- Improve management of addiction
- Partner with law enforcement
- Community awareness and support
- Rigorous, real-time monitoring with adaptive response

On the supply side, the technical response package describes improving prescribing for pain as a strategy. This would include prescription drug monitoring programs, science-based guidelines, pain clinic laws, prescribing defaults in EHRs, prior authorization for risky prescriptions, patient review and restriction programs, naloxone prescriptions, etc. To accomplish this objective, the plan would have to involve payers including Medicaid/Medicare, health systems, pharmacy benefit plans; clinicians; and patients. It would also require partnering with law enforcement, who can assist in enforcing laws, policies and regulations to reduce diversion, abuse, and overdose. They are also key in reducing the availability of illicit drugs. Moreover, the criminal justice system can be used as an entry point for addiction treatment.

On the demand side, to improve the management of addiction, the objective is to increase access to medication-assisted treatment and improve quality and accountability for treatment outcomes and link individuals to treatment and support them through recovery and living with addiction. In addition, increasing access to naloxone for emergency reversals and connecting individuals with treatment should decrease demand. These goals can be accomplished through community awareness and support by increasing awareness of risks and benefits of opioids and promoting economic development to reduce initiation/continuation of drug use.

CDC's response to the epidemic includes three priorities areas: improving data quality and tracking trends; strengthening state efforts by scaling up effective public health interventions; and supplying healthcare providers with resources to improve patient safety. In September 2015, the CDC Overdose Prevention in States Initiative was launched. It has five components: prescription drug monitoring programs, system-level response, policy evaluation/formulation, surveillance, and rapid response. Most states have been funded for this activity.

Several campaigns have been launched to address the epidemic. Dr. Baldwin shared a video from one of the campaigns.
The division is also increasing collaboration with law enforcement. They are currently working in partnership with the DEA's 360 Programs. The DEA has very rich data but there is some data sharing resistance when dealing with active investigations. Strategies are being discussed to overcome this barrier.

The opioid epidemic response is a very non-traditional role for CDC. It is atypical because it's neither a natural disaster nor a terrorist event nor a traditional infectious disease outbreak. It has a rapidly changing nature and is dependent on drug supply and the type of drugs used in a geographic area. And the time horizon for response is unknown and likely to be for many

years. Public health preparedness and emergency response's potential roles in addressing the opioid crisis could include the following:

- Assistance to states and localities that are in crisis
- Enhance readiness to respond when local naloxone supply overwhelmed
- Preparedness for surge capacity in health systems

Some areas for collaboration have been identified but the board was invited to weigh in on others to add to the division's strategy.

Marissa J. Levine, MD, MPH; ASTHO Liaison to BSC

Dr. Levine talked about the opioid epidemic's effects on Virginia and some of the community efforts that are helping at the local level. She presented Virginia data comparing the top three types of unnatural deaths in Virginia and on the total number of prescription opioid, Fentanyl, and/or heroin overdoses, and all opioid overdoses by year from 2007 to 2016.

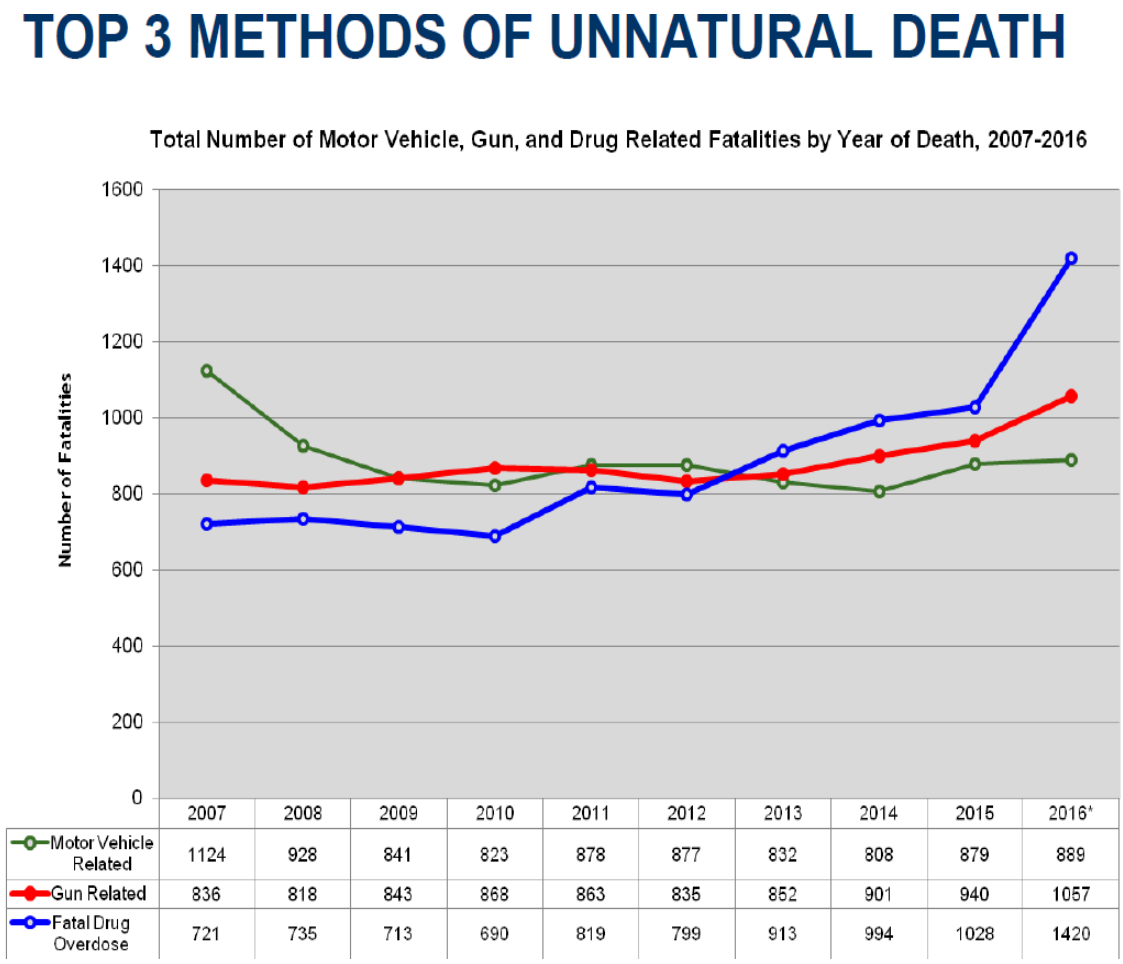

Figure 5. Top 3 Methods of Unnatural Death

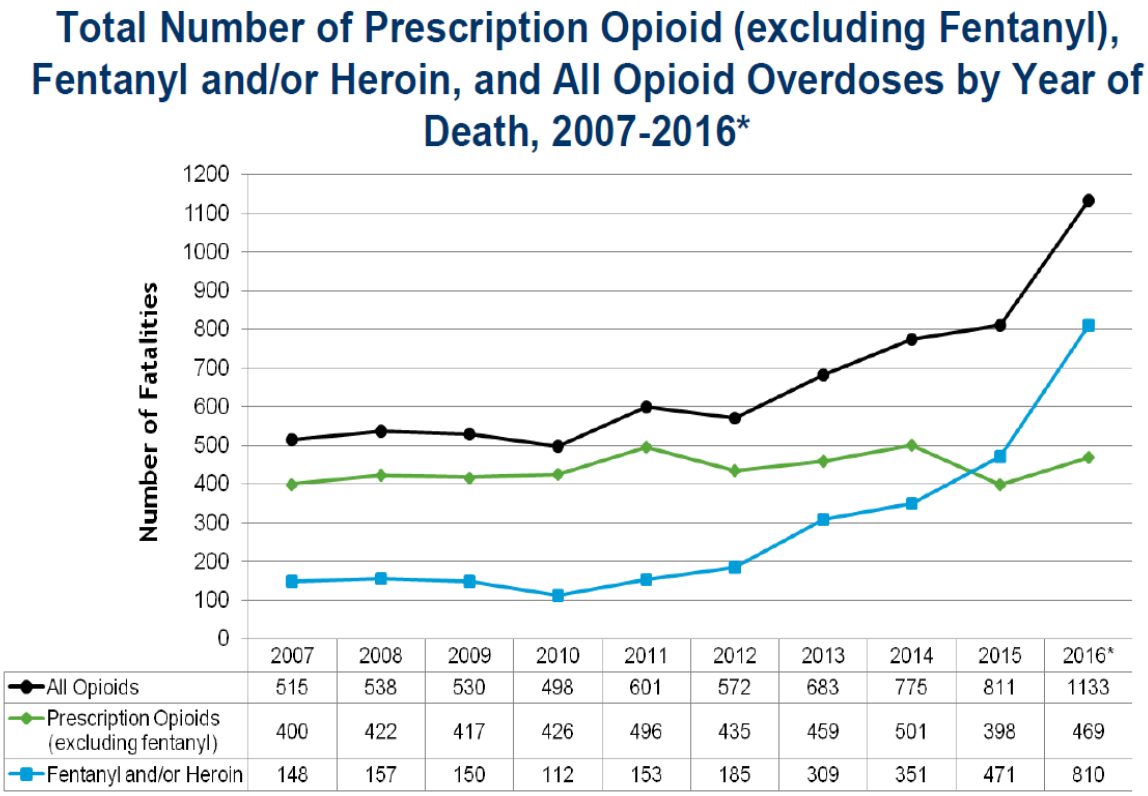

Figure 6. Total Number of Prescription Opioid, Fentanyl and/or Heroin, and All Opioid Overdoses by Year of Death, 2007-2016

There is a question as to whether opioid overdose may have been a contributing factor in gun and motor vehicle related deaths.

