

Report to Congressional Requesters

October 2011

# BIOSURVEILLANCE

Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy





Highlights of GAO-12-55, a report to congressional committees

# Why GAO Did This Study

The nation is at risk for a catastrophic biological event. The Implementing Recommendations of the 9/11 Commission Act directed GAO to report on biosurveillance—to help detect and respond to such events—at multiple jurisdictional levels. In June 2010, GAO recommended that the National Security Staff lead the development of a national biosurveillance strategy, which is now under development.

This report focuses on nonfederal jurisdictions, which own many of the resources that support a national capability. It discusses (1) federal support for state and local biosurveillance; (2) state and local challenges; (3) federal support and challenges for tribal and insular areas and (4) federal assessments of nonfederal capabilities. To conduct this work, GAO interviewed select federalagency, jurisdiction, and association officials and reviewed relevant documents. To collect information on federal efforts and challenges, we also sent standardized questionnaires to seven states and two cities.

## What GAO Recommends

GAO recommends that the National Security Staff ensure the strategy considers (1) existing federal efforts, (2) challenges, and (3) assessment of nonfederal capabilities.

GAO provided a draft of this report to the National Security Staff, and the federal, state and city officials who contributed information. The National Security Staff acknowledged the accuracy of the report, but did not comment on the recommendation.

View GAO-12-55. For more information, contact Bill Jenkins at (202) 512-8777 or jenkinswo@gao.gov.

#### October 2011

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# Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy

## What GAO Found

The federal government has efforts to support health preparedness that state and city officials identified as critical to their biosurveillance capabilities. The efforts these officials identified fell into four categories: (1) grants and cooperative agreements, (2) nonfinancial technical and material assistance, (3) guidance, and (4) information sharing. Within each of the categories, the officials identified specific federal efforts that were essential to their biosurveillance activities. For example, public-health officials described cooperative agreements from the Centers for Disease Control and Prevention that provided resources for disease investigation, as well as guidance on federal priorities. However, as with our June 2010 findings about federal biosurveillance, in the absence of a national strategy, these efforts are not coordinated or targeted at ensuring effective and efficient national biosurveillance capabilities. Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to leverage nonfederal efforts could improve efforts to build and maintain a national biosurveillance capability.

State and city officials identified common challenges to developing and maintaining their biosurveillance capabilities: (1) state policies that restrict hiring, travel, and training in response to budget constraints; (2) ensuring adequate workforce, training, and systems; and (3) the lack of strategic planning and leadership to support long-term investment in cross-cutting core capabilities, integrated biosurveillance, and effective partnerships. A national biosurveillance strategy that considers planning and leadership challenges at all levels of the biosurveillance enterprise may help partners across the enterprise find shared solutions for an effective national biosurveillance capability.

The federal government provides some resources to help control disease in humans and animals in tribal and insular areas, but there are no specific efforts to ensure these areas can contribute to a national biosurveillance capability. Resources include cooperative agreements, disease-specific funding, training, and technical assistance. Surveillance capacity varies among tribes and insular areas, but common challenges include limited health infrastructure including human- and animal-health professionals and systems.

The federal government has not conducted a comprehensive assessment of state and local jurisdictions' ability to contribute to a national biosurveillance capability, as called for in presidential directive. According to federal, state, and local officials, the magnitude and complexity of such an assessment is a challenge. Until it conducts such an assessment, the federal government will lack key information to support a national biosurveillance capability. A national strategy like the one we previously recommended—one capable of guiding federal agencies and its key stakeholders to systematically identify gaps, resources to address those gaps, and investment priorities—would benefit from an assessment of jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise.

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# **Abbreviations**

ArboNet Arboviral Surveillance System

BSL-3 Biological Security Level – Three laboratory CDC Centers for Disease Control and Prevention

DHS Department of Homeland Security

DOI Department of the Interior

ELC Epidemiology and Laboratory Capacity for Infectious

**Diseases Cooperative Agreement** 

eLEXNET Electronic Laboratory Exchange Network

Epi-X Epidemic Information Exchange

ERLN Environmental Response Laboratory Network

FERN Food Emergency Response Network

FoodNet Foodborne Disease Active Surveillance Network
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act

HSPD Homeland Security Presidential Directive
ICLN Integrated Consortium of Laboratory Networks

HIS Indian Health Service

ILINet Influenza-like Illness Surveillance Program

LRN Laboratory Response Network

MMWR Morbidity and Mortality Weekly Report
NAHRS National Animal Health Reporting System
NAHLN National Animal Health Laboratory Network
NEDSS National Electronic Disease Surveillance System

NIFA National Institute of Food and Agriculture
NVSL National Veterinary Services Laboratory
OIE World Organization for Animal Health
PHEP Public Health Emergency Preparedness
PIHOA Pacific Island Health Officers Association
PPACA Patient Protection and Affordable Care Act

SARS Severe Acute Respiratory Syndrome

SCWDS Southeastern Cooperative Wildlife Disease Study TB GIMS TB Genotyping Information Management System

USDA United States Department of Agriculture

USGS United States Geological Survey

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# United States Government Accountability Office Washington, DC 20548

October 31, 2011

The Honorable Joseph I. Lieberman
Chairman
The Honorable Susan M. Collins
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Peter King
Chairman
The Honorable Bennie Thompson
Ranking Member
Committee on Homeland Security
House of Representatives

A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic, could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security. Effective preparation for, detection of, and response to a major biological event requires effective pre- and postdisaster coordination and cooperation among different federal agencies, levels of government, nongovernmental organizations, and the private sector. Timely detection of signs of unusual and potentially dangerous disease is a first step in an effective response to a natural, accidental, or intentional outbreak of a biological event of national concern.

Although the United States has numerous surveillance programs and systems at various levels of government and in the private sector to monitor disease, these programs and systems were developed separately for a variety of mission objectives, and as such are relatively uncoordinated. We reported in June 2010 that federal biosurveillance efforts were dispersed across many federal agencies, but no federal entity had responsibility and authority for coordinating activities to help ensure timely detection and situational awareness for disease outbreaks

with potentially catastrophic consequences. We also reported that the responsibility and capacity for collecting most information and carrying out most health-monitoring activities resides within state and local jurisdictions or with private-sector entities—such as hospitals and other private health-care providers. The federal government generally cannot compel state and local jurisdictions or private-sector entities to provide information or resources to support federal biosurveillance efforts. Instead, individual federal agencies, in pursuit of their missions, attempt to build relationships and offer incentives—like grants—to encourage voluntary cooperation with specific federal efforts.

In October 2007, Homeland Security Presidential Directive-21 (HSPD-21) articulated a vision for protecting the nation from catastrophic disease outbreaks in humans that included a call for a national biosurveillance capability that enhances the timeliness of detection and the quality of situational awareness for response. The national biosurveillance capability described in HSPD-21 relies on, among other things, (1) strong clinician awareness and laboratory diagnostic capacity; (2) a national "common operating picture" that provides a comprehensive picture of the health of communities and the associated threat environment by incorporating information from human health, animal health, agricultural, meteorological, environmental, intelligence, and other data; and (3) a nationwide epidemiologic surveillance system that is robust enough to identify specific disease incidence and prevalence and flexible enough to tailor analyses to new syndromes and emerging diseases.<sup>2</sup> In calling for such a national capability, HSPD-21 reflects the centrality of state and local resources in supporting the capability, stating that state and local government officials should be involved in system design and that the capability should be principally aimed at enhancing the capabilities of state and local governments.

In June 2010, we reported that although the federal government has undertaken some potentially useful steps for supporting a national biosurveillance capability, there is no unifying framework for integrating

<sup>&</sup>lt;sup>1</sup>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).

<sup>&</sup>lt;sup>2</sup>The White House, Homeland Security Presidential Directive 21: Public Health and Medical Preparedness (Washington, D.C.: Oct. 18, 2007).

# Prior GAO reports in Response to 9/11 Commission Act Mandate

GAO-10-171, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing (December 18, 2009)

What we found: The Department of Homeland Security's (DHS) National Biosurveillance Integration Center was not fully equipped to carry out its mission because it lacks key resources—data and personnel—from its partner agencies, which may be at least partially attributed to collaboration challenges it has faced.

What we recommended: DHS work with its interagency partners to establish a strategy and performance measures for collaboration. As of March 2011, DHS had not finalized a collaboration strategy, but officials reported that they had been working with interagency partners to develop it.

