



NBSB National Biodefense Science Board

**Filling Critical Gaps: Comprehensive Recommendations for
Public Health Preparedness, Response, and Recovery from the
National Biodefense Science Board**

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Washington, DC**

The National Biodefense Science Board was created and given authorities under the Pandemic and All-Hazards Preparedness Act of 2006 ([Public Law No. 109-417](#)) and initially chartered in 2007. The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 ([Public Law No. 113-5](#)) broadened membership to require a representative with pediatric expertise and someone who serves as a state, tribal, territorial, or local public health official. The 2013 law also expanded the duties of the NBSB with respect to emergency medical countermeasures development by HHS and real-time, all-hazards biosurveillance capabilities. Between 2016 and 2018, the board was also known as the National Preparedness and Response Science Board. The board has [13 voting members](#) with a broad range of expertise in science, medicine, bioethics, and public health; there are as many as 19 ex officio, non-voting representatives from federal agencies.

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BACKGROUND

On 28 September 2020, the National Advisory Committee (NAC) Program in the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) requested the National Biodefense Science Board (NBSB or the Board) to review the 2007 Homeland Security Presidential Directive 21 (Public Health and Medical Preparedness) (HSPD-21) and subsequently provide recommendations that could potentially be used to update HHS's and ASPR's priorities for health emergency preparedness, response, and recovery. The full text of that request is in Appendix 1. Appendix 2 contains a full roster for the NBSB.

Briefly, the NBSB was asked to consider the following overarching questions:

1. What, if any, of the 2007 focus areas (biosurveillance, countermeasures stockpiling and distribution, mass casualty care, or community resilience) should remain as highest priorities for capacity development by HHS?
2. How might those focus areas be modified, updated, or expanded to promote additional advances in public health and medical preparedness in the United States?
3. What, if any, should be new HHS focus areas for public health and medical preparedness?

The NBSB chairperson accepted the request, which was transmitted to the rest of the board. In subsequent working group and administrative meetings, the members of the NBSB received informational presentations from federal agencies and other non-federal subject matter experts, discussing numerous issues and challenges. While HHS and the National Security Council began a formal (internal) review of past accomplishments based on HSPD-21, the NBSB recommendations in this report focus on current and future challenges, opportunities, and requirements. In other words, these recommendations represent potential priorities for HHS when proposing action items for a future update of Administration policy and strategy.

Additionally, in developing the recommendations contained in this report, the Board recognizes that HHS and other parts of the federal government are already deeply engaged in improving the health emergency infrastructure and related systems as a result of the COVID-19 pandemic, with implementation of many new programs and lessons learned. While the document is organized by major theme, rather than by "type" of recommendation, the Board is knowingly providing recommendations that are intended to help sustain ongoing efforts and innovations (e.g. supportive recommendations) while also providing recommendations that highlight critical gaps that remain inadequately addressed or for which long-term sustainability remains in question (e.g. incentivizing recommendations).

The NBSB has a long history of providing advice and recommendations to HHS; many such recommendations remain relevant today. However, the Board appreciates and commends the remarks made previously by Dr. Robert Kadlec, the former ASPR between 2017 and 2021, that if all problems are a priority, then no problem is a priority. The recommendations from the NBSB in this report supplement

and augment other recommendations published in 2019 and 2020 that support HHS as it seeks to identify priorities to better prepare for and respond to emerging and evolving public health threats, as well as recovering from events that cause physical, social, and emotional damages. When developing the next iteration of strategic priorities, HHS leaders and staff members should additionally consider the specific recommendations regarding training and preparedness for clinicians [published on September 11, 2019](#); those regarding the integration of clinical disaster response training into community and state preparedness efforts [published on May 13, 2020](#); and the recommendations aimed at significantly increasing the capacity of the United States to develop, produce, and distribute emergency medical countermeasures (MCMs) including vaccines, therapeutics, and diagnostics, [published concurrently on May 13, 2020](#).

RECOMMENDATIONS

Key Finding

The United States is just beginning to identify key lessons learned from the COVID-19 pandemic as they relate to strengths and gaps in our country's disaster preparedness and response system, which are of central concern to ASPR, HHS, and the country as a whole. One overarching lesson that is abundantly clear and of pressing importance from the perspective of the NBSB is the need to ensure that the United States is always prepared to implement an immediate, effective, and coordinated public health response *that is guided by scientific knowledge and protected from undue political influence*. Similar to the Congressional Budget Office or the Federal Reserve Bank, HHS should consider how to develop a centralized, core public health emergency communication and coordination function that is inherently insulated from political considerations, with the ability to independently develop, directly distribute, and frequently update public health messages with scientific principles in mind, guided by analysis of available data, with inputs from the nation's leading experts.