Virginia decided to examine regional differences to see if they could better define the target audiences. Virginia regional maps show the concentration of fatal prescription opioid overdoses and fatal Fentanyl and heroin overdoses by locality. Pairing this type of data with other data like socioeconomic status, neonatal abstinence syndrome discharge data, and hepatitis C reports could help better identify the populations of concern.

For example, the cases of neonatal abstinence syndrome have increased over time in Virginia. Most of these cases occur in the southwestern part of Virginia. In 70% of those cases, Medicaid was used as the payer source for hospitalization. Also, more than 70% of neonatal abstinence syndrome-related hospital discharges were among white, non-Hispanic infants.

Injection drug use is the primary risk factor for hepatitis C infections in the U.S. among the 18- to 30-year-old population. Regional maps show an increasing rate of reported acute and chronic hepatitis C infections in Virginia. The southwest region of the state has the greatest burden of new infections.

Virginia is taking a public health approach to address this epidemic focused around data and surveillance. Primary, secondary, and tertiary prevention goals have been defined along with

correlating preventive interventions. The approach's success will ultimately need leadership and policy support to be successful. The governor has created an Executive Leadership Team on Addiction. Thus far, the approach has worked well but it is still a work in progress. Below is an illustration of the structure of the Governor's Executive Leadership Team on Addiction framework.

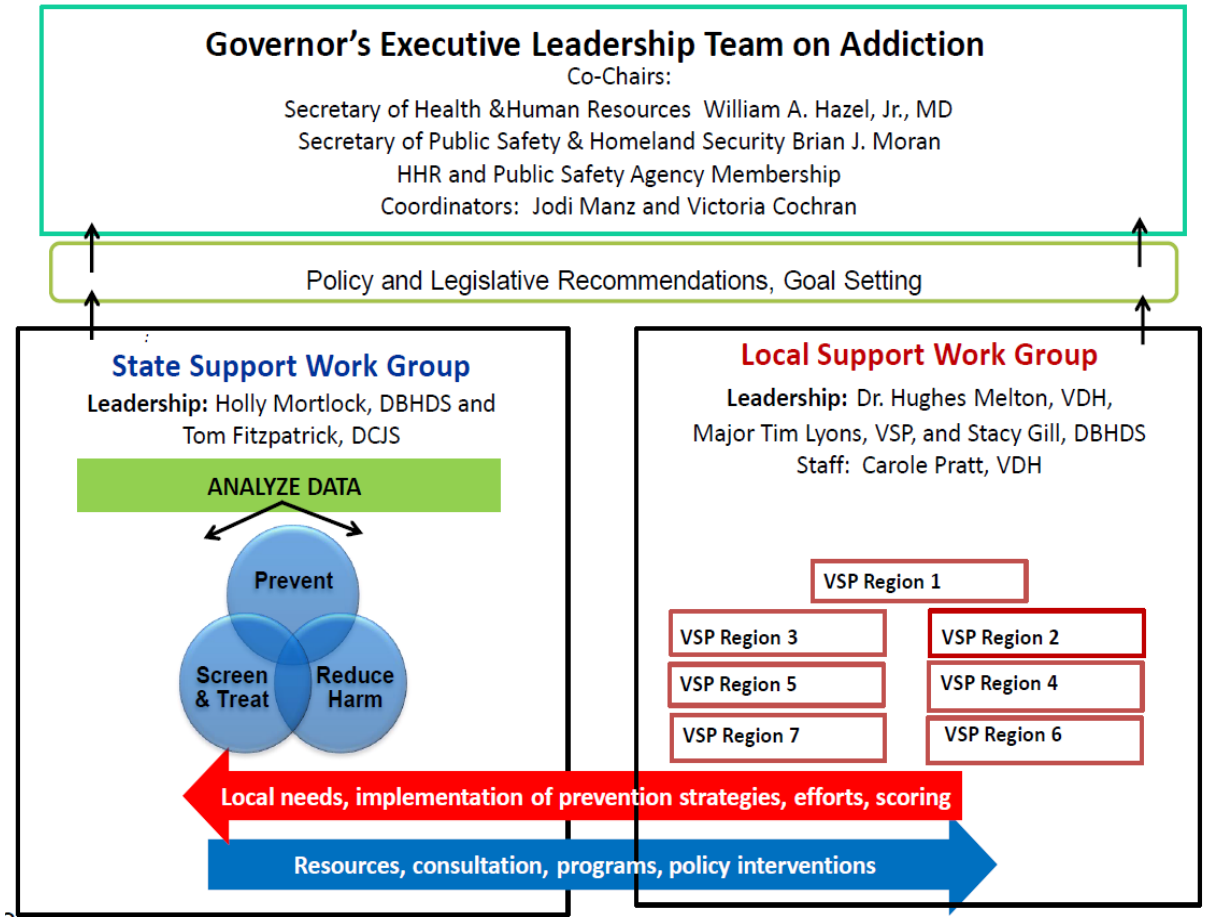

Figure 7. Governor's Leadership Team on Addiction

One tool Virginia utilized was a dashboard to give a more granular view of the epidemic. The dash board includes state summaries of trend data for hepatitis C cases, HIV diagnosis, and opioid overdoses. Virginia is in the early stages of using the dashboard but feedback thus far has been positive.

At the end of 2016, Virginia released its Plan for Well-Being Campaign. The pillars of the plan all begin from a healthy, connected community which establishes a strong start for children. To be successful, the plan requires a system of heath care and preventive actions. All these components will accomplish the goal of well-being. Objectives to accomplish the goal require factoring health into the broader policy decisions; investing in children; promoting a culture of health and prevention; and creating a connected system of health care.

Dr. Levine ended her presentation by presenting several resources used in Virginia that may be helpful to other states and localities. They are listed below.

- Virginia Opioid Addiction Dashboard: http://www.vdh.virginia.gov/data/opioid-overdose

- Virginia Plan for Well-Being: http://www.virginiawellbeing.com

- Virginia Health Opportunity Index: https://www.vdh.virginia.gov/omhhe/hoi/

- Virginia Addiction, Prevention and Recovery Resources: http://vaaware.com/

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

DSLR is deliberating on the proper relationship of public health preparedness and response activities to the opioid epidemic. It is also trying to determine how best to support its stakeholders and how localities are responding to the crisis. DSLR asked ASTHO to determine how states are managing the opioid overdose emergency. These data are preliminary, but give an idea of how states are organizing.

Since 2014, four states have invoked statewide emergencies to address the opioid crisis. Declarations were used to allocate funds for addiction services; expand naloxone access; authorize the issuance of a standing order for opioid antagonists; procure supplies; and establish statewide response programs. In 2014, Massachusetts expanded naloxone access, added mandatory prescription monitoring, prohibited prescribing and dispensing of certain pain medication, and allocated funds for addiction treatment services. Virginia, in 2016, instituted a statewide standing order for dispensing of opioid antagonists. In February 2017, Alaska established a statewide overdose response program and a statewide standing order for dispensing of opioid antagonists. Lastly, as of March 2017, Maryland responded by coordinating resources, informing the public, and procuring supplies and equipment.

In February 2017, ASTHO queried jurisdictions on their current opioid epidemic response activities. As of March, 43 jurisdictions responded to three key questions. Question 1: Has your jurisdiction issued any executive or administrative orders or declarations that provides emergency powers needed for response to the opioid epidemic? Thirty-six indicated no; 7 (16%) said yes. Question 2: What is your jurisdiction's current stance on using an incident command structure as a platform to help organize and coordinate your response? Twenty-four (61%) of the respondents said yes and 15 said no. Question 3: Has your jurisdiction/agency officially activated its emergency operations center for the opioid crisis? Forty indicated no, while only 2 (5%) said yes.

Discussions with the some State Preparedness Directors provides more granularity. Some of the responses are listed below.

- "This is a very different type of public health emergency…"
- "This is not a hurricane…there is no discernable beginning, middle, or end..."
- "This response may last for generations…"

The states have proposed convening a forum to share information, best practices, lessons learned, and response strategies.

Recommendations/Comments:

- From an operational and local perspective, rather than adding Naloxone to the SNS, consider forward deploying it to hospitals similar to how CDC has managed the CHEMPACK Program. Also, in partnership with law enforcement entities, think about Naloxone kits that can be placed in police vehicles and administered in a field situation as a means for augmenting the EMS response. This may lead to faster dissemination to areas where it's needed.

- This is a social determinants of health issue which relates to the resilience and community engagement parts of the preparedness work, as well the emergency response. So, think about the whole continuum.

- Another issue is the burden of the opioid crisis on the child care and foster care system. They should be examined and those stakeholders should be a part of the community response partnerships as well.

- Put the social determinants of health behind the frameworks you are creating; otherwise, you will be "chasing your tail". Think about how to work determinants into the work that we do. Maybe there's pre-primary prevention work that should be completed. Are you linking in health equity and health disparity stakeholders into the efforts? The links are community resilience, social capital, and social cohesion. Look at the underlying issues to further attack the epidemic.

- Consider portraying the data from an action perspective. Use aspects of the determinants to find correlations to the outcome.

- Make it easier to become a treatment center. Another issue is stigma from being a treatment site. Take away some of the stigma of being known as a treatment site by offer virtual training or offer training to multiple people in the community. Use the Extension for Community Healthcare Outcomes (ECHO; an innovative model to train community-based providers to deliver state-of-the-art care for common, chronic diseases in vulnerable, under-served communities) Project as a model.

- Use social network analysis to provide predictive information that can identify emerging "hot spots" for increased opioid overdose incidents. May inform the "4th wave", e.g. drug distribution-related patterns.

- This is a prime example of where medical anthropologists and sociologists should be employed. They can help to look at the broader activity that is happening in society in general and the current regions affected by the epidemic.

- This may not be "a" problem but several different problems that are causing the epidemic. And depending on the problem, what agency helps to solve it? If it's a social determinants issue, then this is a socioeconomic problem. Also, think beyond mortality and expand the crisis to connect to other issues like foster care. Find ways to frame this so the crises can be connected. Is it a law enforcement issue? Also, determine what type of outcome is desired.

