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BIODEFENSE

The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance

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GAO Highlights

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April 2016

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The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance

Why GAO Did This Study

The nation's biodefense enterprise is the whole combination of systems at every level of government and the private sector that can contribute to protecting the nation and its citizens from potentially catastrophic effects of a biological event. It is composed of a complex collection of resources, programs, and initiatives, designed for different purposes and dedicated to mitigating various risks, both natural and intentional.

In an era of rapid transit and global trade, the public health and agricultural industries, as well as natural ecosystems including native plants and wildlife, face increased threats of naturally occurring outbreaks of infectious disease and accidental exposure to biological threats. Also, threats of bioterrorism, such as anthrax attacks, highlight the continued need for biosurveillance systems that provide early detection and warning about biological threats to humans.

This statement summarizes GAO's work on challenges to building and maintaining the nation's biodefense and biosurveillance. This statement is based on GAO work issued from December 2009 through March 2016 on various biodefense and biosurveillance efforts. GAO also reviewed the 2015 report of the Blue Ribbon Study Panel on Biodefense for updates, but has not independently assessed the entirety of the conclusions, recommendations or methods. To conduct the prior work, GAO reviewed relevant laws, presidential directives, policies, strategic plans, and other reports; surveyed states; and interviewed federal, state, and industry officials, among others.

View GAO-16-547T. For more information, contact Chris Currie at 404-679-1875 or curriec@gao.gov.

What GAO Found

The biodefense enterprise is fragmented and does not have strategic oversight to promote efficiency and accountability. Specifically, the biodefense enterprise lacks institutionalized leadership enterprise-wide to provide strategic oversight and coordination. In 2011, GAO reported, there are more than two dozen presidentially appointed individuals with biodefense responsibilities and numerous federal agencies with mission responsibilities for supporting biodefense activities, but no individual or entity with responsibility for overseeing the entire biodefense enterprise. In 2011, GAO reported that the Homeland Security Council (HSC) should consider establishing a focal point for federal biodefense coordination. In December 2014, National Security Council (NSC) staff, which supports the HSC, told GAO that two of its directorates work together as the focal point for federal biodefense efforts. This is an important step in promoting a comprehensive and coordinated approach to biodefense, but strategic leadership issues persist. In October 2015, a report by the Blue Ribbon Study Panel on Biodefense stated strategic leadership issues persist and called for a focal point to provide strategic leadership, noting that elevating authority above the agency-level can help overcome the challenges faced by the biodefense enterprise. The Study Panel found that White House councils and offices generally only become involved when a specific biodefense issue affects a prominent ongoing responsibility—a method which is not consistent with our call for a strategic approach.

In 2011, GAO also reported that while some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biodefense responsibilities that can be used to guide the systematic identification of risk; assess resources needed to address those risks; and prioritize and allocate investment across the entire biodefense enterprise. GAO reported that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a national strategy, to help ensure efficient, effective, and accountable results, and suggested the HSC take action. However, as of February 2016, such a strategy had not been developed.

Biosurveillance, an aspect of biodefense, also faces key challenges at all levels of government that transcend what any one agency can address on its own, and our more recent and ongoing work continues to highlight these challenges. In 2010, GAO recommended the HSC establish a focal point to lead the development of a national biosurveillance strategy that clarifies roles and responsibilities, provides goals and performance measures, and identifies resource and investment needs, among other elements. However, the recommendations have not been fully implemented. Since 2009 GAO's has also identified challenges with specific biosurveillance capabilities. Specifically, GAO has identified biosurveillance capability challenges with, among other topics, (1) state and local public heath capabilities, (2) animal health surveillance capabilities, and (3) two Department of Homeland Security biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the BioWatch Program (which aims to provide early indication of an aerosolized biological weapon attack). However, not all recommendations have been implemented.

Chairman Johnson, Ranking Member Carper, and Members of the Committee:

I am pleased to be here today to discuss our work on defending the nation against biological threats. Biodefense includes measures to prevent, detect, respond to, and recover from harm or damage caused by microorganisms or biological toxins to humans, animals, or the food supply. According to Homeland Security Presidential Directive 10 (HSPD-10), published in April 2004, successful implementation of the nation's biodefense enterprise requires optimizing critical cross-cutting functions such as information management and communications, research and development, and acquisition.[1] Within biodefense, biosurveillance, as defined by the July 2012 National Strategy for Biosurveillance, is the ongoing process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health, for the purpose of (1) achieving early detection and warning, (2) contributing to overall situational awareness of the health aspects of the incident, and (3) enabling better decision making at all levels.

Threats of bioterrorism, such as anthrax attacks, and high-profile disease outbreaks, such as Ebola in West Africa and emerging arboviruses like chikungunya and Zika in the Americas, highlight the continued need for systems that provide early detection and warning about biological threats to humans. Additionally, recent outbreaks of highly pathogenic avian influenza in domestic poultry and wild birds in 21 Midwestern and Western states in 2014, 2015, and 2016 underscore the importance of maintaining effective surveillance systems within the broader context of biosurveillance (to include plant and animal). The disruption of the agriculture or food production systems can present a serious threat to the national economy, trade, and human health. Numerous federal agencies, encompassing much of the federal government, have mission responsibilities for supporting biodefense and biosurveillance activities.