GAO-10-645, Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a Strategy and a Designated Leader, (June 30, 2010)

What we found: Biosurveillance activities were dispersed across federal agencies and no single entity had responsibility or authority for coordinating a strategic approach to building and maintaining a national biosurveillance capability.

What we recommended: The National Security Staff create a focal point to lead development of a national strategy. In August 2011, the National Security Staff informed us that it had created a Sub-Interagency Policy Committee within its Domestic Resilience Group to coordinate the development of a National Strategy for Biosurveillance.

Source: GAO.

dispersed capabilities and responsibilities and no entity with authority to guide the implementation of a national effort that encompasses all stakeholders with biosurveillance responsibilities. We recommended that the National Security Staff designate a focal point to develop a national biosurveillance strategy.<sup>3</sup> According to National Security Staff officials, they have designated a Sub-Interagency Policy Committee, which they said serves as the focal point for an ongoing effort to develop the national biosurveillance strategy.

The Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) directed us to examine the state of federal, state, local, and tribal biosurveillance efforts and the use of resources to implement and execute biosurveillance systems.<sup>4</sup> This report, which focuses on nonfederal, governmental—state, tribal, local, and insular—biosurveillance capabilities, is the third in a series designed to respond to that mandate.<sup>5</sup> Given the centrality of nonfederal jurisdictions in supporting a national biosurveillance capability, and to respond to the state, local, and tribal aspect of the 9/11 Commission Act's mandate, this report focuses on the following questions:

- 1. In the absence of a national biosurveillance strategy, what federal efforts support state and local jurisdictions' biosurveillance capabilities?
- 2. What challenges, if any, have selected state and local jurisdictions faced in building and maintaining biosurveillance capabilities?
- 3. How does the federal government support tribal and insular participation in a national biosurveillance capability and what challenges does it face?
- 4. To what extent has the federal government assessed nonfederal jurisdictions' capacity to contribute to a national biosurveillance capability?

<sup>&</sup>lt;sup>3</sup>GAO-10-645.

<sup>&</sup>lt;sup>4</sup>Pub. L. No. 110-53, § 1102, 121 Stat. 266, 379 (2007).

<sup>&</sup>lt;sup>5</sup>In consultation with congressional staff, we expanded the scope of this work to include insular areas, in addition to the state, local, and tribal levels specified in the mandate. 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.

To address our objectives, we reviewed key legislation and presidential directives related to biosurveillance, including the Homeland Security Act of 2002,6 the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.7 the Pandemic and All-Hazards Preparedness Act of 2006,8 and Homeland Security Presidential Directives (HSPD) 9,9 10,10 and 21. This report focuses on surveillance efforts for zoonosesdiseases that can be transferred between animals and humans—and other emerging infectious diseases with the potential to cause catastrophic human health effects. 11 At the federal level, we consulted officials at the Departments of Agriculture (USDA), Homeland Security (DHS), Health and Human Services (HHS), and the Interior (DOI), which have key missions, statutory responsibilities, directives, or programmatic objectives for biosurveillance activities within the scope of this report, including protecting human and animal health and national security. We also discussed biosurveillance at the state and city level with officials from the Department of Justice's Federal Bureau of Investigation.

To provide perspectives on the federal efforts that support state biosurveillance capabilities and the challenges officials face building and maintaining those capabilities, we selected a nongeneralizable sample of

<sup>&</sup>lt;sup>6</sup>Pub. L. No. 107-296, 116 Stat. 2135 (2002).

<sup>&</sup>lt;sup>7</sup>Pub. L. No. 107-188, 116 Stat. 594 (2002).

<sup>&</sup>lt;sup>8</sup>Pub. L. No. 109-417, 120 Stat. 2831 (2006).

<sup>&</sup>lt;sup>9</sup>The White House, Homeland Security Presidential Directive 9: Defense of United States Agriculture and Food (Washington, D.C.: February 3, 2004).

<sup>&</sup>lt;sup>10</sup>The White House, Homeland Security Presidential Directive 10: Biodefense for the 21st Century (Washington, D.C.: Apr. 28, 2004).

<sup>&</sup>lt;sup>11</sup>Our June 2010 work on biosurveillance efforts at the federal level explored surveillance for the following biosurveillance domains: human health, animal health, plant health, food, and the environment (specifically, air and water). Given further complexity arising from the number of and variation among states, localities, tribes, and insular areas, we narrowed the disease scope for this report. We focused on zoonotic disease agents because of the particular threats associated with them—detailed later in this report—and because threats from zoonotic disease agents clearly illustrate the potential benefits of an integrated biosurveillance capability. Given the focus on surveillance for zoonoses and other emerging infectious diseases in humans, certain federal efforts—for example, DHS's air monitoring system, BioWatch—are not discussed. Similarly, certain types of waterborne, foodborne, plant, or animal diseases—for example Foot and Mouth Disease—that could have devastating economic consequences or dire human health effects are not the focus of this report.

seven states based on a variety of factors that might affect biosurveillance efforts—including the structure of a state's public health system, its geography, and its amount and type of agriculture. The states selected were Utah, Colorado, New Jersey, California, Delaware, North Carolina, and Mississippi. In each of these states, we interviewed three groups of officials: (1) officials in public-health departments, (2) officials in state agriculture departments, and (3) officials in various departments that included wildlife infectious-disease control and monitoring in their missions. We also interviewed public-health officials with responsibility for human infectious-disease control and monitoring in two cities with an increased risk of bioterrorism—New York City and Washington, D.C.—that received direct funding from federal agencies to support preparedness capabilities. Among other things, we discussed the federal efforts that support their biosurveillance capabilities and the challenges they face in building and maintaining biosurveillance capabilities.

We analyzed the information collected during state and city interviews and developed follow-up questionnaires to confirm and enhance information from the interviews about the federal programs and initiatives that support state and local biosurveillance capabilities and the challenges officials face. We sent follow-up questionnaires to public health departments in all seven states and two cities and to agriculture and wildlife officials in the seven states. Within each public-health department, we sent separate questionnaires to laboratory and epidemiology officials. In total, we distributed 32 questionnaires and received 27 responses. Of the 27 respondents, 7 were epidemiologists, 7 were public health laboratory officials, 6 were state agriculture officials, and 7 were state wildlife officials. All of the public-health, agriculture, and wildlife departments represented by the 27 respondents had also been represented in our initial interviews. However, in some cases the lead official who responded to the questionnaire had not attended the interview.

The questionnaires had a section on federal support for state and local biosurveillance capabilities and a section on challenges. The content of the federal-support section varied for human-health and animal-health respondents, but the challenges section was the same for both. We asked respondents to consider federal-support efforts and challenges over the last 2 years. Because the states and cities in this review were not selected in a probability sample, neither the information derived from interviews with officials nor the questionnaire responses are generalizable across the 50 states or the tens of thousands of localities in the United States. Rather, both the interviews and the questionnaire results offer

some perspective on the value of select federal activities and challenges faced by a group of state and city officials who are actively engaged in efforts to detect and respond to major disease events. In addition, although we interviewed officials responsible for public-health emergency management in most state public-health departments that we visited, we did not administer follow-up questionnaires to the officials responsible for planning and preparing for emergency response, because their response focus was generally not central to our scope. Because this report focuses on detection of and situational awareness of potentially catastrophic zoonotic and emerging infectious-disease events, certain federal efforts that federal agencies consider important for supporting state and local preparedness may not have been identified by state and city officials during our interviews and follow-up questionnaires.

To consider the relationship between our findings at the nonfederal level and our previous findings at the federal level about building and maintaining a national biosurveillance capability, we reviewed our June 2010 findings about the centrality of nonfederal capabilities to a biosurveillance enterprise. We also reviewed our June 2010 findings about the purpose of a national biosurveillance strategy and the benefits it could provide for guiding the effort to support a national biosurveillance capability. We determined that because the federal government relies on nonfederal resources to support a national biosurveillance capability, our June 2010 findings about using the strategy to determine how to leverage resources, weigh the costs and benefits of investments, and define roles and responsibilities were particularly germane to the federal government's efforts to partner with nonfederal biosurveillance enterprise partners to support a national biosurveillance capability.