- Provide more education because most people don't know the depth of the problem. People are often given the prescriptions for these drugs and don't ask for it and/or never use it. This increases the likelihood of children gaining access to prescribed opioids. Consider a buy-back program or trade in program for those who don't use their prescriptions. Employ a more aggressive campaign that really gives a more realistic view of the epidemic.

- Would it be valuable to set up a model state programs with benchmarks? A set of generic steps that all states should be doing could be created with the flexibility of adding more to address the unique needs of the states. In Maryland, people want immediate access to drug treatment programs. Also, there need to be solutions for those who are not necessarily drug-seeking individuals to be able to access care. Lastly, the prescriber side of the equation has been relatively unattended to compared to other areas. People are still prescribing narcotics around the country in high doses. The U.S. government should provide stronger guidance in this area.

- No single discipline has a final say on this issue. We're dealing with "wicked messes". Determine the heuristics in both identifying and coping with the problem. You only cope; you don't manage. CDC should form a taskforce that looks at the heuristics that cut across so many of the wicked problems it faces daily.

- There's opportunity for relationships and cross sector partnerships. In West Virginia, some partners are mobilizing a medical clinic but they're also going to repackage the concept to use it for harm reduction as well.

Preparedness Updates from Liaison Representatives

Association of State & Territorial Health Officials (ASTHO)

The association continues to work on the Zika response, following up activities from prior years, and bringing awareness through situational awareness reports and the information disseminated through CDC and others. ASTHO has a Zika taskforce and maintains its "Zika: Simple Answers" on the ASTHO site, as well as provided a report to the U.S. Virgin Islands at CDC's request.

The agency met as an association and identified its top five priorities going forward:

- Supporting well-being, disease prevention, and health promotion as key strategies to improve health and reduce healthcare cost.
- Assuring domestic health security and rapid response to public health emergencies.
- Strengthening the public health infrastructure at the state and territorial level to deliver essential public health services.
- Implementing public health programs to meet specific needs and address the priorities of states and local health agency partners.
- Improving health outcomes and delivering return on investments across the public health enterprise.

Recommendations/Comments:

- Dr. Inglesby would like to see the ASTHO's assessment of any implications caused by the President's new budget.

Council of State & Territorial Epidemiologists (CSTE)

CSTE also continues to work with CDC on the Zika response and will host a workshop on Zika and lessons learned at their annual meeting.

The National Academies Forum on Medical and Public Health Preparedness for Disasters and Emergencies meeting was held in March 2017. This was a two-day meeting. CDC as well as some of the states were present. Several gaps were identified. One was BARDA and the continued development of countermeasures. Another topic was critical drug shortages and how the supply chain can easily be disrupted. Also, a discussion occurred related to long-term loss of electricity and the challenges it would cause for public health response with lack of access to data and surveillance.

CSTE provided comments on new federal quarantine laws indicating the new laws were a vast improvement and appreciated that the laws were revamped to reflect the realities of today.

The National Health Preparedness Security Index was released in late April 2017 and CSTE was very involved in that work as well.

The association will continue to work with CDC on the other emerging diseases and thanked CDC for allowing CSTE to have a voice in its work.

National Association of County & City Health Officials (NACCHO)

NACCHO, as well, is supporting efforts with the local health departments and federal partners related to Zika. One effort that is being done in coordination with CDC is assessing local vector control capabilities within ten priority jurisdictions. A report was created and can be found on NACCHO's website. Clearance was received in coordination with CDC from OMB to go to phase 2, which will assess the remaining 41 states along with Washington, DC.

The Preparedness Summit was held a few weeks ago and there were over 1,700 attendees. The association continues to host six preparedness-related workgroups where NACCHO provides feedback and input on national preparedness priorities and guidance. The agency has also established a rural health section to address gaps in that aspect.

The agency and CDC facilitated a workshop on identifying and prioritizing critical infrastructure and personnel for pandemic emergencies. The intent was to gather feedback on a tool, which is currently in development, and to give local health departments a roadmap for engaging their partners in the planning process and overcome various obstacles.

To enhance efficacy and efficiency of MCM distribution at the local level, members of the NACCHO Countermeasure Workgroup participated in a stakeholder meeting and gave CDC operational resource guide feedback. They are also participating in the ORR review and refresh activities. A long-term MCM distribution and dispensing considerations document was created. It includes input from CDC reviewers and will be released soon.

NACCHO will examine ways to support local health departments with building and enhancing the public health response and preparedness capabilities. This is a continuation of the program, Public Health Ready. Entities in 36 local and regional agencies were recently recognized. The agency also continues to work with partner organizations and local health departments to educate the administration and policymakers on the impact of PHEP funding at the local level.

Local health departments are engaged in prevention and response efforts for the opioid epidemic. They are educating healthcare providers and community members about the epidemic, surveillance, available tools, harm reduction and treatment strategies, and the syringe exchange.

One of the upcoming priorities is the PAHPA reauthorization. The desire is to build awareness and catalyze action around the reauthorization. Over the next six months, the association will synthesize feedback from the Summit. NACCHO will work with CDC and members to provide input and feedback on the upcoming PHEP capability refresh. Lastly, it will examine

administrative preparedness in an effort to build on existing efforts to better define administrative and policy barriers for the efficient use of resources at the local level.

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

Thomas Inglesby, MD; Chair, OPHPR BSC

No public comments

After the reviewing of housekeeping notes, the meeting was adjourned at 4:47 PM.

Thursday, May 11, 2017

Welcome & Call to Order/ Roll Call

Thomas Inglesby, MD; Chair, OPHPR BSC

The second day of the May 2017 BSC Meeting was called to order by Dr. Inglesby at 8:41 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.

OPHPR Policy Initiatives and Updates

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

Ms. Gallagher reviewed some updates and priorities for each of the teams within her office: budget, legislation, partnership, planning, evaluation, and policy communication. She also reported on one of the products of Planning Evaluation Team and requested the board's feedback on improvement and evolution of the product to support a variety of activities in OPHPR.

For fiscal year '17, Congress passed and the President signed appropriations for the remainder of the fiscal year through September. OPHPR maintained a total $1.4 billion budget: $575 million for the strategic national stockpile, $668 million for preparedness and response. That is comprised of $660 million for the PHEP Program and $8 million for preparedness research projects. The budget also includes $162 million for CDC preparedness and responses. It calls out $23 million to fund BioSense. The preparedness and response budget funds a variety of activities within CDC including DSAT, emergency operations planning, CDC response, and preparedness-related activities across the agency. There were no changes to the report or bill language so it's basically a continuation of level funding and direction. One disappointing part is the public health emergency response fund was not included. Hopefully, this will not be the case in the future.

Overall, CDC's FY 17 budget was decreased by $13 million. Most cuts were minor across several budget lines with the exception of chronic disease, which had a $60 million cut. There were some increases for a few areas such as $50 million for the opioid epidemic, $5 million for polio eradication, and $3 million for global disease detection.

The full FY18 budget has not been released but will be released at the end of May. The President did release a blueprint budget in March, which is very high-level and gives indications about budget and policy priorities for the administration. Overall, HHS was

decreased in funding by 18%. There were no indications of how the decreases would be distributed across the various operating divisions. There were indications of places for significant increases including programming related to the 21st Century Cures Act but no specifics of where the funds would lie.

There was some FY18 budget content related to preparedness and response. According to the report, the budget reforms key public health emergency preparedness and prevention programs. For example, the budget restructures similar HHS preparedness grants to reduce overlap and administrative cost and it redirects resources to states with the greatest need. It went on to say the budget also creates a new federal emergency response fund to rapidly respond to public health outbreaks such as Zika virus. There's no indication on the level of funding proposed and what that means to CDC. The BSC will be given an update when more details become available.

The main legislative priority is the PAHPA reauthorization. CDC along with other operating divisions have presented their ideas. The next steps are to have conversations among the different operating divisions of HHS to decide what the requests will be to Congress in terms of PAHPA reauthorization. Specific details could not be discussed but in general there were several ideas about ways to more efficiently and effectively get resources disseminated and to operating at an appropriate speed, scope and scale during an emergency response. There will probably be opportunities for those outside of the government to provide comments and suggestions.

With regards to partnership, the office is continuing to hold DC partner meetings and expanding the scope of the groups who are invited. Another objective is to balance the content more between programmatic updates and policy and strategy discussions. The office is also increasing peer individual meetings with OPHPR leaders and their partner groups. A partner speaker series is being planned. ASTHO visited for a day recently and presented their organization and its priorities. This was found to be very valuable. More of those types of presentations will be coming.

Joint partnership and legislative strategies are being developed. The budget and legislation and partnership teams work on these issues. Each member is assigned to a division in order to focus on content and gain greater subject matter expert expertise. Next step is for them to work together and to determine ways to move programmatic priorities forward through partnerships and communication interaction with the Legislative Branch.

More official communications will be developed, hopefully, tailored to individual partner's needs. "On Public Health Security" which is a monthly newsletter will continue. Other materials are also being developed for partners to share with various decision-makers.

The Preparedness Snapshot Report was disseminated to the board. It also included state by state pages. Activities to prepare the report have been occurring since 2008 annually, as part of the PAPHA requirement. In 2016, some informal interviews were conducted with partners,

CDC, states, and partner organizations. Information received informed changes made in 2017 and those to come. Some of the feedback comments: overall, people like the look and feel of it; states said they use it with their state leadership and for providing information to those on the Hill. States like the one page back and front format. Areas for change: more candid information about gaps or shortcomings and risk and cost of funding cuts; more stories; and additional contextual information on data sources.

Some of the changes made this year: Data were streamlined and the layout improved. This work was done in coordination with the Communications Office. The report provides a good overview of the PHEP program and grantees as well as all of the work of OPHPR. The changes for next year will include improving the impact of the data and success stories.

