NBSB National Biodefense Science Board

Summary of the Proceedings of the National Biodefense Science Board

June 10-11, 2019

Washington, D.C.

DEPARTMENT OF HEALTH & HUMAN SERVICES USA

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Contents

Executive Summary

The National Biodefense Science Board (NBSB or the "Board") meets periodically in person and in public as required by legislation to review, discuss, and evaluate information and perspectives relevant to selected topics. Through the Office of the Assistant Secretary for Preparedness and Response (ASPR):

> *The Board provide[s] expert advice and guidance … regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate … [and] on other matters related to public health emergency preparedness and response.*[1]

The Board held a public meeting in Washington, DC, on June 10-11, 2019, to consider a number of matters, including topics assigned to the two active working groups – the All Hazards Science Response Working Group (AHWG) and the Disaster Medicine Working Group (DMWG) – and receive updates on recent advancements in several of ASPR's preparedness and response programs. As required by law, the general public were invited to attend the Board's meeting through the Federal Register; they were able to attend in person or connect by phone and webinar. The designated federal officer (DFO) instructed members of the public to email comments or questions to NBSB@hhs.gov or post them in the chat box for the webinar. All appointed board members were present during the roll call, either in person or by phone. Also present at various times were *ex officio* representatives from ASPR, the Centers for Disease Control and Prevention (CDC), the National Aeronautics and Space Administration (NASA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Dr. Sally Phillips, Deputy Assistant Secretary and Director of the Office of Strategy, Policy, Planning, and Requirements (SPPR), provided welcome remarks and participated in an initial, open discussion with the board members, which is described in more detail in Section 1 of this report. Briefly, Dr. Phillips outlined a number of important strategic and operational changes in ASPR, some of which were the result of the Pandemic and All Hazards Preparedness and Innovation Act of 2019, that will ensure that the United States continues to make improvements to preparedness

[1] Section 319M of the Public Health Service (PHS) Act (42 U.S.C. 247d-7f) as added by section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by section 404 of the Pandemic and All Hazards Preparedness Reauthorization Act and Section 222 of the PHS Act (42 U.S.C. § 217a).

for, responses to, and recovery from public health and medical emergencies of all types and from all sources.

As requested by the DFO, the AHWG met away from the public meeting for several hours on June 10 and 11 to finalize their review of the National Biodefense Strategy (NBS). They were asked previously to define criteria that the Department of Health and Human Services (HHS) might use to prioritize future activities under the NBS. Prior meetings of the AHWG occurred by teleconference on May 23 and June 4 to address this topic. Dr. Elizabeth Leffel, Co-Chair for the AHWG, and CAPT Theresa Lawrence, Policy Director in the SPPR, presented the following high-priority criteria to the full NBSB and the public on June 11:

1. *Time to successful completion*: the time required to complete implementation of target goals or objectives for the NBS.
2. *Time to demonstrated engagement of communities*: time required to achieve targeted engagement at all levels of state, local, tribal, and territorial (SLTT) governmental and relevant community stakeholders.
3. *Impact of implementation*: magnitude and duration of effect on health (human, animal, and environmental/ecosystem).
4. *Resource needs*: availability of government and nongovernment resources such as people, budget, equipment, and materials.

After some discussion, a quorum of board members voted unanimously to support the recommended criteria. In their discussion, they noted that their recommendation does not imply that other or additional criteria might be needed (or more appropriate) for specific programs. The Board further recommended (unanimously) that program leaders develop specific metrics and milestones based on these criteria and others.[2] Section 2 and Appendix 2 of this report provide more details on the work of the AHWG and the presentation on June 11, respectively. The recommendations are also available in a separately published briefing on the ASPR website.

ASPR asked the NBSB to consider the special training needs of healthcare facility staffs (clinicians and clinical support staff, to be defined) and develop evidence-based recommendations. A major disaster with long-term impacts would require healthcare providers in affected communities to exercise a combination of special clinical protocols, contingency care (such as healthcare in an alternate site), crisis standards of care, and ultimately a restored balance of usual health system functions. The DFO assigned the topic to the DMWG, which received presentations to support their work during the public portion of the meeting. Those presentations are summarized in Section 3 of this report. The DMWG discussed the topic at

[2] Recommendations from the NBSB can be transmitted to the leadership in multiple ways. In this case, the staff officer responsible for coordinating NBS-related activities in HHS was present at the time of the vote and also received a copy of these recommendations that were presented to the full Board.

length and agreed to continue to review the issues and develop recommendations for public review at a later meeting of the NBSB.

Another component of the agenda for the public meeting involved providing the board members with updates on some of ASPR's current preparedness and response programs. In 2018 and 2019, ASPR initiated a number of new strategic activities within the agency, such as the Regional Disaster Health Response System (RDHRS) and the Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation, and Ventures (DRIVe). In general, the programs aim to leverage talent and experts at the local, state, regional, and national levels, including private companies, to form regional partnerships to enhance immediate responses to public health emergencies (RDHRS) and increase the breadth and speed of medical countermeasure (MCM) development (DRIVe).

The NBSB also received presentations on a number of programs and activities that continue to support ASPR's operational mission. The third quadrennial iteration of the National Health Security Strategy (NHSS) is significantly different from previous versions. In particular, the 2019-2022 NHSS now aligns more closely with the National Security Strategy and National Defense Strategy and is more tightly focused on addressing threats deemed to be of greatest concern. ASPR also made significant changes to the Emergency Support Function (ESF)-8 Incident Response Framework, resulting in deployment of command functions and authorities during a response farther into the field. There were also presentations on the National Veterinary Response Team (NVRT), which continues to provide One Health support to the National Disaster Medical System (NDMS); the Technical Resources Center, Assistance Center, and Information Exchange (TRACIE), which continues to evolve as a key national resource for preparedness and response lessons learned; and the HHS emPOWER Program, which helps incident responders to identify medically vulnerable individuals in a disaster area. Section 4 of this document contains abstracts from the presentations about ASPR's preparedness and response programs.

Lastly, Dr. Gray Heppner, the co-chair for the AHWG, and Dr. Geoffrey Ling, formerly of the Department of Defense (DoD) Advanced Research and Production Authority (DARPA), introduced a new topic to the NBSB. Dr. Heppner presented an analysis of potentially devastating emerging infectious disease scenarios that indicates the need for much faster development of MCM than is currently possible. He focused on the challenges related to future implementation of advanced technologies for just-in-time or on-demand production of emergency MCM. Dr. Heppner described a number of targets and strategic challenges related to rapid vaccine development, manufacturing, and deployment that require a combination of scientific advancement and coordinated policy decisions. Dr. Ling presented a new concept for biochemical synthesis of drugs and protein-based biologics at the facility level or bedside. The AHWG will continue to consider this topic over the following months. An abstract of Dr. Heppner's and Dr. Ling's presentations is in Section 5 of this report.

The NBSB public meeting adjourned at approximately 4:30 p.m. Eastern Time (ET) on June 11, 2019. The next public meeting is scheduled for September 11, 2019, in Washington, DC.

Section 1: Call to Order and Introductory Remarks

Meeting Administration

The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) hosted the National Biodefense Science Board (NBSB or the "Board") at a public meeting on June 10-11, 2019, in Washington, DC. The Board was asked to consider a number of matters, including topics assigned to the two active working groups, and receive updates on recent advancements in several of ASPR's preparedness and response programs. As required by law, the general public were invited to attend the meeting through the Federal Register; they were able to attend in person or connect by phone and webinar. The designated federal official (DFO) instructed members of the public to email comments or questions to NBSB@hhs.gov or post them in the chat box for the webinar. All appointed voting members were present during the roll call, either in person or by phone. There were also (at various times) *ex officio* representatives from ASPR, the Centers for Disease Control and Prevention (CDC), the National Aeronautics and Space Administration (NASA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). The DFO explained the requirements for disclosure of conflicts of interest among the board members; no one declared any conflicts of interests at that time. Appendix 1 contains a list of all board members in attendance and federal agency representatives.

