

NBSB

National Biodefense Science Board

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Public Meeting Summary

September 28, 2021
11:00 AM – 1:00 PM ET



ASPR

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Roll Call

NBSB Appointed Members

Prabhavathi Fernandes, PhD, NBSB Chairperson

Carl R. Baum, MD, FAAP, FACMT

Mark Cicero, MD

David Gruber, MA

Gray Heppner, MD,

Craig Klugman, PhD

Elizabeth Leffel, PhD

David Schonfeld, MD, FAAP

Joelle Simpson, MD, MPH

David Witt, MD, FIDSA, CIC

Mike Usman, MD, MMM (Readiness & Resilience Working Group)

Ex Officio Representatives

Mamadou Diallo, PhD, MS, National Science Foundation

Marc Shepanek, PhD, National Aeronautics and Space Administration

Dianne Poster, PhD, Department of Commerce

Mike Smith, MPhil, PhD, Department of Defense (DoD)

Isaf Al-Nabulsi, PhD, Department of Energy

Joanne Andreadis, PhD, Centers for Disease Control and Prevention

Brooke Courtney, JD, MPH, Food and Drug Administration

Ian Watson, Deputy Assistant Secretary, Office of Strategy, Policy, Planning & Requirements (SPPR), HHS
Office of the Assistant Secretary for Preparedness and Response (ASPR)

Guest Subject Matter Experts

Aneesh Mehta, MD, Affiliate Faculty, Emory Vaccine Center and Associate Professor of Medicine in the Division of Infectious Diseases, Lead Investigator for the Special Pathogen Research Network, Emory University School of Medicine

Vikram Mukherjee MD, FRCP(Edin), Assistant Professor, NYU Grossman School of Medicine, Director of Medical ICU, and Director of the Special Pathogens Program, Bellevue Hospital

John J. Lowe, PhD, Assistant Vice Chancellor for Inter-professional Health Security Training and Education and Associate Professor of Environmental, Agricultural and Occupational Health in the College of Public Health, Director of Research, Nebraska Biocontainment Unit and Executive Director of Education, Global Center for Health Security, University of Nebraska Medical Center

Other Federal Staff

CAPT Christopher Perdue, MD, MPH, USPHS,
Designated Federal Official, SPPR

Richard Hunt, MD, FACEP, Office of Emergency
Management and Medical Operations
(EMMO), ASPR

Darrin Donato, Domestic Policy Division Branch
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Maxine Kellman, DVM, PhD, PMP, SPPR

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Zhoowan Jackson, SPPR

Tabinda Burney, SPPR

Mariam Haris, MPP, SPPR (CTR)

Megan Hoffmann, MPH, SPPR (CTR)

AC Camacho, DoD

Lisa Edwards, DoD

Meeting Overview

The National Biodefense Science Board (NBSB or the Board) met on September 28, 2021 in a teleconference that was available for public observation and participation via the platform's Q&A feature. The NBSB's Chairperson, Dr. Fernandes, and Ms. Nikki Bratcher-Bowman, Principal Deputy Assistant Secretary in ASPR, provided opening remarks. Next, Dr. Hunt introduced the National Special Pathogen System (NSPS), followed by a detailed presentation from Vikram Mukherjee, MD, New York University (NYU)/Bellevue Hospital, with additional comments and discussion with Aneesh Mehta, MD, from Emory University School of Medicine and John J. Lowe, PhD, University of Nebraska Medical Center (UNMC). In the last part of the meeting, the NBSB heard from members of the public who volunteered to provide remarks. Details from the remarks, presentations, and discussion are summarized below.

Welcoming Remarks

Ms. Bratcher-Bowman, who served as the Acting ASPR from January through June 2021, expressed her appreciation for the Board's continuing work during a very challenging period of time. She highlighted several operational activities, including expansion of the availability of monoclonal antibody therapeutics, deployment of responders from the National Disaster Medical System to serve in COVID-19 hotspots, and support to the HHS Administration for Children and Families at Emergency Intake Sites for unaccompanied migrant children along the U.S. southern border. Ms. Bratcher-Bowman emphasized the important role of the NBSB in the ongoing COVID-19 after-action review process. In addition to addressing scientific challenges and strategies that put evidence into action, the NBSB can contribute to improved communication and coordination with non-federal stakeholders, mental health during disasters, and recovery.

