2019 Biodefense Public Report
Implementation of the National Biodefense Strategy
PREFACE

The National Biodefense Strategy (NBS or the Strategy) was released on September 18, 2018 and guides the U.S. government’s efforts to reduce the risk of, prepare for, respond to, and recover from biological incidents, whether naturally occurring, deliberate, or accidental in origin. National Security Presidential Memorandum-14 (NSPM-14) directs implementation of the Strategy, including the development of this Biodefense Public Report. This report does not primarily address activities related to the coronavirus disease 2019 (COVID-19) pandemic because the data collection period concluded well before the HHS Secretary’s declaration of a public health emergency regarding the COVID-19 pandemic. Therefore, the content of this report is diverse and highlights some of the efforts across the U.S. government to address all biological threats.

Development of this report followed the timeline laid out in NSPM-14. Work began among federal departments and agencies to collect biodefense data in late 2018, the first year to capture biodefense programs and activities across the federal government, and continued through the first half of 2019. This report describes a sampling of specific achievements and programs undertaken by federal agencies that reduce the risk of biological threats to the American people.

In addition to the specific programs captured here, many other activities continue to be implemented across the federal government to protect the United States from a wide range of biological threats. Some of the efforts that have been described within this report, and many activities that have not been reported here, support the ongoing COVID-19 response. Future public reports will address federal biodefense activities related to the COVID-19 pandemic.

Continued implementation of the NBS will better prepare the nation to protect public health, agriculture, critical infrastructure, and the environment against biological threats.
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OVERVIEW

Biological threats, whether naturally occurring, accidental, or intentional, can have major impacts on global public health, the economy, and national security.

The National Biodefense Strategy (NBS or Strategy) and its implementation plan, directed by National Security Presidential Memorandum 14 (NSPM-14) released on September 18, 2018, set the strategic direction for the United States to combat these threats, whether they arise from natural outbreaks of disease, accidents involving high-consequence pathogens, or the actions of terrorists or state actors. NSPM-14 directs federal agencies, through a series of required annual activities, to implement the Strategy.

In its first year of implementation, the U.S. government (USG) conducted a foundational assessment of the federal biodefense enterprise by reviewing past, present, and planned efforts to address biological threats. Federal biodefense programs, projects, and activities reduce the risk of biological threats and make a difference at the state, local, tribal, territorial (SLTT), national, and international levels. Advances in the biodefense enterprise, such as new and improved vaccines, treatments, and diagnostics, have also improved the nation’s preparedness and response capabilities. However, despite these many achievements and notable successes, there remain gaps, shortfalls, and opportunities for improvement.

This public report provides an overview of the biological threat environment; describes the NBS and NSPM-14; summarizes the Fiscal Year (FY) 2019 Biodefense Assessment; provides examples of efforts to enhance biodefense including enabling risk awareness and preventing, preparing for, responding to, and recovering from bioincidents; identifies high-level federal priorities; and describes stakeholder engagement activities to date.

THREAT ENVIRONMENT

The 21st century health security environment is increasingly complex and dangerous; it demands that we act with urgency and undertake a singular, coordinated effort to save lives and protect Americans. The Strategy addresses this complexity by recognizing that biological threats may be naturally occurring, accidental, or deliberate in origin and may impact plant, animal, and human health, the economy, and the physical environment.

“Outbreaks of disease can cause catastrophic harm to the United States. They can cause death, sicken, and disable on a massive scale, and they can also inflict psychological trauma and economic and social disruption.”

National Biodefense Strategy

We have witnessed the economic and human suffering impacts of naturally occurring outbreaks such as influenza, Ebola, African swine fever, Zika virus, citrus greening, severe acute respiratory syndrome, and coronavirus disease 2019 (COVID-19). The September 2019 Council of Economic Advisers Report estimates that seasonal influenza alone costs the United States approximately $361 billion per year and projects that an influenza pandemic could have significant impact, costing half a million lives and between $413 billion and $3.79 trillion, depending on its severity and scope.
The acquisition or development and use of biological weapons are within the aspiration of potentially hostile state actors, terrorist groups, and lone-actors. The anthrax mailings of 2001, costing five lives and sickening 17, and an estimated $320 million in cleanup costs, are a reminder of the serious nature of this threat.\textsuperscript{1} Exposures due to laboratory accidents also present a concern. For example, a leaking pipe at a laboratory exposed nearby cattle to foot and mouth disease virus in the United Kingdom.\textsuperscript{2} Lapses in biosafety practices in U.S. federal laboratories also serve as a reminder of the importance of constant vigilance over the implementation of biosafety and biosecurity standards.

\begin{quote}
“Biological and chemical materials and technologies—almost always dual-use—move easily in the globalized economy, as do personnel with the scientific expertise to design and use them for legitimate and illegitimate purposes.”
\end{quote}

2018 Worldwide Threat Assessment

Although progress has been made over the past several decades in our preparedness for a biological incident, additional work remains to ensure the public health and security of the American people. Biological threats, technology, and threat actors are constantly evolving, and our defenses must keep pace. The Strategy brings together departments and agencies from across the federal government, as well as SLTT, private sector partners, and international partners to better coordinate our efforts and ensure that we are prepared to meet new and emerging threats.