To understand how the federal government supports biosurveillance in tribal and insular areas, we consulted officials from HHS's Indian Health Service (IHS); HHS's Centers for Disease Control and Prevention's (CDC) Office of State, Tribal, Local and Territorial Support; CDC's Office of Surveillance, Epidemiology, and Laboratory Services, CDC's National Center for Emerging and Zoonotic Infectious Diseases, USDA's Office of Tribal Relations; USDA's Animal and Plant Health Inspection Service; DOI's Bureau of Indian Affairs; and DOI's Office of Insular Affairs, which

<sup>&</sup>lt;sup>12</sup>The biosurveillance enterprise is the whole combination of systems and resources at every level of government and the private sector that can contribute to timely detection and situational awareness of potentially catastrophic biological events.

have responsibility for working with tribal or insular councils and governments, generally, or on health-related matters. In addition, to develop additional context about health infrastructure and surveillance in insular areas, we interviewed representatives from the Pacific Island Health Officers Association (PIHOA), an association that works in the U.S.-Affiliated Pacific Islands to provide regional healthcare solutions and strengthen crosscutting public-health infrastructure. <sup>13</sup>

To evaluate the extent to which the federal government has assessed nonfederal jurisdictions' capacity to contribute to a national biosurveillance capability, we reviewed relevant presidential directives and federal-agency documents, along with our prior work and recommendations on building and maintaining a national biosurveillance capability, for criteria. We determined that such an assessment is called for in HSPD-10<sup>14</sup> and CDC's National Biosurveillance Strategy for Human Health<sup>15</sup> and is a critical activity for developing an effective national strategy containing the elements we advocated in prior work on national strategies. To determine what types of assessment activities had been undertaken and whether an enterprisewide assessment of nonfederal biosurveillance capabilities had been conducted, we reviewed relevant assessments and federal documents. We also interviewed federal officials at all five federal departments previously listed, officials in each of the seven states, officials in the two cities, and officials at 10 professional and research institutions that include public health, animal health, or laboratories in their missions about assessment efforts, to determine whether they had participated in or had any familiarity with an enterprisewide assessment of nonfederal capabilities. More detailed information about our scope and methods appears in appendix I.

<sup>&</sup>lt;sup>13</sup>The findings in this report about insular areas focus on the U.S.-Affiliated Pacific Islands. With the exception of Puerto Rico and the U.S. Virgin Islands, all commonwealths, territories, possessions, and freely associated states of the United States fall within the U.S.-Affiliated Pacific Islands.

<sup>&</sup>lt;sup>14</sup>HSPD-10 states 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. Because nonfederal entities play a critical role in biosurveillance, such an assessment would necessarily include the capability of nonfederal entities to support a biosurveillance capability.

<sup>&</sup>lt;sup>15</sup>In response to HSPD-21's charge for HHS to enhance biosurveillance for human health, CDC created the National Biosurveillance Strategy for Human Health with input from federal and other partners. The strategy states that an assessment is needed of the current workforce and the assets invested.

We conducted this performance audit from August 2010 to October 2011 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.

# Background

# Biosurveillance in Brief

As shown in figure 1, biosurveillance is a concept that emerged in response to increased concern about biological threats from emerging infectious diseases and bioterrorism. Biosurveillance is carried out by and depends on a wide range of dispersed entities, including state, tribal, local, and insular jurisdictions. As we reported in June 2010, because of the vast array of activities and entities associated with effective biosurveillance, ongoing interagency and intergovernmental collaboration is crucial.<sup>17</sup>

<sup>&</sup>lt;sup>16</sup>In January and April 2011, we briefed congressional staff on our preliminary findings.

<sup>&</sup>lt;sup>17</sup>GAO-10-645.

Figure 1: Biosurveillance in Brief



#### What is it?

In the biological context, surveillance is the ongoing collection, analysis, and interpretation of data to help monitor for pathogens in plants, animals, and humans; food; and the environment. The general aim of surveillance is to help develop policy, guide mission priorities, and provide assurance of the prevention and control of disease. In recent years, as concerns about consequences of a catastrophic biological attack or emerging infectious diseases grew, the term biosurveillance became more common in relation to an array of threats to our national security. Biosurveillance is concerned with two things: (1) reducing, as much as possible, the time it takes to recognize and characterize biological events with potentially catastrophic consequences and (2) providing situational awareness—that is, information that signals an event might be occurring, information about what those signals mean, and information about how events will likely unfold in the near future.



### Why is it important?

Although catastrophic events are rare, there are a number of threats of biological origin with the potential to cause catastrophic consequences. Since the 1970s, newly emerging diseases have been identified at the unprecedented rate of one or more per year. Moreover, terrorism experts have warned that both terrorists and nations have sought to obtain biological weapons. Finally, the nation's food and agriculture systems face threats from natural and intentional origin that could have devastating consequences in terms of both health and economic loss.



### How is it done?

Biosurveillance requires effective organizational systems, people, and technologies to ensure the nation's ability to detect a biological event with potential for catastrophic consequences and to provide situational awareness for response that gives decision makers and the public accurate information about how to prevent, manage, or mitigate catastrophic consequences. The backbone of biosurveillance is traditional disease-surveillance systems, which help professionals to recognize unusual disease signals and analyze their meaning, but generally have inherent limitations that affect the speed with which their results can be determined, communicated, and acted upon. Numerous federal, state, local, and private-sector entities with responsibility for monitoring plant, animal, and human health, food, and the environment have roles to play both in supporting traditional surveillance activities and in designing systems to focus specifically on enhancing detection and situational awareness. Because of the vast array of activities and entities associated with effective biosurveillance, ongoing interagency and intergovernmental collaboration is crucial.

Source: GAO analysis of agency data (data); Art Explosion (images).

Traditional Disease Surveillance Supports Biosurveillance

The backbone of biosurveillance is traditional disease-surveillance systems. Traditional disease-surveillance systems are 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. State and local public-health

#### **National Notifiable Disease List**

The Council of State and Territorial Epidemiologists, in consultation with CDC, updates the list of notifiable conditions and national surveillance case definitions every year. The list includes those diseases that CDC and state public-health officials have identified as posing a serious public-health risk for which case reports would help inform prevention and control efforts. State public-health departments verify cases of notifiable diseases, monitor disease incidence, and identify possible outbreaks within their states. States voluntarily report their notifiable disease data to CDC to support the National Notifiable Diseases Surveillance System. The agency publishes current data on notifiable diseases in its Morbidity and Mortality Weekly Report.

Source: GAO.

agencies have the authority and responsibility for carrying out most public-health actions, including disease surveillance and response to public-health emergencies in their jurisdictions. 18 State laws or regulations mandate disease reporting at the state and local level, but the state-based systems are coordinated at the national level by a voluntary set of reporting criteria and case definitions. For example, the mainstay of traditional disease surveillance in humans is the National Notifiable Diseases Surveillance System, through which state public-health departments voluntarily report their notifiable disease data to CDC. The National Notifiable Disease List includes those diseases that CDC and state public-health officials have identified as posing a serious publichealth risk for which case reports would help inform prevention and control efforts. Diseases on the nationally notifiable list range from sexually transmitted diseases, such as Human Immunodeficiency Virus and syphilis, to potential bioterrorism agents, such as anthrax and tularemia.

Similarly, to help protect the nation's agricultural sector, USDA has routine reporting systems and disease-specific surveillance programs, which rely on state-collected data, for domesticated animals and some wildlife that can provide information to support the early detection goal of biosurveillance. Many states have a statutory or regulatory list of diseases that animal-health officials are required to report to the state departments of agriculture. State animal-health officials obtain information on the presence of specific, confirmed clinical diseases in the United States from multiple sources—including veterinary laboratories, public-health laboratories, and veterinarians—and report this information to USDA's National Animal Health Reporting System (NAHRS). This system is designed to provide data from state animal-health departments on the presence or absence of confirmed World Organization for Animal Health reportable diseases in specific commercial livestock, poultry, and aquaculture species in the United States.

For wildlife, USDA's Animal and Plant Health Inspections Service's

Wildlife Services division is charged with conducting surveillance of

<sup>&</sup>lt;sup>18</sup>This allocation of responsibility reflects the fact that protection of public health is primarily a state responsibility. However, the federal government has acquired certain public-health responsibilities over the years, including acting in support of state and local public-health agencies. This kind of distribution of power between the central government and the states is called federalism, a term we use later in this report.

wildlife to detect zoonotic or other diseases that may pose threats to agriculture. The division's National Wildlife Disease Program is charged with conducting routine surveillance for targeted diseases and responding to mortality and morbidity events, particularly those occurring near humans or livestock. The program has wildlife disease biologists in most states that work to coordinate with state, local, and tribal officials to conduct surveillance and respond to events. In addition, DOI's U.S. Geological Survey's (USGS) National Wildlife Health Center is charged with addressing wildlife disease throughout the United States. This center provides disease diagnosis, field investigation, disease management and research, and training. It also maintains a database on disease findings in wild animals and on wildlife mortality events, although there is currently no national reporting system for wildlife diseases.

