National Biodefense Science Board
Public Meeting Summary

1:00 PM – 3:00 PM

Attendance[1]

Voting Members

Prabhavathi Fernandes, PhD, FISDA
NBSB Chairperson
Carl R. Baum, MD, FAAP, FACMT
John G. Benitez, MD, MPH
H. Dele Davies, MD, MSc, MHCM
David W. Gruber, MA
Craig Klugman, PhD
Elizabeth Leffel, PhD, MPH
Joelle Simpson, MD, MPH
Tammy Spain, PhD, PMP
Mahmoud Usman, MD, MMM
David J. Witt, MD

Ex Officio Members

Marc Shepanek, PhD, National Aeronautics and Space Administration
Isaf Al-Nabulsi, PhD, Department of Energy
Dan Ellis, Department of State

Federal Staff

Julia Limage, PhD, Director, Office of Strategy, Policy, and Requirements, Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS)

Mr. Darrin Donato, Director, ASPR Policy Division

CAPT Christopher L. Perdue, MD, MPH, U.S. Public Health Service (USPHS), NBSB Designated Federal Official, ASPR Policy Division

Tabinda Burney, MS, ASPR Policy Division

Robert Johnson, PhD, Director of Medical Countermeasure Program, Biomedical Advanced Research and Development Authority (BARDA)

Melanie C. Wright, PhD (CTR), BARDA

Ashley Cecere, MS, Special Assistant to the Director, BARDA

Meeting Overview

The National Biodefense Science Board (NBSB or the Board) held a public meeting on August 28, 2023, to review two sets of draft recommendations that had been previously published online for public review. CAPT Perdue opened the meeting with a roll call and required statements; Dr. Julia Limage provided opening remarks. Led by Dr. Fernandes, the board members discussed several public comments, with three individuals providing their remarks verbally during the meeting. Board members subsequently made

[1] Full roster in Appendix 1.

numerous edits to both documents. The Board voted on each set of recommendations separately and, with a quorum of voting members present, each was approved unanimously.

Detailed Meeting Summary

Administrative Business and Welcoming Remarks

CAPT Perdue conducted roll call (11 board members present with 2 authorized positions vacant) and briefly described the purpose of the NBSB. He highlighted key requirements for advisory committees established by the Federal Advisory Committee Act and briefly explained the ethics rules that apply to the board members. There were no reported conflicts of interest.

Dr. Julia Limage, Director of the ASPR Office of Strategy, Policy, and Requirements, provided opening remarks. Dr. Limage thanked the voting and ex officio members for their work, as well as partners who aided in the research and creation of the recommendations being considered by the board. The board was asked on behalf of the HHS Secretary to consider lessons from the COVID-19 pandemic and distill those down into several concrete priorities for HHS and ASPR, including ways in which to address the needs of vulnerable populations. Dr. Limage noted that ASPR is currently working to sustain systems that were built during the pandemic response so that they remain available for the next major public health threat, no matter what it may be. This includes programs that provide support and coordination for public health and medical supply chains, coordinating distribution of federal emergency health resources, disaster telehealth, and revitalization of the strategic national stockpile, among others. HHS is working with non-federal partners and Congress to stay on track and put resources to the best use possible. Dr. Limage highlighted that ASPR holds the principles of equity, inclusion, diversity, and transparency as cornerstones of its strategic plan and operational ethic.

Special Presentation

Dr. Robert Johnson, Director of Medical Countermeasure Programs at BARDA – Next Generation COVID-19 Vaccines and Therapeutics: Prioritizing Product Attributes to Broaden Accessibility

Project NextGen is an effort co-led by BARDA and the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) to coordinate among federal agencies and the private sector to advance the pipeline of new, innovative vaccines and therapeutics for COVID-19, which would ultimately be approved by the U.S. Food and Drug Administration (FDA). The goal is to be able to produce large quantities of highly effective commercial products that are generally perceived as being more accessible, thereby increased utilization and overall population protection. *Project NextGen* has three main lines of efforts: vaccines, therapeutics, and enablers (**Figure 1**). BARDA is advancing development efforts to examine immune responses across vaccines, including further understanding of how correlates of immunity predict the success of vaccine candidates. Therapeutic development will emphasis pre-exposure prophylaxis and drugs that are more effective in immunocompromised populations. Enablers includes investment in development of transformative technologies that decrease cost and increase the speed of production, improve access, and increase overall efficacy of products through current good manufacturing practices.