**NBS, NSPM-14, AND SUMMARY OF THE YEAR 1 ASSESSMENT**

The NBS, released on September 18, 2018, provides a new and improved framework to enable better collaboration and cooperation across the federal government and with non-federal stakeholders. The Strategy sets the course for the United States to combat serious biothreats, arising from natural outbreaks of disease, accidents involving high-consequence pathogens, or the actions of terrorists, state, or lone-actors.

The NBS encompasses five goals for strengthening the biodefense enterprise:

1. Enabling risk awareness to inform decision-making across the biodefense enterprise;
2. Ensuring biodefense enterprise capabilities to prevent bioincidents;
3. Ensuring biodefense enterprise preparedness to reduce the impacts of bioincidents;
4. Rapidly responding to limit the impacts of bioincidents; and
5. Facilitating recovery to restore the community, the economy, and the environment after a bioincident.
Addressing Biodefense Threats: By the Numbers

- 70% of emerging infectious diseases in humans originate in animals
- 7,500 disease events in United States wildlife tracked and investigated since 1980
- $413B-$3.97T estimated cost of a future influenza pandemic
- 600M doses of seasonal influenza vaccines produced annually in the United States
- 18,502 cleared imported shipments of plant products and seed
- 1,173 different pest species intercepted
- 183M head of livestock in the United States
- 2,072 foreign animal disease investigations conducted in 2018
- 2.8M antibiotic resistant infections occur each year in the United States
- 33 innovative research projects supported by CARB-X to fight antibiotic resistance
- 72% reduction in United States orange production due to citrus greening
- 20 USDA-ARS scientists working on projects to produce resistant citrus varieties and sustainable management solutions

All numbers accurate as of 2018

Figure 1: The effect of biodefense threats on U.S. health security and national security and U.S. efforts to mitigate these threats.
Pursuant to NSPM-14, the Biodefense Steering Committee (BSC), chaired by the Secretary of Health and Human Services (HHS) and comprised of Cabinet members, is responsible for monitoring and coordinating NBS implementation. The Biodefense Coordination Team (BCT), currently led by the HHS Assistant Secretary for Preparedness and Response (ASPR), assists the BSC in overseeing and coordinating implementation of the Strategy. The BCT was established in December 2018 and meets weekly to coordinate NBS activities. The BCT also engages SLTT, the private sector, and international partners, as appropriate. Since the release of the Strategy and NSPM-14, federal agencies have:

- Developed a Request for Information to collect data from 15 departments and their components and built a database to capture and analyze this data;
- Completed a foundational assessment of the collected and compiled data; and
- Performed an extensive after-action process and implemented changes for the second annual round of data collection and assessment.

In 2019, the federal government conducted an assessment of the biodefense enterprise, as directed in NSPM-14. The foundational assessment included a review of past efforts to address biological threats. The assessment indicated many of these efforts have yielded achievements in risk awareness, prevention of, preparedness for, response to, and recovery from bioincidents—whether naturally occurring, deliberate, or accidental in origin. Strengthening routine and emergency public health capabilities, along with technological advances such as new and improved vaccines, treatments, diagnostics, and the establishment of a more robust medical countermeasure (MCM) product pipeline, coupled with the enhanced ability to respond rapidly with a research response to emerging infectious diseases, have improved biodefense enterprise preparedness and response capacity and capabilities.

NSPM-14 mandates that each year, within 90 days of the approval of the assessment, the BCT shall summarize the assessment and prepare, subject to the approval of the BSC and in coordination with the National Security Council (NSC) staff, a public report describing the actions taken to reduce the risk of biological threats to the American people. The following section highlights efforts undertaken by federal agencies that reduce the risk of biological threats to citizens of the United States. These highlights are a representative sample of specific achievements and programs ongoing in 2018, the first year captured in NBS data collection. Many other activities are ongoing across the federal government to protect the United States from biological threats.
BIODEFENSE HIGHLIGHTS — Biodefense Programs Reduce the Risk of Biological Threats and Make a Difference at the SLTT, National, and International Levels

Advancing Biodefense Enterprise Risk Awareness: Goal 1 Biodefense Highlights

Goal 1: Joint Criminal-Epidemiologic (Crim-Epi) Investigations Training

Bioincidents can dramatically affect the nation—including impacts on health and wellbeing, agriculture production, the food supply, critical infrastructure, and the economy. The Federal Bureau of Investigation (FBI) Weapons of Mass Destruction Directorate (WMDD) works with federal agencies and SLTT governments, the private sector, academia, and international partners to prevent and mitigate threats associated with the intentional misuse of biological materials. These efforts position biodefense stakeholders—at all levels of government and the private sector—to prevent such cases that could affect our citizens’ health directly or indirectly by adversely affecting our farms or food-manufacturing infrastructure.