Presentations

"National Special Pathogen Systems (NSPS)", Richard Hunt, MD, FACEP, Senior Advisor for the National Healthcare Preparedness Program, ASPR EMMO.

ASPR announced the launch of the NSPS in mid-2021 with the long-term vision of creating a nationwide, systems-based, networked approach to preparing for and responding to the most dangerous infectious diseases. NSPS will operate similar to other hub-and-spoke systems, such as the national trauma system and the national systems for cardiac and stroke care. NSPS is an evolution of the original Regional Ebola Treatment Network and the National Emerging Special Pathogen Training and Education Center (NETEC).

The NSPS aims to strengthen response at local, state, and national levels. ASPR funded the NSPS using COVID-19 emergency supplemental appropriation, with an initial \$350 million to support its four components. NSPS initially includes:

- 10 regional Ebola and other special pathogen treatment centers (RESPTCs)
- 62 health care coalition grantees within the Hospital Preparedness Program (HPP)
- 55 special pathogen treatment center sub-recipients
- The original NETEC partners

As ASPR's healthcare readiness program portfolio grows, components will be added and existing components will evolve and potentially take on advanced roles.

“National Special Pathogen System of Care (NSPS)”, Vikram Mukherjee, MD, FRCP(Edin), NYU/Bellevue Hospital.

The National Emerging Pathogens Training and Education Center (NETEC) was tasked by ASPR to develop a strategy and implementation plan for the NSPS, which began with a gap analysis. Examples of findings from the gap analysis include inadequate surveillance infrastructure, limited healthcare readiness at the local level, unstandardized systems for data collection and reporting, and limited financial preparedness (Table 1 contains a complete list). The mission statement of NSPS is to increase the capabilities of the United States' public health and healthcare systems to safely and effectively manage individuals who are suspected or confirmed to being infected with special pathogens.

A consortium of three major healthcare institutions lead the NSPS: Emory University Medical Center, NYU/Bellevue Hospital, and UNMC. As an example of the current capabilities of the NETEC, the consortium and partners delivered 42 readiness and response consultations during the COVID-19 response, with participation from 50 states, the District of Columbia, and 4 U.S. territories. They were able to reach 10,000 participants during educational webinars and documented more than 250,000 views of related content on YouTube. NETEC partners also supported rapid implementation of a COVID-19 therapeutic clinical trial across all the 10 RESPTCs, with 30% of all trial participants recruited via the Special Pathogens Research Network.

Table 1. Results of NETEC system gap analysis related to preparedness for special pathogens.