Over the past 15 years, we have reported that complex interagency and intergovernmental efforts can benefit from developing a national strategy, and that interagency and intergovernmental activities can benefit from the leadership of a single entity with sufficient time, responsibility, authority,

[1] *Homeland Security Presidential Directive 10: Biodefense for the 21st Century (2004).*

and resources needed to provide assurance that the federal programs are well coordinated, and that gaps and duplication in capabilities are avoided.[2] We also have an ongoing body of biosurveillance work spanning more than a decade in which we have examined specific surveillance programs and activities carried out by the Department of Homeland Security (DHS); the Departments of Health and Human Services (HHS); and Agriculture (USDA); and several other federal departments and agencies.[3] We have identified broad, cross-cutting issues in leadership, coordination, and collaboration that arise from working across the complex interagency, intergovernmental, and intersectoral biosurveillance enterprise.

This statement describes a range of historical and present challenges to building and maintaining the nation's biodefense and biosurveillance. This statement is based on our prior work issued from December 2009 through March 2016 on various biodefense and biosurveillance efforts. We also reviewed the 2015 report of the Blue Ribbon Study Panel on Biodefense

[2]See GAO, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Washington, D.C: Sept. 20, 2001), and C*ombating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

[3]See, for example, GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: Sept. 30, 2004), which discusses select federal and nonfederal human disease surveillance in humans; GAO, *Global Health: U.S. Agencies Support Programs to Build Overseas Capacity for Infectious Disease Surveillance*, GAO-07-1186 (Washington, D.C.: Sept. 28, 2007), which discusses four key programs aimed at building overseas surveillance capacity for infectious diseases in humans; GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: Dec. 18, 2009); GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010); GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, GAO-12-55 (Washington, D.C.: Oct. 31, 2011); GAO, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (Washington, D.C.: Sept. 10, 2012); GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, GAO-13-424 (Washington, D.C.: May 21, 2013), which discusses the Department of Agriculture's efforts to better detect and control new or reemerging diseases in animals; GAO*, Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center*, GAO-15-793 (Washington, D.C.: Sept. 24, 2015); GAO, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established*, GAO-16-99 (Washington, D.C.: Oct. 23, 2015).GAO, *Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak,* GAO-16-470T (Washington, D.C., Mar.2, 2016).

for selected updates.[4] The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. To conduct our prior work, we reviewed reports from the bipartisan Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Center), relevant presidential directives, laws, regulations, policies, strategic plans, and other reports; surveyed states; and interviewed federal, state, and industry officials, among others. More information on our scope and methodology can be found in each of the reports cited throughout this statement.