Welcome and Opening Discussion[3] with Dr. Sally Phillips

The NBSB continues to be an important part of HHS and key asset for ASPR to achieve and maintain readiness for public health and medical emergencies. Authorized originally in 2006 with the Pandemic and All Hazards Preparedness Act, and reauthorized in the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2019,[4] the NBSB has contributed significantly to many of today's systems and programs. Among its other important work, the NBSB has provided guidance for the National Disaster Medical System (NDMS), the Strategic National Stockpile (SNS), and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

Going into the future, the 2019 authorizing legislation strengthens authorities for the Hospital Preparedness Program (HPP) and NDMS, provides new authorizations to establish guidelines for the Regional Disaster Health Response System (RDHRS), and updates and codifies the PHEMCE. Among other things, it also enhances authorities to reassign federally funded personnel temporarily during a declared emergency and the ability of the Biomedical Advanced Research and Development Agency (BARDA) to target, identify, fund, coordinate development of, and license critical new medical countermeasures (MCMs). The legislation reconstitutes the

[3] Remarks from all speakers and presenters, as well as discussion among the board members, are summarized in this report, with a focus on information and observations relevant to the work of the NBSB. This document is not a transcript, though all speakers have reviewed and approved their respective texts.

[4] The legislation passed Congress on May 16, 2019, and was signed into law on June 24, 2019 (several days after the NBSB public meeting).

National Advisory Committee on Children and Disasters (NACCD)[5] and calls for two new advisory committees to focus on the impacts of disasters on seniors and individuals with disabilities, respectively. ASPR underwent an organizational realignment in 2017-2018 to respond more effectively to 21st century threats, resulting in transformation of ASPR to a more operational agency. ASPR's strategy focuses on leading and strengthening public health security capabilities, developing the RDHRS, and advancing an innovative MCM enterprise.

Questions from board members led to a more detailed discussion about the transfer of the SNS to ASPR. Careful coordination with CDC has ensured that there are no gaps in response capacity and provided the involved staff members with ongoing transition support. CDC will focus on maintaining the existing coordination with state and local partners. As the SNS continues to evolve and refine its processes, ASPR will develop coordinated communications for all stakeholders.

[5] The original NACCD functioned between August 2014 and September 2018, after which it terminated according to statute. Reconstitution of the NACCD requires approval of a new charter and selection of a new board member, a process that is ongoing.

Section 2: All Hazards Science Response Working Group (AHWG)

Summaries of Presentations and Discussion

The Board was asked to consider how HHS might define criteria to guide future assessments and program decisions to support implementation of the NBS. The AHWG met by teleconference on May 23 and June 4 before the in-person meeting and again on June 10 apart from the concurrent public meeting. The working group developed a set of recommendations (below) that they presented to the full NBSB during the public meeting as required by the Federal Advisory Committee Act (FACA).

CAPT Theresa Lawrence, Director of the Policy Division in ASPR's Office of Strategy, Policy, Planning, and Requirements, first provided a brief update on the status of the implementation of the NBS, which aims to prepare for, respond to, and recover from bioincidents from all causes. Implementation of the NBS (as of June 11) included engagements with the public through the Biodefense Summit in Washington, DC, hosted by the National Academies of Science, Engineering, and Medicine on April 17, 2019, and targeted outreach among key stakeholders. The Biodefense Coordination Team solicited public comments through the Federal Register and at the Biodefense Summit; the public may continue to comment by sending emails to NBS@hhs.gov. During the subsequent "Biodefense Assessment" phase, agencies must identify impediments and challenges to NBS implementation, as well as opportunities for resource alignment and elimination of redundancies, and gaps in the biodefense enterprise. A public report will be completed in the fall of 2019. A more detailed summary of the report from the working group to the NBSB is available in Appendix 1 of this document.

Final Recommendations

In brief, the working group recommended four criteria to help establish consistent priorities among multiple programs:

1. *Time to successful completion*: the time required to complete implementation of target goals or objectives for the NBS.
2. *Time to demonstrated engagement of communities*: time required to achieve targeted engagement at all levels of state, local, tribal, and territorial (SLTT) governmental and relevant community stakeholders.
3. *Impact of implementation*: magnitude and duration of effect on health (human, animal, and environmental/ecosystem).
4. *Resource needs*: availability of government and nongovernment resources such as people, budget, equipment, and materials.

The Board recognized that other criteria might be needed or more appropriate for specific program goals and further recommends that HHS develop subsequent milestones, metrics, and end states. **A quorum of the NBSB discussed these on June 11, 2019, and agreed unanimously to recommend them to HHS.**

Section 3: Disaster Medicine Working Group (DMWG) Presentations

Mass casualty events caused by a CBRN agent, including pandemics, will require many healthcare providers of all types to function outside of their normal training and scope of practice. Community-based providers – physicians, nurses, and other licensed providers – could be required to make clinical decisions as "first-line responders" for an extended period. With limited evidence and a lack of guidelines, ASPR asked the DMWG to provide recommendations on how to ensure that clinicians and other first-line healthcare facility staff receive the training and support they need to provide appropriate care during a mass casualty event. The goal of this discussion is to identify the currents gaps in proficiencies among clinicians and other healthcare staff in general and other factors that prevent their effective involvement in a disaster response that can be addressed by HHS and ASPR. The board members acknowledge that "disaster medicine" is itself already adequately defined by other groups; and the established systems for initial clinical training, ultimately leading to licensing and certifications, are outside of the purview of the NBSB. A number of subject matter experts were invited to the public meeting to provide background and perspectives.

Abstracts of Presentations

Disaster Medicine Education of Community Clinicians – Mark K. Hunter, MD, PhD, Director for the Center for Family Medicine, University of South Dakota Sanford School of Medicine

Because primary care providers are present before an emergency, remaining on the front lines of the disaster response and in the community during recovery, their proficiencies in providing comprehensive healthcare in the context of an overshadowing health emergency can be critical. Surveys indicate that only two-thirds of medical schools introduce topics related to disaster medicine. There are no specific requirements for post-graduate training in disaster medicine or medical licensing, including for the emergency medicine specialty, though several medical societies maintain guidelines that include disaster medicine training for residents. An evidence-based approach to enhancing proficiencies of clinicians to respond to a disaster would be twofold: an evaluation of the impacts of training methods, and developing evidence for the effectiveness of clinical interventions in a disaster scenario. Few studies support an evidence-base for disaster medical training, though it appears that exercises and online training are more effective in increasing clinicians' skills than other types of pedagogy. However, there is little useful data linking such knowledge with provider practices or patient outcomes in a disaster. There are still not enough patient-oriented or learner-oriented studies to develop the needed evidence. A well-recognized, operational strategy, such as the plan-do-study-act cycle, applied to disaster medical training, could be a useful addition to academic hospitals' current planning to support the development of useful evidence.

Development of South Dakota's Annual Disaster Medical Training Day – Janet Lindemann, MD, MBA, Professor Emeritus, University of South Dakota Sanford School of Medicine

Two major events, the 9-11 terrorist attacks and the *Amerithrax* attacks in 2001, inspired faculty in the health professions schools at the University of South Dakota (USD) to develop a 1-day interdisciplinary program to prepare students to respond to natural disasters and CBRN threats. Developed in collaboration with the South Dakota Department of Health and the Area Health Education Center, the USD model, in use since 2001, has three major strengths: leverages interdisciplinary collaboration, capitalizes on current events, and appeals to the sense of obligation of the students. The annual curriculum uses scenarios based on recent events, but always includes immunization practices, recognition of anaphylaxis, and use of points of distribution for stockpiled MCM because those are common components of the state's emergency response plans. As a result of the USD training program, South Dakota's State Emergency Registry of Volunteers (SERV SD) online registry allows health professions students to volunteer for recognized response roles with the state's emergency management program.