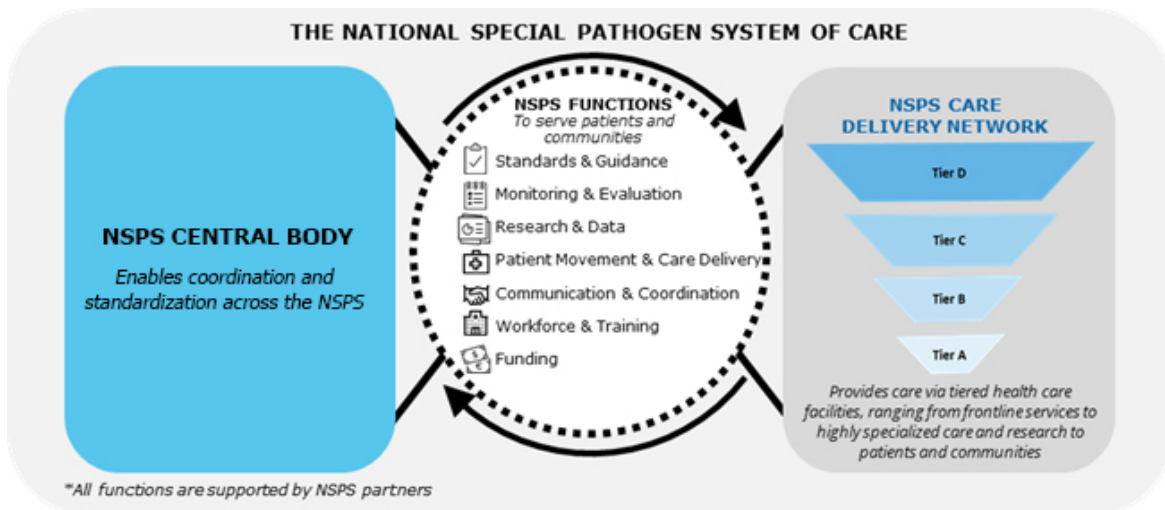
Topic	Gap
Care Delivery	<ul style="list-style-type: none"> • Limited access to specialized special pathogen care • Unaffordable costs of special pathogen care • Insufficient and unequal surge capacity at facilities across the United States • Uncoordinated, inconsistent, and unscalable clinical guidance for various special pathogen scenarios • Disjointed development and distribution of therapeutics • Inequitable care to minority groups as 1) leading facilities are uniformly located in wealthy and non-diverse counties and 2) fewer upward transfers from known diverse counties despite higher death count in such counties
Communication and Coordination	<ul style="list-style-type: none"> • Inconsistent partnership between health care and public health • Unclear roles of various stakeholders in the special pathogen ecosystem across readiness, response, and recovery • No trusted coordinating entity to ensure a coordinated special pathogen response • Limited coordination between health care leaders and policymakers in policy development and implementation (e.g., licensure, emergency funding)
Workforce	<ul style="list-style-type: none"> • Limited quantity of special pathogen-trained healthcare workers • Additional burden placed on an overworked and stretched response workforce • Limited special pathogen education, training, and regular drills
Research and Knowledge Generation	<ul style="list-style-type: none"> • Operational networks and research networks are not appropriately connected • Early-clinical findings are disseminated informally and non-systematically • Minimal timely, easily accessible, and transparent clinical and health systems research

Topic	Gap
Data and Technology	<ul style="list-style-type: none"> • Unstandardized clinical research and health systems data collection and reporting • Inadequate and heterogeneous surveillance infrastructure • Non-timely and inconsistent sharing of data between institutions and with public health agencies • Limited views of health care readiness at the local level
Monitoring and Evaluation	<ul style="list-style-type: none"> • Inconsistent standards and expectations in quality of care between the federal government, SLTT public health departments, and health care delivery systems • Varied special pathogen readiness assessments
Financial Sustainability	<ul style="list-style-type: none"> • Limited financial preparedness of care delivery facilities • Unincentivized special pathogen health care beyond grants, which are not a reliable source of funds to maintain readiness • Minimal return on investment (ROI) for the capital investment required to build and maintain adequate facilities to cope with special pathogens
Supply Chain	<ul style="list-style-type: none"> • Unclear and inconsistent recommendations for PPE, ventilators, vaccines, and other equipment recommendations • Low quantity and inconsistent quality control in PPE, ventilators, vaccines, and other equipment

Specific gaps highlighted during the NBSB meeting included lack of health equity for racial and ethnic minority groups, inconsistent partnerships between health care and public health systems, workforce stress and diminished morale, and lack of formal mechanisms to disseminate evidence, standards, and research outcomes. In addition, Dr. Mukherjee emphasized lack of connected data and information technologies, financial sustainability, and supply chain reliability.

The purpose of the NSPS is to provide a coordinated and standardized healthcare network that will provide high-quality, safe, patient-centered care for those suspected of or confirmed with infection by a special pathogen (Figure 1). The aspiration of the system is to save lives through a sustained, standardized system of care that enables healthcare personnel and administrators to provide agile and high-quality care across the care continuum.

Figure 1. Depiction of the National Special Pathogens System of Care



NSPS aspires to be responsive, accountable, high-quality, equitable, scalable, and sustainable. It is being designed to support a small cohort of Ebola patients, who require many high-intensity resources, or the needs of many thousands of patients during a pandemic.

