



National Biodefense Science Board Public Meeting Summary

May 26, 2021

Attendees¹

NBSB Voting Members

Prabhavathi Fernandes, PhD, Chairperson
Carl R. Baum, MD, FAAP, FACMT
H. Dele Davies, MD, MSc, MHCM
David W. Gruber, MA
Craig M. Klugman, PhD
Elizabeth Leffel, PhD, MPH
David Schonfeld, MD, FAAP
Joelle N. Simpson, MD, MPH
Alan M. Tennenberg, MD, MPH
David J. Witt, MD, FIDSA, CIC (retired)
Mahmood “Mike” Usman, MD, MMM (non-voting working group member)

Ex Officio Members

Joanne Andreadis, PhD (Centers for Disease Control and Prevention) (CDC)
Isaf Al-Nabulsi, PhD (Department of Energy)
Mamadou Diallo, PhD, MS (National Science Foundation)
Marc Shepanek, PhD (National Aeronautics and Space Administration)
Michael A. Smith, MPhil, PhD (Department of Defense)
M. Camille Hopkins, DVM, MS, PhD (Department of the Interior/U.S. Geological Survey) (USGS)
Eric Carlson (Department of State)
Brooke Courtney, JD, MPH (Food and Drug Administration) (FDA)

Senior Officials / Invited Guests

D. Christian Hassel, PhD, Acting Principal Deputy Assist Secretary, Office of the Assistant Secretary for Preparedness and Response (ASPR)
RADM Theresa Lawrence, PhD, Policy Division Director (ASPR)
Daniel Jernigan, MD, MPH, Acting Deputy Director for Public Health Science and Surveillance (CDC)

ASPR National Advisory Committee Team

Darrin Donato, Domestic Policy Branch Chief
CAPT Christopher L. Perdue, MD, MPH, USPHS, Designated Federal Official (DFO)
LCDR Clifton Smith, MPH, USPHS, NBSB Executive Secretary
Maxine Kellman, DVM, PhD, PMP, NBSB Alternate DFO
Zhoowan Jackson, DFO for the National Advisory Committee on Children and Disasters
Mariam Haris, MPP, Analyst
Megan Hoffman, MPH, Analyst

¹ For a full roster of the NBSB, including full titles, positions, and office locations, see the [NBSB webpage](#).



Meeting Overview²

The National Biodefense Science Board (NBSB or the Board) met on May 26, 2021. CAPT Perdue opened the meeting with a brief overview of the purpose of the NBSB, the requirements for public participation established by the Federal Advisory Committee Act, an overview of the rules related to disclosure of potential conflicts of interest, and instructions for public participation ([see posted slides](#)). Dr. Fernandes provided welcome remarks, followed by Dr. Hassell who spoke about new and ongoing program activities, as well as current challenges, in ASPR (see below). Dr. Jernigan provided a comprehensive update on CDC's Data Modernization Initiative (DMI) (see below). Drs. Hassel and Jernigan both addressed questions from the public. The NBSB working group co-chairs presented the recommendations that they had developed, and the Board discussed a comment that was sent by email by a public participant (see below). and voted on the recommendations provided by the working groups and addressed one comment from the public.

Synopses of Discussion and Presentation

ASPR Update by Dr. D. Christian Hassell, Acting Principal Deputy Assistant Secretary, ASPR.

Accomplishments over the past year include the developing, manufacturing, and administering of millions of doses of three COVID-19 vaccines at an unprecedented timescale through partnerships with private industry, CDC, BARDA, and others. ASPR National Disaster Medical Systems (NDMS) has sent medical teams across the country in a surge to support hospitals and other clinical settings, while BARDA led the development of novel COVID-19 therapeutics, including monoclonal antibodies, and diagnostic systems. Dr. Hassell highlighted the formation of the ASPR Supply Chain Control Tower, which will continue to monitor key components of the public health preparedness industrial base, helping to identify where critical materials are coming from, going to, and determine the federal government's role in facilitating supply chain logistics. ASPR has launched the Industrial Base Expansion program to strengthen and stabilize the sourcing of active pharmaceutical ingredients (API), needles, syringes, and other ancillary supplies that are needed for pandemic response.