Recommendations/Comments:

- The snapshot report is much more interesting to read than numbers so I commend you.

- One challenge state and local preparedness directors are still struggling with is translating to elected officials and leadership. For large-scale events like Zika and Ebola, capture some of the information and "stories" that states and locals have with regards to their response in the snapshot. This is more appealing when talking to a mayor or governor.

- Affiliates need to mobilize from the outside to help the new administration understand the impacts of possible cuts.

- A systematic plan to collect feedback from local, state and federal organizations that contribute to health security would be helpful to enable OPHPR to communicate the nature, scope, and impact of their contributions.

- CDC's chronic disease center has a template online to assist states and localities in writing their success stories. Maybe for the PHEP Impact Project, develop a four- to six-page template for the states to use with more current data and current stories. It would make for a nice companion piece.

- National Institute for Minority Health and Disparities has a number of FOAs coming forth that ask discovery questions. NIH also supports projects investigating communication of risk and communication inequalities. See if there is a way to systematically explore these opportunities on the research side to complement and mitigate some of the coming budget cuts.

- Explore whether more local information could be included on particular threats and the workforce supported by the programs. If there are no restrictions to reporting

those numbers, it would be great to see, like number of diseases, number of outbreaks, and numbers and types of health department emergency responses. Evaluate numbers with regards to vulnerable populations. Document number of people working on PHEP support and their roles in the effort.

- Include also stories of prevention (not only the stories of "what goes wrong"), like when prevention is done well and the result is zero outbreaks or minimal outbreaks. Avoid reports on exercises but instead use actual occurrences.

- At least once a month have a meeting to talk about the reasons a prevention effort worked. Show how preventing a crisis improved productivity, days loss, etc. An infographic can be useful to fully illustrate your findings.

- Make a video that can be used before OPHPR visits/tours to introduce visitors to the activities they are about to see.

- Helpful to track budgets overtime and the impact of PHEP investments to capture a trend.

- Think about the stories being built from the county and local level or even community level (vs. state-level) and how grantees can do proactive media partnerships. Consider proactively funding some organization to develop these stories.

Risk Management at CDC

Enterprise Perspectives: Kim Jennings; Director, Business Integrity and Strategic Management Unit, Office of Chief Operating Officer

The purpose of Ms. Jennings' presentation was to provide the BSC with an overview of the Enterprise Risk Management (ERM) approach being used by CDC, to review the Ebola Risk Assessment, Mitigation, and Management Planning (ERAMMP) Project, and to present the value and benefits of the ERM.

The new federal guidance requires federal agencies to integrate risk management into strategic planning and implement an Enterprise Risk Management (ERM) framework. In June 2015, the Office of Management and Budget (OMB) released revised Circular No. A-11 including Section 270, ERM guidance, as part of FY 2017 budget preparation and guidance. Lastly, in July 2016, the OMB released revised Circular No. A-123, which included specific guidance to implement ERM at Federal agencies. The OMB's revisions to Circular No. A-123 and A-11 reflected efforts to integrate ERM activities with agency strategy, budget, performance management, and internal control efforts.

ERM is very different than traditional risk management. It is a holistic approach to addressing the full spectrum of an organization's significant risks (strategic, reputational, operational,

financial, and compliance) by considering risks as an interrelated portfolio rather than addressing risks only within silos. The ERM is the next step in building CDC's risk management program and looks at risk across segments and from both the bottom-up and top-to-bottom perspectives to see what risks need to be monitored the most. The organizations that have adopted ERM use risk information to improve decisions related to strategic planning, budgeting, as well as, integrate portfolio management across programs and activities.

The updated OMB A-123 guidance requires federal agencies to use an ERM framework to manage the full spectrum of risks by linking risk to agency mission and objectives. The process ensures mitigation of the risk is embedded into daily processes and not addressed in silos. Financial and compliance risks are often the most visible and heavily regulated risk areas. Internal Control and Risk Management, like OMB A-123, Federal Manager's Financial Integrity Act (FMFIA), and the Chief Financial Officers Act, will be part of the ERM framework.

The ERM is being deployed in four stages.

- Stage 1: Identify and score risks
- Stage 2: Prioritize risks and develop risk responses
- Stage 3: Implement risk response strategies
- Stage 4: Monitor risks and report

The office is currently in stage three and will soon move to stage four.

ERM is the framework that business risk management initiatives should use to guide the identification, planning, implementation and monitoring of key activities to improve CDC's emergency response operations. Communication spans the lifecycle of this process to improve the risk culture and risk awareness at the agency.

Ms. Jennings provided some background on the Ebola Risk Assessment, Mitigation, and Management Planning (ERAMMP) Project. The Emergency Ebola funding pursuant to the Consolidated Appropriations Act, 2015 (H.R. 83) required the Secretary, HHS to provide a plan to prevent fraud and waste of the Ebola funding. HHS was directed to develop this oversight plan working with the HHS Office of Inspector General (OIG). The plan was required to focus on specific areas of risk and align to CDC's organizational strategic goals with regard to Ebola funding:

- Avoid funds diversion
- Avoid reimbursement manipulation
- Minimize CDC's loss potential for grants funds used for unintended purposes and enhance CDC's ability to track grant funding
- Carry out CDC's Ebola implementation plan successfully and as intended

Additionally, CDC was asked to conduct environmental scanning using the SWOT (strengths, weaknesses, opportunities and threats) and PESTLE (political, economic, social, technological, legal and environmental) analysis formats as components of strategic management, where

CDC would study various economic, political and social factors that might affect the accomplishment of the Ebola objectives. This project is part of the overall HHS/CDC risk management plan.

The ERAMMP project analysis leverages data and information collected to date, including site visits to Sierra Leone, Liberia and Guinea; review of various financial reports, like spend plans, budget execution reports, review of Global Health Security and Ebola Internal Coordination Unit reporting and tracking data, departmental memos; and interviews conducted with over 100 participants.

The office is now partnering with DEO's Excellence in Response Operations (ERO) workgroups to further discussion around risk mitigation. The ERAMMP's pillars will be merged into the ERO's Workgroups structures. Below is an illustration of the process.

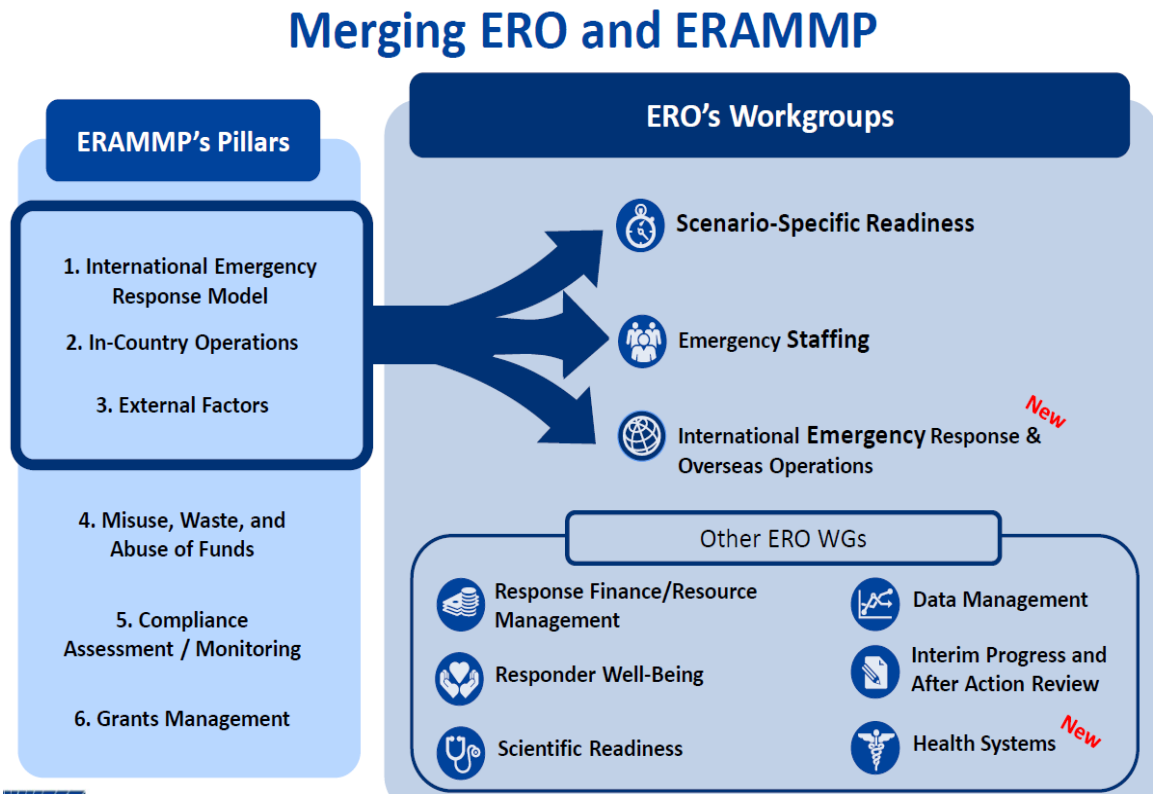

Figure 8. Merging ERO and ERAMMP

The value of ERM is realized when ERM is embedded into strategy and performance. The ERM is valuable because it:

- Opens and improves the channels for communication and dialogue about opportunities and risks;
- Offers agency and OPHPR leadership a comprehensive view of risk across an organization from both a "top-down" and "bottom-up" perspective;
- Allows for more informed decision-making at all levels of OPHPR and CDC;

- Encourages a more proactive approach to risk management;
- Coordinates risk management-related activities, like risk assessments, internal controls, and OIG audits to develop meaningful insights across risk management areas;
- Prevents duplication across the agency by leveraging best practices or lessons learned; and
- Results in "fewer surprises" that may negatively impact the OPHPR mission and reputation.