Disease-reporting systems help professionals to recognize unusual disease signals and analyze their meaning, but generally have inherent limitations that affect the speed with which their results can be determined, communicated, and acted upon. Many surveillance programs incorporate other methods of surveillance that have the potential to augment and enhance the detection and situational-awareness benefits of traditional disease reporting. For example, syndromic surveillance uses health-related data collected before diagnosis to look for signals or clusters of similar illnesses that might indicate an outbreak. An example of syndromic surveillance data is prediagnostic health-related information like patients' chief complaints recorded by hospital emergency room staff. However, we reported in September 2004 and November 2008 that the ability of syndromic surveillance to more-rapidly detect emerging diseases or bioterror events has not yet been demonstrated. 19 Another method used in disease surveillance efforts is sentinel surveillance, in which practitioners monitor for specific disease events in a targeted subset rather than an entire population. Sentinel surveillance can also promote early detection, for example by monitoring sentinel chicken flocks and testing for the presence of antibodies to arboviruses, such as West Nile virus, which could be spread by mosquitoes to humans.

# One Health Initiative

Recognizing that human and animal diseases are interconnected, several organizations—including the American Medical Association, the American Veterinary Medical Association, USDA, and HHS—have taken steps to support the One Health concept, which is a worldwide strategy for expanding interdisciplinary collaboration and communications in all aspects of health care for humans and animals.

Source: One Health Initiative

<sup>&</sup>lt;sup>19</sup>See GAO, Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts, GAO-04-877 (Washington, D.C.: Sept. 30, 2004) and Health Information Technology: More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program, GAO-09-100 (Washington, D.C.: Nov. 20, 2008).

Numerous federal, state, local, and private-sector entities with responsibility for monitoring animal and human health have roles to play both in supporting traditional surveillance activities and in designing systems to focus specifically on enhancing detection and situational awareness.

Biosurveillance Roles and Responsibilities in Nonfederal Jurisdictions Conducting biosurveillance is a shared responsibility among multiple local, state, and federal agencies, as well as among professionals across various disciplines in state, tribal, local, and insular jurisdictions. However, there is variation in organization and structure among public-health, animal-health, and wildlife functions at the state, tribal, local, and insular levels. For example, as shown in figure 2, a state's public-health structure may or may not be centralized.

States have no local health departments. 8% States have a centralized structure, 20% where state health agencies provide 37% local public health services. States function with some combination 35% of decentralized and centralized public health structures, where state and local health departments share responsibility for providing services at the local level or services are provided through the state or an agency organized or operated by local governments. States have a decentralized structure, where local health departments often collaborate with, but are organizationally independent of the state health agency.

Figure 2: State and Local Public Health Structure

Source: GAO analysis of Association of State and Territorial Health Offcials data.

On the other hand, livestock and poultry health is largely centralized within state departments of agriculture, relying on accredited veterinarians

across the state for detection. By contrast, wildlife disease surveillance largely lacks structure entirely and is dependent upon chance observations of unusual numbers of sick or dead wildlife, or both, being observed and reported to state or local wildlife agencies. The exception is USDA's National Wildlife Disease Program, which coordinates national surveillance and reporting of targeted diseases that may pose threats to human health or agricultural resources.

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

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. Epidemiologists may study disease in populations of animals as well as among human populations. Epidemiologists at state health departments are often responsible for analyzing data collected through disease-reporting systems, conducting outbreak investigations, and designing and evaluating disease-prevention and control efforts.
Informaticians	Public-health informaticians use systematic application of information, computer science, and technology to support public health. Public-health agencies at all levels seek staff with expertise in both public-health programs and information systems to help design, implement, and manage computer applications that support public-health goals.
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. Publichealth veterinarians in state health departments are usually housed in epidemiology divisions, but may be employed by the toxicology or environmental divisions in health departments.
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. These professionals are responsible for the conservation and maintenance of wildlife species and work to mitigate public-health and safety problems caused by wildlife, including the spread of zoonotic diseases.
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. Laboratory diagnosticians provide critical expertise to effectively identify and respond to publichealth emergencies through testing and monitoring of diseases. Clinicians can include publichealth nurses, physicians, pharmacists, accredited veterinarians, veterinarian technicians, veterinary pathologists, wildlife biologists, and laboratory diagnosticians.
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 epidemiologists work within the state health departments and lead efforts to analyze data collected through the disease-reporting network, decide when and how to supplement passive reporting with active surveillance methods, conduct outbreak and other disease investigations, and design and evaluate disease-prevention and control efforts. They also transmit state data to CDC, providing routine reporting on selected diseases.
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. These officials also work with their federal government counterparts in the prevention, detection and eradication of a number of foreign and domestic diseases associated with national animal-disease programs.

Nonfederal partner	Description
Laboratories	Public-health and animal-health laboratories serve a critical role in both initial detection and ongoing situational awareness of biological events. For example, public-health laboratories perform almost all testing to detect and monitor newly emerging infectious diseases such as West Nile virus and Severe Acute Respiratory Syndrome (SARS). For more information about these laboratories, see app. II.

Source: GAO

Public- and Animal-Health Structures Vary among Tribes and Most Insular Jurisdictions; Many Work with Federal Agency Partners **Tribal Jurisdictions.** As of October 2010, there were 565 federally recognized tribes—340 in the continental United States and 225 in Alaska. Federally recognized Indian tribes are Native American groups eligible for the special programs and services provided by the United States to Indians because of their status as Indians. Under the Indian Self-Determination and Education Assistance Act, as amended, federally recognized Indian tribes can enter into self-determination contracts or self-governance compacts with the federal government to take over administration of certain federal programs for Indians previously administered on their behalf by the Department of the Interior or HHS.

The Bureau of Indian Affairs, within DOI, and the IHS, within HHS, are the primary agencies that operate Indian programs within those two departments. IHS is charged with providing health care to the approximately 1.9 million American Indians and Alaska Natives who are members or descendants of federally recognized tribes. <sup>23</sup> These services are provided at federally or tribally operated health-care facilities, which receive IHS funding and are located in 12 geographic regions overseen by IHS area offices. These IHS-funded facilities vary in the services that

<sup>&</sup>lt;sup>20</sup>75 Fed. Reg. 60,810 (Oct. 1, 2010); 75 Fed. Reg. 66,124 (Oct. 27, 2010).

<sup>&</sup>lt;sup>21</sup>The federal government recognizes Indian tribes as distinct, independent political communities that possess certain powers of self-government. Federal recognition confers specific legal status on a particular Native American group, establishes a government-to-government relationship between the United States and the tribe, imposes on the federal government a fiduciary trust relationship to the tribe and its members, and imposes specific obligations on the federal government to provide benefits and services to the tribe and its members.

<sup>&</sup>lt;sup>22</sup>Pub. L. No. 93-638, 88 Stat. 2203 (1975) (codified as amended at 25 U.S.C. § 450-458ddd-2).

<sup>&</sup>lt;sup>23</sup>IHS defines an Indian tribe as any Indian tribe, band, nation, group, Pueblo, or community, including any Alaska Native village or Native group, which is federally recognized as eligible for the programs and services provided by the United States to Indians because of their status as Indians.

they provide. For example, some facilities offer comprehensive hospital services, while others offer only primary-care services. Although American Indian tribes are sovereign entities, IHS facilities follow disease-reporting regulations and use disease-reporting channels for the state in which tribal patients geographically reside. For example, tribal patients who live within the boundaries of Utah, New Mexico, or Arizona could use the same IHS facility in Shiprock, New Mexico. If a patient whose tribal residence is geographically located in Arizona presents at the Shiprock facility with a disease that the state of Arizona has designated as reportable, IHS would report it to Arizona public health officials. Tribes that manage their own health services use the national notifiable disease reporting system.

Land-based agricultural resources are vital to the economic and social welfare of many tribes. The Intertribal Agriculture Council is an organization of tribal agriculture producers and conducts programs designed to further the goal of improving tribal agriculture by promoting the Indian use of Indian resources through contracts and cooperative agreements with federal agencies.