Additional Discussion with the NSPS Subject Matters Experts (SMEs)

Dr. Fernandes asked how NETEC/NSPS would address the needs of rural facilities and populations. The NSPS SMEs replied that they have already begun reaching out to a variety of locations, including critical access hospitals in urban and rural settings, as well as facilities within the Indian Health Service. Those site visits confirmed the need for a well-defined, easily accessible, tiered system that would include technical support and patient transport to specialized facilities.

Dr. Andreadis asked how NSPS would meet the unique needs of children, pregnant mothers, and other at-risk individuals. The SMEs replied that NSPS has dedicated subgroups focusing on children and pregnant women, and the coordinators intend to continue to expand to conduct training and information sessions that are specific to vulnerable groups. Addressing the needs of at-risk individuals is an integral component of the NETEC/NSPS mission, including adapting crisis standards of care and engaging with national experts and specialty organizations. The intent is to create formal linkages to hospitals and facilities that specialize in services for at-risk groups.

Dr. Witt asked how the NSPS would extend to support the large number of private hospitals and underfunded municipal hospitals, ensuring that health care providers are engaged in preparedness activities. A variety of incentives need to be considered, according to the SMEs, which will help to bring non-academic medical centers into the network. They are examining the feasibility of offering monetary incentives for disaster readiness, adaptation of federal payment models, establishment of special operating funds, and other policy mechanisms with financial benefit for participation. In addition, SMEs for NSPS indicated that they will continue to capitalize on current momentum to strengthen interdisciplinary collaboration, which includes stronger and sustained engagement with professional medical societies beyond the traditional infectious disease groups.

A public attendee asked about using the Hospital Preparedness Program (HPP) grants to establish requirements that support the NSPS model. Dr. Hunt commented that HPP provides resources for and guidance to grantees that allow them to evolve their systems to improve overall disaster preparedness and response, which would include connections with NSPS. He added that engagement with health professional societies is critical, as is engagement with professional training programs (medical and nursing schools, etc.) and organizations that set standards for graduate education.

Mr. Gruber asked about the involvement of (or potential to involve) the large national laboratories that specialize in biodefense research and diagnostics, including federal facilities. The NSPS leads explained that they already have an arrangement with laboratory experts at the University of Texas Medical Branch (UTMB) to serve as special advisors for the strategy. Additionally, the laboratory and diagnostic advancement working groups are looking at bringing technologies from outside the U.S. to augment the Laboratory Response Network. NETEC already includes a biorepository network that can be utilized for NSPS, allowing dangerous pathogens to be stored temporarily or permanently and shipped safely if needed, and the intent is to continue to expand laboratory participation.

Mr. Gruber also asked about how the NSPS would support the complex coordination requirements for transportation of patients who have dangerous infections, such as Ebola, and the challenges related to

hazardous waste disposal. Recognizing the significant gaps and challenging remaining, which NETEC has begun to address, NSPS will continue to focus on every aspect of patient care and safe facility operation. Dr. Mehta mentioned that the NETEC system was recently exercised during the emergency treatment of a patient at UTMB who presented with a smallpox-like rash. The illness was diagnosed as monkey pox, which is not a special pathogen, yet the incident demonstrated the value of the network approach as well as validity of specific measures.

Dr. Heppner asked about the capacity to address gaps in the current capacity to scale-up for an infectious disease affecting (potentially) thousands of people simultaneously. SMEs reiterated that NSPS is charged with developing a scalable and cohesive system of care overall, adding that it could be aligned and integrated with the hospitals designated as part of the National Disaster Medical System (NDMS).

Dr. Schonfeld followed up with questions about the specific mechanisms that would be used to support the needs of children, including coordination with children's hospitals, especially if a future event has greater direct effects on the pediatric population than COVID-19. Addressing the needs of children and other vulnerable populations is a central focus of NSPS, according to the SMEs. The 10 RSPCT sites are required to maintain or have access to pediatric capabilities, such as Emory University Hospital, which has leveraged NETEC resources to utilize the pediatric biocontainment unit at Atlanta Children's Hospital if needed. In preparation for potential pediatric patients with COVID, Dr. Mehta mentioned that they have worked with facilities to repurpose adult intensive care units to handle more children, which is an effort NSPS will continue to evolve. There are still challenges that must be resolved, such as providing for parental visitation, which may require different practices and technologies from facility to facility and depending on the pathogen involved. The vision is for the NSPS network to have specialized pediatric facilities at every tier.