Background

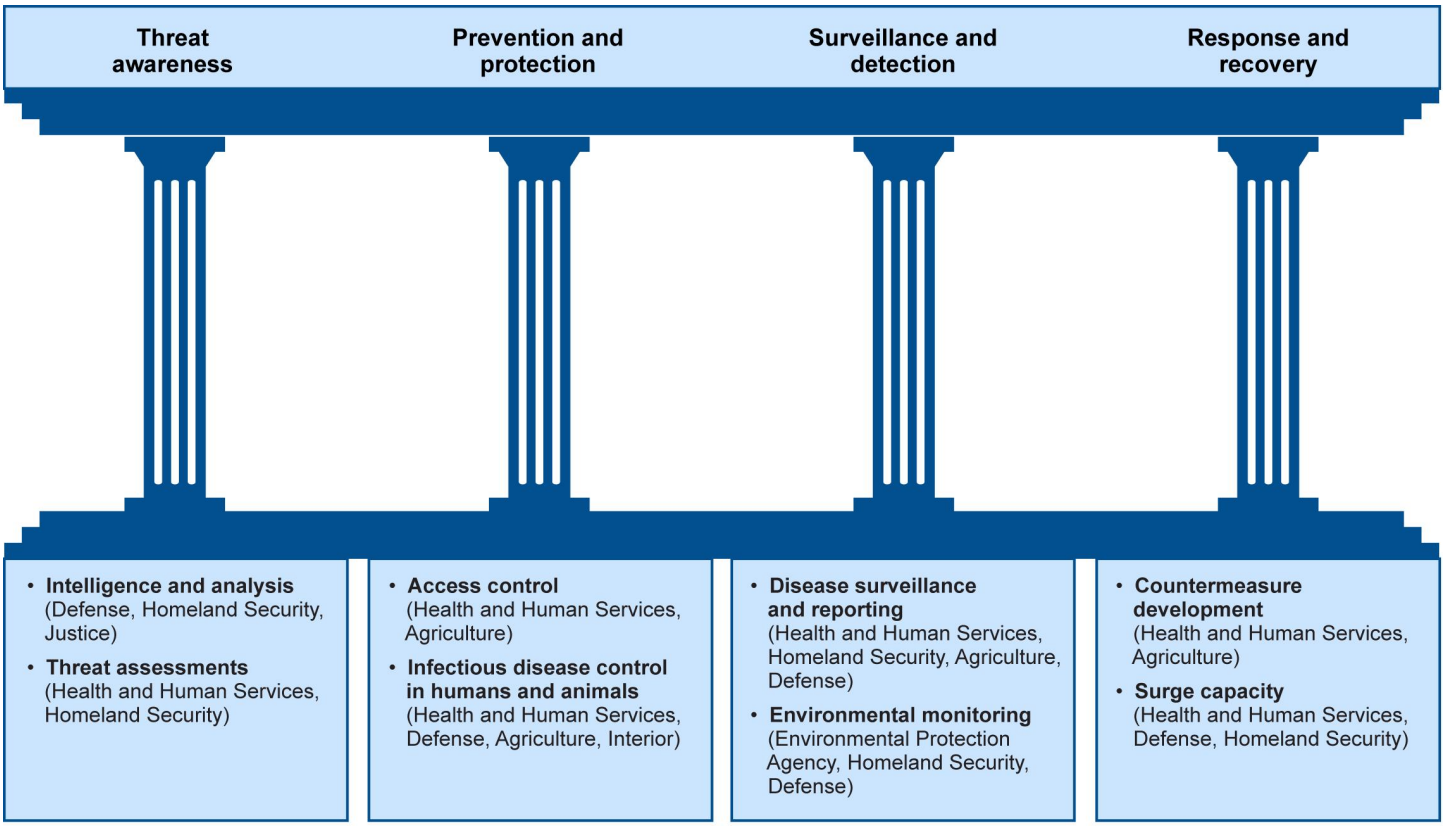
The Biodefense Enterprise

Biological threats that could result in catastrophic consequences exist in many forms and arise from multiple sources. For example, several known biological agents could be made into aerosolized weapons and intentionally released in a transportation hub or other populated urban setting, introduced into the agricultural infrastructure and food supply, or used to contaminate the water supply. Concerned with the threat of bioterrorism, in 2004, the White House released HSPD-10, which outlines the structure of the biodefense enterprise and discusses various federal efforts and responsibilities that help to support it. The biodefense enterprise is the whole combination of systems at every level of government and the private sector that can contribute to protecting the nation and its citizens from potentially catastrophic effects of a biological event. It is composed of a complex collection of federal, state, local, tribal, territorial, and private resources, programs, and initiatives, designed for different purposes and dedicated to mitigating various risks, both natural and intentional.

[4]We have not independently assessed the entirety of the Study Panel's conclusions and recommendations or the methods it used to arrive at them. However, we determined that the select members of panels related to leadership and policy issues had qualifications and subject matter expertise sufficient to provide reliable information on issues related to strategy and leadership across the biodefense enterprise.

Biodefense is organized into four pillars—threat awareness, prevention and protection, surveillance and detection, and response and recovery—and multiple federal agencies have biodefense responsibilities within the pillars. Each of these pillars comprise numerous activities—such as controlling access to dangerous biological agents used in research—that generally require coordination across federal departments as well as with state, local, and international governments, and the private sector. Protecting humans, animals, plants, air, soil, water, and critical infrastructure from potentially catastrophic effects of intentional or natural biological events entails numerous activities carried out within and among multiple federal agencies and their nonfederal partners (see fig. 1).

Figure 1: Pillars of Biodefense



Source: GAO analysis of Homeland Security Presidential Directive 10. | GAO-16-547T

Biosurveillance Threats and Responsibilities

Emerging infectious diseases represent an ongoing threat to the health and livelihoods of people and animals worldwide.[5] Many advances in medical research and treatments have been made during the last century, but infectious diseases are nevertheless a leading cause of death worldwide. In addition to causing nearly one in five human deaths worldwide, infectious diseases impose a heavy societal and economic burden on individuals, families, communities, and countries.[6] Infectious diseases are a continuous threat for reasons that include: (1) emergence—at times rapid—of new infectious diseases; (2) re-emergence of previously-known infectious diseases; and (3) persistence of intractable infectious diseases.