Insular Jurisdictions. The United States has strategic and economic pacts with two jurisdictions in the Atlantic Ocean and six in the Pacific Basin. These jurisdictions are together referred to as insular areas and include the territories of American Samoa, Guam, and the U.S. Virgin Islands; the commonwealths of the Northern Mariana Islands and Puerto Rico; and the freely associated states of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. The pacts with the insular areas include the provision of federal assistance which, for example, can include funding to support publichealth preparedness efforts, such as building and maintaining basic public-health capabilities.

The insular areas rely on district hospitals, laboratories, and clinicians, or other health professionals, to detect and identify a potential disease outbreak or emerging disease. An astute clinician, laboratorian, or other health professional may be the first to identify an emerging disease or a potential outbreak by identifying new patterns in a disease seen in patients at their hospital. To confirm these suspicions, practitioners depend on the laboratory network supported by PIHOA—an association that works to provide regional health-care solutions for the Pacific insular areas. The lab network consists of 10 hospitals and public-health labs, with varying levels of laboratory capacity, in the Pacific insular areas. All the hospital laboratories, except for those in Guam—which has a

### **Vectors Transmit Zoonotic Diseases**

According to CDC, some of the world's most destructive diseases are vector-borne—that is they are transmitted to humans and animals by vectors such as ticks, mosquitoes, or fleas. CDC also contends the United States is at a greater risk than ever from vector-borne diseases—such as West Nile virus, Lyme disease, dengue fever, chikungunya, and Rocky Mountain spotted fever—due to globalization and climate change.



Source: GAO analysis of CDC data (data); CDC, James Gathany (photos).

separate public-health laboratory—play a dual role in providing both clinical and public-health laboratory services in their own jurisdictions. The laboratories in this network have limited testing capabilities, though, and often medical officials must send specimens to Hawaii, the U.S. mainland, or Australia for additional testing.

CDC officials said that the Pacific insular areas present a challenge to global disease spread and detection, because the region has experienced outbreaks of emerging infectious disease and has lower detection capacity. According to CDC officials, in the age of routine air travel and with the rights granted to foreign nationals of some Pacific insular areas under the Compacts of Free Association, the risk of insular residents traveling to U.S. territories, Hawaii, and the mainland with undiagnosed and potentially dangerous infectious diseases is troublesome. Additionally, according to DOI officials, issues surrounding international travel create challenges to ensuring timely response to disease outbreak events in insular areas.

USDA operates disease-eradication and investigation activities, export certification, and surveillance actions in most U.S. insular areas. In addition, USDA's National Wildlife Disease Program has an office in Hawaii that supports activities to conduct surveillance for and respond to outbreaks of disease in wildlife that pose threats to human health and agricultural resources.

DOI's USGS National Wildlife Health Center, located in Madison, Wisconsin, assists state and federal agencies with wildlife health-related issues and has a Honolulu Field Station, which is staffed by a wildlife disease specialist and three biological technicians. The Honolulu Field Station was established to serve state and federal agencies in Hawaii and the Pacific, including the insular areas. The Honolulu Field Station provides training to biologists regarding response to unusual wildlife mortalities and performs laboratory and field investigations to determine the cause of death in wildlife.

Humans, Livestock, Wildlife, and the Spread of Zoonotic Diseases

About 75 percent of the new diseases that have affected humans over the past 10 years are zoonotic and have been caused by pathogens originating from an animal. Many of these diseases have the potential to spread through various means over long distances and to become global problems. As shown in figure 3, these emerging and reemerging diseases transmit between animals—including livestock and wildlife—and humans. In some cases, disease transmission is direct, in others the animals act

as intermediate or accidental hosts, while in others transmission occurs via arthropod—for example, mosquitoes or ticks—vectors. Examples of such emerging and zoonotic diseases include: West Nile virus, H1N1, SARS, avian influenza, and rabies. Potential bioterrorism threats also include the use of zoonotic diseases as weapons of mass destruction, such as anthrax, plague, tularemia, and brucellosis.

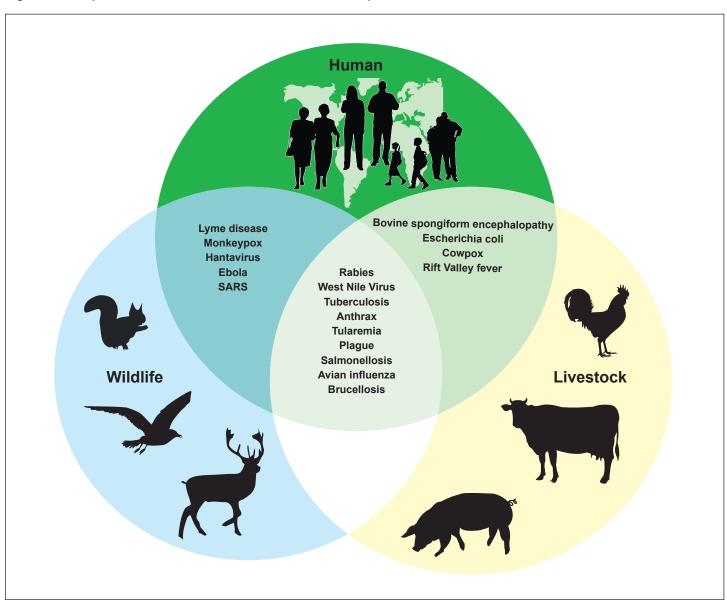


Figure 3: Examples of Zoonotic Diseases and Their Affected Populations

Source: GAO analysis of USGS data (data); Art Explosion (images).

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 vectors 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. DOI's USGS 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.

We Previously Recommended That the National Security Staff Develop a National Biosurveillance Strategy

### **Brucellosis and Feral Swine**

According to USDA, more than 4 million feral swine are found in at least 35 states and destroy farmland and crops, compete with native wildlife for food, and can spread disease to other animals and people.



Hunting feral swine is a popular sport among hunters, and also serves as a population control method which wildlife agencies support, but there are more than 24 diseases that people can get from feral swine. While most of these diseases are spread by eating undercooked meat, the germs that cause swine brucellosis are spread by swine through birthing fluids and semen. People become exposed to the germs through contact with an infected swine's blood, fluids, or tissues (such as muscles, testicles, liver, or other organs). Domestic swine are also threatened by brucellosis through contact with infected feral swine.

Source: GAO analysis of USDA data (data); USDA (photo).

In June 2010, we reported that while some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biosurveillance responsibilities that can be used to guide the systematic identification of risk, assessment of resources needed to address those risks, and the prioritization and allocation of investment across the entire biosurveillance enterprise. We found that the decision makers responsible for developing a national biosurveillance capability are spread across multiple agencies and departments, and rely on support from state and local authorities. We noted that our prior work on complex undertakings like biosurveillance can benefit from strategic oversight mechanisms, such as a focal point and a national strategy, to coordinate and lead efforts across the multiple federal departments with biosurveillance responsibilities. We recommended that the Homeland Security Council, which was established to serve as a mechanism for ensuring coordination of federal homeland security-related activities and development of homelandsecurity policies, should direct the National Security Staff to establish a focal point and charge this focal point with the responsibility for developing a national biosurveillance strategy.<sup>24</sup>

In August 2011, the National Security Staff reported that it had created a biosurveillance Sub-Interagency Policy Committee, under the guidance of the Domestic Resilience Group, to serve as a focal point in order to coordinate the development of a National Strategy for Biosurveillance. They said the strategy, and the implementation guidance to it, will define the overall purpose of the U.S. government biosurveillance effort, and will pay particular attention to the assignment of roles and responsibilities. These efforts are the first steps taken to address the findings in our June 2010 report.

<sup>24</sup>GAO-10-645.

Absent a Strategy and Biosurveillance-Specific Capability Efforts, Existing Federal Activities Help Support State and Local Capabilities In the absence of a national biosurveillance strategy, the federal government has some efforts, including emergency preparedness, disease-specific surveillance, and laboratory enhancement programs, that provide resources and information that state and city officials say are critical to their efforts to build and maintain capabilities. The federal programs and initiatives that officials identified during interviews as useful for supporting their biosurveillance capabilities generally fell into four categories, which respondents to our follow-up questionnaire ranked in descending order of importance as follows: (1) grants and cooperative agreements, (2) nonfinancial technical and material assistance, (3) guidance, and (4) information sharing.<sup>25</sup> As we reported in June 2010, about federal biosurveillance activities, without a strategic approach to build and maintain a national biosurveillance capability, these efforts continue to be uncoordinated and not specifically targeted at ensuring the most-effective and efficient biosurveillance capability.