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

Mr. Bryant reviewed DEO's Excellence in Response Operations (ERO) Initiative, which was started six months ago. It was designed to put the agency in a better place to start the next response by learning from past history, others in response, data, and information across the agency. The work started with seven workgroups ranging from scenario-specific readiness, emergency staffing, responder wellbeing, response finance, data management, and scientific readiness.

Two more workgroups have been added. The eighth workgroup is the International Emergency Response Workgroup. The ninth workgroup is assessing the interface between CDC's Preparedness and Response Operations and the nation's healthcare sector.

Below is an example of the CDC After Action Review Process. After action reports were examined going back to 2012; ~ 300 tasks associated with corrective actions plans were identified.

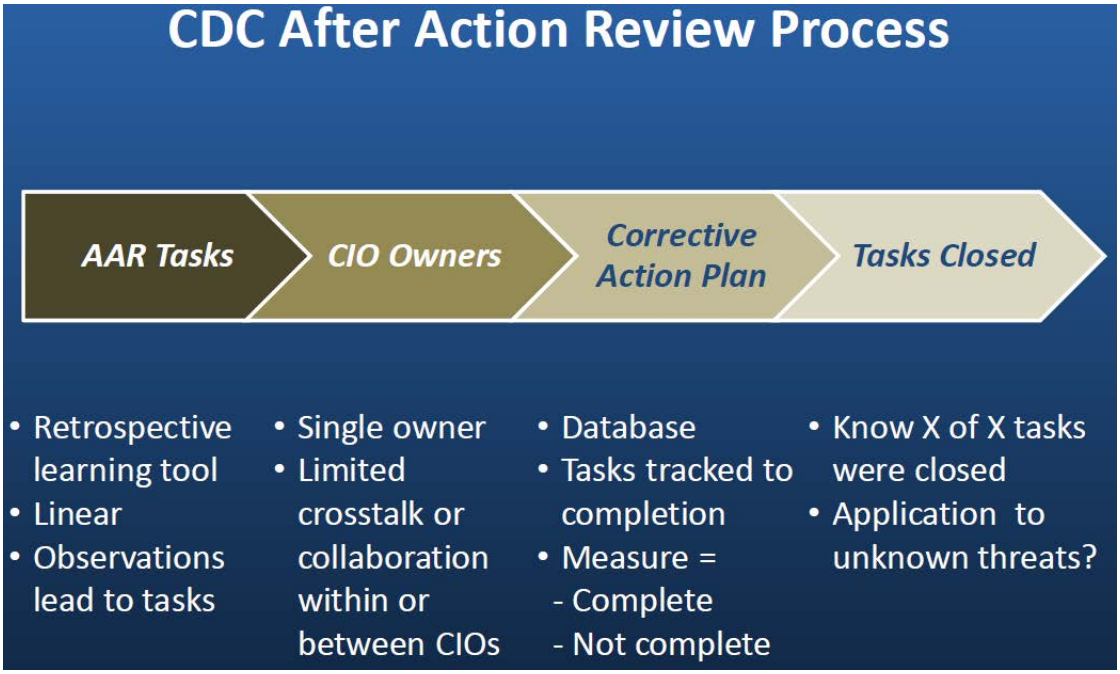

Figure 9. CDC After Action Review Process

More work needs to be done to take this to the next step and determine the systems holistically across the agency that the findings represent.

The aim is to leverage risk management as a way to improve emergency response. The process involves collecting sources of information from risks identified from after action reviews, workgroup-identified risks, and previous risk assessments or discussions and disseminating that information to the ERO Workgroups. The workgroups employ a multidisciplinary-stakeholder engagement process. These individuals examine the systems holistically across the agency and determine ways to build capacity and capability.

Currently, risk statements have been adjudicated with eight of the nine workgroups. Context and detail have been added to make them as meaningful as possible. The next step is to finish identifying the activities that have to be completed in order to mitigate risks, devise a strategy, address agency vulnerability, and address the objectives. The end goal is to place the agency in a posture to do three things: address today's preparedness and response risks, anticipate tomorrow's risk, and build capacity that can be used to address the unthinkable crises.

Eric Carbone, PhD, MBA; Director, Office of Applied Research

Dr. Carbone provided the BSC with OPHPR's approach to ERM. The first phase of the ERM process involved initial identification and scoring of risks, as well as potential consequences of these risks. Each identified risk is rated by impact and likelihood, along with speed of onset and other factors. OPHPR divisions identified 22 distinct risks in the first phase of the ERM process. The identified risks are of the following types: operational, strategic, financial, reputational, and compliance. Of the 22 risks, 14 are operational in nature.

The 22 risks were further categorized. Below are the groupings.

- 5 - Human Resources/Workforce (e.g.–risk of not retaining talent; risk of sustained stress on employees related to high ops tempo)
- 4 - Financial (e.g.–risk of reduced appropriations; risk of funding lapses for grant awardees)
- 3 - Information Technology (e.g.–risk of cancellation of critical IT infrastructure updates; risk of compromise to necessary data access)
- 2 - Grants Management (e.g.–risk associated with implementation of major changes in structure of cooperative agreement supporting states/localities)
- 8 - Other Program-specific risks

All risks get an initial score based on risk of impact and risk likelihood. With regard to risk impact, about 15% of identified risks are classified high impact; around 25% are classified as medium-high impact, and roughly 60% are considered either medium or low impact (or not yet classified). For risk likelihood, 10% are considered almost certain; 15% are considered likely; and 75% are considered possible or unlikely (or not yet categorized). These factors drive mitigation planning and resourcing.

As an illustration, Dr. Carbone provided example risk statements by divisions.

- DEO: If DEO staff lack critical emergency management skills, then we may be unable to effectively support public health emergency responses.
- DSAT: If the division's budget is reduced by {X percent} the division would have to substantially reduce the amount of effort expended to ensure compliance with [select agent and toxin] regulations.
- DSLR: If the {external partner} cannot complete the {grants performance monitoring system}, then program will need to reallocate limited resources to an expensive IT development project.
- DSNS: If the program cannot acquire sufficient SNS product, due to market and/or manufacturing limitations, to maintain an operational readiness capability as mandated by the Public Health Emergency Countermeasures Enterprise (PHEMCE), then there may be avoidable mortality and morbidity during a public health emergency.

These are examples only and not issues that are currently occurring.

The next steps in the RM process is to further define and assess the identified risks; develop and document risk responses and mitigation strategies; and identify and add cross center risks that are not currently represented by the division-identified risks.

Several questions and thoughts were presented to the BSC for deliberation.

- Risks are identified as separate and distinct…yet many appear to be interrelated and issues often "cascade". Does this change how we approach assessment and mitigation?
- There may be risks in the organization that are not widely known – or considered "risky" to publicly identify. Are there disincentives that work against the ERM process? How do we uncover and address "obscured" or hidden risks?
- ERM assumes, by definition, that we can identify risks. Are there risks that are outside the frame of our institutional knowledge and experience? If so, how can we consider or mitigate unknown risks?
- Evidence from cognitive psychology and decision-science suggests people aren't all that good at estimating risk. How do we overcome various fallacies in thinking as we consider risk and mitigation?

Commentary: Ian Mitroff, PhD; BSC Member

Dr. Mitroff spoke on the risks of risk management. Elements that are inseparable and systematic are the identification of risk, scoring, and prioritization. Organizations that are more advanced at doing risk management do not leave the assessment or identification to one group of individuals. They have different teams, who are given assignments, to come up with their own list of risks. Better organizations take part in exercises that review risky scenarios. Risks that are rated low in probability and consequence by one group may be rated

differently by another group based on different assumptions and vice versa. This underscores the fact that no one team can be responsible for identifying risks.

Organizations should also look at denial mechanisms. The more that an organization uses denials or rationalizations of why the organization won't experience certain crises, the lower its performance, the higher its vulnerability, the more crises it experiences, and the longer time it takes to respond.

There is no such thing as an isolated risk or crisis. They're all interrelated and are capable of setting off a chain reaction. It's also important to identify the range of risk. Crisis management is systemic requiring a broad set of potential crises. Dr. Mitroff and his colleagues have identified 12 to 14 "families" of potential crises risks. The best organizations pick at least one of the families and connect the dots.

He concluded with some recommendations and observations. Look at the organization systemically and never trust a single member to identify all the risks—often people at the bottom can see more crises than those above. This will never be a fully-bounded, well-structured exercise; however, it's a creative exercise and demands novel approaches and ideas to thinking about the unthinkable. Do not trust any absolute method of scoring a crisis. Instead raise assumptions around how risks are identified, scored, and prioritized.

One of the worst things that a crisis does is cause existential shock. It invalidates all the assumptions an organization makes as to why they will not get into a crisis. This leads to stress and other bad psychological states. This is why looking at assumptions is critical.

Recommendations/Comments:

- There's an actual and perceived risk. Often the effects of perceived risk are worse than those associated with the actual risk. Build in a process to try to identify organizational "perceptions" by using psychologists.

- Do not separate physical risks from psychological. They must be treated simultaneously.

- Try thinking about risk management from the converse of the "If…, then…" risk statements. Risk management typically recommends prevention, mitigation, or avoidance and has negative connotations. Provide a more positive and creative way of doing risk management and problem solving. Utilize both sides of the rationale and thinking not just around the negative framing but also the positive framing. This may create opportunities for improved outcomes; for example, a decline in funding might be accompanied by greater flexibility in funding authorities.

- The biggest risk of all is reputational risk. Map out pathways to reputational risks and connect them to organizational culture. It will help to mitigate some of the

psychological denial. Teases out crisis management as a separate part of risk management and think more about lessons learned to discern systemic ways that might increase risk in the future. Consider forming a cross-disciplinary group that can answer questions about the riskiness of their work and provide advice regarding likelihood of identified risks.

- Do a stakeholder analysis and determine which are the most critical stakeholders and how they can be influenced.

- Risk is also the ability to do day to day activities and it has to be done separate from the financial piece. Also, risks might not be for CDC alone, but rather manifest as state or local public health system risks.