Working in collaboration, the FBI WMDD and Centers for Disease Control and Prevention (CDC) within HHS filled a critical gap identified in the wake of the anthrax investigation in 2001 by establishing the Crim-Epi Investigations Model for multi-sectoral collaboration and information sharing. The Crim-Epi Model has become not only the gold standard for public health and law enforcement collaboration in the United States, but international partners, such as the International Criminal Police Organization, have adapted this model. Additionally, the Animal-Plant Health (APH) Joint Crim-Epi Investigations course was designed to incorporate the principles of law enforcement and animal and plant health investigations and represents a collaborative effort among FBI, United States Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS) Veterinary Services, and Oklahoma State University. The APH Joint Crim-Epi Model was shared with the 182 countries of the Biological and Toxin Weapons Convention (BWC) 2019 Meetings of Experts.³

Goal 1: National Biosurveillance Integration Center (NBIC)

Whether dealing with a bioterrorism attack or a newly emerging epidemic, early awareness that a potential bioincident is happening in a community provides the opportunity for a more rapid assessment of the situation and earlier response, potentially saving lives. The Department of
Homeland Security’s (DHS) NBIC is one example of work across the federal government to provide early awareness tools to federal and SLTT officials.

In partnership with the University of North Carolina, NBIC oversaw the development of the National Collaborative for BioPreparedness program, which deployed a nationwide adaptable framework that gives users an aggregated view of syndromic data allowing for the detection of unusual syndromes that may be indicative of a larger concern. This allows entities at every level of government to assess emerging biological threats through analytics and visualization of anomalous trends in emergency medical services data. The application of this framework has been applied to biological threats and other issues such as the opioid epidemic, hospital availability during disasters, and motor vehicle crashes in 41 states; the framework is currently covering 56 percent of national emergency medical services calls and continues to expand, improving our nation’s ability to detect and respond to bioincidents.

![Figure 2: Example of seasonal trend of influenza-like illness in the United States over a two-year period reflected in Emergency Medical Services data](image)

**Goal 1: Multidrug-Resistant Organism Repository and the Antimicrobial Resistance Monitoring Research Program**

Multidrug-resistant organisms pose a very serious threat to public health and our healthcare system. To better protect our nation from this threat, the Department of Defense (DOD) developed the Multidrug-resistant organism Repository and Surveillance Network (MRSN), to ensure timely identification and communication of natural outbreaks of multidrug-resistant bacteria. MRSN has produced more than 75 reports on outbreaks and has developed a screening protocol for new pathogens, including *Candida auris*—a pathogen identified as an urgent threat on the threat list in the 2019 CDC Antibiotic Resistance Threats in the United
**States Report.** MRSN supports the protection of our nation’s service members while also guiding the development of new diagnostic and therapeutic MCMs through its repository of well-characterized, clinically relevant organism isolates.

### Advancing Biodefense Enterprise Prevention: Goal 2 Biodefense Highlights

**Goal 2: Improving Biosafety and Biosecurity to Reduce the Risk of Biological Threats**

New scientific tools and understanding have created unprecedented opportunities for progress in life sciences research, medicine, and agriculture. Researchers are now capable of using novel scientific technologies and synthetic biology to advance medicine and pharmaceuticals. Synthesis technologies help to advance therapeutic and diagnostic strategies, and the gene-editing system using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) is a versatile tool, for example, in the search for a Human Immunodeficiency Virus cure and CRISPR-assisted DNA Detection—a promising method for developing diagnostic tests.

Coincident with this era of opportunity, there are elevated concerns about emerging infectious diseases, bioterrorism, and criminal acts involving the misuse of biotechnologies and hazardous biological agents. Laboratory lapses in biosafety and biosecurity could lead to significant public health and economic consequences, particularly if they involve potential pandemic pathogens and/or lack of oversight of dual use research of concern. Preventing the acquisition of equipment, expertise, and pathogenic material for illicit purposes and improving biosafety, biosecurity, and oversight practices in the United States and abroad, are important tenets of our ongoing activities and commitment to national and global health security and international non-proliferation frameworks such as the BWC, United Nations Security Council Resolution (UNSCR) 1540, and the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.
Multiple departments and agencies work cooperatively with domestic and international entities, including academia, industry, non-governmental, professional, and international organizations to strengthen responsible conduct in the life sciences and crowd source the development of training and educational resources on the culture of biosafety and biosecurity. Examples of actions taken by the USG to improve biosafety and biosecurity include implementing federal programs and frameworks and participating in interagency and international collaborations (Table 1); and releasing guidance documents and developing resources for the public.

**Biosafety and biosecurity highlights:**

- Released *Guiding Principles for Biosafety Governance: Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines*.
- Released *Guidance on Managing Solid Waste Contaminated with a Category A Infectious Agent*.
- Developed a best practices checklist for federal agencies to use when constructing high-containment laboratories.