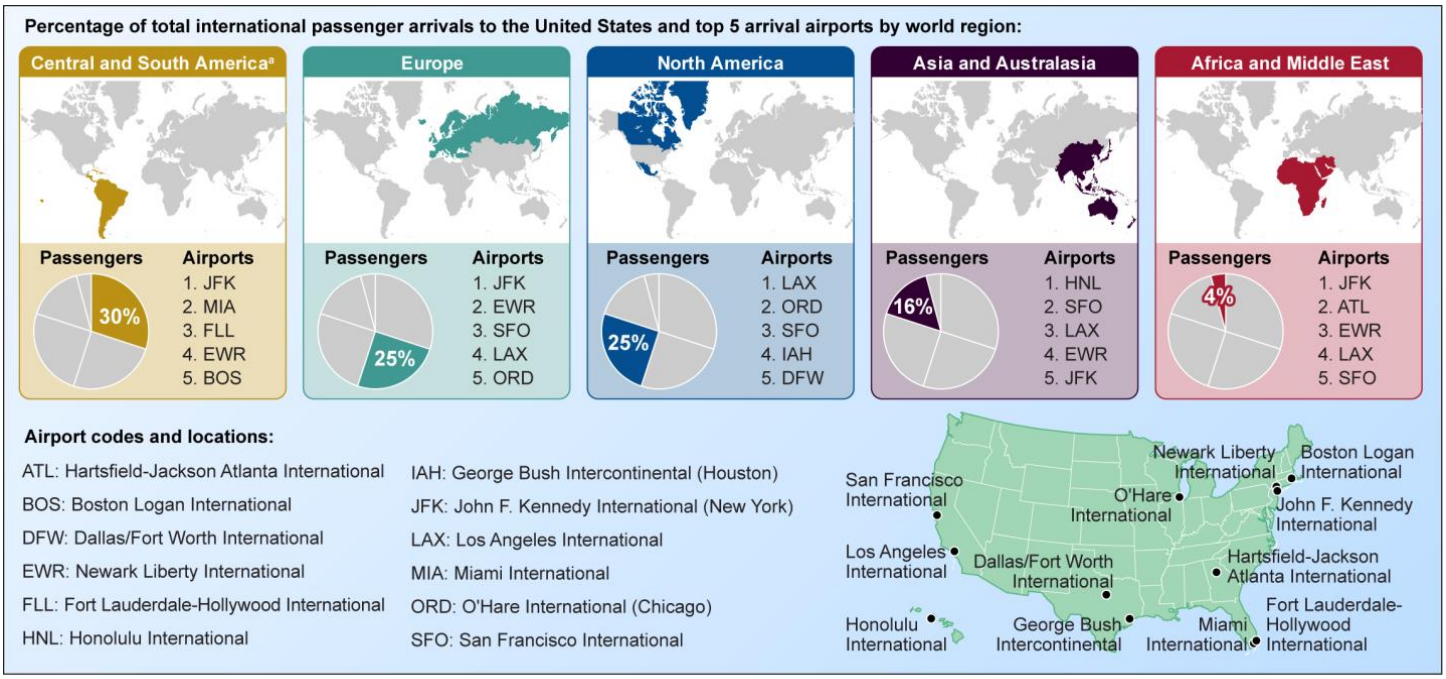
In an era of rapid transit and global trade, the public health and agricultural industries, as well as natural ecosystems including native plants and wildlife, face increased threats of naturally occurring outbreaks of infectious disease and accidental exposure to biological threats. According to the World Health Organization, infectious diseases are not only spreading faster, they also appear to be emerging more quickly than ever before. The ongoing outbreak of Zika virus in the Americas has heightened travel-related concerns regarding the spread of the virus. As of March 23, 2016, 273 cases of continental U.S. travel-associated Zika virus disease have been reported, according to Centers for Disease Control and Prevention (CDC). Figure 2 shows passenger arrivals from five regions of the world and the top five airports receiving passengers whose travel originated from each of these regions in 2014.[7]

[5]According to the Centers for Disease Control and Prevention (CDC), an emerging infectious disease is a disease whose incidence in humans has increased in the past two decades or threatens to increase in the near future.

[6]Institute of Medicine, Emerging Viral Diseases: The One Health Connection (Washington, D.C.: National Academies Press, 2015).

[7]See GAO, *Air Travel and Communicable Diseases: Comprehensive Federal Plan Needed for U.S. Aviation System's Preparedness.* GAO-16-127.(Washington, D.C.: December 16, 2015).

Figure 2: Top Five U.S. International Arrival Airports for Five Global Regions, 2014



Sources: GAO analysis of Department of Transportation data and Map Resources. | GAO-16-547T

According to the World Health Organization, about 75 percent of the new diseases that have affected humans in recent years are zoonotic and have been caused by pathogens originating from an animal. These emerging and reemerging diseases transmit between animals—including domestic animals and wildlife—and humans. Many of these diseases have the potential to spread through various means over long distances and to become global problems. In some cases, disease transmission is direct, in others the animals act as intermediate or accidental hosts, while in others transmission occurs, for example, via mosquitoes or ticks. Examples of emerging and zoonotic diseases include: Zika, chikungunya, and dengue viruses, West Nile virus, H1N1 (swine) influenza, severe acute respiratory syndrome (SARS), avian influenza, and rabies. Habitat loss and human encroachment on rural and wildlife environments are bringing populations of humans and animals, both farmed and wild, into closer and more-frequent contact. Increasingly, wildlife are involved in the transmission of diseases to people, pets, and livestock, and managing wildlife transmitters is an integral part of efforts to control the spread of zoonotic diseases. Diseases among wildlife can also provide early warnings of environmental damage, bioterrorism, and other risks to

human health.[8] Finally, potential bioterrorism threats also include the use of zoonotic diseases as weapons of mass destruction, such as anthrax, plague, tularemia, and brucellosis.

Transmission and detection of Zika, chikungunya, and dengue viruses

Zika, chikungunya, and dengue viruses are all spread by the *Aedes aegypti* mosquito, pictured below. These mosquitoes typically lay eggs in and near standing water in containers like buckets, bowls, animal dishes, flower pots, and vases. They prefer to bite people, and live both indoors and outdoors. Mosquitoes that spread dengue, chikungunya, and Zika are aggressive daytime biters, but also bite at night. Mosquitoes can become infected when they feed on a person already infected with the virus.

Diagnosing Zika virus infection is complicated because it is difficult to differentiate it from other similar diseases, such as dengue or yellow fever, and some tests for Zika virus antibodies suffer from cross-reactivity with antibodies to similar viruses. For example, a person previously infected with another flavivirus such as dengue could be falsely identified as also having been exposed to the Zika virus (and vice-versa).

