# HOMELAND BIODEFENSE
# SCIENCE AND TECHNOLOGY CAPABILITY REVIEW

PRODUCT OF THE

Biological Defense Research and Development Subcommittee

OF THE Committee on Homeland and National Security

OF THE NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

December 2016

EXECUTIVE OFFICE OF THE PRESIDENT
**NATIONAL SCIENCE AND TECHNOLOGY COUNCIL**
WASHINGTON, D.C. 20502

Dear Colleagues:

The United States has developed considerable biodefense capability through investments that have expanded the Nation's biomedical research infrastructure, fostered international research relationships, and established a medical, public health, and agricultural infrastructure that would be called upon to respond to a bioterrorism attack. These capabilities provide a critical foundation on which to build improved and comprehensive biodefense capabilities.

Recognizing these accomplishments, the White House Office of Science and Technology Policy (OSTP), through the National Science and Technology Council (NSTC), led an interagency effort to identify key science and technology (S&T) needs impeding the ability to counter or respond to the intentional use of biological agents to cause harm to human or animal health in the United States. To produce this report, the Biological Defense Research and Development (BDRD) Subcommittee of the National Science and Technology Council's Committee on Homeland and National Security conducted a comprehensive evaluation of the Nation's biological defense capabilities, identified homeland biodefense science and technology needs, and prioritized them in a two-day session in October 2015. The most important needs are presented in this report. This work sets the stage for subsequent activity by the BDRD, in which Federal departments and agencies will review these needs and formulate actions that should be taken to address them.

Sincerely,

December 19, 2016

Gerald L. Epstein

Chair, Biological Defense Research and Development Subcommittee
Assistant Director for Biosecurity and Emerging Technologies

White House Office of Science and Technology Policy

## About the National Science and Technology Council

The National Science and Technology Council (NSTC) is the principal means by which the Executive Branch coordinates science and technology policy across the diverse entities that make up the Federal research and development (R&D) enterprise. One of the NSTC's primary objectives is establishing clear national goals for Federal science and technology investments. The NSTC prepares R&D packages aimed at accomplishing multiple national goals. The NSTC's work is organized under five committees: Environment, Natural Resources, and Sustainability; Homeland and National Security; Science, Technology, Engineering, and Mathematics (STEM) Education; Science; and Technology. Each of these committees oversees subcommittees and working groups that are focused on different aspects of science and technology. More information is available at www.whitehouse.gov/ostp/nstc.

## About the Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976. OSTP's responsibilities include advising the President in policy formulation and budget development on questions in which science and technology are important elements; articulating the President's science and technology policy and programs; and fostering strong partnerships among Federal, state, and local governments, and the scientific communities in industry and academia. The Director of OSTP also serves as Assistant to the President for Science and Technology and manages the NSTC. More information is available at www.whitehouse.gov/ostp.

## About the Biological Defense Research and Development Subcommittee (BDRD)

The purpose of the BDRD is to provide all relevant Federal agencies a focused forum for coordinating and collaborating on defensive research, development, testing, and evaluation (RDT&E) addressing biological threats to national security, including known biological threat (bacteria/viruses/fungi/toxins) and emerging infectious disease agents that have the potential to significantly affect the environment, plants, animals, and humans both within the United States and throughout the globe. These efforts will provide the United States Government with an improved capability to predict, detect, warn, diagnose, project impact, respond, recover, and attribute causative biological agents due to natural incidents, accidental release, or a deliberate attack. In addition, the BDRD coordinates biosecurity outreach and biosafety activities across the Federal government.

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# Introduction

Biological weapons attacks could be mounted either inside or outside the United States and the effects of an initial attack could spread widely – whether because a contagious agent was used, because travelers exposed in one location may fall ill elsewhere, or because those in other locations will be concerned about being the next target. Disease outbreaks, whether natural or deliberate, respect no geographic or political borders. Preventing and controlling biological weapons threats is extremely challenging. Advances in biotechnology and the life sciences present the prospect of new toxins, live agents, and bioregulators that would require new detection methods, preventive measures, and treatments. These trends increase the risk for surprise. Anticipating such threats through intelligence efforts is made more difficult by the dual-use nature of biological technologies and infrastructure, meaning that the same science and technology base necessary for legitimate scientific, economic, and health applications can also be used for harm. Furthermore, adversaries may use denial and deception to conceal their illicit activities or at least not publicly reveal an attack has taken place until casualties are apparent.