### Table 1: Federal Biosafety and Biosecurity Programs, Frameworks, and Collaborations

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<tr>
<th>Program</th>
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<tr>
<td>Import Permit Program&lt;sup&gt;4&lt;/sup&gt;</td>
<td>CDC</td>
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<td>Select Agent Program&lt;sup&gt;5&lt;/sup&gt;</td>
<td>CDC, APHIS, FBI</td>
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<td>United States Government Policy for Institutional Oversight of Life Sciences Dual Research of Concern</td>
<td>USG-wide</td>
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<tr>
<td>Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens</td>
<td>HHS</td>
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<tr>
<td>Implementation of the biosecurity obligations in UNSCR 1540&lt;sup&gt;6&lt;/sup&gt;</td>
<td>DOS, DOD, DOE, DOJ, HHS</td>
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**Goal 2: Protecting the U.S. Drinking Water Supply against the Risk of Contamination**

During a naturally occurring, accidental, or deliberate biocident, unsafe levels of contaminants may be introduced into drinking water. Maintaining a clean supply of water to American citizens during such incidents is therefore a paramount concern. The Environmental Protection Agency (EPA) works closely with federal and SLTT partners to protect drinking water across our country by providing resources to drinking water programs, drinking water systems, and other stakeholders to help them prepare for contamination incidents.

Understanding the risk is a necessary first step in preventing and preparing for contamination of the drinking water supply. The *America’s Water Infrastructure Act*, signed into law in October 2018, requires that community drinking water systems serving more than 3,300 people conduct...
a risk assessment and update emergency response plans based on the findings from the risk assessment every five years. The EPA is committed to supporting compliance with this new law by providing training and resources such as the Baseline Information on Malevolent Acts for Community Water Systems document, Emergency Response Plan template, and Vulnerability Self-Assessment Tool.

Timely and effective response to contamination requires early detection so that drinking water system operators can implement response plans and take steps to protect public health. Water Quality Surveillance and Response Systems use real time measurements and information from the public to monitor for potential contamination. After piloting the program in five major metropolitan areas, the EPA has developed resources to help communities across the country implement their own Water Quality Surveillance and Response Systems. Following detection, laboratory analysis is necessary to confirm the type of contaminant and the amount present. To address this need, the EPA established the Water Laboratory Alliance, a nationwide network of laboratories operating at all levels of government, to quickly support sampling and analysis in response to a suspected contamination incident.

By providing drinking water systems with tools to detect incidents sooner, identify contaminants quicker, and prepare for an effective response, the EPA is enhancing national biodefense capacity by protecting our drinking water from source to tap.

**Goal 2: The Antimicrobial Resistance (AMR) Challenge**

Since their discovery nearly a century ago, antibiotics have transformed the world, increasing life expectancy and helping to heal serious infections. However, we are now standing on a precipice that could return us to a pre-antibiotic world. Without aggressive action, AMR could limit or possibly reverse our global progress in healthcare, food production, and life expectancy.

In 2018, CDC spearheaded the AMR Challenge, one of the most ambitious global initiatives to date to protect people, animals, and the environment from the growing threat of antibiotic resistance.

> "Antibiotic resistance will never stop, so we can’t either. The success of the AMR Challenge shows that despite the deadly global threat of antibiotic resistance, public health action and global coordination across every country and industry can keep us a step ahead, even when antibiotics cannot."
> **Alex M. Azar II, Secretary, U.S. Department of Health and Human Services**

Given that the AMR threat is multi-sectoral, transboundary, and expanding, it is critical that the United States continues to lead the fight against it and build on the success of the AMR Challenge to combat AMR domestically and abroad.
Goal 2: Discovery of a New Ebola Species

As part of a project funded by the United States Agency for International Development (USAID) and HHS’s National Institutes of Health (NIH), a new Ebola species, the Bombali ebolavirus, was discovered in healthy bats roosting in people’s homes. The presence of the virus, announced by the Government of Sierra Leone on July 25, 2018, represents the sixth species within the Ebola family and is the first Ebola species discovered before an outbreak in humans.

While no direct evidence exists at this time to suggest the new virus has ever infected humans or livestock, USAID partners have developed communications materials to help communities in Sierra Leone proactively reduce their risk of exposure to Ebola and other viruses originating in bats and other animals. Additionally, for the first time in West Africa, CDC discovered Marburg virus in cave-dwelling bats from multiple sites in Sierra Leone. These discoveries will help Sierra Leone and neighboring countries (1) update their diagnostics to ensure they can detect all Ebola and Marburg viruses, (2) set up early warning human and livestock surveillance, and (3) develop communication materials to help reduce people’s risk of exposure.