James Gathany (photograph)

Source: GAO analysis;| GAO-16-547T

Numerous federal, state, local, and private sector entities have roles and responsibilities for monitoring for pathogens in human, animal, plant, food, and the environment. Federal departments, such as the HHS, USDA, DHS, and the Department of Interior, play leading biosurveillance roles for certain domains such as human and animal health, food, and air, but they also rely on support from state and local authorities or partner with other federal agencies. In other cases federal departments or agencies play supporting roles.[9] Officials at all levels of government, as well as Homeland Security Presidential Directive-21's (HSPD-21) vision of a national biosurveillance capability, acknowledge that state and local capabilities are at the heart of the biosurveillance enterprise.[10] According to federal, state, and local officials, early detection of potentially serious disease indications nearly always occurs first at the local level, making the personnel, training, systems, and equipment that support detection at the state and local level a cornerstone of our nation's biodefense posture. While there is variation in organization and structure among public-health, animal-health, and wildlife functions at the state, tribal, local, and insular levels they all share in the nation's biosurveillance responsibility. [11] Some

[8]Department of Interior's United States Geological Survey National Wildlife Health Center, which is the only federal laboratory in the United States dedicated to wildlife disease investigation, focuses on developing methods to reduce or eliminate the transmission of diseases among wildlife, domestic animals, and humans.

[9]In particular, agencies with missions that do not entail health surveillance activities may play a supporting biosurveillance role on an ongoing or ad hoc basis. For example, as demonstrated during the 2009-2010 H1N1 influenza pandemic, the Department of Education provided information on school closings, which enhanced situational awareness. In another example, although the National Weather Service does not have health surveillance responsibilities, the National Biosurveillance Integration Center (NBIC) may at times coordinate with this agency because understanding weather patterns helps predict the course of some outbreaks.

[10]HSPD-21, *Public Health and Medical Preparedness*, was issued in October 2007 to establish a National Strategy for Public Health and Medical Preparedness, which builds upon principles set forth in HSPD-10 with the goal of transforming the national approach to protecting the health of the American people against all disasters.

[11]According to the Department of the Interior's definition, an insular area is a jurisdiction that is neither a part of one of the several states nor a federal district. This is the current term to refer to any U.S. commonwealth, freely associated state, possession, or territory.

of the nonfederal partners with key responsibilities in the biosurveillance enterprise are presented in table 1.

Table 1: Selected Biosurveillance Roles and Responsibilities

	Nonfederal partner	Description
Skilled Personnel	Epidemiologists	Epidemiologists are specialists who study how diseases are distributed and transmitted in populations and the factors that influence or determine this distribution and transmission.
	Informaticians	Public-health informaticians use systematic application of information, computer science, and technology to support public health.
	State public-health veterinarians	State public health veterinarians typically work for the state health department and generally work in zoonotic disease control and prevention with a focus on protecting public health.
	State wildlife professionals	State wildlife professionals are veterinarians, epidemiologists, biologists, or management personnel who work for state departments of wildlife, parks and recreation, or natural resources and environment.
	Clinicians and diagnosticians	Early detection of a bioterrorism event or the emergence of a naturally occurring infectious disease threat may depend on an astute clinician diagnosing the first few cases, or recognizing suspicious clinical signs that require further investigation by experts in infectious diseases.
Organizations	State and local health departments	States, through the use of their state and local health departments, have principal responsibility for protecting the public's health and therefore take the lead in conducting disease surveillance. They verify cases of notifiable diseases, monitor disease incidence, and identify possible outbreaks within their states. Generally, local health departments are responsible for conducting initial investigations into reports of infectious diseases. Local health departments are also responsible for sharing information they obtain from providers or other sources with their state department of health.
	State departments of agriculture	State departments of agriculture provide services and regulations regarding the health of agricultural animals. States maintain a list of reportable diseases and require accredited veterinarians to report disease occurrences. State veterinarians coordinate the efforts of state animal-health officials who have authority for disease reporting, detection, and often, diagnosis.
	Laboratories	Public-health and animal-health laboratories serve a critical role in both initial detection and ongoing situational awareness of biological events.

Source: GAO | GAO-16-547T

Independent Reports on Issues Facing the Biodefense Enterprise

Bipartisan and independent commissions have identified a range of issues facing the biodefense enterprise, many of which mirror our findings. In October 2011, the WMD Center reported its assessment of various capabilities within the U.S. biodefense enterprise in which a team of leading biodefense experts assigned letter grades to each of the capabilities for different types of outbreak. The report assigned low marks to nearly all the capabilities for address large-scale and global disease

outbreaks. For example, the team assigned the grade of D (meets few expectations) to the capability for detecting large-scale infectious outbreaks and the grade of F (fails to meet expectations) to the capability for detecting global contagious outbreaks.[12]

In 2014, a Blue Ribbon Study Panel on Biodefense (Study Panel) was established to assess gaps and provide recommendations to improve U.S. biodefense.[13] The panel's October 2015 final report identified 33 recommendations to execute over the short, medium, and long term. The Study Panel report echoed many of the same challenges highlighted in the WMD Center's report, and highlighted a sense of urgency to address the ongoing and persistent biological threats—both naturally occurring, like Ebola and Zika, and from enemies, like The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) who have advocated for the use of biological weapons. The panel's report identified several themes we have also highlighted in our biosurveillance work, including the lack of a centralized leader, no comprehensive national strategic plan, and no all-inclusive dedicated budget for biodefense.