Federal Grants and Cooperative Agreements Provide Essential Support for State and Local Biosurveillance Capabilities

### Cooperative agreements

Unlike a grant, a cooperative agreement provides for substantial involvement between the federal agency and the recipient in the programmatic or research activity.

Source: Office of Management and Budget.

Nearly all—26 of 27—of the questionnaire respondents identified grants and cooperative agreements as the most important type of federal assistance they receive. During interviews, state and local officials in multiple agriculture, public-health, and wildlife departments said that they are completely or largely dependent on federal funding for biosurveillance-related activities and that their biosurveillance capabilities would be limited without these federal grants and cooperative agreements.

State and city officials we interviewed noted that grants and cooperative agreements generally serve a dual purpose in that they both provide guidance on federal priorities, goals, and objectives and provide financial support to pursue those priorities. For example, when we asked publichealth officials about the federal efforts that support their capabilities, five of nine public-health departments cited the guidance on planning and federal priorities that they receive in conjunction with the Public Health Emergency Preparedness (PHEP) cooperative agreement. At the same time, six of nine public-health departments we interviewed cited PHEP

<sup>&</sup>lt;sup>25</sup>We calculated an overall rank for the importance of federal support categories, as identified by respondents to our questionnaire. We assigned numerical value to each observation, a value of 4 each time a respondent identified a type of federal assistance as most important, 3 for second-most important, 2 for third-most important, and 1 for fourth-most important.

## Capabilities

<u>Capability:</u> In the context of emergency management and related functions, a capability is the combination of leadership and organization, planning, personnel, training, equipment and systems, and assessment needed to successfully execute a particular mission.

Core Capability: For biosurveillance, the particular mission is (1) detecting and characterizing signs of potentially catastrophic disease outbreaks in a timely fashion to minimize their effects and (2) providing situational awareness to respond effectively. Because of the variation in approaches and organization across jurisdictions, the specific activities considered "core" may differ by respondent; however, at a minimum, these would include conducting investigations and providing laboratory diagnostics.

Based on the concepts expressed in interviews with state and city officials, we provided the following definition for "federal efforts that support core capabilities" in our follow-up questionnaire: This federal support is essential to core biosurveillance capabilities. Without this support, it would not be possible to carry out core functions or those functions would be significantly diminished.

A National Biosurveillance Capability: A national biosurveillance capability is the combination of capabilities of all jurisdictions and entities that constitute the biosurveillance enterprise working in concert to achieve the timely detection and situational awareness goals of biosurveillance, particularly for potentially catastrophic biological events.

Source: GAO.

funding as critical for supporting their capability resources, such as additional staff to increase investigation and diagnostic capacity, and for building and maintaining those capabilities identified as priorities. Officials from one public-health department said that the funding they receive for PHEP and another CDC cooperative agreement—Epidemiology Laboratory and Capacity for Infectious Diseases (ELC)—pays the salaries of 70 percent of their communicable-disease staff, including the salaries of their scientists, researchers, physicians, and data analysts. Moreover, these officials said the federal cooperative agreements enable the department to conduct outbreak investigations that were not possible before PHEP and ELC funding was available. Similarly, laboratory officials in one state we visited said that the cooperative agreements enable the department to pay for additional public-health positions, training, and laboratory testing efforts and equipment, and without the cooperative agreements, their laboratory testing capacity would be considerably reduced.

In interviews, agriculture officials in five of seven states said that their departments depend on federal funding to conduct surveillance efforts. For example, officials from three of the states said federal grants and cooperative agreements enable their departments to, among other things, collect and test specimens and purchase equipment for surveillance efforts. Similarly, wildlife officials from four states we interviewed said that their dependence on federal funding dictates priorities for certain surveillance efforts—such as the funding for avian influenza and chronic wasting disease surveillance efforts—and they would likely not conduct active surveillance efforts like these without federal support. <sup>26</sup> In follow-up questionnaires, we asked officials to identify the federal grants and cooperative agreements that were essential to their core biosurveillance capabilities. Table 2 shows the federal grants and cooperative agreements most commonly identified as essential to their core

<sup>&</sup>lt;sup>26</sup>Active surveillance involves actively looking for signs or seeking clinical diagnoses for specific disease agents in specific populations. In contrast, passive surveillance relies on astute clinicians and other existing systems to detect signs or symptoms of disease outbreaks, which often trigger further investigation to identify and characterize disease outbreaks. The federally-supported avian influenza and chronic wasting disease programs are active surveillance programs because wildlife officials collect samples from birds and cervids, and laboratories diagnose the presence or absence of the target diseases in those samples. Without active surveillance programs, wildlife officials generally rely on the public or biologists in the field to notify them of animal die-offs and other signs of disease outbreaks.

biosurveillance capabilities by the 27 officials who responded to our questionnaire, by group. For more information on questionnaire results, see appendix III.

Table 2: Grants and Cooperative Agreements Most Commonly Identified by City and State Questionnaire Respondents as Essential for Supporting Their Core Biosurveillance Capabilities

Grant or cooperative		Respondents identifying the federal initiative as essential	
agreement	Description	Group	Number
Public Health Emergency	CDC provides funding and technical assistance through	Public health epidemiology	7 of 7
Preparedness cooperative agreement (PHEP)	the PHEP cooperative agreement for the development and strengthening of recipients' response capabilities during public health incidents. PHEP awardees include 50 states, 8 territories and freely associated states, and 4 localities.	Public health laboratory	7 of 7
Epidemiology and	CDC supports public health capacity by providing public health departments funding through the ELC cooperative agreement to hire and train staff, buy laboratory equipment and supplies for diagnosing emerging pathogens, and invest in information technology to improve disease reporting and monitoring. CDC also provides technical support and funding, through this cooperative agreement, to states to develop and enhance syndromic surveillance systems.	Public health epidemiology	7 of 7
Infectious Diseases agreement cooperative agreement (ELC) pathogen improve of provides cooperati		Public health laboratory	7 of 7
Avian influenza cooperative agreement	USDA provides funding to states through cooperative agreements for expanded bird monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.	Agriculture	6 of 6
Chronic wasting disease cooperative agreements	USDA provides coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance programs.	Wildlife	6 of 7

Source: GAO.

Note: Each group of officials was asked about just those federal grants and cooperative agreements that pertain to their own field. For example, only public health epidemiologists and public health laboratory officials were asked about PHEP, and only lead agriculture officials were asked about avian influenza grants. Out of the 27 officials who responded to our questionnaire, 7 of the respondents were epidemiologists, 7 of the respondents were public health laboratory officials, 6 of the respondents were state agriculture officials, and 7 of the respondents were state wildlife officials.

Nonfinancial Technical and Material Assistance Helps Build Capacity across Jurisdictional Boundaries Respondents to our follow-up questionnaire ranked nonfinancial technical and material assistance as the second-most important type of federal support for building and maintaining biosurveillance capabilities. According to state and local officials, the nonfinancial assistance efforts they identified help to, among other things, support biosurveillance capacity by improving state and local capacity to identify and diagnose

diseases. For example, state public-health, agriculture, and wildlife officials said that training opportunities sponsored by the federal government help enhance and standardize their laboratory testing methods, epidemiological investigations, and specimen-collection procedures, which helps state and local officials develop more efficient and effective disease diagnostic capabilities. In addition, in interviews, officials from both public health and agriculture said that the chance to work together on concrete projects like avian influenza planning and surveillance projects gave them an ongoing reason to communicate and collaborate.

Public-health officials from five of nine public health departments we visited said, in interviews, that they rely on CDC's subject-matter expertise to either guide their efforts during an event—such as the 2009 H1N1 outbreak—or to answer questions about a specific investigation. Moreover, public-health officials in three of seven states said that without this and other types of nonfinancial assistance, their department would not be able to conduct as many investigations and the efficiency with which they could diagnose a disease would decrease. In addition, public-health officials from one state said the ability to get CDC's help confirming results and to send specimens with unusual characteristics, which are difficult to identify, increases the state's laboratory capacity and improves the efficiency with which the state can diagnose an unusual disease.