- Look at the issues of trust within the organization. Does the organizational culture allow a person to come forward and acknowledge risk without fear or repercussions and threat?

- Determine whether or not you are systematically or efficiently doing risk management and assessment across the public health system more broadly. If it is occurring, where and what is the structure for it, and can it be applied at a higher "system" level and done intermittently with partners?

- Johns Hopkins University's risk manager, Jon Links, has some methods for doing risk assessments in various realms. He uses simple yellow, green, and red to map risks. To succeed you have to accept some risk and there is no such thing as no risk. There are disincentives that work against enterprise risk management because people are worried that if they describe their work in a risk frame that there will be epiphanies and people will see those risks as new risks and want to control them. So, create an environment where people want to talk about risk but not in a way that precedes the end of their program. Regarding fallacies, there's science that talks about collective thinking and getting the wisdom of the organization around particular problems. Jason Matheny at Intelligence Advanced Research Projects Activity (IARPA) has done work around forecasting and could be a resource.

- Stanford accepts that there is some risk that it has to accept, so CDC has to find a balance between some risk and no risk. It's helpful to have many involved to think about what the risks may be and to categorize them.

- Put most effort in things that are most important. Look for a process that will make those areas come to the top so they can be prioritized.

- Recognize that people need downtime to rejuvenate from identifying and responding to risk and that needs to be built into the process.

Global Health Security Initiatives and Updates

Hamid Jafari, MD; Center for Global Health

Dr. Jafari reported on CDC's role in the global health security initiatives. There isn't really a separation between domestic and global, when it comes to health. One can easily impact the other; therefore, engagement with others who are trying to achieve this mission is paramount. CDC is one of the two implementing agencies for the Global Health Security Agenda (GHSA).

CDC's role in advancing health security can be divided into three categories. The first is rapid disease detection and response. This requires nonstop monitoring for outbreaks, supporting robust regional disease detection, and responding rapidly to emergencies. The second is helping countries to increase their capacity. This is accomplished by conducting effective disease surveillance, developing lab capacity and using technology to detect new pathogens, training frontline public health workers, and building strong outbreak response systems. The last role is partnerships. CDC sustains and strengthens partnerships for global health security, including with the private sector, NGOs, and other countries. OPHPR has a role in this work by helping in the development of Emergency Operations Centers (EOCs) for other countries.

Below is GHS governance structure utilized by CDC.

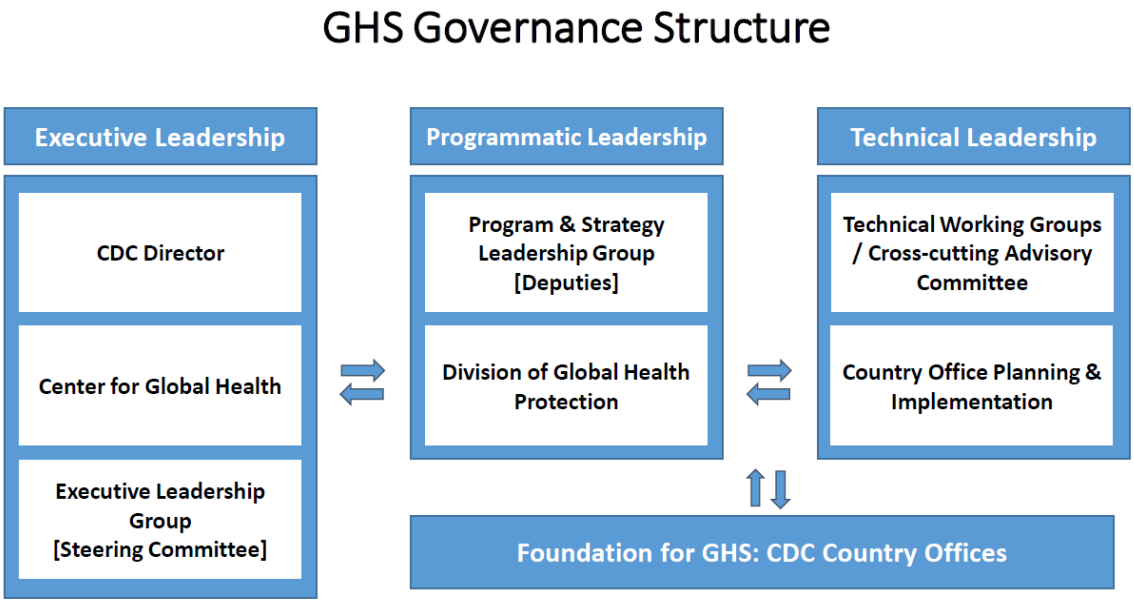

Figure 10. GHS Governance Structure

CDC received supplemental emergency funding that will expire in FY19. The funds are being used for the GHSA Phase 1 countries. Seventeen countries are part of Phase 1. The center works closely with USAID, DoD, and the Department of State on these efforts. There are 16 GHSA Phase 2 countries. In Phase 2, the center has coordinated activities that are supported

by existing programs in the country. The most important components of the work are tracking diseases, building strong laboratory systems, standing up EOCs, and training a public health workforce. While the center also participates in other global health security activities, these four components make up the foundation of its work.

Dr. Jafari pointed out some of the achievements and impacts of the initiative. In the area of laboratory and surveillance, 13 countries were able to detect dangerous pathogens using new equipment and capabilities. Twelve countries trained community members to detect and report potential health threats. Nine countries analyzed surveillance data to inform targeted immunization campaigns.

As far as workforce development, 100% of the countries participated in an established Field Epidemiology Training Program. More than 2,300 individuals were trained in on-the-ground disease detection and rapid response. In addition, more than 475 potential disease outbreaks were investigated and responded to by trainees.

Other achievements include training frontline epidemiologists in Liberia, fighting cholera in Tanzania, investigating polio in Mali, and stamping out infectious disease outbreaks in Pakistan.

Several countries participated in the pilot of a Joint External Evaluation (JEE) tool. The aim of the tool is to evaluate and assess the country's capacity in the longer term across the public health capabilities, specifically those that align with the International Health Regulations. The center continues to support WHO in the Joint External Evaluation process. This process will identify gaps with the country's health systems using a multisector approach. It can also be used to prioritize opportunities for enhanced preparedness and response and to engage with current and prospective donors and partners to effectively target resources towards addressing gaps.

So far, 37 countries have completed the evaluation and there are 32 missions planned. Eighteen JEE reports have been publicly posted to the WHO website and another 14 are in the pipeline for clearance.

The center is also working with the DEO on the Global Rapid Response Team (GRRT). In CY16, GRRT mobilized more than 250 times, providing 9,000 person-days of response support to 23 countries. Those efforts were around cholera, polio, Zika, Ebola, yellow fever, natural disaster, and other miscellaneous events.

There has been strong progress in most GHSA phase I countries. OPHPR is a key agency resource in this effort, and going forward, the center will increase its commitment to GHSA partner countries – political, financial, and technical. The U.S. leadership and work of the CDC are leveraging international resources. But, limiting future funding for GHSA will jeopardize or stop several activities, such as:

- 24/7 disease threat monitoring;

- Rapid response to international threats;
- Strategic regional health protection hubs to catch and control outbreaks at their source;
- Country capacity building to serve as platforms for a range of disease-specific interventions
- Quality and rigor of Joint External Evaluations and action plans
- Country level and global partnerships

Investments now are far less expensive than responses later. The next global pandemic is estimated to cost $6 trillion.

The center asked for the board's advice on four questions:

1. What can CDC do to facilitate continued USG leadership of the Global Health Security Agenda?
2. Has CDC adequately communicated its unique role in global health security and how that protects Americans?
3. How can CDC best communicate the adverse impact of not receiving consistent funding for global health security?
4. Are there strategic or programmatic areas where CGH and OPHPR could be collaborating better?

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

Mr. Bryant presented more information on CDC's participation in GHSA. 82% of countries have activated their response system for an exercise or real emergency and 88% have completed a baseline assessment of national Public Health Emergency Management (PHEM) capacities. Fifty-three emergency managers from across the globe have participated in the PHEM Fellowship and 16 countries have identified a public health EOC facility location.

GRRT is an enabler in a response. For example, it provided ongoing staffing for IMS activations including Zika and polio. It also supported CIO-led response activities through the rapid deployment of staff to infectious disease outbreaks. The team has built capacity by implementing recommendations from the Ebola after action reports and has ongoing collaboration with the DEO-led deployment community at CDC to increase agency readiness, improve deployment systems, and address gaps such as foreign language capacity.

Below is an illustration of the GHS Framework in OPHPR.