Deliberate attacks on the homeland with biological weapons could:

- Cause acute casualty numbers in excess of local clinical capacities, long-term disease and disability, psychological trauma, and mass panic;
- Disrupt critical sectors of our economy and the day-to-day lives of Americans; and
- Create cascading international effects by disrupting and damaging international trade relationships, potentially globalizing the impacts of an attack on United States soil.

Fortunately, the United States has developed considerable biodefense capability through investments that have expanded the Nation's biomedical research infrastructure, fostered international research relationships, and established a medical, public health, and agricultural infrastructure that would be called upon to respond to a bioterrorism attack. These capabilities provide a critical foundation on which to build improved and comprehensive biodefense capabilities.

Since the development of the Nation's biodefense strategy, *Homeland Security Presidential Directive 10 (HSPD-10), National Policy for Biodefense,* the United States has aggressively pursued a broad range of programs and capabilities to confront the biological weapons threat.[1] Among significant accomplishments, the United States has:

- Increased funding for research within the Department of Health and Human Services, including at both the Assistant Secretary for Preparedness and Response's Biomedical

[1] Other Presidential Directives governing aspects of U.S. biodefense strategy include HSPD-9, *Defense of United States Food and Agriculture;* HSPD-18, *Medical Countermeasures against Weapons of Mass Destruction;* HSPD-21, *Public Health and Medical Preparedness;* and Presidential Policy Directive (PPD)-2, *National Strategy for Countering Biological Threats*.

Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH), to prevent, detect, and mitigate bioterrorism;

- Initiated new programs to secure and defend our agriculture and food systems against biological contamination, including the approval and start of construction of the National Bio and Agro-Defense Facility (NBAF);
- Expanded the Strategic National Stockpile of medicines for treating disease victims, operated by the Centers for Disease Control and Prevention (CDC), including ensuring that the stockpile's push packages can be anywhere in the United States within 12 hours of a confirmed biological attack;
- Provided Federal funds to improve the capacities of state and local health systems to detect, diagnose, prevent, and respond to disease outbreaks;
- Worked with the international community to strengthen global, regional and national programs to prevent, detect, and respond to biological weapons attacks, including the development of Presidential Policy Directive 2, Countering Biological Threats; and
- Demonstrated significant improvement in remediation capabilities, including successful demonstration of the remediation of a facility by the Environmental Protection Agency (EPA) and the Department of Homeland Security (DHS).

Recognizing these accomplishments, the White House Office of Science and Technology Policy (OSTP), through the National Science and Technology Council (NSTC), led an interagency effort to identify key science and technology (S&T) needs impeding the ability to counter or respond to the intentional use of biological agents to cause harm to human or animal[2] health in the United States. In alignment with this tasking, OSTP leveraged the existing Biological Defense Research and Development (BDRD) Subcommittee under the NSTC Committee on Homeland and National Security to fulfill the identification and prioritization of key homeland biodefense science and technology needs. (Deficiencies in international biodefense capabilities are also relevant to U.S. biodefense, but they were not evaluated in this study.) The BDRD conducted a comprehensive evaluation of U.S. biological defense capabilities to identify future priorities and actions to support them, culminating in a two-day session in October 2015 in which identified needs were evaluated and prioritized, with the most important ones presented in this report.

The identification and prioritization of S&T issues sets the stage for a second phase of effort in which Federal Departments and Agencies propose actions that should be taken to address these needs. Accordingly, the Departments and Agencies relevant to each identified need are listed in this report. Given that the budgets of some Departments and Agencies have decreased in key biodefense areas since the agency roles and responsibilities were laid out in HSPD-10 in 2004, agencies may not be able to address all the needs outlined below. Therefore, the implementation plan to be developed in this second phase requires making an assessment of the baseline, how much progress can be realistically be achieved against each need and on

[2] Animals include domestic animals (both livestock and companion animals) and wildlife.

what timeframes, the importance of meeting each need compared to other potential areas of investment, and ultimately a determination of what needs will have to remain unmet, at least in the short run. Within these constraints, this implementation plan will provide a blueprint for a future U.S. biodefense program that fully integrates the sustained efforts of the national and homeland security, medical, public health, intelligence, defense and law enforcement communities.