What follows are more specific recommendations to enhance the country's disaster preparedness and response.

One Health Biosurveillance, Risk Assessment, and Situational Awareness

The NBSB advises HHS to strengthen, expand, and formalize existing collaborations within HHS and among other federal departments, public and private research institutions, and private sector organizations to continuously assess emerging human and animal disease risks.

Specifically, the NBSB recommends that HHS:

- Strengthen integration of global and domestic research, health surveillance, and disease prediction capabilities, leveraging new data sources and artificial intelligence, to identify high-consequence changes in patterns of human, animal, and agricultural diseases and conditions, including the impacts of climate change.

- Promote development, sharing, and implementation of medical emergency response and public health-specific, ethical uses for artificial intelligence consistent with the Executive Order on Maintaining American Leadership in Artificial Intelligence as relates to identifying, mitigating, and planning for potential health threats and disaster risks.
- Establish clear data collection and data system interoperability guidelines for One Health threat information and develop a central resource that is accessible to researchers to advance the knowledge base related to emerging illnesses, which includes social and demographic determinants of health.
- Expand efforts to efficiently plan and transparently access and analyze nationwide health system data in real-time to anticipate and improve responses to major health crises, including hospital bed and critical material shortages, supply chain disruptions, and healthcare workforce shortages, which require regional systems and dashboards that link to one another.
- Support development of public health models for impacts of climate change on public health that can inform surveillance programs and research activities.
- Develop a systematic approach and implement a plan for the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) to proactively identify and share information about potential zoonotic and other infectious diseases that threaten human health.
- Support development and utilization of environmentally friendly and minimally invasive methods for surveying arthropod vectors of human disease.

Enhancement of Medical Countermeasures Development, Domestic Manufacturing, and National Supply Chain

The NBSB advises HHS to strengthen relationships with manufacturers of vaccines, drugs, PPE, and diagnostic products, promote on-shoring¹ and alternate sources of essential products, and support systems to quickly scale-up manufacturing when needed.

Specifically, the NBSB recommends that HHS:

- Regularly assess, prioritize, and as needed improve targeting/coordination of funding and incentives for product-focused research and development of emergency MCMs that have broad-spectrum antiviral and antimicrobial activity.
- Enhance PHEMCE processes to rapidly develop requirements for novel MCMs, which includes obtaining inputs from non-federal health officials involved in deployment and administration of products.

¹ In this context, “on-shoring” refers to the production of ingredients, components, and finished products within the United States, whether by establishing new domestic production and service centers or by translocating international production and services.

- Assess US government oversight policies for research conducted with biological agents that might (intentionally or unintentionally) cause widespread and uncontrolled harm to humans, animals, or agriculture, including measures aimed at reducing the risk of increasing virulence or transmissibility in academic, government, private, and citizen science settings.
- Incentivize mechanisms to manufacture, acquire, store, and/or deploy additional resources for control of a vector-borne disease emergency.
- Increase federal funding for appropriate laboratory facilities, programs, training, and field work to increase the understanding of the natural history of zoonotic infectious diseases.
- Increase investment in research and development for *in vitro* and animal model systems, and computational models of human and animal infectious diseases that support development of MCMs.
- Develop strategies and mechanisms to better utilize infectious disease diagnostics for emerging threats, which would include local capacity to develop and utilize novel tests in pre-approved systems, point-of-care and home testing with appropriate monitoring and quality assurance, regulatory support to allow a diversity of valid tests that can be commercially distributed, and a well-organized, secure, and accessible electronic reporting system for test results.
- Increase investments and strengthen public-private partnerships that support development and dissemination of innovative manufacturing technologies and distribution models, while increasing the on-shoring of production capacity, leading to a more reliable, resilient, and redundant national domestic supply of critical medicines and health care supplies.
- Increase investment in the development and stockpiling of artificial and shelf-stable blood products that can be used when blood products are needed in mass quantity and situations where the national blood supply is threatened.

Health Workforce Readiness and Resilience

The NBSB advises HHS to expand existing programs and where needed establish or incentivize new programs and partnerships to improve the readiness and resilience of the health and public health workforce during a healthcare crisis.

Specifically, the NBSB recommends that HHS:

- Coordinate among key professional groups and stakeholders to ensure that every health worker in the United States receives training in disaster preparedness and the principles of effective emergency response, including (among other topics) epidemic infection control and use of personal protective equipment for high-risk infectious diseases.
- Promote and coordinate development of standardized curricula for health professionals (appropriate to their most likely role during a public health emergency) and promote disaster preparedness, response, and recovery education and accreditation in undergraduate and graduate health and public health programs.