Dr. Hassell was asked by a member of the public for more details regarding the initiative to stabilize the availability of API during a public health emergency. This was a question that required assistance from another senior staff member, Ian Watson, Deputy Assistant Secretary and Acting Director of the Office of Incident Command and Control in ASPR. In follow-up, Mr. Watson indicated that decisions regarding specific API and priority mechanisms to strengthen and stabilize API resources during a public health emergency would be determined following release of the White House supply chain report.³

² For the purposes of providing the public and board members with a comprehensive reference resource, this summary document is annotated with hyperlinks to relevant supplemental information, though during the meeting, specific uniform resource locators may not have been provided.

³ The 100-day review report required by Executive Order 14017, titled "[Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth](#)," was released by the White House on June 8, 2021

CDC's Data Modernization Initiative

Dr. Daniel Jernigan, Acting Deputy Director for Public Health Science and Surveillance, CDC.

CDC's [Data Modernization Initiative \(DMI\)](#) is the heart of a national effort to create a totally integrated, high-speed, networked health system that can protect us from any health threat. Importantly, DMI is the most unified, most comprehensive, and broadest-reaching strategy to date, simultaneously modernizing public health surveillance data networks, technologies, and workforce capabilities. The initiative supports public health surveillance, public health-related research, and operational (emergency response) decision-making. CDC is implementing a cross-cutting strategy for modernization that aims to move the United States from tracking threats to preventing them, accelerating lifesaving disease prevention and responses to health threats, and to fortify the public health ecosystem from the local to national level, recognizing that gaps anywhere in the system will leave our nation vulnerable and at risk.

Modernizing the Nation's public health data systems begins with funding to local and state health departments, where the vast majority of event investigation and health data collection occurs, while also building advanced tools and capabilities at CDC that improve utilization data at local, state, and federal levels. This work includes building a public health workforce across the country that is skilled in data science and informatics, implementing best-in-class innovation with partners. The [CARES Act](#) (Public Law No: 116-136) and the [American Rescue Plan](#) have provided tranches of funding for these initiatives.

The COVID-19 pandemic has shown the need for public health to modernize. To do this work strategically, CDC has [created a roadmap for data modernization](#) showing activities that need to be accomplished sequentially to ensure short-term, intermediate, and long-term outcomes that build on one another. The roadmap will guide decisions for allocating resources and provides a structure to track progress. DMI seeks to strengthen public health in five core areas:

1. **Syndromic surveillance** utilizes data feeds from emergency department records for rapid recognition of emerging health threats. This has been expanded to 49 states and 70% of US Emergency Departments (EDs) and is routinely used today to support the current COVID-19 response. More ED facilities are being added. Work is being done to obtain broader data access outside of national emergencies, and CDC programs are migrating data in a [CDC-wide cloud platform](#) to create pandemic dashboards.
2. **Electronic case reporting (eCR)** automates the reporting of specified, predefined diseases and conditions by providing real-time exchange of case report information between electronic health records and public health agencies. Rapid implementation and scaling of eCR, coupled with electronic laboratory reporting over the last year, has been an important part of COVID-19 surveillance, which provide data into the [HHS Protect](#) system for national situational awareness.
3. Traditional **notifiable disease reporting** will be enhanced through [deployment of systems for electronic messaging](#). Case notifications have become more timely and complete. Mapping of data from state systems to CDC reporting templates have improved. Data messaging standards are being used to report data more efficiently to CDC and outdated data transport applications are being replaced.

4. **Electronic laboratory reporting** supports faster, more complete automated, case-based reporting of notifiable conditions to local and state health departments, which can then be passed to CDC and shared among authorized network users. CDC has built [scalable infrastructure](#) to centralize the reporting of lab data to states to be able to handle increase in volume of tests that can be reported in near real time, taking advantage of cloud infrastructure.
5. **Vital records** capture data from about 6 million births and deaths annually that can signal urgent public health trends and be used for emergency response. Data currently come from a variety of disconnected sources, with varying levels of details. Support for vital records has gained increased focus after the funding from the CARES Act. Mortality data flows in varied ways and all are captured in different ways. The initiative is to develop information standards and new [data capture/reporting systems](#) that are uniform and implementation nationally.