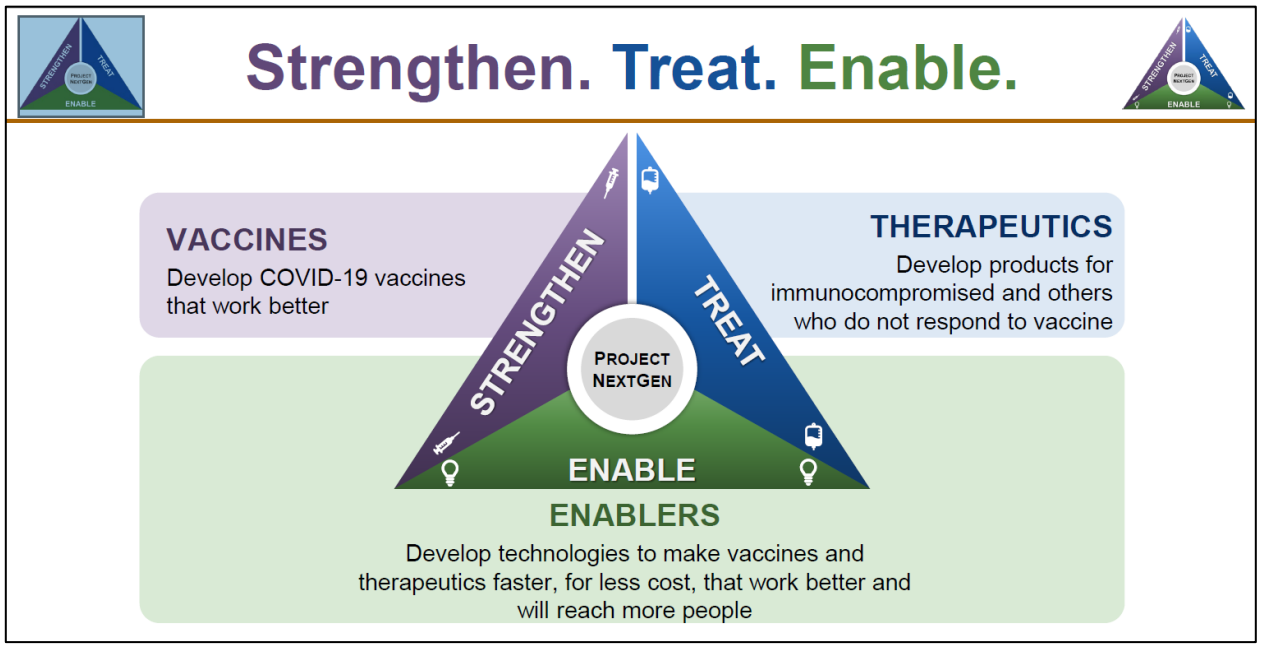

Figure 1. Overview of the three primary goals of HHS Project NextGen.

BARDA aims to invest in technologies that promote increase uptake by all populations. By considering equity and diversity in investment decisions, more of the next generation of COVID-19 vaccines and therapeutics will have attributes that result in products that are more acceptable, with fewer barrier to use, and therefore more equitable. BARDA has engaged with state officials already to begin identifying product characteristics that influence their decisions around acquisition, distribution, and administration. BARDA also asked the NBSB to provide their advice and recommendations on issues related to accessibility and equity. Separate landscape analyses conduct by BARDA outline the strengths, resources, and gaps in the research and development pipelines for different types of vaccines and therapeutics. Across all those compounds, the landscape analysis shows that there are many opportunities for pre-clinical development, with significant investment needed to push candidates through to later phase development and FDA approval. *Project NextGen* has the following implementation priorities currently:

Vaccines

- Centralized Phase I/IIa testing
- Centralized immunogenicity assays to establish correlates of protection
- Phase IIb efficacy trials

Therapeutics

- Emphasis on pre-exposure prophylaxis that would serve immunocompromised population
- Antibodies to target highly conserved regions that work against current and future variants
- Potential expansion to antivirals as warranted

Enablers

- Next generation therapeutics technologies
- Next generation vaccine technologies
- Innovative cGMP manufacturing of vaccines

Appendix 2 contains a full copy of the request from BARDA to the NBSB.

Public Comments and Discussion

Dr. Jerome M. Adams, Distinguished Professor of Practice, Department of Health, Purdue University – Dr. Adams emailed observations to the NBSB in which he emphasized the importance of oral anti-viral medications again COVID-19 that do not result in cross-resistance against existing drugs. He also emphasized the importance of safety and effective with low risk for drug-drug interactions with common prescribed medications.