Advancing Biodefense Enterprise Preparedness: Goal 3 Biodefense Highlights
Goal 3: MCMs to Combat Influenza

In addition to seasonal influenza, which causes 290,000-650,000 deaths worldwide annually, influenza viruses with pandemic potential are of global concern. Pandemic strains of influenza emerge unpredictably and can cause even more extensive morbidity and mortality than seasonal strains. Influenza vaccines limit morbidity and mortality; however, changes in circulating viruses require that vaccines be formulated and administered annually, and do not convey protection against emerging subtypes. On September 19, 2019, the White House issued Executive Order 13887 on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. HHS—through efforts across Biomedical Advanced Research and Development Authority (BARDA), a component of ASPR; CDC; NIH; and the Food and Drug Administration (FDA)—has prioritized the development of rapidly available influenza vaccines that offer greater protection. This work is complex and requires cutting-edge science and an iterative, multi-year interagency process.

For example, the National Institute of Allergy and Infectious Diseases (NIAID), which is a component of NIH, leads HHS’s work in developing a universal influenza vaccine that would eventually protect against all influenza viruses and launched the first clinical trial of a universal vaccine candidate. CDC’s systems provide the scientific basis for vaccine virus selection for each year’s seasonal influenza vaccine, as well as for pandemic influenza vaccine stockpiling.

In addition to vaccines, antiviral drugs are available for prophylaxis and treatment of influenza infection. The federal government supports research on anti-influenza therapies to reduce the human costs of seasonal influenza epidemics, to mitigate potential influenza pandemics before vaccines can be developed and made available, and to increase the public’s access to antiviral drugs.

To safeguard people in America from seasonal and pandemic influenza, HHS agencies have made progress in influenza treatment and prevention:

- NIAID’s Vaccine Research Center launched the first human clinical trial for a universal influenza vaccine candidate.
- FDA approved the first new influenza therapeutic with a novel mechanism of action in more than 20 years.
- BARDA supported two clinical trials of an influenza drug, which found that it reduced or prevented viral shedding and transmission among household members.
- CDC, in partnership with private hospitals and pharmacies nationwide, launched the website MedFinder to help people find pharmacies that have antiviral drugs available making it easier to know where to go to get your prescription filled.
- NIAID launched the Collaborative Influenza Vaccine Innovation Centers, a new network of multi-disciplinary research teams that will work together in a coordinated, focused effort to develop next generation influenza vaccines.

Goal 3: Improving Emergency Public Health Capabilities — A State-Level Example

From 2016 through 2018, a large, multistate outbreak of hepatitis A swept the United States. Hepatitis A is a vaccine-preventable, contagious liver disease that is usually contracted by consuming contaminated food or water. By November 2018, Michigan alone had seen 907 cases, 728 hospitalizations, and 28 deaths.7

To combat this outbreak, health department staff funded by CDC’s Public Health Emergency Preparedness (PHEP) program worked with state communicable disease and immunization programs to decrease the amount of time to report new cases, conduct public health follow-up investigations, and provide public information. The immunization programs of local health
departments increased vaccination outreach and, as of November 2018, provided more than 250,000 doses of hepatitis A vaccine in areas affected by the outbreak. To prepare for and support these activities, Michigan uses PHEP funds for a community health emergency coordination center, which enables coordination of efforts among multiple program areas across the department. When an emergency occurs, the pre-established relationships between preparedness staff and experts who provide services to high-risk populations allow more rapid response to incidents.

All of these activities, made possible through years of building preparedness capacity and partnerships with program areas, have positive outcomes. Michigan, for example, has reported a consistent decline in the number of new cases each month since December 2017, demonstrating the utility of PHEP support across yet another response/public health event.

Goal 3: Preparedness to Protect U.S. Citizens in the Event of a Highly Pathogenic Infectious Disease (HPID) Outbreak

Led by the NSC staff, the Department of State (DOS), HHS, DHS, DOD, and the Department of Transportation coordinated the adoption of a Federal Aero-Medical Evacuation Notification protocol, identifying roles and responsibilities to coordinate evacuation of U.S. citizens and other specified individuals, who have been exposed to or infected by a HPID, to appropriate treatment facilities within the United States from both overseas and within the United States. The protocol addresses federal coordination with SLTT public health officials. In addition, DOS coordinates with DOD on acceptance of an upgraded Generation 2 Containerized Bio-Containment System to improve biosecurity and safety during the aeromedical evacuation of such patients and to mitigate the risk to responders from HPID outbreaks.

DOD has also performed the first in-human testing of the now FDA-licensed vaccine used in the Democratic Republic of the Congo (DRC) Ebola outbreaks, in which, as of 2019 more than 90,000 people have been vaccinated. DOD also performed significant numbers of pre-clinical/animal studies with Ebola virus to evaluate trial samples for this vaccine across the globe. Additionally, DOD implemented its Agile Medical Paradigm strategic framework to optimize MCM delivery by including policy and technology-based solutions to address the root causes of MCM development inefficiencies, as well as indicators for assessing solution execution progress.