CDC continues to build foundational infrastructure to implement the DMI roadmap. Currently CDC is collecting data from many individual points, but the plan is to move towards a hub and spoke model using cloud-based systems. This ultimately means a modernized approach where all data flows through the same place with integration along the way, enabling holistic, secure views among partners. This would also provide consistent data management and better integration with health departments information systems.

Question: Does the DMI include international public health data? CDC's DMI focuses on improving U.S. public health surveillance data using domestic health data, including improving information to specifically address the needs of underserved and minority communities. There are many unique requirements and rules at the national level and within each jurisdiction, as well as technical issues, that must be addressed. The American Rescue Plan offers some funding to better capture and utilize international information for global health security.

Questions: Are data related to food and water sources included in DMI? DMI predominately focuses on human healthcare data, though there are some environmental indicators, such as climate conditions, population mobility, and, for instance, location of cooling towers that could be important to investigate when there are cases of Legionnaires disease, included in the surveillance system.

Presentation of the Recommendations from the NBSB Working Groups

The Board chairperson and working group co-chairs presented separate sections of the recommendation report, leaving time for discussion among the board members. Members of the public were encouraged to provide comments or questions using the Zoom Q&A feature or email NBSB@hhs.gov.

Introduction and Key Finding – Dr. Prabhavathi Fernandes, NBSB Chairperson

One Health Biosurveillance, Risk Assessment, and Situational Awareness – Dr. Elizabeth Leffel, Medical Countermeasures and Operational Research (MCOR) Working Group

Enhancement of Medical Countermeasures (MCM) Development, Domestic Manufacturing, and National Supply Chain – Dr. Alan Tennenberg, MCOR Working Group

Health Workforce Readiness and Resilience – Dr. H. Dele Davies, Readiness and Resilience (R&R) Working Group

Health Facility and Other Infrastructure Readiness and Resilience and Engagement and Communication with the Public during a Health Crisis – Dr. David Witt, R&R Working Group

Discussion of Public Comments

In addition to the questions directed to Drs. Hassell and Jernigan (above), the NBSB received a single comment via email.

- The Keep Antibiotics Working (KAW) Coalition sent a position paper addressed to the NBSB ([see Appendix 1](#)) and a copy of a letter the coalition wrote to HHS Secretary Becerra. Briefly, they stated that they were concerned that the emergence of antibiotic resistant bacteria is linked to overuse and inappropriate use of antibiotics (e.g., use of antibiotics for appropriate indications, types of antibiotics used, and duration of treatment) in food animals. To further prevent development of antibiotic resistance bacteria, the coalition suggested that the NBSB consider recommendations that increase the surveillance for antibiotic resistant bacteria in farmed animals and wildlife, as well as improved monitoring of antibiotic use on farms.
 - Dr. Fernandes noted that use of antibiotics is already restricting by FDA. Antibiotics may not be used in animal farming for growth promotion but may still be used to treat sicknesses among farm animals. There are questions about the appropriate duration for treatment of bacterial infections in animals, which today is largely based on traditional veterinary practices rather than treatment studies. Dr. Fernandes further noted that there are studies ongoing to determine appropriate duration of treatment and asserted that antimicrobial stewardship among human and animals are equally important. She stated that research and development for new classes of antibiotics remains critical as resistance among bacterial is ultimately inevitable.
 - Dr. Klugman commented that there are far too few inspectors to ensure proper use of antibiotics in farm animals and limitations in the ability of regulators to monitor farm animal prescriptions.
 - Dr. Fernandes concurred, noting that the total amount of antibiotics sold in the United States is very large, but details on use or misuse are missing. She also noted that while certain antibiotics may be disallowed for use in animals, there are still molecular analogs (of different names) still available that can contribute to medically important resistance to human drugs.
 - Dr. Fernandes also noted that resistance to antifungal compounds is a rising problem, particularly where those are heavily used for agriculture.
 - Dr. Witt commented that there remain entrenched beliefs about the value and utility of antibiotics in animal farming, which is an issue that needs to be addressed simultaneously.
 - Dr. Fernandes observed that many producers are reacting positively to consumer preferences for meat that is antibiotic free by avoiding the use of antibiotics in animal farming and clearly labeling their packages.
 - Dr. Diallo noted that the National Science Foundation is funding projects to examine the presence of antibiotic resistant bacteria/genes in public water distribution and wastewater systems.
 - Mr. Carlson from State Department expressed appreciation for the discussion, noting that antimicrobial resistance is an important topic of discussion within the interagency.