- Expand the absolute number of infectious disease specialists who are ready to support an emergency response by increasing training and employment activities, incentives, and funding, as well as by supporting income opportunities that attract pre-professionals to the field.
- Increase efforts to improve the capacity of state, local, tribal and territorial health officials, health systems, and medical providers to participate in rapid, pre-approval clinical testing of potential MCM and effectively receive, store, and administer new vaccines and therapeutics.
- Enhance coordination of first responders and on-scene providers during an emergency response by improving mechanisms to provide consistent, evidence-based, just-in-time public health and medical training and guidelines.
- Increase the capacity to identify and mobilize individuals or teams of subject matter experts (SMEs) and supervisory-level health emergency responders to provide direct support to non-federal health agencies, private health care organizations and relevant businesses, and non-governmental organizations. Such teams could provide clinical training and supervision as well as support for incident command, communications, logistics, and other technical support.
- Enhance the availability and access to high quality mental health services and post-incident interventions for health workers and first responders, especially those who provide extended emergency services.
- Develop a supportive infrastructure to ensure safe and high-quality childcare, eldercare, and pet care for families of health workers and first responders during a disaster and in the immediate aftermath so that they can respond effectively to a disaster.
- Conduct a detailed review and develop updates for the National Response Framework Emergency Support Function 8 (ESF8, Public Health and Medical Services) to ensure it better meets the need in future public health and medical disasters.
- Develop model language, in collaboration with appropriate stakeholders (such as the National Association of State Attorneys General), to ensure that in times of disaster, health professional licensure of all types can cross state lines and liability protections are available and understood when altered standards of care are required.

Health Facility and Other Infrastructure Readiness and Resilience

The NBSB advises HHS to expand and further refine existing programs to improve the readiness and resilience of health care systems during a crisis.

Specifically, NBSB recommends that HHS:

- Support enhancements to cybersecurity for health systems and medical devices, including timely sharing of information on noted threats across the health system.
- Increase efforts to ensure transferability and interoperability of all electronic health records at all times, with additional contingencies to support crisis responses when needed.

- Continue to incentivize and develop collaborations among hospitals (within and across jurisdictions) to develop supportive infrastructures and sharing of knowledge and resources (human and material) in disasters.
- Expand emergency-use strategies for telehealth, including extended payment benefits for in-home visits, and coordinate development of deployable, telehealth critical care systems.
- Conduct a comprehensive analysis of, and prepare strategies to mitigate, the impacts of changing weather patterns and severe natural phenomena on public health and health infrastructure, including the combined effects of simultaneous emergencies caused by weather and other public health threats.
- Provide incentives and increase other forms of support for state, local, tribal, and territorial authorities and private health systems to conduct health crisis response exercises for a variety of scenarios.

Engagement and Communication with the Public during a Health Crisis

The NBSB advises HHS to significantly improve its capacity to develop and disseminate timely, accurate, consistent, and trusted advisories, public health messages, and clinical guidelines during a health crisis.

Specifically, the NBSB recommends that HHS:

- During health crises, disseminate clear, simple, and expeditious public health messages and guidelines that are consistent, accurate, and scientifically based, produced by authoritative, technically qualified, scientific leaders who are not influenced by political considerations.
- Strengthen alignment and coordination of communication with health and non-health sector businesses, including those involved in advertising and social media, to improve the flow of information to, and implementation of guidelines by, local organizations and the general public.
- Explore the potential to incentivize and guide implementation of locally recognized and organized civil emergency response groups and aid societies to ensure that no one is forgotten or abandoned during a crisis.

Appendix 1. ASPR Request for Advice and Recommendations from the National Biodefense Science Board (NBSB)

The text of the request is reproduced below for the final report, originally transmitted verbatim on September 28, 2021.

Since publication of Homeland Security Presidential Directive 21 (HSPD 21) “Public Health and Medical Preparedness” in 2007, the United States has experienced numerous serious threats to public health and the health system, some that directly impacted the U.S. population and others that impacted international travel, trade, or transportation. A brief, yet incomplete, list of those include:

- 2009 – pandemic influenza H1N1
- 2011 – earthquake damage to Fukushima Daiichi nuclear power plant
- 2012 – Hurricane Sandy
- 2012 – epidemic MERS-CoV in the Middle East
- 2013 – epidemic avian influenza H7N9 in China and Southeast Asia
- 2014 – epidemic Ebola virus in West Africa
- 2014 – accidental radioactive waste exposures in New Mexico
- 2015 – epidemic MERS-CoV in Eastern Asia
- 2016 – pandemic Zika virus
- 2017 – *WannaCry* ransomware attacks
- 2017 – Hurricanes Harvey, Irma, and Maria
- 2018 – epidemic Ebola virus in Central Africa
- 2019 – pandemic SARS-CoV-2 (COVID-19)