Overall, DOD’s investment and broad portfolio in global health and infectious disease research, including contributions to combating AMR, provided foundational information, infrastructure, and subject matter expert and partnership networks to rapidly respond to unanticipated biothreats and protect Americans from the dangers that these biothreats pose.

Goal 3: Improving Preparedness, Response, and Recovery to Lessen the Impacts of Bioincidents in the Underground Transportation System (UTR)

The EPA has a primary role in providing emergency response for natural, accidental, and intentional incidents. For certain bioincidents, EPA assists in determining the extent of contamination and risk-based cleanup levels, decontamination, and waste management, as seen following the attacks on 9/11.
One week after the 9/11 terrorist attacks, letters containing *Bacillus anthracis* spores, the bacterium that causes anthrax, were mailed to various locations throughout the United States. Response to the incidents and the resulting cleanup required cross-government efforts and illustrated a critical need for improved methods to lessen the impact of future bioterrorism incidents. If a bioincident occurred in a transportation hub, like a subway system, it would require fast and effective remediation to return to normal operations. To address this critical need, EPA’s Chemical, Biological, Radiological, and Nuclear Consequence Management Advisory Division and Homeland Security Research Program collaborated with DHS on the UTR project, which involved multiple federal agencies and national laboratories.\(^8\), \(^9\), \(^10\)

The EPA led several lab-based studies to address capability gaps in sampling, decontamination, and waste management capabilities. This project culminated in the Operational Technology Demonstration conducted in a mock subway station and tunnel at the U.S. Army Fort A.P. Hill’s Asymmetric Warfare Training Center, which identified specific tools and tactics that would be essential for first responders and other national agencies if a subway system were contaminated and a response was required. Knowledge gained from the research and demonstrations enhance EPA’s ability to assist EPA Regional On-scene Coordinators and SLTT decision makers in the preparation for and recovery from a bioterrorism incident. Decision support tools and methodologies created from this UTR project help improve the nation’s preparedness and capability to respond to a biological incident over a wide area.
An infectious disease threat somewhere could be an infectious disease threat anywhere. The USG continually works to develop new and improved measures to protect the public from serious infectious diseases, to accelerate the end of outbreaks at home or abroad, and to reduce deaths and suffering among those infected. The Ebola virus has been a particular concern due to two large, recent outbreaks that threatened to spread well beyond the initially affected areas. The mortality rate during the 2014-2016 outbreak in the West African countries of Liberia, Guinea, and Sierra Leone was 40 percent, and the second outbreak, which began in August 2018 in northeastern DRC, currently has a 66 percent mortality rate. To reduce morbidity and mortality rates and stop the spread of Ebola, the USG has funded and led vital clinical research. Such research has advanced the development of diagnostics, vaccines, and therapeutics to identify, prevent, and treat the disease.

During the current outbreak, NIH and the DRC National Institute of Biomedical Research led a consortium coordinated by the World Health Organization (WHO) to conduct an Ebola therapeutics trial comparing a previously tested therapeutics candidate, ZMapp, to three other candidates. Through this clinical research response, two experimental treatment products known as monoclonal antibody 114 (mAb114) and Regeneron Ebola therapeutic (REGN-EB3), were found to reduce the risk of death from Ebola.
Healthcare-associated transmission of Ebola and healthcare worker infection is also a significant factor in the DRC outbreak. In 2019, CDC collaborated with the WHO and the DRC Ministry of Health to develop and initiate a new infection prevention and control (IPC) training program for a cadre of “IPC supervisors” responsible for training healthcare workers to recognize and prioritize risk at a healthcare facility and determining how to effectively address the IPC gaps that they identify. CDC’s IPC protocols and trainings have reached 1,300 healthcare facilities in the DRC. After the identification of a cluster of Ebola cases in Uganda in 2019, CDC successfully instituted further training to cover 117 additional healthcare facilities in Uganda. No additional cases were reported in Uganda beyond the initial cluster of cases, preventing further spread of the outbreak.

To safeguard people in America and around the globe from Ebola, HHS agencies have made significant progress in diagnostics, treatment, and prevention of Ebola:

- The FDA licensed an Ebola vaccine (the Merck ERVEBO vaccine), which has been widely used to vaccinate individuals in the DRC.
- NIAID scientists and scientists in the DRC, with support from BARDA, developed the Ebola therapy known as mAb114.
- BARDA has also supported the development of REGN-EB3, as well as ZMapp that was also supported by DOD and NIH; NIH, and partners, also evaluated ZMapp through clinical trials.
- The Pamoja Tulinde Maisha (PALM) study revealed the importance of timely Ebola treatment. Therapies are most effective if received within a day after the first signs of illness, resulting in an 81 percent survival rate, compared to a 53 percent survival rate among those who started therapy five days after onset of their first symptoms.
- NIAID and BARDA are supporting the ongoing production of the two leading therapeutics, mAb114 and REGN-EB3, for continued use in the DRC outbreak and to ensure there will be adequate reserve supply for the United States if needed.
- NIH has started a combination therapy study in non-human primates of two experimental Ebola therapies.
- NIAID’s Integrated Research Facility facilitated the development of rapid diagnostics to enable people with Ebola virus disease to be identified and treated early in the course of their disease.
- FDA allowed marketing of the first rapid diagnostic test for detecting Ebola virus antigens in 2019 and has authorized a number of other diagnostic tests for emergency use.
- CDC and ASPR provide technical expertise and resources to the National Ebola Training and Education Center and other Special Pathogen Treatment Centers to increase the capability of U.S. public health and healthcare systems to safely and effectively manage suspected and confirmed patients with emerging infectious diseases.