## Process

The BDRD approached the first phase of this process – the phase described in this report – in two stages. First, it identified homeland biodefense S&T needs; second, it determined the relative priority in addressing them, along with the identification of relevant agencies that should be involved in addressing subsequent implementation issues. (Such a designation does not prejudge the outcome of these implementation discussions, and in particular it does not imply that any agencies so listed will ultimately devote budgetary resources towards meeting that need. In addition, some needs were identified that lie in between areas of established agency responsibility, and for which it is not now clear which agency bears primary responsibility. The relevant agencies for these needs are therefore designated as "to be determined.")

These two stages were conducted as follows:

- Stage I: The goal of this activity was to identify S&T needs articulated by Federal subject matter experts including both science program managers and agency officials in charge of operational programs, to elicit feedback on where additional S&T investments could address operational needs. These officials were asked to provide descriptions of S&T needs and thematic categories characterizing the needs. The organization and structure of the needs and need areas were determined by working groups aligned to the pillars of the extant national biodefense strategy, HSPD-10: Threat Awareness; Prevention and Protection; Surveillance and Detection; and Response and Recovery.
- Stage II: The goal of this activity was to provide coordinated interagency feedback on which needs represent the highest priority to the interagency working group, and to identify which Department or Agency should recommend or coordinate on actions to respond to each of those priority needs. Candidate needs that had been compiled by individual working groups were circulated to a set of Department and agency officials who evaluated and ranked them and then met in person for a two-day session in October 2015 to develop overall interagency priorities. This report reflects the prioritizations developed during and immediately following that session.

Given the breadth of biological agents and toxins available which could be used to harm human or animal health, it was important for the BDRD to narrow the number of potential scenarios to use in identifying and prioritizing biodefense S&T needs. The BDRD used the following scenarios:

- Large-scale aerosolized anthrax attack
- Avian influenza outbreak of indeterminate (but possibly deliberate) origin that has not (yet) spread to people
- A deliberate food-borne bioterrorist attack causing on the order of hundreds of deaths
- An attack causing on the order of hundreds of deaths with a non-anthrax agent of unknown environmental stability (i.e., one that might end up persistent in the environment)
- An attack with an unknown lethal virus for which there are no assays or countermeasures

Note: The needs specified in this document are intended to inform the policy development process and are not intended to reflect budget priorities. The commitment of Federal resources to address these needs will be determined through the annual budget process.

## Threat Awareness

RISK ASSESSMENT

**NEED 1: Improved ability is needed to systematically assess how much risk has been mitigated by biodefense investments.**

The United States requires a periodic net assessment that evaluates progress in implementing HSPD-10 and other biodefense policies, including identifying continuing needs or vulnerabilities in the U.S. biodefense posture, and making recommendations for re-balancing and refining investments among biodefense activities.

RELEVANT AGENCIES: DHS, in coordination with other appropriate Federal departments and agencies

**NEED 2: Improved ability is needed to determine the relative risk of biological events across the full range of potential deliberate attacks against the homeland (e.g., State and non-State, traditional, enhanced, emerging, advanced etc.).**

A critical element of the U.S. biodefense capability is the development of periodic assessments of the evolving biological weapons threat. The United States requires a continuous, formal process for conducting routine risk assessments to guide prioritization of on-going investments in biodefense-related research, development, planning, and preparedness.

RELEVANT AGENCIES: DHS, in coordination with the Office of the Director for National Intelligence (ODNI) and other appropriate Federal departments and agencies

**NEED 3: Improved modeling of the food chain supply system is needed to support prevention strategies and to enable real-time analysis in the event of a credible terrorist claim**.