The Biodefense Enterprise Is Fragmented and Does Not Have Strategic Oversight to Promote Efficiency and Accountability

[12]The WMD Center, *Bio-Response Report Card: 21st Century Biological Threats*, Washington, D.C. (Oct 2011).

[13]*A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. Bipartisan Report of the Blue Ribbon Study Panel on Biodefense (October 2015).

The Biodefense Enterprise Does Not Have Enterprise-Wide Institutionalized Leadership to Provide Strategic Oversight and Coordination

In 2011, we reported that reducing fragmentation in the biodefense enterprise could enhance assurance that the nation is prepared to prevent, detect, and respond to biological attacks with potentially devastating consequences in terms of loss of life, economic damage, and decreased national security.[14] We reported that there are more than two dozen presidentially appointed individuals with some responsibility for biodefense. In addition, numerous federal agencies, encompassing much of the federal government, have some mission responsibilities for supporting biodefense activities. However, there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise. Because none of the federal departments has authority over the entire biodefense enterprise, in 2011 we reported that the Homeland Security Council (HSC) should consider establishing a focal point to coordinate federal biodefense activities. In December 2014 officials from National Security Council (NSC) staff, which supports the HSC told us that two of its directorates work together as the focal point for federal biodefense efforts. According to NSC staff, these focal points provide strategic leadership on all federal biodefense efforts, with responsibilities to coordinate across domestic and global priorities to prevent, detect, and rapidly respond to biological threats. The focal points are to host ongoing meetings with the federal biodefense enterprise to ensure a comprehensive and coordinated approach to biodefense.

We recognize the policy work of the directorates as an important step in promoting a comprehensive and coordinated approach to biodefense, but strategic leadership issues persist. In October 2015, the Study Panel reported on ongoing leadership challenges for the enterprise. The report called for a focal point to provide strategic leadership by elevating authority above what any single agency has to help overcome the challenges faced by the biodefense enterprise.[15] The Study Panel report noted mixed opinions on the effectiveness of the current NSC staff model

[14]See, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*. GAO-11-318SP. Washington, D.C.: March 1, 2011.

[15]The Study Panel evaluated various organizational models to provide leadership, and ultimately recommended that leadership for the biodefense enterprise be institutionalized in the Office of the Vice President and that the Vice President be given budget authority to review and advise, in collaboration with the Office of Management and Budget, all biodefense budgets. Although our prior work called for an entity with sufficient time, resources, and authority to provide strategic oversight across the enterprise, we have not independently evaluated any specific leadership models.

for coordinating biodefense. Some have asserted that efforts remain fragmented under this system, but others pointed to the benefit of having a wider variety of staff involved across the spectrum of biodefense activities. However, the Study Panel found that White House councils and offices generally only become involved when a specific biodefense issue affects a prominent ongoing responsibility—a method which is not consistent with our call for a strategic approach.

The Enterprise Does Not Have an Integrated National Strategy to Guide Priorities and Investments

In 2011, we reported that while some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biodefense responsibilities that can be used to guide the systematic identification of risk; assess resources needed to address those risks; and prioritize and allocate investment across the entire biodefense enterprise.[16] We have also previously reported that choices must be made about protection priorities given the risk and how to best allocate available resources.[17] Further, neither the Office of Management and Budget nor the federal agencies account for biodefense spending across the entire federal government. As a result, the federal government does not know how much is being spent on this critical national security priority. We reported that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a national strategy, to ensure efficient, effective, and accountable results, and suggested the HSC take action.

As of February 2016, NSC staff had not developed such a strategy. Rather, they assert that the *National Strategy for Countering Biological Threats*, the *National Biosurveillance Strategy, and Presidential Policy Directive-8* work in concert to provide comprehensive strategic guidance to stakeholders with biodefense responsibilities. Although these documents demonstrate clear commitment to coordinating interagency biodefense efforts, they do not provide the strategic approach that we suggested in March 2011. For example, the *National Biosurveillance Strategy*, released by the White House in July 2012, does not provide a specific framework for prioritizing and trading off among approaches to build biosurveillance capabilities with limited resources. Moreover, as

[16]GAO-11-318SP

[17]GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, GAO-05-325SP (Washington, D.C.: Feb. 1, 2005).

previously discussed, there are four pillars of the biodefense enterprise, each complex and in need of coordination: (1) threat awareness, (2) prevention and protection, (3) surveillance and detection, and (4) response and recovery. The *National Strategy for Biosurveillance* does not—alone or in combination with the *National Strategy for Countering Biological Threats and Presidential Policy Directive-8*—address all four pillars, and more specifically, it does not address the key fragmentation issues across the biodefense enterprise, such as ensuring strong linkage and identifying gaps in investments across the four pillars.