Goal 4: Plum Pox Eradication

Since 2000, several USDA components, including APHIS and the Agricultural Research Service, working with SLTT partners, and representatives from industry, academia, and communities, have eradicated plum pox from our country. Over the past several decades, plum pox virus—known around the world by its Slavic name, shanka—had spread through several U.S. states and threatened all species of stone fruits. Plant diseases, such as plum pox virus, while not a direct risk to human or animal health, pose significant risk to U.S. agricultural interests and the economy at large. The impacts of a quickly spreading plant disease can have devastating and wide-reaching effects, threatening livelihoods and trade, and creating product shortages for U.S. consumers.

Figure 10: Peach with plum pox virus
Eradication of plum pox required collecting and testing plant samples, removing diseased and suspect trees, using plum pox virus-tolerant plants, and temporarily banning the planting of susceptible stone fruit varieties. By the end of 2018, APHIS and its collaborators had completed three consecutive years of stone fruit field surveys in eastern New York—the last remaining quarantined area in the United States.

After two decades of work, APHIS announced in October 2019 that plum pox had officially been eradicated from our nation. To ensure that we remain free of the disease, APHIS has put in place safeguards, including ongoing monitoring for the disease in stone fruit-producing states, science-based import regulations to prevent the disease’s reentry via nursery stock and propagative material, and continued cooperation with Canada to help prevent plum pox virus incursions from that country. APHIS’s past and continued work to identify and quickly respond to any incursion of disease helps to safeguard a $6 billion industry.

Advancing Biodefense Enterprise Recovery: Goal 5 Biodefense Highlights

Goal 5: Central Veterinary Laboratories (CVLs) Diagnostic Capability Restoration in West Africa

In 2018, USAID funded the United Nations Food and Agriculture Organization (FAO) to renovate the CVLs in Sierra Leone, Liberia, and Guinea. These laboratories provide animal diagnostic services and had been abandoned due to in-country unrest and economic decline. In collaboration with their Ministries of Agriculture, USAID and FAO refurbished the facilities to ensure animal disease testing could be conducted securely and effectively. Skills acquired through USAID-provided trainings for the staff of these laboratories enable them to detect and respond to zoonotic disease threats (diseases that are transmitted from animals to humans).

As these CVLs serve as the government’s only diagnostic veterinary laboratories in-country, they are essential to reviving the animal health sector and to protecting people from zoonotic diseases. These CVLs will diagnose diseases such as rabies, anthrax, avian influenza, and brucellosis, which all have the potential to not only cause illness in humans but also greatly impact the economy through the loss of infected livestock. This international capacity-building activity will increase partner countries’ capabilities for timely detection and diagnosis of dangerous pathogens, which in turn will lessen the chances of these dangerous pathogens entering U.S. borders.
Goal 5: Bioincident Recovery Stakeholder Engagement and Guidance Development

Coordinating recovery support and long-term mitigation activities across all levels of government—as well as international, non-governmental, and private sector partners—drives effective and efficient recovery operations and promotes resilience within communities affected by disasters. To that end, during FY 2019, ASPR hosted a national recovery summit and a series of workshops across the country with the focus on post-bioincident recovery. ASPR’s Division of Recovery used information gathered during the summit and the workshops, along with available publications, to develop national bioincident recovery guidance to advance national, state, and community-based planning for recovery from bioincidents.

The national summit, hosted on October 26, 2018, framed national-level issues and engaged stakeholders from all levels of government and partners outside of the government. The stakeholders identified two primary challenges to recovering from a bioincident: the lack of an intergovernmental standardized framework or organizing structure for bioincident recovery and the difficulty in prioritizing recovery resources to target the greatest areas of impact and need due to the complexity of bioincidents. The national summit also identified two best practices for bioincident recovery: ensuring inclusiveness of a broad array of stakeholders from across the community, and developing guidance for local decision makers, particularly for institutions that will play a major role following a bioincident, to improve coordination during recovery. The national summit also provided a framework for the design of five regional workshops on bioincident recovery.

By engaging more than 200 stakeholders on recovery best practices, needs, considerations, and lessons learned, the regional workshops demonstrated successful collaboration with SLTT public health professionals, non-government partners, and other entities in the private sector.