Globalization and expansive food distribution demands continue to introduce vulnerabilities into the food chain supply system. The United States needs to expand its existing modeling and risk assessment activities to more fully understand the food production and distribution systems that may be vulnerable to intentional adulteration. Building on the work of the DHS Terrorism Risk Assessments, DHS investment in research and technology that provides the ability to better understand supply chain disruptions to the food system, and Health and Human Services (HHS) Food and Drug Administration (FDA)/U.S. Department of Agriculture (USDA) product vulnerability assessments, an enhanced capability to identify vulnerabilities and risks in the agriculture and food systems would enable the identification of opportunities to strengthen weak points in the distribution system in advance of an attack and enable real-time analysis in the event of a terrorist attack (either real or credibly claimed following a foodborne illness outbreak).

RELEVANT AGENCIES: To be determined

<u>BIOLOGICAL THREAT CHARACTERIZATION RESEARCH</u>

**NEED 4: Additional understanding is needed of bioattack consequences for companion animals and wildlife that could complicate response.**

History has demonstrated the understandable importance of considering pets and companion animals during an emergency response requiring human health interventions; many people will not take actions during time of crisis if no accommodation for pets or companion animals is available. Additionally, pets and companion animals may serve as vectors for transmission of a disease or pathogen. For top priority biodefense pathogens such as *Bacillus anthracis* (the causative agent for anthrax), much progress has been made in understanding the natural history of disease in humans and some food production animals; however, understanding disease in pets and companion animals is not well-documented. Furthermore, wildlife species can serve as hosts/reservoirs for diseases that affect people and agricultural animals, and more research is needed to understand the role that wildlife would play in the evolution of, and in complicating the response to, a biological incident.

RELEVANT AGENCIES: To be determined

**NEED 5: Better understanding of the fate and transport of bio-agents in various environments (including food matrices and water infrastructure) is required.**

Biological agent stability in the environment following release has direct bearing on the magnitude of the risk posed to the human and animal population. Research on this topic has been conducted to inform DHS risk assessment modeling efforts such as the Biological Terrorism Risk Assessment, a comprehensive, probabilistic risk assessment that integrates the judgments of the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. However, additional research should be conducted to look, for instance, at additional types of food/agent combinations. A biological agent that is stable (i.e., viable and virulent) for only a short period of time in the environment following release significantly diminishes the need for development and deployment of long-term health interventions such as evacuation from the site of biological agent release, vaccination of those individuals or animals who remain in the contaminated environment, or a total decontamination of that environment. Assessments conducted to date have primarily focused on agents suspected of having long term stability; however, the environmental stability of the range of biological agents or toxins that could be used to cause harm to human, plant and/or animal health has not been fully explored.

RELEVANT AGENCIES: DHS, in coordination with the Environmental Protection Agency, HHS, Department of Defense (DoD), USDA, and the Department of the Interior (DOI)

**NEED 6: Additional scientific understanding of avian influenza virology is critically needed to support development of therapeutic and vaccine interventions.[3]**

Avian influenza continues to represent significant risk to the health of both human and avian populations. Understanding the underlying genetic changes that correlate with pathogenicity, virulence, and transmissibility, as well as the host response to infection are key factors to enhancing medical countermeasure development. There is also a need to understand why some animals are resistant to influenza viruses and others are highly susceptible. The likely genetic basis for this resistance could be identified and applied where possible to reduce the risk of influenza virus outbreaks in animals and prevent subsequent spill-over in, or deliberate use against, humans.

[3] Additional scientific understanding will also support prediction and forecasting of naturally occurring avian influenza outbreaks, but that mission is outside the scope of this biodefense analysis.

RELEVANT AGENCIES: HHS in coordination with USDA and DOI

## Prevention and Protection

**In the two-day October 2015 prioritization session, S&T needs for Prevention and Protection were not prioritized as highly as the other needs described in this document.**

## Surveillance and Detection

**NEED 7: Insufficient ability exists to connect state and local biosurveillance information to the Federal government in a timely manner that would allow for detection of a bioattack, and that would support evidence-based decision-making during response and recovery from a biological event.**

Since the launch of the President's Biosurveillance Program Initiative in 2005, the United States has been working to develop an integrated and comprehensive attack warning system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment. As it was originally proposed and subsequently reaffirmed in various directives and strategies since 2005, including the National Biosurveillance Strategy in 2012, the ingestion of state and local information into a national biosurveillance system would permit the recognition of a biological attack relatively early following the event and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption. Such a system would necessarily be built upon and reinforce existing Federal, state, local, and international surveillance systems, while also likely drawing on sources of information such as social media that were not prominent in 2005.