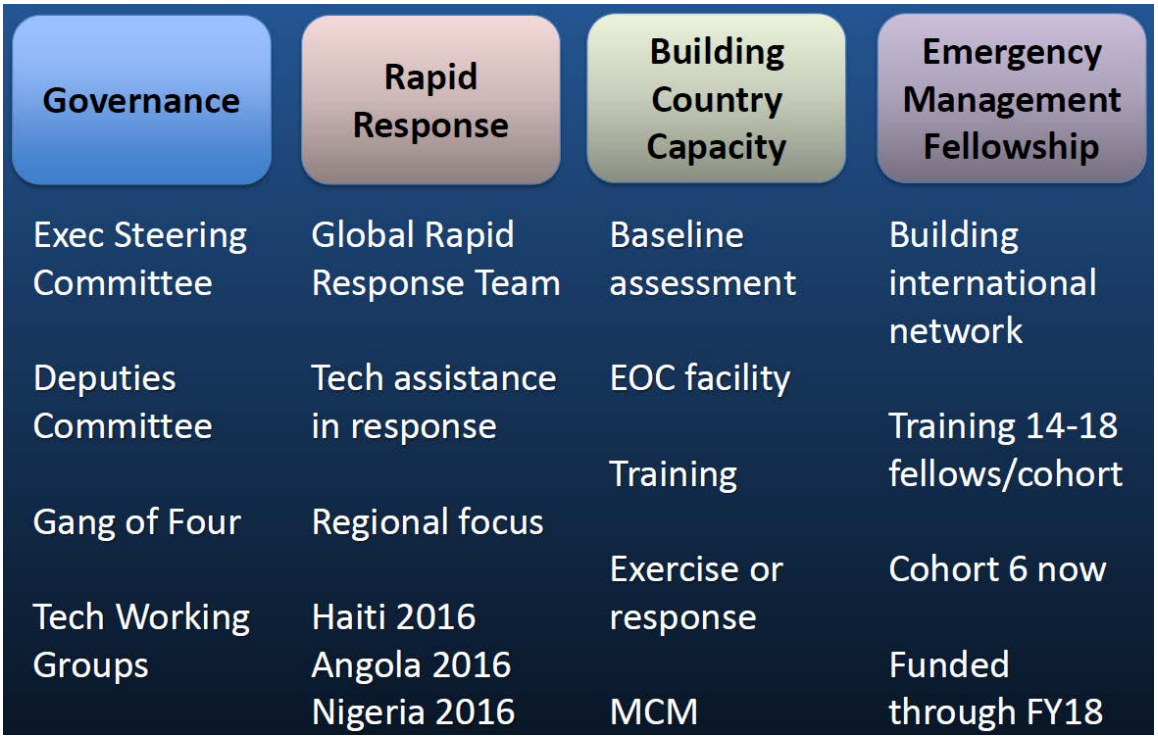

Figure 11. GHS Framework in OPHPR

The PH Emergency Management Fellowship has provided training to six cohorts composed of 53 PHEM Fellows from 28 countries, 15 of which are Phase I GHSA countries. There are 19 international fellow applications for the summer 2017 cohort.

There are some challenges moving forward. One concern is the budget and increased reliance on partners. OPHPR FY18 GHSA budget is 67% less than FY17. Another is working with CIOs to understand priority action packages. A challenge here is deciding what the priorities should be for FY 18 and 19. Some of the efforts are cross-cutting like zoonotic disease, immunization, and antimicrobial resistance. Lastly, determining priority countries and moving to a regional focus is a challenge.

One of the 2017 priorities will be emphasis on CDC-led or CDC-encouraged regional networks. Efforts will create capacity in the WHO regional offices to deliver technical assistance and training, and identify countries with capacity to provide a regional capability. CDC will look for opportunities to align its work with WHO and identify countries who could be centers of influence.

One of the strategies for 2018 is partner and response support. CDC can provide SME support to partners through the Cooperative Biological Engagement Program, USAID, and Public Health Agency Canada. It can travel SMEs during responses for technical assistance and develop risk prioritized contingency plans.

To enhance training, the goal is to complete curriculum development by adding content on rapid response teams, event-based surveillance, and medical countermeasures. The PHEM Fellowship will also continue. In addition, there will be virtual exercises and drills as well as joint functional exercises. Another objective is to share our experience and lessons learned with others by publishing more.

Recommendations/Comments:

- Determine what individuals you are trying to communicate to with regards to GHSA. If it's to the public, messages should be given with consistency. Coordinate messages with other agencies so that the public receives a single, consistent message. Come up with specifics of what the public should be doing.

- Do a better job getting in front of congressional committees, particularly appropriations committees in the Senate and House to help them understand what activities are occurring to protect Americans from large-scale infectious diseases.

- For sustained communications, it's important to identify audiences and then find the appropriate communication strategy for that audience. To engender public support, you must determine ways to frame the issue and come up with culturally-appropriate metaphors.

- There's no better way to understand each of the agencies capabilities and capacity than to work on a training capacity development project or functional exercise together or to support a response together.

- Expand response teams to include communicators. They can be an advocate.

- Public health security is a good term but it does not convey the total meaning. Rather be able to tie this to American's strategic interest. If you can illustrate where risk is being mitigated, the better chance for message uptake. A lot of development work can be done in our backyard that can be tied to America's strategic interest. The oil companies are on the frontline addressing health systems in the countries they work in, and security is one of the top priorities in keeping their employees disease-free while working. They are among the most advanced business sectors with respect to this type of thinking.

- A more urgent goal is to communicate to OMB, the Hill and those who influence those on the Hill in an effort to validate externally the program's worthiness. Paint a better longer-term vision of the programs. Describe the work that needs to get done. The message that GHSA protects the U.S. should be part of the core message. Talk about the consequences of failure and if a program is eliminated.

- Have clear outcomes of what you want from each of the audiences and create a logic model to illustrate how this goal can be accomplished.

- Even if CDC provides representative information on GHSA impacts, countries often want to see and hear information from their locality. Don't "brand" GHSA information as "CDC" information -- partnering with WHO can help in this effort.

- Be very clear and transparent about the work that is done in each division and their unique contributions.

- When communicating to the public, convey how health concerns in another country can become a health concern to those in the U.S. For example, how can a prevention effort taking place in Cameroon, help protect my child here in the U.S.?

Natural Disaster Preparedness and Response

CAPT Ed Dieser, P.E., M.S.; Deputy Associate Director, Office of Environmental Health Emergency Management, National Center for Environmental Health

CAPT Dieser began his presentation by categorizing the different types of natural disasters. They are geological, climatic, or hybrid. Geological disasters are events like earthquakes, volcanic eruptions, tsunamis, and landslides. Climatic disasters include hurricanes, tornadoes, floods, storms, droughts, and wildfires. Hybrid events include complex natural disasters. Floods are the most frequently declared disasters in the U.S. The pie chart below illustrates the number of federally declared disasters in the U.S. since 1964.

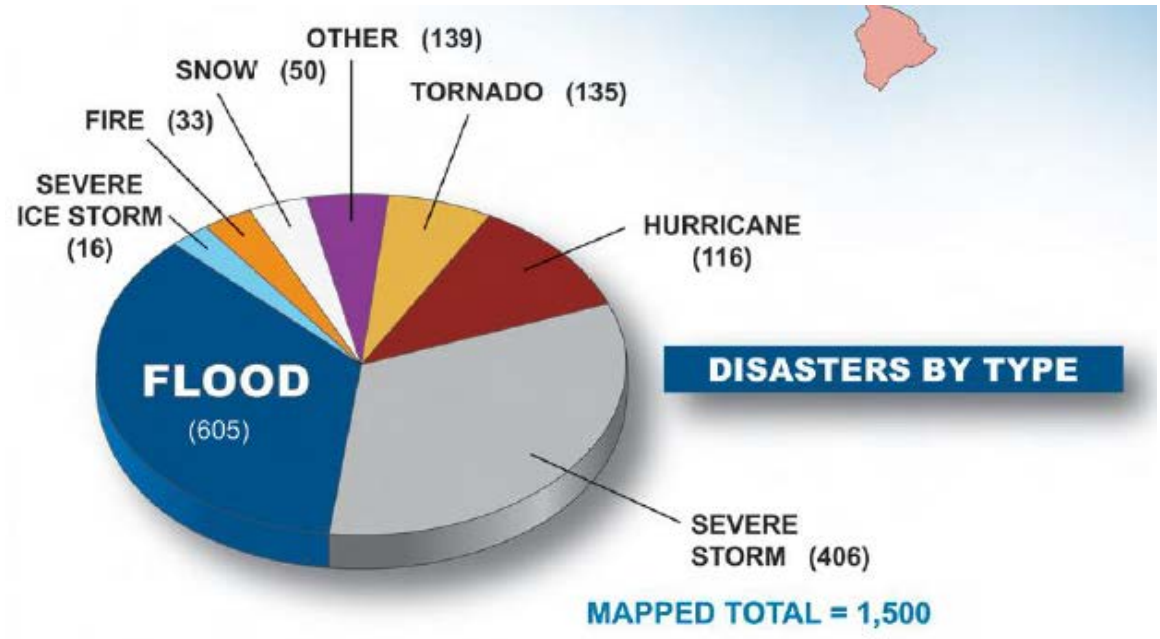

Figure 12. Number of Federally-Declared Disasters in the U.S. Since 1964

CAPT Deiser reviewed some examples of hybrid disasters. The Deepwater Horizon disaster started as a fire and explosion but, because of the chemical components involved, an ecological disaster occurred. The Fukushima disaster was an earthquake that turned into a radiological disaster. Hurricane Sandy was natural disaster that became a devastating infrastructure catastrophe.

It is often impossible to separate the causes of a disaster. For that reason, an all-hazards approach is utilized to respond to these events. The approach involves the use of science, systems, and support to address biological, chemical, nuclear/radiological, and natural disasters.

Disasters cause human impact as well as economic impacts. In the last 12 years, disasters have resulted in $1.3 trillion in damages. Over 2.7 billion people have been affected. And, they have caused 1.1 million deaths.

According to the National Academy of Medicine, public health emergencies occur when the capability of the public health system, communities, and individuals to prevent, protect against, quickly respond to, and recover from health emergencies is overwhelmed. This is seen when the scale, timing, or unpredictability of the event threatens to overwhelm routine capabilities.

Preparedness and response is at the center of NCEH and ATSDR's strategic direction. Their objectives are to implement environmental health programs and interventions to protect and promote health; prepare for and respond to public health emergencies including chemical,

biological, radiological and nuclear incidents, natural disasters, and extreme weather events; and identify, characterize, and monitor health outcomes and environmental exposures to guide actions that protect and promote health. In addition to the emphasis on an all-hazard approach, the agencies also utilize an all-phase approach. An all-phase approach involves preparedness, response, and recovery to address biological, chemical, nuclear/radiological, and natural disasters.

NCEH and ATSDR is the focal point for science-based emergency management of public health consequences of natural and technological disasters. During emergencies, they provide emergency response management in CDC's Emergency Operations Center. Between emergencies, the divisions foster collaboration and conduct planning. This is done through all phases of an emergency event, from prevention to recovery.