Similarly, agriculture officials we interviewed in one state said if they did not have the National Veterinary Services Laboratory (NVSL) to provide confirmation for unusual disease samples, they would be less prepared to handle disease outbreaks. Finally, wildlife officials from one state said working in the field with federal officials to trap animals and collect samples has enhanced their relationships with federal officials, their knowledge of new sampling procedures and surveillance data management, and their ability to work with USDA officials during the grant process. In follow-up questionnaires, we asked officials to identify the federal nonfinancial and technical assistance efforts that were essential to their core biosurveillance capabilities. Table 3 shows the federal nonfinancial and technical assistance efforts most commonly identified as essential to their core biosurveillance capabilities by the 27 officials who

<sup>&</sup>lt;sup>27</sup>The NVSL is a federal laboratory that serves as in international reference laboratory and conducts tests and confirms tests for other laboratories. See also app. II.

responded to our questionnaire, by group. For more information on questionnaire results, see appendix III.

Table 3: Types of Nonfinancial Assistance Most Commonly Identified by City and State Questionnaire Respondents as Essential for Supporting Their Core Biosurveillance Capabilities

		Respondents Identifying the Federal Initiative as Essential	
Nonfinancial Assistance	Description	Group	Number
Expert consultation for epidemiological investigation	CDC provides support to state and local officials during outbreaks through conference calls, one-on-one discussions, and the provision of epidemiology aides to assist public-health departments with their investigations.	Public health, epidemiology	6 of 7
Standards to improve disease reporting	Federal agencies develop standards, such as the Public Health Information Network, to improve disease reporting and information sharing. The Public Health Information Network is a national initiative to improve the capacity of public health organizations to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements.	Public health, epidemiology	6 of 7
Secondary laboratory confirmation	CDC provides secondary laboratory confirmation testing support to state and local public-health departments to confirm unusual diseases or to verify positive test results for select agents—biological agents and toxins that have the potential to pose a severe health threat.	Public health, epidemiology	6 of 7
		Public health, laboratory	7 of 7
Laboratory equipment	CDC supplies state public-health laboratories with critical reagents and assays for a wide variety of laboratory tests to ensure laboratory tests are properly conducted.	Public health, epidemiology	6 of 7
		Public health, laboratory	7 of 7
Laboratory testing of specimens with unusual characteristics	CDC provides laboratory-testing support to states and localities, including the testing of specimens with unusual characteristics, which may be difficult for state or local laboratories to identify.	Public health, laboratory	7 of 7
Training	Federal agencies provide various types of training opportunities to state and local officials, including training that covers new sampling and testing methods, new reporting standards, or safety standards.	Public health, laboratory	7 of 7
Equipment and supplies	Federal agencies provide states with equipment and supplies, such as sampling kits, assays, and personal protective equipment, to help states conduct outbreak investigations.	Agriculture	5 of 6
Laboratory testing	Several federal laboratories support states' efforts to diagnose a disease. For example, NVSL is a federal reference laboratory—a laboratory that conducts and confirms tests for other laboratories. The Foreign Animal Disease Diagnostic Laboratory tests for highly contagious diseases such as foot-and-mouth disease. The USGS National Wildlife Health Center is the only federal laboratory in the United States dedicated to wildlife disease investigation and offers laboratory support to states for wildlife disease diagnostics. USDA's National Wildlife Research Center has the ability to provide surge diagnostics for wildlife samples when necessary.	Wildlife	3 of 7

Source: GAO.

Note: Each group of officials was asked about just those types of federal nonfinancial assistance that pertain to their own field. Out of the 27 officials who responded to our questionnaire, 7 of the respondents were epidemiologists, 7 of the respondents were public-health laboratory officials, 6 of the respondents were state agriculture officials, and 7 of the respondents were state wildlife officials.

Most Guidance Accompanies Federal Funding Programs, but Officials Also Find Other Guidance Useful

The category of federal assistance ranked third overall in importance by state and city questionnaire respondents is guidance. Additionally, during our site visits, the majority of state and city officials we interviewed—16 of 23—said the primary source of federal guidance related to biosurveillance accompanies federal grants and cooperative agreements and serves the purpose of shaping programmatic goals, objectives, and priorities. For example, the public-health epidemiologists and laboratory director for one city said that the detailed capability guidance that accompanied the most recent round of PHEP funding helped the city perform a gap analysis, the results of which will serve as a planning guide over the next 5 years. In addition, four of nine public-health departments we spoke with discussed guidance that supports their efforts to build and maintain biosurveillance capabilities by supporting specific activities that constitute their capabilities, for example, guidance regarding standardized case definitions, disease-reporting requirements, and sampling procedures for unusual or emerging disease agents. Public-health officials in one state we visited said that guidance on standardization is essential to ensure states are able to move information to CDC more efficiently, and without standardization it would be difficult to exchange information with their partners. Similarly, agriculture officials in one state we visited said federal sampling standards help interpret information about disease occurrence in other states, because the significance of results is uniform nationwide. These officials said that without this guidance, they would need to develop protocols state-by-state to interpret results, which would lead to a loss of efficiency in animal diagnostic laboratory protocols and interpretation of results.

In follow-up questionnaires, we asked respondents to characterize the various types of guidance, which had previously been identified in interviews, as very useful, moderately useful, somewhat useful, or not useful in supporting their biosurveillance capabilities. Table 4 shows the sources of federal guidance the 27 officials who responded to our questionnaire—by group—most commonly identified as very useful for supporting biosurveillance capabilities. For more information on questionnaire results, see appendix III.

Table 4: Types of Federal Guidance Most Commonly Identified by City and State Questionnaire Respondents as Being Very Useful for Supporting Their Core Biosurveillance Capabilities

Type of nonfinancial		Respondents identifying the federal initiative as very useful	
assistance	Description	Group	Number
Federal guidance for disease-reporting requirements	Federal agencies develop disease-reporting requirements for state and local jurisdictions for those diseases posing a serious public-health, animal-health, or economic risk for which case reports would help inform prevention and control efforts.	Public health, epidemiology	5 of 7
Federal guidance for standardized case definitions	Federal agencies provide guidance for standardizing case definitions to improve disease reporting and information sharing. For example, CDC published the Case Definitions for Infectious Conditions Under Public Health Surveillance, which provides uniform criteria for state health-department personnel to use when reporting notifiable diseases to CDC.	Public health, epidemiology	5 of 7
Federal guidance regarding safety and security measures for specimen handling	Federal agencies provide states and localities with guidance concerning the appropriate methods for handling, storing, and shipping specimens.	Public health, epidemiology	5 of 7
Federal guidance for best practices for laboratory testing protocols	Federal agencies provide states and localities with guides outlining the best practices for laboratory testing protocols.	Public health, laboratory	6 of 7
Federal priorities, goals, and objectives communicated through grant and cooperative agreement guidance	provides instructions to state agencies about applying for and executing federal projects with funding, including federal	Agriculture	4 of 6
		Wildlife	3 of 7

Source: GAO

Note: Each group of officials was asked about just those types of federal guidance that pertain to their own field. Out of the 27 officials who responded to our questionnaire, 7 of the respondents were epidemiologists, 7 of the respondents were public health laboratory officials, 6 of the respondents were state agriculture officials, and 7 of the respondents were state wildlife officials.

Information-Sharing Tools and Analytical Products Provide Critical Information about Disease Outbreaks

Information-sharing tools and analytical products was the category ranked fourth in importance by our 27 questionnaire respondents. In interviews, officials said that without the knowledge they gain through these tools and products they would lack critical information about emerging-disease situations in neighboring states and throughout the nation. For example, public-health officials in one state noted that they would lack context about a health situation in their state without the knowledge they gain through these systems and reports about incidents in neighboring states and throughout the nation. In addition, they said these tools are useful in helping them to better understand baselines for various diseases they observe in their own jurisdictions. Public-health officials in another state we interviewed noted that without the information provided by PulseNet, their ability to detect foodborne outbreaks would be diminished.

# Southeastern Cooperative Wildlife Disease Study (SCWDS)



The wildlife agencies of 19 states (shaded on map) and Puerto Rico and the U.S. Geological Survey of DOI fund regional wildlife research and service projects through SCWDS, and USDA's Veterinary Services provides support for national and international surveillance activities where diseases may spread among wildlife and livestock. SCWDS provides wildlife-disease expertise to state and federal agencies responsible for wildlife and domestic livestock resources. SCWDS aims to detect causes of illness and death in wildlife, characterize the effect of diseases and parasites upon wild animal populations, identify disease interrelationships between wildlife and domestic livestock, and determine the role of wildlife in transmission of human diseases.