National Center for Disaster Medicine and Public Health (NCDMPH) – Kandra Strauss-Riggs, MPH, Education Director

Homeland Security Presidential Directive (HSPD)-21 established NCDMPH (or the "Center") at the Uniformed Services University of Health Sciences to centralize coordination of education and research in disaster medicine. The Center's work involves reviewing existing evidence, sponsoring research and training activities, and providing educational material to the public. NCDMPH collaborates with other components of the DoD, CDC, the Veterans Health Administration, the National Institute for Standards and Technology, Johns Hopkins University Applied Physics Laboratory, and many others. A new review, which will be published online soon, revealed more than 3,600 disaster training activities online but very low levels of funding for disaster science. While the online training contains large amounts of content, the courses are not necessarily consistent or systematically structured as a logical course of study for clinicians. Common themes among current training activities include the need for "big picture" situational awareness during a disaster, methods and practices for triage and patient distribution, and clinical skills specific to each hazard. The current core competency set and training provided by NCDMPH are available to clinicians who are interested. While useful as a source for teaching clinical standards, the current material by itself is not a systematic way of training the clinical workforce. Today, clinical CBRN response training is not integrated into established health professional training, and there are no incentives for busy clinicians to step away from an active practice to learn additional skills. Some medical specialty associations (emergency medicine, family practice, pediatrics, for instance) have developed disaster medicine competency models, but those are not widely implemented in training or practice. Clinicians and patients, who are accustomed to high-tech services, diagnostics, and therapeutics, with plenty of hospital beds, could have more difficulty adapting to sudden, significant, and prolonged resource limitations. Ironically, the typical challenges related to lower resource availability for rural providers and patients may lead to greater resiliency and resourcefulness in an emergency.

Nebraska's Severe Winter Storm, Straight-line Winds, and Flooding in 2019 – H. Dele Davies, MD, MS, MHCM, Senior Vice Chancellor for Academic Affairs and Dean for Graduate Studies, University of Nebraska Medical Center (UNMC), Omaha, NE

From March 9 to April 1, 2019, Nebraska faced several winter events that included a bomb cyclone, major flooding, straight-line winds, and a sustained period of significant cold with heavy snowfall, frozen ground, frozen rivers and streams, and blizzard conditions. The governor of Nebraska declared a state of emergency for all 93 counties on March 12, 2019, and submitted an expedited request for a federal disaster declaration. On March 21, 2019, the Federal Emergency Management Agency (FEMA) Disaster Declaration 4420 was signed by the President of the United States. UNMC worked with the state and federal government to address the impacts of flooding, including emergency protection for residents, agricultural issues related to livestock and farming, transportation issues, housing issues, water facilities issues, and debris management.

Observations from Children's National Health System – Joelle Simpson, MD, MPH, Medical Director for Emergency Preparedness, Children's National Health System, Washington, DC

In 1984, the federal Emergency Medical Services for Children (EMSC) program was signed into law with a mission to reduce disparities in emergency care for children, whether during a full-scale disaster or everyday emergencies. Beginning in 2001, with the Task Force on Terrorism, the American Academy of Pediatrics (AAP) has aimed to ensure children's needs were considered in all emergency preparedness planning efforts. The AAP Disaster Preparedness Advisory Council, created in 2007 after Hurricane Katrina, helps the organization to develop and implement a strategic plan for disaster preparedness. With a lack of emergency disaster care for a large portion of children in the United States, more facilities and networks need to talk through disaster plans or conduct disaster drills that focus on the unique needs of children.

One Health: The Intersection of Human, Animal and Environmental Health – Cheryl Stroud, DVM, PhD, Executive Director, One Health Commission

One Health is an important concept that provides a pathway to planetary health and global biosecurity that depends on healthy animals and ecosystems. Sharing information across sectors is difficult because of the siloing among academic tenure and publication systems, political agencies and appropriations, and scientific disciplines. The economic impacts of zoonotic disease outbreaks, such as the human immunodeficiency, Nipah, and Ebola viruses, illustrate the critical need to break down systemic silos. Comprehensive implementation of One Health can have important benefits for animals and ecosystems that ultimately enhance human health outcomes. For example, animals can serve as sentinels for human health risks from environmental contamination and infectious agent exposures, but information emerging from the veterinary sector is often difficult to incorporate into the human health sector. Despite many decades of veterinary science, human medicine only recently recognized *Bartonella* species as an etiological agent for some chronic diseases in humans, including degenerative neurologic syndromes, arthritis, chronic fatigue, fibromyalgia, and granulomatous lesions. Antibiotics resistance is also a quintessential One Health issue, with the oceans and soil potentially serving as reservoirs and amplifiers for antibiotic resistance genes. While challenges remain, there have been some advancements in adopting One Health policies and strategies. The State Department, U.S. Agency for International Development, U.S. Department of Agriculture (USDA), and CDC all have made efforts to develop One Health collaborations. One

Health collaborations are important for disaster preparedness and biodefense, as we learned from Hurricane Katrina. Following after-action reviews and commitments to improve response operations across the spectrum, we are beginning to see significant cross-sectoral planning ahead of disasters that enhance One Health resilience and recovery.

A One Health Approach to Biosecurity Threats in the 21st Century – Laura Kahn, MD, MPH, MPP, Research Scholar, Program on Science and Global Security at the Woodrow Wilson School of Public and International Affairs, Princeton University, NJ

One Health provides an inherent all-hazards approach to disaster preparedness, serving as a platform to examine and address global biosecurity threats. According to World Bank modeling, by 2050, much of the planet will become too hot and too dry for agriculture, potentially leading to widespread crop failures and famine. With food insecurity and higher average food prices, civil society can become unstable and violent. Human migration from hotter, less habitable to cooler climates is anticipated to increase as the planet warms. A balanced approach to One Health biosecurity will be required to protect food crops and livestock from various threats such as infectious diseases and pests. Responsible genetic engineering and integrated pest management will be essential to ensure food production while avoiding the decimation of important insect pollinators. Vector control and vector-borne disease risks are closely tied to climate change; increasing global temperatures will likely result in an expansion of vector-borne disease zones. Worsening food insecurity potentially increases incentives to harvest wild food, risking increased contact between zoonotic pathogens and human populations. Intensive food animal production to meet nutritional and cultural demands adversely impacts the microbial biome of the planet. Global fecal matter production from livestock is tremendous and poorly managed, especially in developing countries, leading to food and water contamination. Antibiotics are available over the counter in many countries and are overused, contributing to worsening antimicrobial resistance. Public mistrust and misperception of scientific advancements, such as vaccines and genetically modified organisms, makes addressing global health and food security issues more challenging. A multidisciplinary, One Health approach will be essential to developing effective biosecurity policies in the 21st century.

Next Steps

The DMWG will meet by phone during subsequent months to continue to discuss the challenges related to clinical proficiencies and training for a mass casualty event, inviting other subject matter experts as needed, and prepare recommendations for HHS. Recommendations from the DMWG could be considered at the next public meeting on September 11.