RELEVANT AGENCIES: HHS, DHS, USDA, DoD, DOI, and other appropriate departments/agencies

**NEED 8: Insufficient options and architectures exist for indoor environmental detection that provides information useful to facility operators (e.g., train stations, airports) before clinical cases appear.**

Detecting the aerosol release of pathogens within indoor targets may be particularly challenging simply due to the large number of potential facilities that could be attacked. While the government has invested in a network of outdoor environmental detectors, a parallel Research and Development R&D effort optimized for indoor detectors and an appropriately aligned investment strategy have not yet been established, nor have sufficient technical requirements specific to indoor detection been developed.

RELEVANT AGENCIES: DHS, in coordination with DOT, GSA, HHS, EPA, and other relevant Federal departments and agencies

## Response and Recovery

EVENT CHARACTERIZATION

**NEED 9: Increased ability is needed to address massive demand for environmental surveillance, sampling, and detection assets in the aftermath of an attack.**

Following suspected or confirmed release of a biological agent, the demand for surveillance and detection capabilities to delimit the area of impact will be extensive. Sampling the environment is one of the most critical front-end activities for an effective and timely response to any bioterrorism or biohazard incident, yet the current methods to sample and subsequently analyze environmental samples remain cumbersome and resource intensive. Additionally, the recovery rates and limits of detection from current methods need improving to better inform health-protective decisions on re-occupation and re-use of facilities. Currently, surge capacity for environmental surveillance following biological agent detection is addressed using increased rates of air sampling and BioWatch filter testing, air, soil and surface sampling, and increased syndromic and diagnostic testing on individuals who may have been exposed to the biological agent upon first release or subsequent re-aerosolization. While this approach could be implemented effectively in one geographic location following biological agent release, two or more locations needing similar event characterization will exceed current biosurveillance and detection capacities, including laboratory capacity to analyze these samples (see Need 11).

RELEVANT AGENCIES: DHS and EPA, in coordination with HHS, DoD, DOI, and USDA

**NEED 10: Improved ability is needed to characterize a biological event, including characteristics of the biological agent used, the area exposed, and the population at risk, rapidly enough for decision-maker timeframes and public reassurance needs and to inform real-time response and self-protection guidance.**

Following the identification and confirmation of an attack using a biological agent, decision-makers will be expected to provide guidance to the responding public health or animal health providers as well as to the public to support safety actions and to provide reassurance regarding response and recovery operations. Thus, the Federal government requires the capability to rapidly characterize the biological agent used in the attack, as well as characterizing the nature of the event. This requires, for example, understanding the stability

of the agent in the environment (i.e., indoor and outdoor surfaces, water, and food), whether or not the biological agent is sensitive to available antimicrobials and therapeutics, the most appropriate types of personal protective equipment; the area exposed, and the population at risk. One pressing challenge for event characterization is determining more precisely how rapidly different types of information must be made available, considering the need to provide actionable information to decision-makers and the public in the context of the necessary tradeoffs between urgency, comprehensiveness, and accuracy.

RELEVANT AGENCIES: DHS, HHS, DoD, DOI, USDA, the Department of Labor/Occupational Safety and Health Administration (OSHA), and EPA, in coordination with other relevant Federal departments and agencies

**NEED 11: Insufficient technical staff and lab infrastructure exists to surge for real-time crisis-research or lab processing needs in a post-attack environment, which would be a huge impediment to a successful response.**

As described in Need 10, the ability to rapidly characterize a biological agent following attack is critically important for informing response and recovery operations. Ensuring the availability of technical staff and lab infrastructure to surge for real-time crisis-research or lab processing needs in a post-attack environment is paramount. One mechanism to address laboratory capacity shortfalls is the Integrated Consortium of Laboratory Networks (ICLN), a homeland security infrastructure comprising a coordinated and interoperable system of federal laboratory networks that provides a venue to address resource limitations when emergencies overwhelm the lab testing resources of any one network. ICLN capabilities should be addressed when considering how to address this need. In addition, part of the necessary laboratory infrastructure concerns the ability of the labs to obtain samples from infected patients. Protocols are needed for reaching out to acute and convalescent patients as well as for sample collection that addresses all ethical issues, including gaining appropriate patient consent, so that needed samples to characterize a pathogen can rapidly be acquired.