BIODEFENSE PRIORITIES

Nearly all federal departments and agencies contribute to the biodefense mission of the U.S. government to effectively prevent, prepare for, detect, respond to, and recover from biological threats to human, animal, plant, and environmental health. NSPM-14 directs those departments and agencies, in coordination with the Assistant to the President for National Security Affairs, to prepare joint policy guidance (Guidance) on priority areas of biodefense. The Guidance shall be informed by the assessment, and considered by departments and agencies when they develop their annual budget requests. The 2019 Biodefense Assessment provided a foundational analysis of ongoing programs and identified priority areas. The overarching USG biodefense priority is to increase the USG biodefense enterprise capability and capacity. This includes initiatives planned, programmed, or being executed by departments and agencies that specifically:

- Strengthen biosurveillance;
• Improve USG knowledge and data management;
• Advance MCM development and effective use; and
• Strengthen global capacities for health security and countering biological weapons.

Our nation faces diverse and rapidly evolving biological threats. The evolving biological threat landscape compels us to assess risks to the biodefense enterprise and prioritize actions in a strategic and comprehensive manner. Further improvements must be made to effectively prepare for and respond to bioincidents.

STAKEHOLDER ENGAGEMENT

SLTT, non-federal, and non-governmental preparedness and capacity-building are also vital elements of a robust biodefense enterprise. To support ongoing collaboration, the NBS and NSPM-14 include a mandate to reach beyond the federal government to engage with SLTT, non-federal, and non-governmental stakeholders. Input from stakeholders is critical to building and maintaining a biodefense enterprise capable of protecting the American people from the wide-ranging threats the nation faces today. To that end, the BSC and BCT held a public engagement meeting on April 17, 2019, solicited feedback and perspectives of stakeholders in response to a Federal Register Notice (FRN), and conducted targeted outreach. 16

The April 17, 2019, Summit for the Implementation of the NBS (the Summit) was held at the National Academy of Sciences in Washington, D.C. Those who attended the event in person were able to engage with panelists after each presentation to further the conversation, to pose questions, and to gain clarification on the topics, goals, and objectives discussed. Individuals also participated by webinar. During the Summit, participants were asked to address questions specifically related to the goals of the NBS. Questions focused on significant gaps or challenges, either at the national level or within the private sector, the highest priority actions addressing the goals, new initiatives planned by various sectors that would contribute to filling gaps in risk awareness, and proposed initiatives that would be most effective in enhancing biodefense-related decision-making by leaders.

In addition to convening a public meeting, the federal government announced the Call for Public Comments: NBS Implementation. Commenters were asked to submit responses to questions that were also based entirely on the five NBS goals and objectives. Commenters submitted their responses via email to ASPRBI0@hhs.gov. The comment period opened on April 2, 2019, and closed on May 1, 2019. Information about stakeholder engagement on biodefense, including the meeting summary of the Summit and the summary of written comments are available at www.phe.gov/biodefense. Suggestions offered at the public engagement meeting and through the FRN served as a foundation for discussion and development of stakeholder inclusive efforts, were considered in the internal deliberations of the BCT, and informed the assessment.

Engaging the public is vital given the critical importance of biodefense to the protection of the American people. The BSC and BCT recognize that extensive public consultation is also crucial for implementing measures to enhance the existing framework for biodefense and for ensuring the measures are appropriate, practical, and acceptable. Continued strengthening of biodefense will require informed and sustained action on the part of the federal government, SLTT, non-federal, and non-governmental stakeholders. The BCT will continue to engage multi-sectoral stakeholders to enhance U.S. biodefense.
CONCLUSIONS

The NBS sets the course for the United States to combat the real and serious 21st century biothreats to our country, as evidenced by the ongoing COVID-19 pandemic. The biothreats we face continue to grow and evolve. To safeguard our nation, implementation of the Strategy must be brought to bear quickly and effectively. The 2019 Biodefense Assessment provided a foundational analysis of ongoing programs and identified priority areas. The federal agencies with roles and responsibilities pertaining to biodefense continue to take actions to help meet the goals and objectives of the Strategy to reduce the risk of biological threats to the American people and preserve our national and economic security. All levels of government, including non-federal and international partners, are needed to prevent, prepare for, respond to, and recover from bioincidents, thus improving our nation’s biodefense enterprise. Action is needed to continue implementation of the Strategy and address priority areas to better prepare the nation and protect the public health, agriculture, the environment, and other sectors against biological threats.
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<tr>
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CITATIONS

1. Total Decontamination Cost of the Anthrax Letter Attacks; Schmitt K; Zacchia, N.A., February 2012; https://pdfs.semanticscholar.org/16fe/ca9d8ec07e34bf146153e8052b28c2d5d0e2.pdf.


4. CDC Import Permit Program; Centers for Disease Control and Prevention; December 2019; https://www.cdc.gov/cpr/ipp/index.htm.