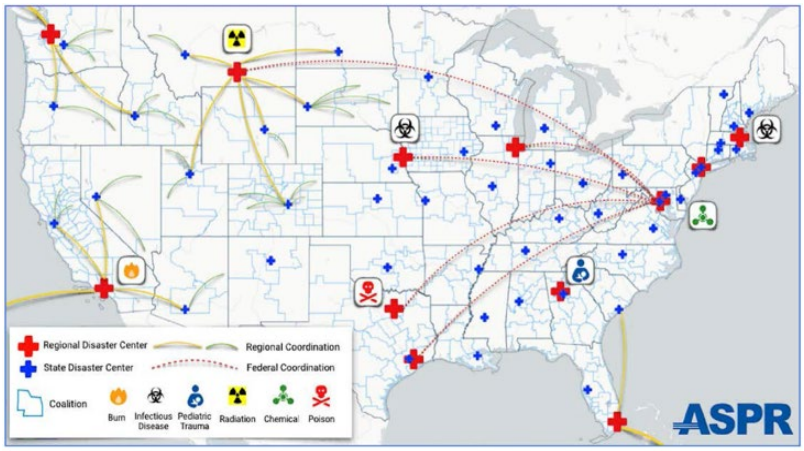
Section 4: ASPR Program Updates

Abstracts of Presentations

Introduction to the Regional Disaster Health Response System (RDHRS) – Lauren Walsh, MPH, DrPH(c), Senior Program Coordinator

Authorized in 2019 in the Pandemic and All Hazards Preparedness and Innovation Act, RDHRS is built on the foundations of the HPP, which currently provides $255 million to 62 state and local health departments. Leveraging the structure of HPP and the regional healthcare coalitions, RDHRS provides funding directly to hospitals and health systems to help them prepare to handle a major patient surge during a disaster. RDHRS aims to develop networked health emergency plans at the state and multi-state levels, with documented procedures for health information and resource sharing for highly specialized medical care. The regionalized systems will be more self-sufficient and faster in their responses, organizing and acting without immediate federal assistance (Figure 1). ASPR is currently funding two pilot sites to develop and validate templates, metrics, and guidelines to improve alignment across the region, improve systems for situational awareness, expand partnerships, develop highly specialized medical capabilities, and conduct exercises. ASPR provided $3 million each to Nebraska Medicine to coordinate with the three neighboring states in HHS Region 7 and Massachusetts General Hospital to coordinate among states in HHS Region 1. The pilot sites have had a number of accomplishments already, including development of a legal reference guide to support regional coordination and responses, an inventory of volunteers, establishment of hospital-hosted medical support teams and deployable medical assets, identification of training gaps for providers, and a framework for the development of medical emergency operations centers, knowledge management, and shared situational awareness systems. The pilot sites have also drafted a set of essential elements of information specific to the regional coordination of specialized surge management as well as coalition-level readiness metrics. RDHRS-related activities furthermore support sustainment of readiness systems, having led to updates to state legislation and changes to states' emergency procedures. In the next phase, ASPR intends to fund additional RDHRS sites in each FEMA region, with an additional focus on region-to-region coordination and collaboration, further reducing the need for federal medical aid in disasters.

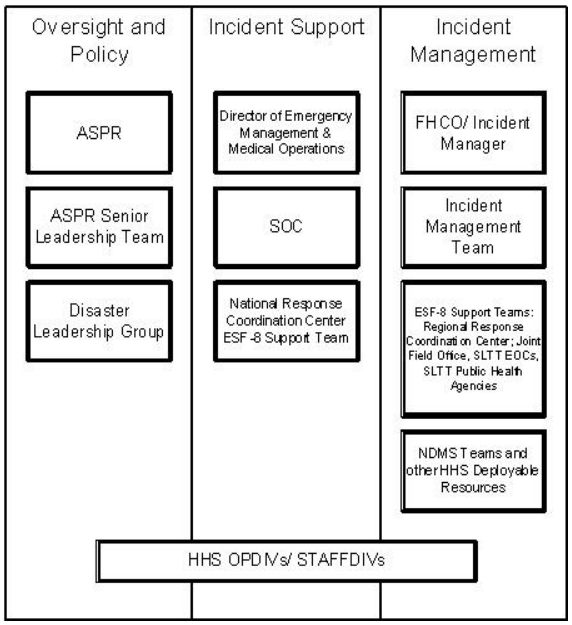
Figure 1.Notional (sample) diagram of the future network of the Regional Disaster Health Response System.



HHS/ASPR Incident Response Framework Overview – Pam Evans, Program Director, Office of Emergency Management and Medical Operations, ASPR

After the 2017 hurricane season, ASPR conducted a comprehensive review of corrective action plans for several years past, concluding that ASPR's incident command structures for ESF-8 required significant updates. The new, comprehensive, overarching Incident Response Framework ensures that command and control elements for national events are geographically and operationally as close to the incident as possible. Existing resources in ASPR were reorganized to delegate response decisions to the field element called the Incident Management Team (IMT) (Figure 2), which functions based on the principles of the FEMA Incident Command System (ICS). Operational oversight and policy coordination and the ASPR incident support structures remain in Washington, DC, at all times to ensure situational awareness, interagency coordination, and planning and logistical support, but do not direct day-to-day actions in the field. The Federal Health Coordinating Officer (FHCO) in the IMT serves as the incident manager. The deputy FHCO for Mission Generation (MG) serves as the coordinator between the Incident Support Team, the HHS administrators and emergency coordinators in the affected region, and the state and local incident commands. The FHCO-MG helps to assess the event, identify resource gaps, and coordinate operational requirements and mission assignments. The deputy FHCO for Mission Execution (ME) exercises traditional operational control over the deployed resources, including oversight for daily operations, planning, logistics, administration, and finance. The new IMT also has a section dedicated to information management, which reports to the FHCO-ME in the same way as the other ICS sections. This model for command and control was phased in during the 2018 hurricane response season, with some refinements of the framework reflected in the final document approved in 2019.

Figure 2. Diagram of ASPR's Incident Response Framework.



National Veterinary Response Team – CDR Wanda Wilson-Egbe DVM, MPH, DACVPM, Chief Veterinary Officer, National Disaster Medical System, ASPR

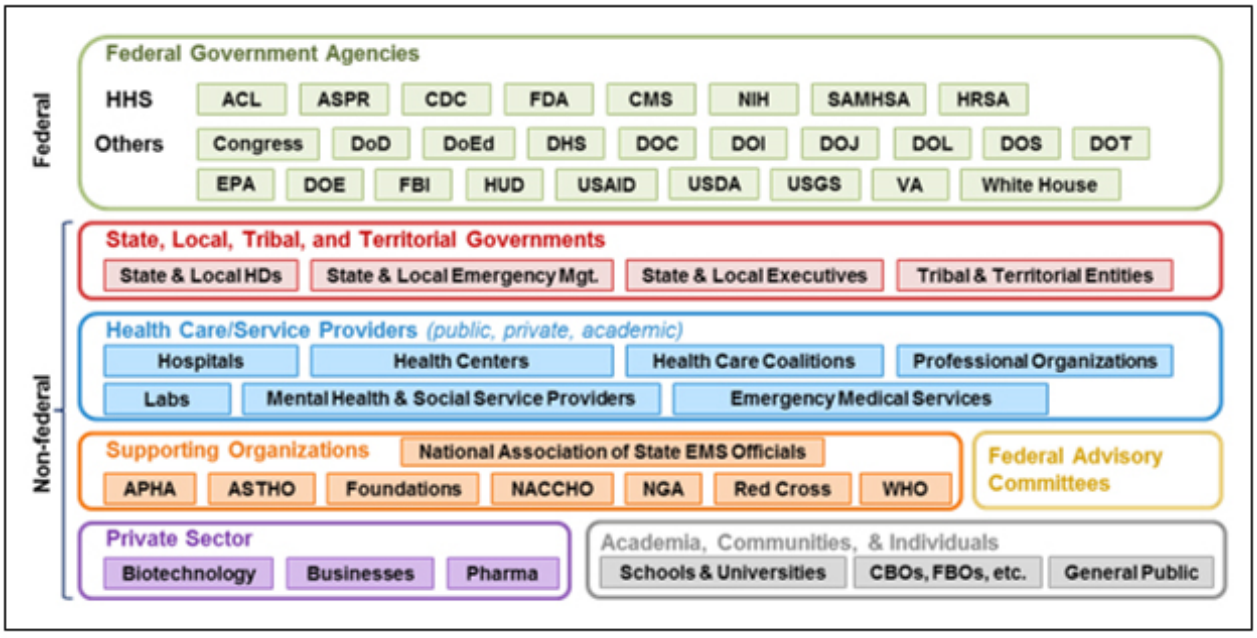
NDMS is a federally coordinated healthcare system and partnership among HHS, the Department of Homeland Security, DoD, and the Veterans Health Administration. The purpose of NDMS is to support SLTT authorities following disasters and emergencies by supplementing health and medical systems and response capabilities. ASPR employs NDMS to provide patient care, patient movement, and definitive care, as well as veterinary services, and fatality management support when requested. Within NDMS is the National Veterinary Response Team (NVRT), which has more than 20 years of experience supporting animal health during disasters.