RELEVANT AGENCIES: DHS, HHS, USDA, DoD, DOI, and EPA, in coordination with other relevant Federal departments and agencies

**NEED 12: Insufficient modeling exists of the actual hazards posed by spread of pathogens within infrastructures (subways, etc.), including potential loss of service of the affected infrastructures themselves, to inform preparedness and real-time response decisions.**

Should a biological agent be released directly into, or adjacent to, an indoor environment in which there is both high volume population movement and air exchange (e.g., underground subway systems, airport and train station terminals, food production and other animal facility enclosures, etc.), it will be critical to understand the spread of the contamination, including the spread from inside a facility to outside, to protect human or animal health and rapidly return the infrastructure to normal operations.

RELEVANT AGENCIES: DHS, HHS, EPA, DoD and USDA, in coordination with other relevant Federal departments and agencies

**NEED 13: Non-strain specific or prioritized ways to create environmental detection and threat characterization assays for the range of bioattack pathogen strains are needed.**

The U.S. government has developed a robust set of assays specifically targeting known strains of biological agents that could be used to cause harm to human, plant or animal health. However, the evolving nature of the biological threat and the potential of a wide variety of pathogens to be developed and used in a biological attack alongside the lengthy and costly assay development process, demand a different approach to future assay development.

RELEVANT AGENCIES: DHS, HHS, DoD, USDA, and EPA

RISK COMMUNICATION

**NEED 14: Insufficient ability exists to characterize and mitigate disproportionate public reactions, including fear and desire for inappropriate response.**

A critical enabling capability during response and recovery activities following a biological attack is effective risk communication. Timely communications with the general public and the medical and public health communities can significantly influence the success of response efforts, including health- and life-sustaining interventions and reduction of unnecessary economic damage. The U.S. Government should develop communication strategies, plans, products, and channels to reach all segments of our society, including those with physical or language limitations. These efforts will ensure timely domestic and international dissemination of information that educates and reassures the general public and relevant professional sectors before, during, and after an attack or other public health emergency. These efforts should also

take into account the possibility of incomplete or misleading information being propagated through social media, network news, or other channels, and seek to develop tools to promote the distribution of accurate information to the American public.

RELEVANT AGENCIES: DHS, in coordination with HHS and USDA, in addition to other appropriate Federal departments and agencies.

DIAGNOSTICS

**NEED 15: Insufficient ability exists to credibly and rapidly distinguish between exposed and non-exposed populations.**

Following confirmation that a biological agent was released in a manner that could cause harm to an indeterminate number of individuals, the U.S. Government will need a diagnostic mechanism to identify those who actually need prophylaxis, while calming unnecessary fears from those who have not been exposed. While the U.S. Government has supported the development of clinical diagnostics that can provide confirmation of disease from several of the most significant biological select agents and toxins , the inherent delays associated with performing bedside testing and limitations on expanded deployment of the diagnostics reduce their utility during a mass exposure setting. Furthermore, given the broad range of potential biological pathogens that could be used in an attack on the human population, single pathogen diagnostics are not optimal for a productive, long-term biodefense posture. Self-administered tests, to the extent that they are credible and technologically feasible, could be very helpful in reducing public angst and managing demand for medical countermeasures.

RELEVANT AGENCIES: HHS, DoD, and USDA.

MEDICAL COUNTERMEASURES

**NEED 16: Insufficient ability to produce and deploy a novel medical countermeasure (MCM) rapidly enough to protect the public from the health effects following an attack with a biological agent.**

Since the establishment in 2006 of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates Federal efforts to enhance preparedness for chemical, biological, radiological and nuclear threats and emerging infectious diseases from a medical MCM perspective, HHS and Federal government partners have made great strides in developing MCM for top priority biological threat agents. However, as evidenced by the Ebola outbreak in 2014, the ability of the U.S. Government to bring to licensure novel MCM during an emergency biological event (natural or manmade) is severely limited. Had the Ebola outbreak been initiated through an intentional act or should a terrorist choose to use a biological agent not currently prioritized for MCM development through the PHEMCE, the United States would not be in a position to develop and bring a novel MCM to Emergency Use Authorization (EUA) regulatory approval in the timelines needed to save lives. The U.S. Government should invest in pathogen/agent-independent therapeutics (i.e., broad-spectrum antimicrobials or MCM that act upon a common set of human physiologic mechanisms within the immune system), or the ability to produce and distribute a novel countermeasure in real-time.