Dr. Fernandes asked about the role of the NETEC/NSPS to support the integration of health information systems. Information systems continue to be a major gap at every level of the system, according to the SMEs. NSPS is considering pilot tests to understand how a national system can be structured and sustained to support agile and equitable responses to future events.

Dr. Klugman commented on the importance of maintaining focus on individual patients and families, protecting autonomy and shared decision-making. SMEs explained that NSPS is being developed to provide a patient-centered approach, yet they recognize that there are opportunities to improve patients' experiences and involvement in the treatment process. Dr. Mehta mentioned, as an example, that they have invited patients and families to provide feedback on their experiences following treatment for Ebola, which resulted in improvements to some protocols, but that there remain areas for improvement that partners in NSPS will explore.

Public Remarks to the NBSB

The following are synopses of remarks provided by pre-registered speakers.

Dr. Amar Kamath, from PerkinElmer, Inc., described the companies' work in laboratory-based food, agricultural, and human biological testing. Dr. Kamath suggested a 3-prong approach to better global detection and response: (1) biological monitoring of zoonotic disease global hotspots for pathogen spillover, which would include testing of food, water, and waste, with rapid screening for human illnesses and local containment; (2) a global early-warning system that includes assessment of the effectiveness of early interventions; and (3) shared containment, isolation, treatment, and quarantine

protocols that include rapid, mobile response systems. Dr. Kamath stated that international mechanisms would be needed to collaborate on developing such a system and monitoring implementation, which could, for example, be built off existing systems for global pandemic influenza.

Dr. Alex Isakov, Professor of Emergency Medicine and Director of Pre-hospital and Disaster Medicine at Emory University, remarked on the challenges facing pre-hospital emergency medical services (EMS) in the United States, which includes 911 centers, poison control centers, on-scene first responders, and the air and ground patient transportation systems. He stated that EMS is a highly heterogeneous set of capabilities and capacities, which combines elements of public health and public safety. Dr. Isakov suggested several topics for EMS-related research and development to advance the field:

- Studies of environmental controls (health hazard evaluations) in ambulances, with the development of standards for a wide variety of vehicles.
- Research and validation of policies and work practices for occupational health protection for EMS practitioners.
- Material science to improve effectiveness and ensure affordability of personal protective ensembles (PPE).
- Human factor studies in occupational settings to understand the limits for safe use of PPE ensembles, PPE lifecycles, fitness standards, and the effects on performance of clinical skills.

Dr. Isakov also mentioned the need to continue to implement reimbursement strategies for the use of telehealth and advancements in EMS that were developed during the COVID-19 pandemic. He added several other challenges that need to be addressed, including improving operational efficiency or “wall time” (i.e., reducing ambulance patient offload time¹), supply chain integrity, vaccine hesitancy, and mental health resilience for EMS providers.

Dr. Nathan Myers, Professor of Political Science and Public Administration at Indiana State University, is an academic advisor to the Continuity of Supply Initiative (CoSI). Dr. Myers spoke to the NBSB about mechanisms to improve national procurement of PPE and other material to protect frontline health workers. He described a model framework for “resilient procurement” that combines market-based incentives with coordination across federal, state, and local governments, healthcare, and public health systems. The cooperative procurement approach that he described builds different levels of pricing into the PPE contract, which accounts for changing demands and difficulties with the supply chain. The framework requires that manufacturers provide information about their suppliers under various circumstances (i.e., normal operation vs. stressed operation), allowing for higher pricing to achieve adequate volume when the circumstances are objectively more difficult. While prices and volumes are negotiated as a group, all individual purchasers must sign the contract, with the option for smaller purchasers to buy large volumes in advance and draw down on that quantity over time. Visibility among all parties is achieved through a shared information system.

Dr. Fernandes thanked the board members and public attendees, and the meeting adjourned at 1:05 p.m.

¹ Explanatory note added by the DFO for the meeting summary.