The NVRT core capabilities include treating ill or injured service animals, pets, working animals, laboratory animals, and livestock; supporting USDA in assessing disease risks in livestock or poultry; and preventing and controlling zoonotic diseases to protect human health.

National Health Security Strategy: 2019-2022 – Darrin Donato, Domestic Policy Branch Chief, Office of Strategy, Policy, Planning, and Requirements, ASPR

As required under the Public Health Service Act, the quadrennial NHSS is a capstone document for health security that aligns closely with the National Security Strategy and the National Defense Strategy. The 2019 NHSS is significantly different from past documents, using information from the intelligence and public health sectors for a threat-based approach prioritizing preparedness activities against evolving, emerging, and potentially catastrophic events. It is unique from, but complementary to, the NBS and Health Security National Action Plan based on the 2016 Joint External Evaluation. The three pillars of the NHSS promote a strategic focus on current and emerging 21st century health security threats: (1) employing whole of government and whole of society approach to link and mobilize the operational capabilities of all sectors; (2) ensuring readiness and operational capabilities to mitigate the impacts of pandemics and CBRN threats; and (3) partnering with the private sector to ensure preparedness of the healthcare system and rapid development of necessary countermeasures. The NHSS is selective in its strategic focus, addressing well-recognized chemical, biological, and radiological risks, and also addressing emerging threats. NHSS recognizes the importance of the interfaces between human health, animal health, environmental health, SLTT governments, and the private sector (Figure 3).

Figure 3. Array of partners involved in implementation of the National Health Security Strategy 2019-2022.



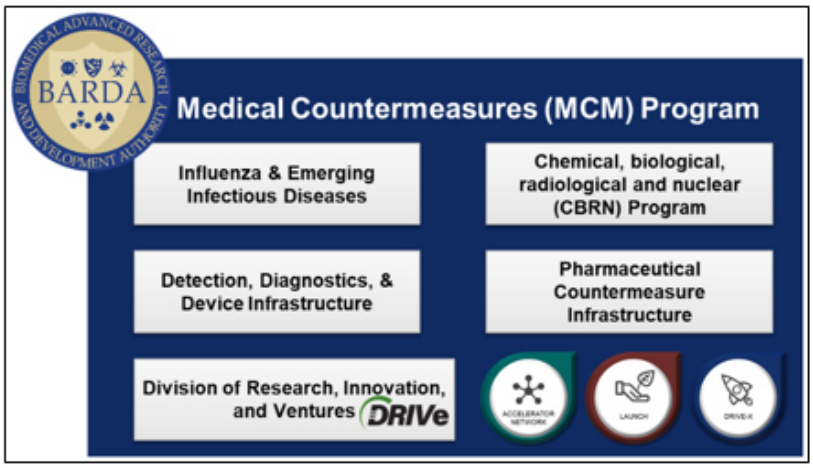
Implementation of the NHSS aims to improve public health and medical preparedness, response, and recovery and also protect against new or evolving threats such as cybersecurity

risks to the healthcare system and adverse health impacts from increasing severity and frequency of severe weather events.

DRIVe Overview – Gary L. Disbrow, PhD, Acting Director of BARDA Medical Countermeasures Program

After many successful years, the work of BARDA has resulted in 45 licensed MCMs so far. The new Division of Research, Innovation, and Ventures (DRIVe) will further catalyze, incentivize, and empower the private sector to partner with the federal government and each other to accelerate MCM innovation. DRIVe is derived from the authorities in the *21st Century Cures Act*, which calls on the federal government to conduct activities that bring biosurveillance, therapeutics, vaccines, and other counter-measures innovations to market more quickly (Figure 4). The *DRIVe Accelerator Network* leverages the creativity and talent of innovators and entrepreneurs around the country to develop and market health security solutions. *DRIVe-X* is an initiative that provides a simplified "Easy Broad Agency Announcement" (EZ-BAA) process for companies to submit a 2,000-word abstract online to apply for limited funding (no more than $750,000 with demonstrated cost-share) for an initial startup partnership. *DRIVe Launch* will be an initiative to establish third-party, medical innovation partnerships to maximize the use of venture-capital practices for mission-focused research and development companies. DRIVe has invested $7.2 million already in 14 individual grants, with an awardee-match of $5.8 million. There are three major impacts areas: presymptomatic disease diagnostics (e.g., during the incubation period) through *Early Notification to Act, Control, and Treat* (ENACT); prevention of deaths from sepsis through *Solving Sepsis*; and development of novel countermeasure administration systems, rapid development and manufacturing of novel diagnostics, and development of broad-acting therapeutics through *Other Disruptive Innovations* (ODIn).

Figure 4. BARDA's Medical Countermeasures Program and the three components of the new Division of Research, Innovation, and Ventures (DRIVe).

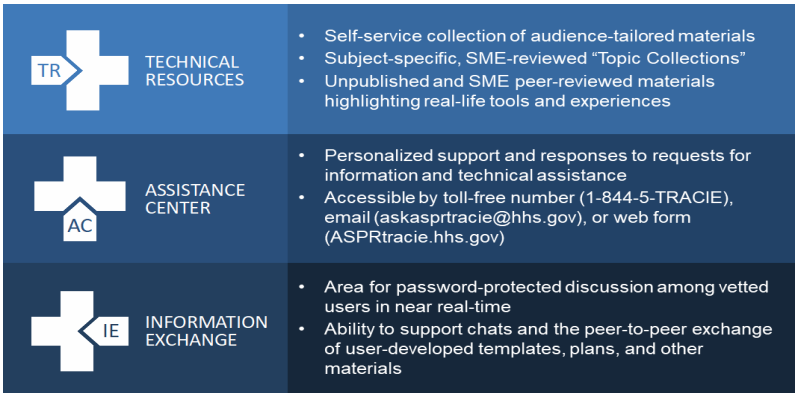


ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) – John Hick, MD, Hennepin County Medical Center, Lead Editor for TRACIE

ASRP developed TRACIE to aggregate, analyze, and amplify lessons learned from around the country in a one-stop knowledgebase and resource for technical assistance in medical preparedness and response. ASPR TRACIE subject matter experts review and curate material to

present the best and most comprehensive resources in a specific topic area (Figure 5). Users of the system then rate and comment on those documents to further validate or amplify their findings. ASPR TRACIE staff are available to respond to technical assistance requests via email (askasprtracie@hhs.gov), toll free number (844-5-TRACIE), or online (ASPRtracie.hhs.gov). They provide assistance in the use of the system and facilitate independent, unmoderated peer-to-peer exchange. The website currently has 57 topic collections. As an extraordinary example of the formulation of lessons learned, ASPR staff traveled to Las Vegas in December 2017 to conduct semi-structured interviews to capture detailed information about the city's response to the mass shooting that occurred in October 2017. While this is not a routine activity for ASPR, the interviews resulted in important updates to the *Hospital Surge Capacity and Immediate Bed Availability* topic collection (and others) and the development of no-notice incident tip sheets for hospitals and emergency medical services (EMS). TRACIE also provides a number of tip sheets and planning tools, such as the Hospital Disaster Pharmacy Calculator, to help hospital administrators and clinicians to consider key planning factors.

Figure 5. The three primary functional domains in ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE).