RELEVANT AGENCIES: HHS and DoD

**NEED 17: Shelf-life limitations and cold-chain storage requirements significantly increase the overall cost of stockpiling many MCM developed exclusively for the low probability, high consequence nature of a biological attack.**

The U.S. Government has invested billions of dollars in the development, production, acquisition and storage of MCM with a limited shelf life and extensive cold-chain storage requirements for a small number of top priority biological agents that could be used in an attack. While this approach is critical for a small number of biological agents with known significant human mortality, it is not sustainable for a more expansive set of MCM needed to prevent illness and death from a broader range of biological agents. The U.S. Government should invest in MCM formulation strategies that make any MCM inert and therefore stable indefinitely until activated and needed for use. Until such indefinitely stable MCMs are available to meet all high priority needs, strategies and/or resources will be required to ensure the significant investments made in developing and acquiring the current MCM assets are not lost.

RELEVANT AGENCIES: HHS and DoD

**NEED 18: The United States does not directly produce or currently store in bulk the precursor ingredients for many key MCM, rendering the nation vulnerable to disruption of the supply**

**chain that would be necessary to produce additional quantities of those MCM following a biological attack**.

The current supply chain for many MCM that comprise the foundation of the U.S. biodefense response architecture is vulnerable to intentional interruption (e.g., by an attack on or contamination of key ports of entry) or to other disruptions (e.g., international travel advisories, labor stoppage, natural disasters) that could compromise the ability of the United States to respond and recover from biological attack.

RELEVANT AGENCIES: HHS, in consultation with DHS

**NEED 19: Improved availability of medical countermeasures is required to stop the spread and treat the effects of a biological attack on the animal population.**

Prevention of the harmful effects both to animal health and the economy are a key component of the nation's biodefense framework. Research and development of veterinary medical countermeasures for both known (e.g., anthrax and avian influenza) and unknown biological agents that can cause harm to animal health must be developed. There is a need to evaluate novel technologies that reduce the time required to produce a vaccine, to invest in the development of novel vaccine technologies to produce a broader or universal clinical protection, and the development of vaccine platforms that can be used in multiple animal species.

RELEVANT AGENCIES: To be determined

<u>MASS CASUALTY RESPONSE</u>

**NEED 20: Better tools and techniques are needed to train and enable the public health and medical workforce to provide necessary response capabilities following a biological attack.**

A well-trained public health and medical workforce is critical to ensuring the highest level of efficiency and effectiveness in protecting America's health. The workforce needed today and in the future must be able to solve multifactorial problems, use new technology, and work collaboratively across the public health and medical sectors. They will also have a need for continuing education and training. Investments to date in public health and medical infrastructure – workforce and technology – have been substantial; however, to ensure the

skills exist for naturally occurring outbreaks, both known and novel pathogens, and ultimately the high consequence events related to intentionally released agents, investments need to be maintained and expanded in some areas. The U.S. Government has developed tremendous resources for public health and clinical care capacity development, but these are not just-in-time systems. A major infusion into task-oriented training and development (e.g., to include simulation work) could benefit the everyday workforce and lead to more efficient and adaptable training that is just-in-time and keyed to the crisis at hand. Given that the USPHS Commissioned Corps can quickly deploy to meet a variety of training and other workforce needs to address this item, enhanced USPHS recruitment strategies can also contribute to addressing the stated needs.