Mr. Dieser then highlighted the differences in his divisions' role to that of OPHPR and DEO. NCEH and ATSDR works on science-based investigations and interventions, while OPHPR and DEO's roles are operational in nature. They both work with policy, communication, and coordination. Flexibilities incorporated into the EOC structure have allowed NCEH and ATSDR to conduct emergency operations at CDC's satellite campuses with the help of DEO. He also pointed out the difference between incident command and incident management. Incident command is only done in the locality where the event is taking place. CDC conducts incident management, where it manages the science and public health functions to support the state and local responders.

During the 2016 Hurricane Matthew, NCEH divisions created an incident management (IM) structure that aligned with the needs of the response. Going forward, that structure will probably be modified using lessons learned from the 2017 Gotham Shield functional exercise. Critical disaster response actions include science, collaboration, coordination, communication, and the function of conducting a response; these actions need to be supported by the IM structure.

Preparedness comes in many forms at CDC. The first form is disaster risk reduction. Disasters result as a combination of exposures to one or more hazards; a susceptible population; and insufficient capacity to reduce negative impacts. Disasters are hazards multiplied by vulnerability, where vulnerability is the exposure to the hazard and susceptibility and the resilience. The goal in disaster risk reduction is to reduce exposure and susceptibility to hazards, while improving preparedness and resilience. For example, in the case of fire prevention, risk reduction would include public education, participation in fire drills, and use of smoke detectors and sprinkler systems, or in the case of flood prevention, its education, signage, zoning, and engineering.

NCEH provides technical assistance to federal, state, local, territorial and international stakeholders. In addition, they have engaged with many sectors of government, like the White House Subcommittee for Disaster Risk (SDR), International Working Group of SDR, United Nations International Strategy for Disaster Reduction Intergovernmental Expert

Working Group, and U.S. National Platform for Disaster Risk Reduction (DRR), regarding health policy.

Preparedness efforts also includes partnerships with OPHPR's DEO for plans, training, exercises, and evaluations. Recently, NCEH has worked with DEO on the following activities:

- Finalizing the CDC Emergency Response Plan's Chemical Annex
- Updating the CDC Emergency Response Plan's Radiological / Nuclear Annex
- Incident Manager Training and Development Program
- Training strategic plan development
- Co-Leading collaboration with ASPR training with regions and recent exercises, e.g., Cascadia Rising (earthquake and tsunami scenario), Gotham Shield (radiological event)

In an effort to increase learning and improve future response capability, NCEH is developing after action reports for Flint MI Water Quality Crisis, Hurricane Matthew, Gotham Shield, and Japan's Fukushima Response.

The public health effects caused by a natural disaster can include a wide range of health and safety concerns including direct and indirect injuries and illnesses, latent health effects, and limited access to safe food, water, and shelter. Societal expectations are for safe food and water, shelter, and health and medical care. NCEH conducts community health assessments and public health surveillance, and implements registries when populations at-risk of adverse health outcomes need to be monitored over time. Environmental health assessments are also conducted to provide exposure assessments, risk characterization, and dose-response assessments. Environmental health services provide food, water, sanitation, and hygiene inspections, shelter assessments, and vector control.

All responses are local; therefore, coordination takes place with local/state partners, like the health departments, environmental agencies, emergency management, and law enforcement. There's also coordination with national health and non-health partners like HHS, FEMA, FDA, EPA, DOE, and DoD. The division supports the Center for Global Health for international natural disasters. Some key field coordination partners are ATSDR regional offices, which are embedded in the EPA regions, and ASPR.

For communication, the divisions depend on the CDC EOC's Joint Information Center (JIC). There's also coordination with federal/state/local partners like health departments and organizations, elected officials and emergency management, news media, and internet and social media outlets to provide information. Public health information includes fact sheets, guides, checklists, public safety announcements and recommendations, as well as travel advisories

Mr. Dieser ended his presentation with questions for the BSC.

- How might CDC increase its capability for natural disaster emergency management?

- For which disaster(s) are the public health, healthcare, and emergency management sectors least prepared?
- Where should NCEH and ATSDR focus their emergency management resources (time and money)?
- Where should NCEH and ATSDR focus its collaboration with OPHPR (current and future) to achieve the greatest impact?

Recommendations/Comments:

- Keep in mind that there are no natural disasters. All disasters are human caused. This is even in the cases of events such as floods and tsunamis because humans make the decision of where to live and build, not Mother Nature. Also, factor the effects of global warming on natural hazard.

- Biggest problem our jurisdiction has associated with natural disasters is elderly placement in shelters. They can't go to a regular shelter but are not sick enough to go to hospitals. Finding placement for elderly individuals with chronic health conditions has been difficult. It would be helpful to investigate other sheltering "options".

- Remember to include evacuation and sheltering of pets in the planning process. Many people identify their pets as family members and refuse to leave their pets behind when an emergency occurs.

- ASPR has the emPOWER Project (https://empowermap.hhs.gov/) that identifies individuals who are dependent on electricity for medical and assistive equipment, such as home ventilators and wheelchairs. These data can help a community prepare ahead of time to ensure these individuals are identified and provided emergency assistance. But, even with this information, there's a group of individuals whose vulnerabilities aren't really known until the disaster happens.

- Consider studying Hurricane Sandy. Flooding occurred in areas where it was not anticipated and it has been deemed the East Coast Hurricane Katrina.

- Make sure we're supporting people in recovery who have lost access to their normal services and support systems. This is particularly pertinent to the opioid epidemic and other types of addictions.

- DHS has a chemical terrorism risk assessment. I would like to see from the local/state level a response to different categories and volumes of chemicals to examine capability and capacity needed for a response over time.

- At DHS, a lot of the information received related to chemicals is proprietary, i.e., protected. We are looking for ways to get this type of information to emergency

managers. We would like to partner with NCEH to develop more guidance on disseminating that type of information.

- Outside of bioterrorism pandemic, the country is poorly prepared for a tsunami in the Northwest, nuclear terrorism, nuclear power plant emergencies, dirty bombs, and long-term regional power failures, particularly for places that are really cold during the winters. The power failures also present problems for other elements like ATMs, heating, hospitals, water, etc. It's also not healthy to falsely reassure that all is under control. In your science role, do needs assessments so that candid discussions can occur around what is available now and what is needed.

- When the JEE was conducted, vulnerabilities were exposed in the context of rad/nuc events. But the evaluation does not get to a granular layer to highlight specific vulnerabilities. What is NCEH doing to identify and prepare for more specific vulnerabilities that result from a nuclear or radiological event?

- U.S. is also not preparing for a chaotic mass evacuation that may be associated with a public health emergency.

- Think about how to prepare and respond to a large scale electromagnetic pulse which may disrupt or damage electronic equipment or cause physical damage.

Public Comment Period

No public comments.

Meeting Recap & Evaluations, Action Items & Future Agenda

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

The board responded to meeting evaluation questions via electronic polling. Dr. Groseclose then thanked the BSC as well as CDC staff who supported the meeting for all their hard work. He invited the board to let the CDC leadership know of ways to make the meetings better going forward. Members were allowed to give further comments about the meeting process.

- The questions asked of the BSC at the end each presentation were very valuable. It should be replicated in future meetings.

- From a local level perspectives, these meetings allow for us to be better informed and gives us a message to take back to our agencies.

- I feel the Division Director updates are an efficient way to understand in the big four areas of what is happening. It also provides a chance to interact with the division directors.

- It's good to have a combination of key activities in standard areas but also pull out big-picture, thorny issues that opens dialogue and requires further thought.

- I really enjoyed the opioid epidemic overview.

- Having a lot of time for discussion is good so other viewpoints can be heard. This was very helpful.

RADM Stephen C. Redd, MD; Director, OPHPR

Dr. Redd felt the quality of the discussion was outstanding. The meeting was reconfigured to allow more discussion. He felt this process results in great input and recommendations from the BSC. The board asked Dr. Redd what perspectives he felt were missing. He will take some time to ponder the question. He ended in thanking the board, as well, for its work.

Thomas Inglesby, MD; Chair, OPHPR BSC

Dr. Inglesby referenced a quote from one of his colleagues in his closing remarks. "It's on us collectively to show the value of our efforts." For the BSC and CDC, that is the charge to make the best case that the preparedness activities that have been occurring are incredibly important to the country. It's also important to talk about what still needs to be done going forward to improve public health preparedness and response. He is very impressed with the work done by OPHPR. He ended his remarks by giving thanks to the CDC leadership and staff and the board for their work.

With no other comments, the meeting was adjourned at 2:45 PM.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the May 10-11, 2017 meeting of the OPHPR BSC are accurate and complete.

June 20, 2017_____ _____/S/_____

Date 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
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Atlanta, GA

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APPENDIX B: BSC MEMBER ATTENDANCE ROSTER

BSC Meeting Attendance Roster
Atlanta, GA – May 10-11, 2017

NAME	AFFILIATION	DAY 1 (May 10, 2017)	DAY 2 (May 11, 2017)
Inglesby, Thomas	Chair and SGE	In person	In person
Brandeau, Margaret	SGE	In person	In person
Mitroff, Ian	SGE	Phone	Phone
McKinney, Suzet	SGE	In person	In person
Erika James	SGE	In person	In person
Wooley, Dawn	SGE	In person	In person
Viswanath, Kasisomayajula	SGE	In person	In person
Alonzo Plough	SGE	In person	In person
Brent Pawlecki	SGE	In person	In person
Catherine Stemp	SGE	In person	In person
Bradley Dickerson, DHS	Ex Officio	In person	In person
Jack Herrman, NACCHO	Ex Officio	In person	In person
Wireman, Jodi, DoD	Ex Officio	In person	In person
Marissa Levine (ASTHO)	Liaison	In person	Absent
Michele Askenazi (NACCHO)	Liaison	In person	In person
Patricia Quinlisk (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