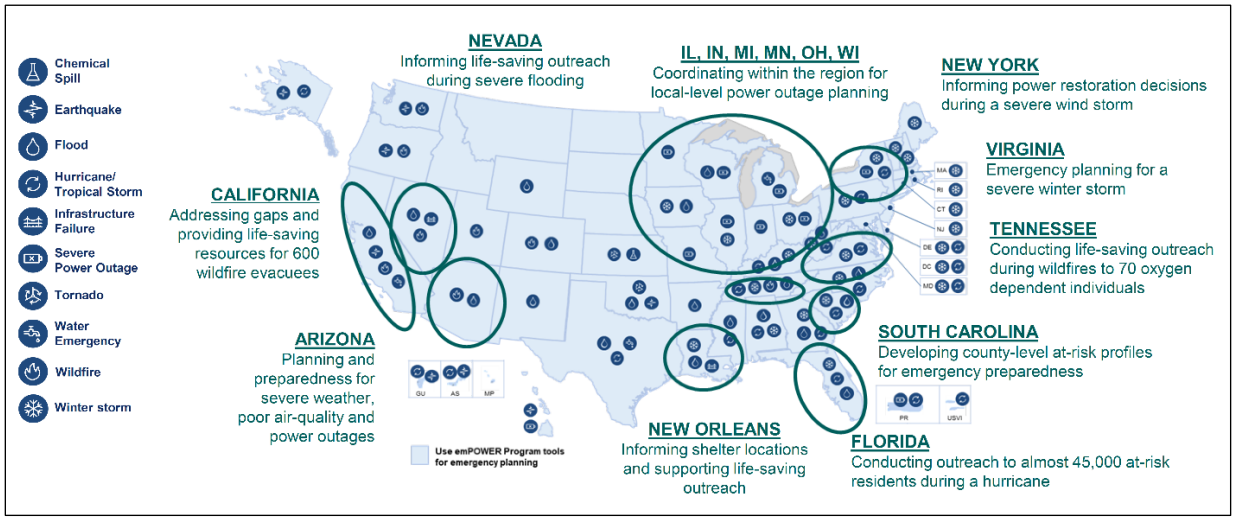
Related to disaster medicine, *crisis care* refers to the immediate healthcare-related decisions made when a health system is overwhelmed; whereas, *crisis standards of care* refers to the organizational support that healthcare institutions and government agencies implement systematically as a part of an emergency response plan. Consistency and fairness across the affected population is critical. Institutions should have systems in place to provide (or acquire) and organize "stuff, staff, space, and systems," with enough specialized expertise on hand to adapt clinical practice and workflow to the nuances of the situation.

HHS emPOWER Program – Kristen Finne, Director, HHS emPOWER Program, Office of Emergency Management and Medical Operations, ASPR

To help communities nationwide to protect the health of more than 4.1 million Medicare beneficiaries who live independently with electricity-dependent medical equipment and healthcare services, ASPR collaborated with the Centers for Medicare and Medicaid Services (CMS) to launch the HHS emPOWER Program in 2013 (Figure 6). The emPOWER program provides dynamic data and mapping tools, such as the Representational State Transfer (REST) Service and online training, which so far has been used to anticipate, plan for, and respond to the needs of at-risk individuals in over a 150 emergencies. For example, during Hurricane Matthew, emPOWER data was used in Florida to *robocall* 44,500 potentially at-risk individuals. Reaching 17,000 homes, the action identified 169 people who needed urgent medical

assistance. The program has since launched a voluntary *emPOWERing State Medicaid and Children Health Insurance Program* pilot to help states and territories develop at-risk pediatric and adult datasets based on the unique coverage of their own programs. Future capabilities will include virtual assistants with artificial intelligence to help first responders to improve rapid identification of at-risk individuals.

Figure 6. Since 2013, communities in all 50 states and 5 territories have used the HHS emPOWER Program before, during, and after the following emergencies and will continue to request and use emPOWER data in the coming years.



Section 5: Exploring Topics in Biodefense Science

Abstracts of Presentations

Rapid Development of Vaccines and Other Biologics for Emerging Infectious Diseases: Stopping Epidemics (Disease X) in the Era of Synthetic Biology, One Health, and Complex Societies – COL(R) Gray Heppner, MD, Chief Medical Officer, Crozet BioPharma, LLC, and COL(R) Geoffrey Ling, MD, PhD, CEO, On Demand Pharmaceuticals

Dr. Heppner began his presentation with the following "bottom lines up front" –

- Mitigation for new bioterrorism or natural pandemic threats (Disease X) requires rapid pathogen characterization, rapid MCM development, and effective MCM use.
- Time to MCM deployment is the critical factor in limiting death and morbidity in a pandemic.
- Use of "MCM on demand" requires work today to establish new policy, plans, and capabilities.
- The technical ability to create an MCM is only one determinant of benefit; deployment and use require significant SLTT collaboration and risk communication strategies.

Global risk assessments by the U.S. intelligence community and World Health Organization (WHO) continue to indicate that international outbreaks and pandemics represent serious health and economic threats. Population growth, suburban development, and the speed and regularity of international travel increase the risk of rapid spread of zoonotic diseases beyond their origin where humans, animals, and the environment interact in new ways. New technologies result in new risks from a variety of bioengineered threats, including the ability to increase the transmissibility and lethality of pathogenic viruses or recreate them *de novo*. Analyses of infectious disease scenarios indicate that improved timeliness of vaccine production and administration ultimately provides the greatest benefit. Modeling also indicates that the time to administration of vaccine must precede the natural peak of the outbreak by many weeks to be effective. Ultimately, to use on-demand vaccines and other MCM successfully requires strategic integration with biosurveillance, component formulation and design, stability of the supply chain for precursor material, manufacturing and scale-up capacities, safety oversight, slipstream pathways to resolve clinical and regulatory issues, and establishment of public trust and acceptance of rapid response MCM.

Dr. Ling presented another potential approach to emergency medical responses to Disease X, which is the ability to manufacture therapeutics and other lifesaving compounds on demand, potentially very close to the bedside. Miniaturization of computer components and robotics, as well as novel packaging of reagent systems, could lead to relatively small (hospital-room-sized), containerized "factories" that synthesize, purify, and package multiple drugs when needed. In testing, compounds can achieve the purity and efficacy characteristics required for FDA licensing. Biopharmaceutical manufacturing – the creation of metabolically active proteins, such as insulin, using enzyme reagents in cell-free systems – is another important frontier that

could ultimately be used to create vaccines and other immunomodulators. Prototype platforms have been built and are at various stages of maturity.

Next Steps

Over subsequent months, the AHWG will work to further define the scope of the discussion regarding development of vaccines and other MCM for emerging infectious diseases and consider recommendations on this topic.