RELEVANT AGENCY: HHS

**NEED 21: Insufficient understanding exists of how personal protective equipment (PPE) needs depend on the role that different responders play following the release of a biological agent (e.g., different PPE needs for clinicians taking care of sick patients vs. responders working in the environment contaminated with the biological agent), and insufficient mechanisms exist to develop better PPE (e.g., cooler, allowing for great dexterity and flexibility to wearers, etc.).**

The most efficient way to provide protection against biological agents is through barrier protection (i.e., the use of appropriate PPE) so that individuals are never exposed in the first place. Moreover, workers are exposed every day to pathogens and chemical agents, and enhanced PPE might reduce their risks as well. Development of new PPE requires a paradigm shift, as currently available PPE is cumbersome including multiple layers of in-hospital materials that are hard to get into and out of and require ongoing testing and training to ensure safe use. An infusion of resources could transform the PPE development field from improving the materials applied to the same methods of protection to innovative approaches to what and where the barriers are created.

RELEVANT AGENCIES: HHS, DoD, and the Department of Labor/OSHA, in coordination with other Federal departments and agencies

SITE MITIGATION AND DECONTAMINATION

**NEED 22: Development and testing of methods for mitigating the spread of contamination**.

After a wide area contamination incident, responders will need gross decontamination and other mitigation technologies in order to enable movement into and between contaminated zones. Such zones may include critical infrastructure that is essential to keep on-line or get back on-line. Mitigation technologies, such as methods for gross decontamination and inhibiting the spread of contamination, need to be developed and assessed.

RELEVANT AGENCIES: EPA, in coordination with other appropriate Federal departments and agencies

**NEED 23: Developing and assessing methods and strategies to improve decontamination capability and capacity for wide area releases of anthrax and other biological-agents or toxins that may persist in the environment.**

The ability to decontaminate an individual facility or wide area after a biological attack is a function of many factors (e.g., agent, surface type). Even where efficacious decontamination methods exist, the capacity needed for decontamination of a wide-area incident does not. In addition, most decontamination methods have not been tested against biological agents other than anthrax, which potentially results in the unnecessary use of harsh decontaminants that adversely impact materials such as sensitive equipment. Users of this equipment are also negatively affected. New decontamination methods that are widely available, user friendly, economical, and ideally have low human and environmental (natural and built) impact need to be identified, modified, and evaluated. Assessment of the methods should incorporate process variables that include diverse, realistic environmental and operating conditions for a variety of surfaces, including complex materials such as soil and dirty concrete.

RELEVANT AGENCIES: EPA, in coordination with HHS, DHS, USDA, DoD, and other appropriate Federal departments and agencies

**NEED 24: Better understanding is needed of the transport and fate of biological agents, and the need for development of decontamination and contaminated water management procedures for drinking water distribution systems and waste water collecting systems and treatment facilities.**

Contamination of drinking water can occur through the direct introduction of biological agents via numerous access points into the distribution infrastructure. This infrastructure, and water

flow patterns within it, are extremely complex and vary over time. Following a contamination event, real time hydraulic modeling and rapid characterization will be critical to be able to isolate certain segments of a distribution system and flush contaminated drinking water. Response efforts to mitigate and decontaminate wide area biological attacks will likely impact waste water collection infrastructure and treatment facilities. Although containment and treatment technologies exist, these activities will likely result in volumes of water that cannot be easily handled with existing capabilities. Development of mobile, rapidly deployed treatment systems would increase water treatment capability. Additional work is necessary to develop and test rapid field test -kits for characterization of contamination, decontamination procedures for drinking water distribution, waste water collection (including residential plumbing), and waste water treatment plants.

RELEVANT AGENCIES: EPA and HHS, in coordination with DOI and other appropriate Federal departments and agencies

WASTE MANAGEMENT

**NEED 25: Developing and assessing methods and strategies to improve waste management following a biological contamination event.**

Waste management following a biological contamination event, including disposal of animal carcasses, has been identified as a major impediment to a successful clean up and return to normalcy for an affected area. This is true for contamination of single buildings, a wide-area, critical infrastructure and/or a food or agriculture event. The issue of waste management was recently thrust into the center of the rather limited Ebola event in 2015. Insufficient scientific knowledge of biological agent fate and transport within various treatment and disposal options hinder rapid decision-making and complicate the response.

RELEVANT AGENCIES: EPA and USDA, in coordination with other appropriate Federal departments and agencies