



National Biodefense Science Board

Public Meeting Summary

November 30, 2023

1:00-3:30 PM

Roll Call

Voting Members

Prabhavathi Fernandes, PhD, FIDSA, NBSB Chair

John G. Benitez, MD, MPH

Carl R. Baum, MD, FAAP, FACMT

H. Dele Davies, MD, MSc, MHCM

David W. Gruber, MA

Craig M. Klugman, PhD

Elizabeth Leffel, PhD, MPH

Joelle N. Simpson, MD, MPH

Tammy Spain, PhD, PMP

Mike Usman, MD, MMM, MPH

David J. Witt, MD, FIDSA, CIC

Marc Shepanek, PhD, National Aeronautics and
Space Administration

Rosemary Hart, JD, Department of Justice

Federal Staff

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

LCDR Clifton Smith, MPH, USPHS, Committee
Management Officer, ASPR

Darrin Donato, Director, ASPR Policy Division

Robert Johnson, PhD, ASPR Biomedical
Advanced Research and Development
Authority (BARDA)

Melanie Wright, PhD, BARDA

Krystal Hayes, MPH, ASPR Office of External
Affairs

Mariam Haris, MPP, ASPR Policy Division

Megan Hoffmann, MPH, ASPR Policy Division

Jacob Pluznik, MPH, ASPR Policy Division

Laura Gardiner, ASPR Policy Division

Ex Officio Members

Joanne Andreadis, PhD, Centers for Disease
Control and Prevention

Herbert O. Wolfe, PhD, Department of
Homeland Security

Aimee Kopolow, PhD, Administration for
Strategic Preparedness and Response (ASPR)

Overview

The National Biodefense Science Board (NBSB) met on November 30, 2023, for a public meeting to discuss two sets of recommendations developed by each of the standing working groups (subcommittees). In general, the NBSB provides expert advice and guidance to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Assistant Secretary of Preparedness and Response (ASPR) on preventing, preparing for, and responding to adverse health effects of emergencies. After the required statements by the designated federal official (DFO) and roll call, the Board reviewed the recommendations in detail, listen to and discussed public comments, and voted to approve both sets of recommendations without changes. The approved recommendations are available on the ASPR website [NBSB | Public Meeting: November 30, 2023](#).

Public Speakers

Dr. Andrew Wang spoke on behalf of *The People's CDC* regarding affordable access to COVID testing, support for updated vaccines, and enhancing protection in healthcare settings. He requested that the Board's recommendations include oral therapeutics that provide pre-exposure prophylaxis as well as antiviral treatment. He stressed that countermeasure should be easily affordable and accessible,

especially for those who have insurance with limited coverage or those who are uninsured, and recommended that royalties from countermeasures be used for that purpose. Lastly, Dr. Wang recommended additional efforts to detect SARS-CoV-2 in indoor settings and significant improvements to ventilation and air purification.

Sondra DePalma, Senior Director for regulatory and professional practice with the *American Academy of Physician Assistants* (AAPA), stated that physician assistants/physician associates (PAs), are an essential component of disaster preparedness and response. AAPA observed administrative and functional barriers to the optimal utilization of PAs during the pandemic due to communication from government agencies, specificity of regulatory waivers, and declarations under the PREP Act that used physician-centric or nurse-centric language. The lack of an express mention of PAs left administrators, regulators, and others to exclude PAs from their critical care response operations. The AAPA encouraged the NBSB to explicitly include PAs as essential healthcare practitioners in disaster preparedness planning and response.

Dr. Harold Hibbert, representing the Democrats Abroad Thailand COVID-19 Task Force, presented the challenges obtaining vaccine by Americans living abroad individuals. U.S.-approved vaccines were not available outside of the United States, forcing people to take local vaccines (if permitted to so by respective national authorities) or return to the United States to get vaccinated. He expressed concern that the return of U.S. citizens or permanent residents to the United States to get vaccinated increased the importation of COVID-19 variants from around the world. He recommended that there need to be policy and logistical solutions that allow Americans abroad to receive U.S.-approved vaccination during a declared public health emergency.

Enlli Lewis, regulatory policy and research coordinator for *1DaySooner*, and **Dr. Robert Kadlec** presented lessons learned during COVID-19 related to the rapid development and authorization of vaccines for emergency use. Dr. Kadlec noted that in doing so, the FDA was forced to pause review and approval of other medicines. He and Ms. Lewis advocated for legislation to authorize and fund a permanent, streamlined, emerging pathogens preparedness and response capacity at FDA and recommended that 1% of the funding for the current Project NextGen be used to support that effort.

Comments Submitted by the Public

Dr. Fernandes summarized written comments received by the NBSB related to the draft recommendations that were published on the ASPR website for public review ahead of the meeting.

Lynn Albizo, Vice President of Public Policy for the Immune Deficiency Foundation, stated that vaccines for COVID-19 are inherently less effective in those who have pre-existing immune deficiencies. She advocated for greater emphasis on the development of “a continuous stream of therapeutics,” especially oral antiviral drugs, that have minimal drug-drug interactions, which would be more beneficial than for vaccines among people who are unable to develop immunity.

Cyndy Anzek, MA, the South Carolina Director for Walton Options for Independent Living, asked the NBSB to consider how to include “people with disabilities into the process of reaching recommendations aimed at readiness and training for the U.S. health workforce and considerations for the next generation of COVID-19 vaccines and therapeutics.”