Dr. Anna Hullinger, Regional Public Health Emergency Preparedness Coordinator, School-Based Vaccination Coordinator, and Medical Reserve Corps Coordinator, Dartmouth University – Dr. Hullinger offered comments on public health response and preparedness through the lens of regional public health preparedness and response. In her previous position as a regional public health emergency coordinator in New Hampshire, she noted that the Medical Reserve Corps was limited by available funding and support. She highlighted the importance of additional funding and support for Medical Reserve Corps, including during steady state, and how important regional public health networks are in understanding populations and addressing the needs of their constituents.

Annie Scrimenti, MS, from the Association for Molecular Pathology (AMP) – Dr. Scrimenti stated that there were many clinical and research scientists were on the frontlines during the COVID-19 response.

Melissa Trumbull, Director, Programs and Initiatives, National Association of Emergency Medical Technicians (NAEMT) – Emergency medical services (EMS) are an integral component of responses to pandemics and medical crises, including outbreaks of diseases, bombings, mass shootings, and natural disasters. EMS has a significant role in biodefense. Beyond transporting patients, EMS providers works as contact tracers, testers, vaccinators, and administrators for antibodies. Ms. Trumbull suggested that EMS be included in several of the Board's recommendations.

Discussion of Public Comments and Recommendations

The NBSB discussed the public comments and considered several recommendations to the draft reports that were published. Some of the edits were for spelling, grammar, or sentence clarity, but some were more substantive and described below.

Prioritization of Product Attribute Categories to Maximize Access for Next Generation COVID-19 Vaccines and Therapeutics

- Issue: Recommendation 4 - Therapeutics
  - Add / Edit Language
    - Change – Added bullet; *Different mechanisms of action (new targets) – avoiding or reducing cross-resistance with new drugs and ensuring potential for lower frequency for development of resistance.*
    - Change – Edited bullet; *Ability to target multiple RNA viruses – this would help the government be prepared for future public health emergencies caused by RNA viruses of other uncertain lineage.*
    - Change – Edited bullet; *Multiple routes of administration – Oral and intravenous formulations to accommodate outpatient and hospitalized patient treatment; Oral antivirals are highest priority to improve access.*
    - Change – The word "polypharmacy" was replaced with "Toxicity from interactions between the new therapeutic and multiple medicines taken for a variety of indications, such as hypertension, diabetes, chronic immunologic diseases etc. should be minimized.

Disaster Preparedness and Response Operations Lessons from COVID-19

- Issue: EMS, add call out
  - A. Improving operational public health and health system data for disaster response
    - Change – EMS data added as an additional source for pre-hospital data for prediction and response.
  - Section 6 - Standardize and formalize procedures for obtaining timely operational data from the health system.
    - Change: Line added; *Pre-hospital data for prediction and response, such as from EMS*.
- Issue: Detection systems, add call out specific to using all available laboratories previously cleared and approved
  - Section 2 - Increase the ability to use novel diagnostic tests in an epidemic or infectious disease emergency.
    - Change – Sentence updated; *One additional critical component of that strategy would also allow for the use of laboratory developed testing procedures without employing duplicative regulatory requirements to better leverage the capacity of all types of clinical laboratories. In addition, ~~additionally~~ authorization.*
- Issue: Antimicrobial resistance; add call out
  - Section 5 - Focus efforts on multi-pathogen and broad-spectrum pathogen detection.
    - Change – Sentence updated; *Improve the identification of local infectious disease cluster, including resistant pathogens and potential epidemics and pathogen specific tests including antibiotic and drug resistance.*
- Issue: Address shortage of infectious disease professionals and antimicrobial stewardship professionals and teams; add call out
  - Change – No change; Overall shortage of professionals in every discipline addressed in previous report.
- Issue: Address current national action plan and related gaps; add call out
  - Change – No change; Infectious disease personnel shortages and ongoing work addressed in previous report.
- Issue: Access to data
  - Change – No change; Access to data and issues related to incomplete data sets, limitations of federal oversight, and data privacy, including protecting privacy through anonymization, addressed in previous report.
- Issue: Animal health; add call out
  - Change – No change; Included in current report and covers animal health and farm workers, as related to One Health.
- Issue: Consider multi-pathogen and broad-spectrum detection products and / or technologies; add call out
  - Change – No change; Specific technologies beyond scope of current recommendations; Board acknowledges rapid diagnostic need and that BARDA and other agencies are addressing.