Similarly, the Study Panel's 2015 report identified the lack of a comprehensive national strategy and dedicated budget as challenges. The Study Panel noted that leadership issues were exacerbated by the lack of a comprehensive biodefense strategy and a unified approach to budgeting, which they called vital to any strategic interagency effort for the nation's biodefense capabilities. They called for a unified approach to budgeting and prioritizing biodefense efforts. The Study Panel noted that the nation lacks a comprehensive, cohesive, and regularly updated strategy resulting in disorganization and loss of institutional knowledge associated with changes in administrations.

Biosurveillance Faces Similar Challenges

Much like biodefense, biosurveillance faces key challenges that transcend what any one agency can address on its own. We have identified challenges related to the nation's ability to detect and respond to biological events.[18] Our findings have identified challenges at all levels of government, and our more recent and ongoing work continues to highlight these challenges.

Enterprise-wide Leadership and Strategy Challenges

In June 2010, we found that there was no integrated approach to help ensure an effective national biosurveillance capability and to provide a framework to help identify and prioritize investments.[19] Without a unifying framework and an entity with the authority, resources, time, and responsibility for guiding its implementation, we concluded that it would be very difficult to create an integrated approach to building and

[18]See GAO-10-645; GAO-12-55; GAO-15-793; and GAO-16-99.

[19]GAO-10-645.

sustaining a national biosurveillance capability.[20] We recommended the HSC establish a focal point to lead the development of a national biosurveillance strategy that clarifies roles and responsibilities, provides goals and performance measures, and identifies resource and investment needs, among other elements. However, the recommendations have not been fully implemented.

The NSC staff, which supports the HSC, convened an interagency policy group that guided the completion of the National Strategy for Biosurveillance in July 2012, which addresses the intent of our recommendation to establish a focal point. However, our review of the strategy determined that the strategy alone did not fully meet the intent of our recommendation because, among other things, it did not provide the mechanism we recommended to identify resource and investment needs, including investment priorities. Subsequent to the release of the strategy, the NSC staff published a companion implementation plan, but it is not yet clear the extent to which the plan has been widely shared among and adopted by interagency decision makers as a means to help identify opportunities to leverage resources and direct priorities.

The National Strategy for Biosurveillance also does not address issues we raised related to state and local biosurveillance efforts, and that we previously recommended. In October 2011, we reported that nonfederal capabilities should also be considered in creating a national biosurveillance strategy. The backbone of biosurveillance is traditional disease-surveillance systems—designed to collect information on the health of humans and animals to support a variety of public-welfare and economic goals. These systems support biosurveillance efforts by recording national health and disease trends and providing specific information about the scope and projection of outbreaks to inform response. Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to strengthen and leverage nonfederal partners could improve efforts to build and maintain a national biosurveillance capability. Moreover, efforts to build the capability would benefit from a framework that facilitates assessment of nonfederal

[20]See GAO-10-645; GAO, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Washington, D.C: Sept. 20, 2001), and Co*mbating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise. Such an assessment of capabilities that support biosurveillance is called for in HSPD-10, which notes that the United States requires a periodic assessment that identifies gaps or vulnerabilities in our biodefense capabilities—of which surveillance and detection is a key part—to guide prioritization of federal investments. However, in a 2011 report, we noted that the federal government had not conducted a comprehensive assessment of state and local jurisdictions' ability to contribute to a national biosurveillance capability.[21]

While the size, variability, and complexity of the biosurveillance enterprise makes an assessment difficult, we concluded in our October 2011 report that the federal government would lack key information about the baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise until it conducts such an assessment. To address these issues, and building on our June 2010 recommendation to develop a national biosurveillance strategy, we recommended for such a strategy to (1) incorporate a means to leverage existing efforts that support nonfederal biosurveillance capabilities, (2) consider challenges that nonfederal jurisdictions face, and (3) include a framework to develop a baseline and gap assessment of nonfederal jurisdictions' capabilities. However, the July 2012 strategy did not adequately address the issues we raised related to state and local biosurveillance and acknowledged but did not meaningfully address the need to leverage nonfederal resources.

Challenges for Biosurveillance Capabilities

Our recent work has also identified challenges with specific biosurveillance capabilities. Specifically, we have identified biosurveillance capability challenges with, among other topics, (1) state and local public heath capabilities, (2) animal health surveillance

[21]GAO-12-55. In 2011, we reported that certain aspects of public-health capabilities have been assessed by federal agencies and professional associations. For example, CDC's guidance associated with the Public Health Emergency Preparedness (PHEP) cooperative agreement began to define elements, priorities, resource considerations, and metrics for building and assessing public-health surveillance, epidemiology, and laboratory capabilities. However, in 2013, we reported on ways to better assess the effect of cooperative agreements on awardee preparedness, including that of the PHEP. We reported that creating comprehensive performance management systems with realistic targets and incremental milestones would aid in assessing performance. However, as of September 2015, HHS was still working to address our recommendations. See, *National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals,* GAO-13-278 (Washington, D.C.: March 2013).

capabilities, and (3) two DHS specific biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the BioWatch Program.[22] In our October 2011 report on nonfederal biosurveillance efforts, we found many of the challenges that state and local officials identified were similar to issues we reported regarding biosurveillance at the federal level. We noted that many of the challenges facing the biosurveillance enterprise were complex, inherent to building capabilities that cross traditional boundaries, and not easily resolved.