- Dr. Hopkins from USGS expressed appreciation for the work of the Board, noting that USGS has numerous biosurveillance and risk assessment activities that complement the NBSB recommendations. Additionally, she noted the need for legislation and policy specific to the veterinary community to conduct microbial treatment studies among animals.
- Without objection, Dr. Fernandes suggested this as a topic for more detailed discussion by the NBSB.

Vote on Recommendations

In a roll-call vote, all voting members present approved the recommendations as presented.

Adjourn

CAPT Perdue adjourned the meeting at 13:20 Eastern time.



Appendix 1: Letter (2 pages) from the Keep Antibiotics Working Coalition to the National Biodefense Science Board, May 26, 2021.

May 25, 2021

CAPT Christopher L. Perdue
Executive Director
National Advisory Committees
NBSB Designated Federal Officer
Washington, DC, Office

Re: National Biodefense Science Board Public Teleconference

"All countries need to have the laboratory, trained workforce, surveillance, and emergency operations capabilities to prevent, detect, and respond to disease threats. Until then, the goal of [pandemic preparedness and] global health security remains an unfinished journey." [Michael Osterholm, December 2017](#)

AMR as a slow moving pandemic

The purpose of the National Biodefense Science Board (NBSB) is to “provide expert advice and guidance on scientific, technical, and other matters of special interest to the Department regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.” Deadly viral and bacterial organisms are constantly emerging throughout the world, posing an exorbitant risk to human and animal health. As illustrated by COVID-19’s arrival, we are in many ways unprepared to handle a pandemic and its associated health and economic ramifications. Like COVID-19, Ebola, H1N1 swine influenza, and SARS, many disease threats often spread in animal populations before causing illness in people. Because of this, a One Health approach to biodefense is necessary.

One of these disease threats that requires a One Health approach is antibiotic resistance (ABR) - a slower moving, but just as deadly pandemic that is rendering life saving drugs ineffective. Antibiotic resistance can complicate the response to other public health threats by leaving patients vulnerable to untreatable secondary bacterial infections. As illustrated by COVID-19, these health threats can worsen antibiotic resistance by increasing the overall use of antibiotics or weakening stewardship efforts in healthcare facilities.

We urge NBSB to make sure that federal agencies address the public health emergency that is antibiotic resistance when addressing biodefense. Conservation, surveillance, and infection control need to be the focus of efforts to control this threat. Recent history has shown that new drug development is both costly and uncertain, and therefore should not be the central component of an ABR biodefense strategy.

More must be done to ensure antibiotics are not overused or used inappropriately on farms, in hospitals, or in doctor's offices. In the United States, systems must be developed to monitor for resistant pathogens and resistance determinants on farms, in the environment, and in healthcare settings. Finally we need to do a much better job of reducing the risk of illness both in humans and animals.

The NBSB should recommend the following:

- 1. Recommend HHS build systems to quickly identify new and emerging infections:** HHS must sufficiently invest in staff, infrastructure and resources to rapidly identify and track new human infections, especially the 75% of which originate or "emerge" from animals, either wildlife or farmed animals. HHS should seek strengthened authority to access farms for disease monitoring and investigation. These crucial data on infections must then be analyzed and reported in a transparent manner that utilizes a One Health approach. Since 2004, the GAO has repeatedly urged the USDA and FDA to work together in building a system to collect mandatory antibiotic use and resistance data at the farm-level, and integrate them with equivalent human data, as Europe has been doing since 2011. This should be done in tandem with the creation of a system to monitor for viral diseases with pandemic potential such as influenza and corona viruses. This must be prioritized.
- 2. HHS should set targets for reducing antibiotic overuse in humans and animals. HHS should also restrict antibiotic use in food animals to the treatment of disease and the control of diagnosed outbreaks, and limit the duration of antibiotic use in animals to no more than 21 days.**

Thank you for your consideration.

Please see our attached letter to HHS Secretary Becerra on additional actions HHS should consider when specifically addressing antibiotic resistance and the overuse of antibiotics in the food production sector.

Sincerely,

Keep Antibiotics Working