Appendix 1: National Biodefense Science Board Roster

VOTING MEMBERS

Chair, Prabhavathi Fernandes, PhD, FIDSA
Biotechnology and Pharmaceutical Executive,
Chair of GARDP Scientific Advisory Board and Board Members for OpGen, Ocugen, and Aelin Therapeutics
Chapel Hill, NC

Carl R. Baum, MD, FAAP, FACMT
Professor of Pediatrics and Emergency Medicine
Yale University School of Medicine; Toxicology Consultant, Connecticut Poison Control Center
New Haven, CT

COL John G. Benitez, MD, MPH, USAR
Emergency Preparedness Liaison Officer – TN, U.S. Army North, FEMA Region 4
Nashville, TN

H. Dele Davies, MD, MSc, MHCM
Readiness and Resilience Working Group Co-Chair
Senior Vice Chancellor for Academic Affairs and Dean for Graduate Studies and Professor of Pediatrics and Epidemiology, University of Nebraska Medical Center
Omaha, NE

David W. Gruber, MA
Associate Commissioner for Regional and Local Health Operations, Texas Department of State Health Services
Austin, TX

Craig M. Klugman, PhD
St. Vincent de Paul Professor, Department of Health Sciences, DePaul University
Chicago, IL

Elizabeth Leffel, PhD, MPH
Countermeasures and Operational Research Working Group Co-Chair
President, Leffel Consulting Group, LLC
Eagle Rock, VA

Joelle N. Simpson, MD, MPH
Chief of Emergency Medicine and Medical Director for Emergency Preparedness, Children's National Hospital, and Associate Professor of Pediatrics & Emergency Medicine, George Washington University School of Medicine & Health Sciences
Washington, DC

Tammy Spain, PhD, PMP
Senior Project Manager, The FlexPro Group/Network Partners, and CMC Project Manager for Drug Development, Paragon Bioteck, Inc.
Fruitland Park, FL

Mahmood (Mike) Usman, MD, MMM, MPH
Medical Director, Beacon Health Options of Pennsylvania
Cranberry Township, PA

David J. Witt, MD, FIDSA, CIC
Readiness and Resilience Working Group Co-Chair
Infectious Disease Consultant, Regional Epidemiologist, Kaiser Permanente Northern California
Oakland, CA

(currently 2 vacancies)

EX OFFICIO MEMBERS

Department of Health and Human Services (HHS)

Office of the Assistant Secretary for Health
RDML Paul Reed, MD, USPHS
Deputy Assistant Secretary for Health, Director of the Office of Disease Prevention and Health Promotion
Washington, DC

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

National Institutes of Health
Ian Simon, PhD
Senior Advisor, National Institute of Allergy and Infectious Diseases
Bethesda, MD

Administration for Strategic Preparedness and Response (ASPR)
D. Christian Hassell, PhD
Acting Director, Office of Preparedness
Washington, DC

Food and Drug Administration
Brooke Courtney, JD, MPH
Senior Regulatory Counsel, Office of Counterterrorism and Emerging Threats, Office of the Commissioner
Silver Spring, MD

White House Executive Office of the President

Stephanie Guerra, PhD
Assistant Director for Biosecurity, Office of Science and Technology Policy
Washington, DC

U.S. Department of Agriculture

Jack Shere, DVM, PhD
Associate Administrator
Animal & Plant Health Inspection Service
Greenbelt, MD

Department of Commerce

Dianne L. Poster, PhD
Special Assistant & Associate Director for Laboratory Programs, Office of the Director, National Institute of Standards and Technology
Gaithersburg, MD

Department of Defense

Kevin Wingerd, PhD
Director, Chemical and Biological Medical Program, Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense
Alexandria, VA

U.S. Department of Energy

Isaf Al-Nabulsi, PhD
Senior Technical Advisor & Japan Program Manager, Office of Health and Safety, Office of Environment, Health, Safety and Security
Washington, DC

Department of Homeland Security

Herbert O. Wolfe, PhD, MS
Deputy Assistant Secretary for Health & Acting Director, Office of Health Security
Washington, DC

Department of the Interior

M. Camille Hopkins, DVM, MS, PhD
Wildlife Disease Coordinator, U.S. Geological Survey Ecosystems Mission Area
Reston, VA

Environmental Protection Agency

Gregory Sayles, PhD, MS
Director, National Homeland Security Research Center
Washington, DC

Intelligence Community

Kelly B. Chafin
Office of the Director of National Intelligence
Washington, DC

National Aeronautics and Space Administration

JD Polk, DO, MS, MMM, CPE, EdD, FACOEP
Chief Health and Medical Officer, Office of the Chief Health and Medical Officer
Washington, DC

National Science Foundation

Mamadou Diallo, PhD, MS
Director of the Environmental Engineering Program, Division of Chemical, Bioengineering, Environmental, and Transport Systems, Directorate for Engineering
Alexandria, VA