Appendix 1: Attendees at the NBSB Public Meeting on June 10-11, 2019

Voting Members

Prabhavathi Fernandes, PhD (retired)
NBSB Chairperson
Chapel Hill, NC

Carl Baum, MD., FAAP, FACMT
Professor of Pediatrics, Yale University School of Medicine
New Haven, CT

John Benitez, MD, MPH
Medical Director of Emergency Preparedness and Environmental Epidemiology, Tennessee Department of Health
Nashville, TN

Virginia A. Caine, MD
Health Director, Marion County Public Health Department & Associate Professor of Medicine, Indiana University School of Medicine
Indianapolis, IN

Mark Cicero, MD
Associate Professor in Pediatrics (Emergency Medicine) & Director of Pediatric Disaster Preparedness
Yale University School of Medicine
New Haven, CT

H. Dele Davies, MD, M.Sc., M.H.C.M.
Vice Chancellor for Academic Affairs & Dean for Graduate Studies, University of Nebraska Medical Center
Omaha, NE

Donald G. Heppner, MD
Chief Medical Officer and Managing Partner, Crozet BioPharma Consulting, LLC
Crozet, VA

Noreen A. Hynes, MD, MPH
Director, Geographic Medicine Center in the Division of Infectious Diseases, Associate Professor at Johns Hopkins University School of Medicine & Associate Medical Director of Johns Hopkins Hospital Biocontainment Unit
Baltimore, MD

Elizabeth Leffel, PhD, MPH
President, Leffel Consulting Group, LLC
Berryville, VA

David Schonfeld, MD, FAAP
Professor of the Practice in the University of Southern California School of Social Work and Pediatrics & Director of the National Center for School Crisis and Bereavement
Los Angeles, CA

Joelle N. Simpson, MD, MPH
Medical Director for Emergency Preparedness, Children's National Health System &
Program Director for Emergency Medical Services for Children - DC Program
Washington, DC

Catherine Slemp, MD, MPH
Public health consultant to West Virginia Department of Health
Milton, WV

Tammy Spain, PhD
CMC Project Manager, Paragon BioTeck, Inc.
Tampa, FL

Federal agency representatives (non-voting)

Sally Phillips, RN, PhD
Deputy Assistant Secretary, Director of the Office of Strategy, Policy, Planning and Requirements, Office of Assistant Secretary for Preparedness and Response (ASPR)
Washington, DC

Chris Hassel, PhD
Senior Science Advisory, Office of the Assistant Secretary for Preparedness and Response
Washington, DC

Joanne Andreadis, PhD
Associate Director for Science (Acting), Center for Preparedness and Response, Centers for Disease Control and Prevention
Atlanta, GA

Marc Shepanek, PhD
Deputy Chief of Medicine of Extreme Environments & Research Assistant Professor at the Uniformed Services University Medical School
Washington, DC

Gregory Sayles, PhD, MS
Director of National Homeland Security Research Center, U.S. Environmental Protection Agency
Washington, DC

Brooke Courtney, JD, MPH
Senior Regulatory Counsel, Office of Counterterrorism and Emerging Threats, U.S. Food and Drug Administration
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LCDR Cliffon Smith, MPA
Evaluation/Public Health Analyst, Policy Division, SPPR, ASPR
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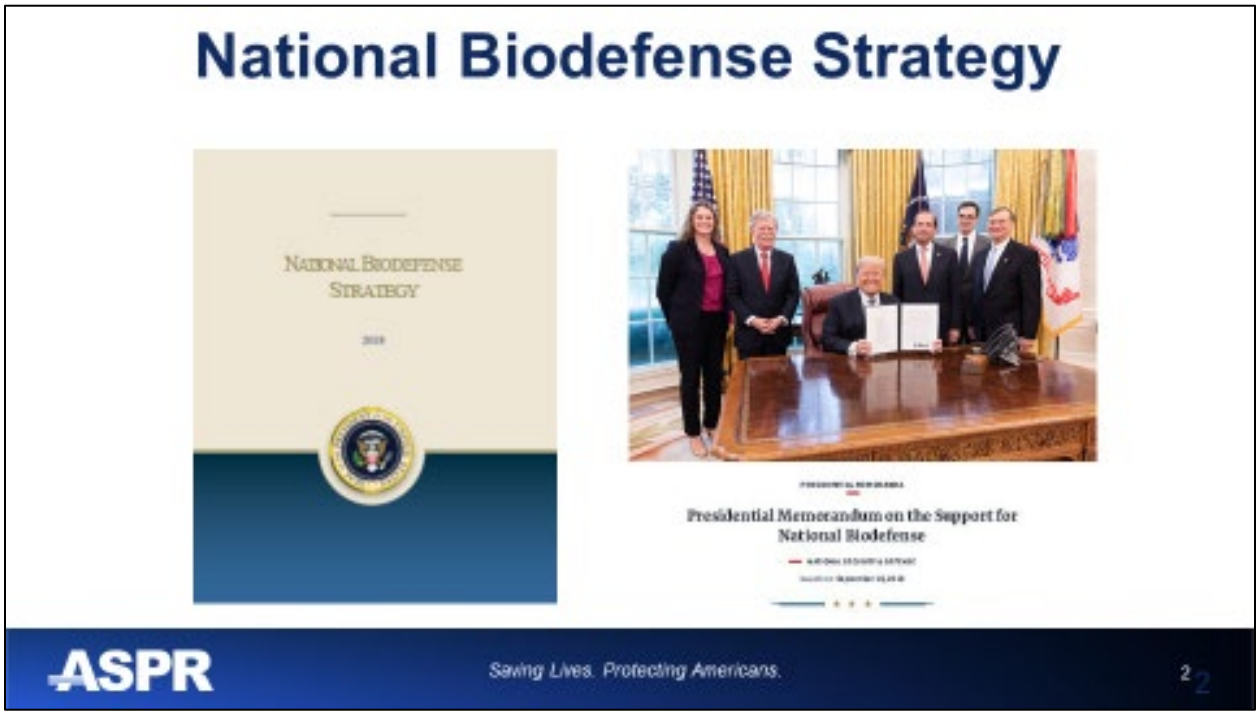
Mariam Haris
Policy Analyst, SPPR, ASPR
Washington, DC

Appendix 2. Summary of Presentation by the AHWG and NBSB Discussion, June 11, 2019.

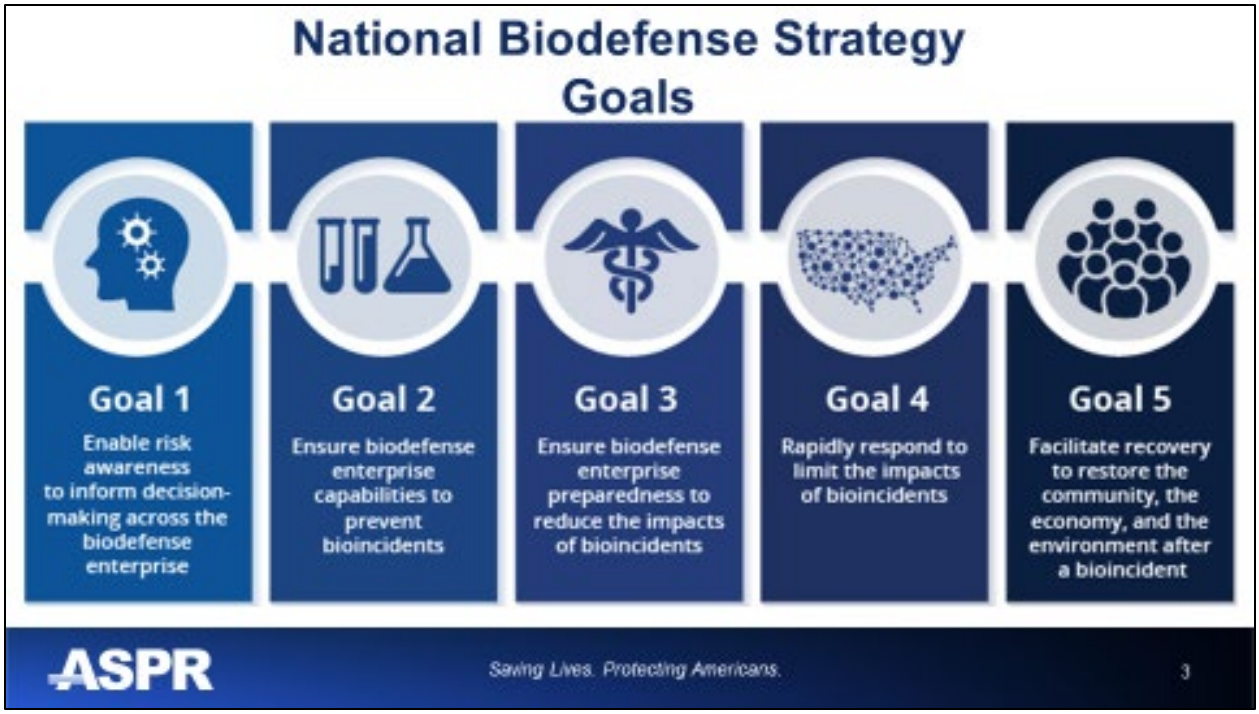
Elizabeth Leffel, PhD, MPH, President of Leffel Consulting Group, LLC, Co-Chair for the All Hazards Response Science Working Group (AHWG); and CAPT Theresa Lawrence, PhD, Policy Division Director, Office of Strategy, Policy, Planning, and Requirements, ASPR

The members of National Biodefense Science Board (NBSB or the "Board") are among the nation's preeminent scientific, public health, and medical experts, providing advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS). These issues cover topics regarding current and future chemical, biological, radiological, or nuclear (CBRN) agents, whether naturally occurring, accidental, or deliberate.