HSPD 21 was forward-looking in establishing national policies and implementation goals that directed, incentivized, and guided improvements in a number of specific technical areas. The overarching goals of the directive were to improve capacity, resiliency, and interconnectedness among state, local, Tribal, and territorial (SLTT) systems; and to strengthen their interoperability with federal programs. Those priorities specifically applied to human health and health systems, deferring considerations regarding animal health, food and agriculture defense, global health, health threat intelligence, and laboratory biosecurity to other policy statements. The outcomes of work conducted as a result of HSPD 21 are evidenced in a vast variety of reports, publications, and technical manuals, a comprehensive review of which would be beyond the scope of the NBSB.

Appendix 1 contains a detailed list of the directives, milestones, and deliverables; the following paragraphs briefly summarize the HSPD 21 focus areas.

Biosurveillance – HSPD 21 directed HHS to (continue to) formulate and establish a comprehensive national system predicated on the primacy of SLTT public health authorities and the systems operated by jurisdictional authorities, requiring connectedness and interoperability through information technologies. HHS, DoD, VA, and DHS were additionally required to establish an *Epidemiologic Surveillance Federal Advisory Committee* to support the national system and publish the national biosurveillance plan as a component of the HSPD 21 implementation plan, though such a committee does not exist today.

Countermeasure Stockpiling and Distribution – HSPD 21 specified six milestones, including plan templates for local medical countermeasure (MCM) deployment, collection of and planning based on more detailed data regarding local capacities, annual review of the contents of the Strategic National Stockpile (SNS), increased information sharing about SNS contents with SLTT officials, and development of mechanisms to coordinate among agencies’ and international organizations MCM stockpiles.

Mass Casualty Care – With five specific milestones, HSPD 21 directed HHS to lead efforts to strengthen the National Disaster Medicine System (NDMS), increase use of federally-owned health facilities for national emergencies, and identify and eliminate regulatory and legislative barriers at the Federal level and assist the SLTT levels. HSPD 21 also called for a *Federal Advisory Committee for Disaster Mental Health*, though such a committee does not exist today.

Community Resilience – HSPD 21 directed a variety of agencies to collaborate to promote comprehensive community medical preparedness, supported specifically by increasing threat information sharing, including classified information, with SLTT officials, improved federal grant programs, federally-led enhancement of national disaster training for all types of personnel, and establishment of a joint HHS-DoD program for Disaster Medicine and Public Health as well as the National Center for Disaster Medicine and Public Health (NCDMPH) at the Uniformed Services University. To further enhance community preparedness, HHS was directed to collaborate with DHS and DOT to establish an Office for Emergency Medical Care in HHS.

In understanding the purpose and scope of HSPD 21, and a general understanding of progress since the 2007 directives for public health and medical preparedness, ASPR is requesting advice and recommendations that will inform new, national priorities and long-term goals for HHS.

ASPR requests that the NBSB consider the following questions and prepare a response, within the scope of the NBSB charter and conforming to all FACA requirements, by November 13, 2020. To be clear, the goal of this request is for forward-looking recommendations, rather than evaluating the individual, detailed accomplishments that resulted from HSPD 21. Regarding the scope of the discussion, the NBSB should consider not only biological threats, but any that could catastrophically affect the U.S. public health or health system, warranting national preparedness attention, major improvements in a whole-of-society approach, and potential federal investment and partnerships.

1. What, if any, of the 2007 focus areas (biosurveillance, countermeasures stockpiling and distribution, mass casualty care, or community resilience) should remain as highest priorities for capacity development by HHS? How might those focus areas be modified, updated, or expanded to promote additional advances in public health and medical preparedness in the United States? Consider the following additional questions:
 - a. What should be HHS’s over-arching goals for each focus area?
 - b. What, if any, are the specific recommendations and measurable outcomes for implementation?
 - c. Does the NBSB recommend any specific milestones (i.e. 2 years from now, 5 years, etc.)?
2. What, if any, should be new HHS focus areas for public health and medical preparedness? Consider the following additional questions:

- a. What are the highest priority, modern threats to public health and the health system? What should be HHS's over-arching goals related to those threats?
- b. What, if any, are the specific recommendations and measurable outcomes for implementation?
- c. Does the NBSB recommend any specific milestones (i.e. 2 years from now, 5 years, etc.) for the specific recommendations?

Appendix 2. Roster for the National Biodefense Science Board as of May 26, 2021.

Voting Members

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