State and Local Public Health Capabilities. In 2011, we found that state and local officials identified common challenges to developing and maintaining their biosurveillance capabilities such as (1) state policies in response to state budget constraints that restricted hiring, travel, and training; (2) obtaining and maintaining resources, such as adequate workforce, equipment, and systems; and (3) the lack of strategic planning and leadership to support long-term investment in crosscutting core capabilities, integrated biosurveillance, and effective partnerships.[23] For example, state and local officials we surveyed reported facing workforce shortages among skilled professionals—epidemiologists, informaticians, statisticians, laboratory staff, animal-health staff, or animal-disease specialists. We also found that although the federal government provided some resources to help control disease in humans and animals in tribal and insular areas, there were no specific efforts to ensure that their efforts can contribute to the national biosurveillance capability. Additionally, in 2011, we found that nonfederal partners relied heavily on grants and cooperative agreements to sustain their biosurveillance capabilities. For example, the Public Health Emergency Preparedness cooperative agreement (PHEP) and the Epidemiology and Laboratory Capacity for Infectious Diseases cooperative agreement (ELC) were essential for public health epidemiology and laboratory staff. We concluded that without assessing the baseline nonfederal capabilities that support biosurveillance, identification of investment needs for a national biosurveillance capability cannot be established.

Animal Surveillance Capabilities. In the area of animal surveillance, we reported in May 2013 that USDA's Animal and Plant Health Inspection

[22]DHS's BioWatch program aims to provide early indication of an aerosolized biological weapon attack.

[23]See, GAO-12-55.

Service (APHIS) had developed a new approach for its livestock and poultry surveillance activities, but had not yet integrated these efforts into an overall strategy with goals and performance measures aligned with the nation's larger biosurveillance policy.[24] Under its prior approach, APHIS focused its disease surveillance programs on preventing the introduction of certain foreign animal diseases and monitoring, detecting, and eradicating other reportable diseases already present in domestic herds. Under this previous approach, information about nonreportable diseases, including those that are new or reemerging, was not always captured by the agency's disease surveillance efforts. We also reported in 2013 that under its new approach APHIS had begun to broaden its approach by monitoring the overall health of livestock and poultry and using additional sources and types of data to better detect and control new or reemerging diseases. For example, APHIS had been monitoring for the presence of pseudorabies—a viral swine disease that may cause respiratory illness and death—at slaughter facilities, but under the new approach, it proposed monitoring these facilities for a range of other diseases as well. However, we concluded that without integrating APHIS's new approach to livestock and poultry surveillance activities into an overall strategy with goals and measures aligned with broader national homeland security efforts to detect biological threats, APHIS may not be ideally positioned to support national efforts to address the next threat to animal and human health. We recommended that APHIS integrate its new surveillance approach with an overall strategy that guides how its new approach will support national homeland security efforts to enhance the detection of biological threats. However, while the agency agreed, this recommendation has not been implemented.

DHS Biosurveillance Efforts. In 2015, we identified persistent challenges related to two of DHS's biosurveillance capabilities, NBIC and the BioWatch program.[25] We reported in 2009 that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced.[26] For example, some partners reported that they did not trust NBIC to use their

[24]GAO-13-424.

[25]See, GAO-15-793 and GAO-16-99.

[26]GAO-10-171.

information and resources appropriately, while others were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated. In the 2009 report, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. DHS agreed, and in August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, and articulate the value that NBIC seeks to provide to its partners, among other things. In September 2015, we reported that despite NBIC's efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and efforts, a variety of challenges remained. Notably, many of its federal partners continued to express uncertainty about the value NBIC provided. We identified options for policy or structural changes that could help NBIC better fulfill its biosurveillance integration mission, such as changes to NBIC's roles, but we did not make specific recommendations.[27]

Additionally, since 2012, we have reported that DHS has faced challenges in clearly justifying the need for the BioWatch program and its ability to reliably address that need (to detect aerosolized biological attacks). In September 2012, we found that DHS approved a next-generation BioWatch acquisition in October 2009 without fully developing knowledge that would help ensure sound investment decision making and pursuit of optimal solutions.[28] We recommended that before continuing the acquisition, DHS reevaluate the mission need and possible alternatives based on cost-benefit and risk information. DHS concurred and in April 2014, canceled the acquisition because an alternatives analysis did not confirm an overwhelming benefit to justify the cost. Having canceled the next generation acquisition, DHS continues to rely on the currently-deployed BioWatch system for early detection of an aerosolized biological attack. However, in 2015, we found that DHS lacks reliable information about the current system's technical capabilities to detect a biological attack, in part because in the 12 years since BioWatch's initial deployment, DHS has not developed technical performance requirements for the system.[29] We reported in October 2015

[27]GAO-15-793.

[28]GAO-12-810.

[29]GAO-16-99.

that DHS commissioned tests of the current system's technical performance characteristics, but without performance requirements, DHS cannot interpret the test results and draw conclusions about the system's ability to detect attacks. DHS is considering upgrades to the current system, but we recommended that DHS not pursue upgrades until it establishes technical performance requirements to meet a clearly defined operational objective and assesses the system against these performance requirements. DHS concurred and is working to address the recommendation.

Chairman Johnson, Ranking Member Carper, and Members of the Committee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

GAO Contact and Staff Acknowledgments

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