For background, the White House released the National Biodefense Strategy (NBS) on September 18, 2018, to set the course for the United States to combat serious biothreats that our country faces, whether they arise from natural outbreaks of disease, accidents involving high-consequence pathogens, or the actions of terrorists or state actors.

The NBS details the federal government's plans for coordinating its biodefense efforts with national and international partners, industry, academia, nongovernmental entities, and the private sector.



Goal 1: Enable risk awareness to inform decision-making across the biodefense enterprise.

The United States will build risk awareness at the strategic level through analyses and research efforts to characterize deliberate, accidental, and natural biological risks; and at the operational level through surveillance and detection activities to identify biological threats and anticipate biological incidents.

Goal 2: Ensure biodefense enterprise capabilities to prevent bioincidents.

The United States will work to prevent outbreaks and the spread of infectious diseases, including minimize the chances of laboratory accidents. The United States will also strengthen biosecurity to prevent hostile actors from obtaining or using biological material, equipment, and expertise for nefarious purposes consistent with U.S. Government's approach to countering weapons of mass destruction.

Goal 3: Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents.

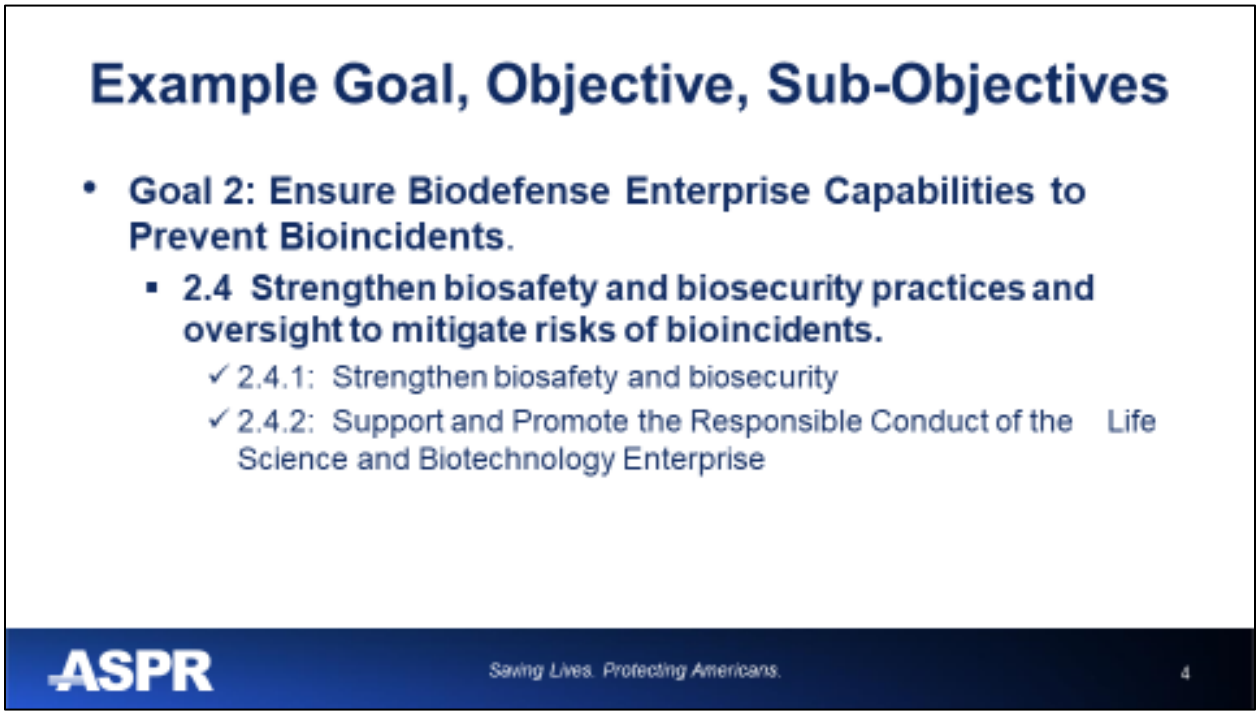
The United States will take measures to reduce the impacts of bioincidents, including maintaining a vibrant national science and technology base to support biodefense; ensuring strong public health infrastructure; developing, updating, and exercising response capabilities; establishing risk communications; developing and effectively distributing and dispensing medical countermeasures; and preparing to collaborate to support biodefense.

Goal 4: Rapidly respond to limit the impacts of bioincidents.

The United States will rapidly respond to limit the impacts of bioincidents through information-sharing and networking; coordinated response operations and investigations; and effective public messaging.

Goal 5: Facilitate recovery to restore the community, the economy, and the environment after a bioincident.

The United States will take actions to restore critical infrastructure services and capability; coordinate recovery activities; provide recovery support and long-term mitigation; and minimize cascading effects elsewhere in the world.



Each NBS goal has an overarching objective, accompanied by sub-objectives to outline a range of immediate and long-term actions towards progress. The goals are aligned to focus on immediate and future biological threats, through short-, medium-, and long-range metrics. An example of that framework for developing more specific end states, metrics, and milestone is Goal 2, objective 2.4 (strengthen biosafety and biosecurity practices and oversight to mitigate risks of bioincidents), with several supporting activities (or subobjectives) (2.4.1 – strengthen biosafety and biosecurity; 2.4.2 – support and promote the responsible conduct of the life science and biotechnology enterprise).

Working from a draft document developed during the December 13, 2018, NBSB public meeting, the AHWG was asked to define key criteria that could be used to prioritize biodefense activities. Without excluding other possible factors, these criteria are intended to help standardize the metrics for success for HHS, recognizing that milestones, metrics, and end states for all agencies still require finalization.

Note on the AHWG process: along with inputs from several members of the NBS coordinate team in ASPR, the board members discussed many different options, ultimately reaching consensus on four criteria for further discussion by the full Board in the public meeting.

The working group developed the following four criteria; the NBSB discussed a number of considerations:

1. **Time to Successful Completion**: time required to evaluate actions that progress the implementation of the goals/objectives of the NBS
    a) Define metrics: short-, medium-, long-range goals
    b) Emphasize completion and quality of outcomes

2. **Time to Demonstrated Engagement of Communities**
    a) Measure engagement and buy-in (e.g., NHSS measured how many groups made it to the local level)
    b) Consider “Engagement of Communities,” removing “targeted” due to the implication of excluding some communities
    c) Consider how to define and prioritize communities

3. **Overall Impact on Realization of Goals 1-5 of NBS**
    a) Consider interagency buy-in and metrics (inclusive of security/defense, health, and environmental federal partners)
    b) Consider standardized metrics that measure impact: deaths averted, lives saved, DALYs (disability-adjusted life years), and money saved

4. **Resource Requirements**
    a) Consider budget impacts of new or large-scale events at the local, state, and federal levels
    b) Consider government and nongovernment resources and in-kind support of staffing, equipment, and materials

Following this presentation, the NBSB voted on the final four criteria and additional statements. Refer to Section 2 of the June 10-11 summary of proceedings report for full details.