Jerome Adams, MD, MPH, Executive Director of Health Equity at Purdue University, advocated for greater access to oral antiviral drugs against the COVID-19, which should be produced in large quantities through public-private partnerships. He wrote that those drugs should have minimal drug-drug

interactions, target components of the virus that minimizes the potential for resistance, and avoid the development of cross-resistance among other drugs.

Kevin Kavanagh, MD, MS, Chairman of the Board of Directors for Health Watch USA, advocated for increased use of non-pharmaceutical strategies to prevent COVID-19 transmission “until highly effective pharmaceuticals and vaccines can be developed and deployed.” He advocated for the required use of N95 masks by providers caring for those with infectious respiratory illnesses of all types, which would have the added effect of sustaining the supply chain, and greater use of negative pressure isolation.

Mitchell Berger, MPH, writing independently, suggested that the NBSB recommendations include “a behavioral health component in emergency preparedness training for a wide range of professionals and the general”, which would “encompass substance use disorder topics as well as mental health.” He notes that the draft recommendations “do not discuss generalized training in behavioral health disaster-related topics for first responders, health professionals, volunteers... public health professionals, and others.”

Melissa M. Trumbull, Director for Programs and Initiatives for the National Association of Emergency Medical Technicians (NAEMT), highlighted the large volume and variety of emergency preparedness training that NAEMT has developed and the emergency medical service (EMS) resources available for public health responses. She pointed to prior comments that NAEMT has made to federal agencies and Congress stating the need to improve resources for EMS and ensure those systems and professionals are included in preparedness strategies and response plans under Emergency Support Function 8.

Review and Discussion of Recommendations: *Enhancing Benefits from Federal Investments in the Development and Production of the Next Generation of COVID-19 Vaccines and Therapeutics*

Dr. Fernandes and Dr. Leffel provided a summary of the recommendations, which were published on the NBSB public meeting webpage prior to the meeting. In addition to the recommendations, the board members made the following observations.

Dr. Fernandes: Many pharmaceutical companies receive grants and funding by BARDA, but the public typically only hear of the few successes in creation of vaccines and therapeutics; commercial failures, which are to be expected with developmental work, are not always evident. Because of its overall success and public value, the model that BARDA used during the COVID-19 pandemic is being copied in other countries. The recommendations being discussed are aimed at improving approaches to minimize the cost to the U.S. government.

Dr. Klugman: Balancing the interests of private companies and the interest of the American taxpayer is a challenge. The federal government asks private companies to take on risk and set aside other projects and profitability while maximizing fairness and public benefits. Companies can give something back to the taxpayer but only if they remain in good financial standing.

Mr. Gruber: The recommendations do not have to be an all or nothing approach. Taking a few steps is better than nothing for future pandemic preparedness.

Dr. Witt: Investment considerations during the first three months of the pandemic have to be weighed against the perceived risk of mortality at the time, seeking to achieve benefits to the country and the world.

Review and Discussion of Recommendations: Training and Readiness for the U.S. Health Workforce

Dr. Davies and Dr. Witt provided a summary of the recommendations, which were published on the NBSB public meeting webpage prior to the meeting. In addition to the recommendations, the board members made the following observations.

Dr. Davies noted that there have been at least 16 other recommendations that have come from the NBSB and each one of those have addressed different aspects of training. The new recommendations aimed to be higher level, bringing those previous training recommendations all together. The goal was to try to pull together all the different pieces of training that are currently going and provide a roadmap for integration of disaster preparedness.

The Board believes that every single healthcare practitioner, whether an emergency responder or person working in a lab, need to be competent to some degree in emergency response. During a disaster, everyone must be brought together in a cohesive and concerted effort and there needs to be alignment between the clinical and non-clinical professions, including public health practitioners, emergency managers, and bioethicists. The Board feels strongly that the implementation of these recommendations needs to be regularly monitored and that ongoing external feedback will be critical

Dr. Witt added that the overall strategy needs to address the distinction between emergency response roles in the healthcare workforce and public health workforce. Despite the fact that much of healthcare and educational systems are private, with variable regulation and variable credentialing in each state, the Board believes that everyone in the healthcare workforce needs appropriate training for their roles in an emergency. There are very few incentives for a mid-level or senior health professionals to take advanced training or develop advanced expertise and most disaster training programs are for emergency medicine physicians, with very few being for pharmacists, nursing, or other medical specialists.

Dr. Baum: The pipeline for the workforce is very long and tedious which is addressed in the document. It is very important to show trainees what to expect at the end of the pipeline.

Dr. Simpson: The research component broadens how training might be informed by disaster science, as is the case with basic life support and advanced cardiac life support courses, which have changed over time. There need to be protocols for disaster research and disaster science across the translational spectrum, including coverage of mental health concerns.

Dr. Klugman: The importance of interprofessional efforts need to be stressed here as they are of extreme importance in responding to a disaster situation. We should not be training doctors, and nurses, and PAs separately in this. An interprofessional effort develops the lines of communication and trust between disciplines that is essential to be able to function well in a disaster or crisis situation.

Adjournment:

Mr. Donato presented a plaque (virtually) to Dr. Fernandes in recognition of six years as a board member and chairperson.

CAPT Perdue adjourned the meeting at 3:30 p.m.