Administrative Points of Contact

CAPT Christopher Perdue, MD, MPH, USPHS
Designated Federal Official
Office of Strategy, Policy, and Requirements, ASPR
Washington, DC

LCDR Cliffon Smith, MPH, U.S. Public Health Service
Executive Secretary, Policy Analyst
Office of Strategy, Policy, and Requirements, ASPR
Washington, DC

Department of Justice

Rosemary Hart, JD
Special Counsel, Office of Legal Counsel
Washington, DC

Department of State

James Levy
Deputy Assistant Secretary (acting), Bureau of Oceans and International Environmental and Scientific Affairs
Washington, DC

Nuclear Regulatory Commission

Patricia A. Milligan, RPh, CHP
Senior Advisor for Emergency Preparedness
U.S. Nuclear Regulatory Commission
North Bethesda, MD

Department of Veterans Affairs

vacant

www.phe.gov/NBSB
NBSB@hhs.gov

Appendix 2. Text of request from the Biomedical Advanced Research and Development Authority (BARDA) to the National Biodefense Science Board

Next Generation COVID-19 Vaccines and Therapeutics: Prioritizing Product Attributes to Broaden Accessibility

While the current COVID-19 vaccines and oral antivirals are very effective at preventing serious illness and death, there remains an urgent need to sustain and ideally improve protection again SARS-CoV-2. Ideal vaccines should have wider protection against variants and longer duration of protection, and therapeutics need to be available and acceptable to all populations. The Biden Administration recently announced Project NextGen, a joint program between the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID) to accelerate and streamline the development of next generation COVID-19 vaccine and therapeutics to address these challenges.

A key goal of Project NextGen is to invest in COVID-19 vaccine and therapeutic candidates that have favorable attributes that potentially increase access to prevention and treatment by better meeting the needs of America's diverse population. For our purposes, we emphasis the five A's of access defined by Penchansky and Thomas[1]:

- Availability – adequacy of vaccine and therapeutic supply at locations
- Accessibility – transport resources, time, and cost to reach supply resources
- Accommodation – how vaccines and therapeutics are made available to patients (appointment systems, hours of operation, telehealth, self-administered, clinic-administered)
- Affordability – relationship between cost and patients' insurance, income, and ability to pay
- Acceptability – relationship between patients' attitudes and motivations to specific characteristics of vaccines, therapeutics, and the manner in which they are delivered.

Published literature[2-8] identifies some attributes of vaccines and therapies that support broader access, including, but not limited to, safety and efficacy across broad and diverse populations, breadth of protection among variants, onset and duration of protection, storage and shelf-life conditions, mode of delivery, number of doses required for effect, and coadministration with other vaccines or drugs.

Although ideal vaccines and therapeutics will possess the optimal attributes described above, that is rarely possible. Oftentimes, this requires trading off one specific attribute against another. For example, treatments with efficacy across broad populations may cost more or possess less desirable storage or shelf-life conditions. There is little information available to support prioritization of attributes that specifically improve access, which makes it difficult to select among those attributes when there are budget constraints for product development. Furthermore, there is no guidance related to the trade-off between the rapid availability of safe and effective but less optimal products and the additional time required to develop products with more favorable profiles.

Based on the need to establish product development goals that improve access, BARDA seeks input from the NBSB regarding the product attributes that should be considered, and how they should be prioritized, for future COVID-19 vaccines and therapeutics. BARDA would like to request the NBSB to consider the following questions:

1) In addition to the product attributes listed above, what additional attributes does the advisory board recommend BARDA consider that would increase domestic access to vaccines and therapeutics, respectively?
2) Separately for vaccines and therapeutics, which of all the attributes identified are *highest priority* for broad and equitable access? Which are lower priority?
    a. Among attributes that are *highest priority*, describe any relevant details, such as target performance criteria, that are important for consideration.
    b. Describe any relevant (specific or general) principles that should be considered regarding the trade-offs between the **rapid availability** of safe and effective but less optimal products and the **additional time** required to develop products with high priority attributes.
    c. Describe how different population characteristics such as geography, age, race, socioeconomic status, or underlying health conditions may be associated with different attributes and priorities.
        i. If product attributes are prioritized differently between diverse populations, are there particular population needs that should be prioritized for next generation COVID-19 vaccines and therapies?
    d. Describe how different circumstances or contextual factors beyond product attributes, such as policies, supportive technologies, or communication strategies, may impact prioritization among the different product attributes.

REFERENCES

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