Source: GAO analysis of SCWDS data (data); MapQuest

Likewise, agriculture officials we interviewed in one state said without the compiled information that federal agencies share with them—for example. disease data on USDA's Veterinary Service Laboratory Submissions website—they would be operating blindly and would need to spend time contacting other states to know what is happening outside their borders.<sup>28</sup> They said this information is particularly useful when it comes to animal movement across state lines, so that they are aware of those diseases of concern in different areas of the country. Similarly, wildlife officials from one state said that the information shared by federal agencies provides awareness of disease threats in their state and information about how to respond if they encounter the disease in question. They said that the lack of this information could delay the state's detection of a potentially devastating disease, because outbreak signals—like animal die-offs would have to trigger an investigation in their state—before they had any awareness of looming disease threats. In follow-up questionnaires, we asked officials to identify the types of information sharing tools and analytical products that were essential to their core biosurveillance capabilities. Table 5 shows the types of information sharing tools and analytical products most commonly identified as essential to their core biosurveillance capabilities by the 27 officials who responded to our questionnaire, by group. For more information on questionnaire results, see appendix III.

<sup>&</sup>lt;sup>28</sup>Some federal information is available only to the state where the data were collected; in other cases regional or state-by-state information is available. For example, according to officials, USDA's Veterinary Service Laboratory Submissions website provides data about other states' wild bird avian influenza activity, but for most of its disease modules the data are restricted to officials in the state where they were collected.

Table 5: Types of Information-Sharing Tools and Analytical Products Most Commonly Identified by City and State Questionnaire Respondents as Essential to Supporting Their Core Biosurveillance Capabilities

Type of information- sharing tools and analytical products		Respondents identifying the federal initiative as essential	
	Description	Group	Number
PulseNet	PulseNet is an early warning system for outbreaks of foodborne diseases. The network has participants from public-health laboratories in all 50 states, federal regulatory agencies, and some state agricultural laboratories and is coordinated by CDC. PulseNet contributes to the identification and investigation of outbreaks of foodborne and bacterial diseases through comparison of the molecular "fingerprints" of foodborne pathogens from patients and their food, water, and animal sources.	Public health, epidemiology	7 of 7
		Public health, laboratory	7 of 7
Meetings and conferences sponsored by professional associations	Professional associations sponsor meetings and conferences, in association with federal partners. In addition to providing information about a specific topic, these events help foster information sharing between state and federal officials.	Agriculture	5 of 6
USDA Veterinary Service Laboratory Submissions website	State officials can submit and access disease data, such as wild-bird avian influenza data, through the USDA Veterinary Services Laboratory Submissions site.	Agriculture	5 of 6
Information and reports of disease occurrence from the Southeastern Cooperative Wildlife Disease Study (SCWDS)	SCWDS, which receives funding from the Department of the Interior and the United States Geological Survey (USGS) National Wildlife Health Center, provides reports and coverage maps that identify disease occurrence for select diseases.	Wildlife	5 of 7

Source: GAO.

Note: Each group of officials was asked about just those types of federal information-sharing tools and analytical products that pertain to their own field. Out of the 27 officials who responded to our questionnaire, 7 of the respondents were epidemiologists, 7 of the respondents were public health laboratory officials, 6 of the respondents were state agriculture officials, and 7 of the respondents were state wildlife officials.

In June 2010, when we recommended that the National Security Staff lead the development of a national biosurveillance strategy, we noted that an effective national biosurveillance strategy could help identify the resources currently being used to support a biosurveillance capability, additional resources that may be needed, and opportunities for leveraging resources. <sup>29</sup> Although not generalizable to the whole biosurveillance enterprise, our findings suggest that there are existing federal resources that nonfederal officials find essential to their efforts and could provide a starting point for considering how to leverage nonfederal resources.

<sup>&</sup>lt;sup>29</sup>GAO-10-645.

Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to leverage existing efforts and resources in federal, state, tribal, local, and insular jurisdictions could improve efforts to build and maintain a national biosurveillance capability.

State and Local
Officials Reported
Challenges Related to
State Policies, Core
Capability Resources,
and Planning and
Leadership to Support
Biosurveillance
Capabilities

State and city officials we spoke with reported a variety of challenges in building and maintaining biosurveillance capabilities. These challenges generally fell into three different groups: (1) state policies enacted in response to fiscal constraints, (2) obtaining and maintaining resources to support capabilities, and (3) leadership and planning challenges. In the follow-up questionnaire, we asked respondents how challenges identified in the interviews affect their capabilities and to rank the top three challenges they face. For each challenge respondents identified facing, we asked them to indicate whether or not the current combination of resources, leadership, and planning in their jurisdictions were adequate to address that challenge. The challenges reported here are only those that respondents indicated are not currently adequately addressed. For additional information about questionnaire results related to challenges, see appendix IV.

State Policies May Constrain Hiring, Travel, and Information Technology, Even When Federal Funding Is Available One set of challenges that state and city officials described to us had to do with the state and local budget crises and the policies states have put in place to respond to this challenge. Specifically, in interviews with state public-health, agriculture, and wildlife departments, multiple officials reported barriers that state policies presented for building and maintaining a biosurveillance capability. Among these barriers were (1) an inability to use federal funding for new positions because of state hiring restrictions, (2) an inability to attend national trainings and conferences (even when federal travel funding is available) because of state travel restrictions, and (3) an inability to participate in training and other online forums sponsored by federal agencies and professional associations because of state restrictions on when and how they can use information technology in their offices.

In follow-up questionnaires, 20 of 27 respondents identified these kinds of state policies as a challenge to building and maintaining biosurveillance capability. One respondent who ranked this kind of challenge among the top three challenges noted that state policies on hiring require the use of contractors rather than full-time equivalent personnel. As a consequence,

the respondent noted, the knowledge accrued through the course of onthe-job training leaves the agency when a given contract ends.

Although federal agencies who work to help support capabilities in state and local jurisdictions have limited ability to directly affect state policies, CDC officials say they are aware of the issue and agree that it is a challenge—in some cases severely hampering states' ability to move forward with capability building. The CDC officials said they have discussed the issue with their state and local partners as part of a larger effort to explore various funding options to help better support capability building.

### State and City Officials Report Concerns about Resources

A second set of challenges reflected general concerns about the resources that support biosurveillance capabilities, such as appropriately trained personnel, systems, and equipment. Nineteen of 27 respondents to our follow-up questionnaires reported facing workforce shortages among skilled professionals—epidemiologists, informaticians, statisticians, laboratory staff, animal-health staff, or animal-disease specialists. One respondent who rated this particular challenge among the top three noted that noncompetitive salaries had resulted in lack of interest in positions and high turnover. As a consequence, according to the respondent, investments in training yield lower returns and quality of the overall workforce is affected.

Sixteen of 27 questionnaire respondents reported problems with training availability. A state wildlife official who rated training availability as the top current challenge noted that without proper training, staff in the field—who often have duties other than disease surveillance—lack an understanding of the importance of surveillance and reporting, as well as knowledge of the techniques to carry it out. Fourteen of 27 questionnaire respondents indicated issues with workforce competency—hiring and retaining professionals with adequate training and education. One of the respondents that rated this challenge among the top three noted that without properly trained staff to support them, initiatives languish. She also noted that the need for the few skilled personnel to provide on-the-job training and education consumes time and affects workflow.

Fifteen of 27 questionnaire respondents reported that keeping up with ongoing systems maintenance and enhancement needs has been challenging. One respondent who rated ongoing systems maintenance and enhancement among the top three challenges said that public-health informatics, including state-of-the-art database systems and effective

electronic linkages, are critical to surveillance, but place demands on resources to attract and maintain public-health informatics expertise and support database applications. Thirteen of 27 questionnaire respondents reported challenges maintaining adequate laboratory capacity. One laboratory official who ranked this among the top three challenges stated that many at the public-health lab are nearing retirement and it has been difficult to attract and retain younger laboratory scientists to work in public health.

State and City Officials Report Leadership and Planning Challenges That Could Be Considered in a National Biosurveillance Strategy

The third set of challenges state and city officials that we interviewed reported included (1) difficulty planning for longer-term capability-building efforts because of uncertainty from year to year about whether project funds would be available; (2) difficulty planning to invest in basic capabilities for multiple disease threats because federal funding has focused on specific diseases rather than strategically building core capabilities; (3) limited leadership and planning—at all levels of the biosurveillance enterprise—to support regional and integrated disease data-surveillance approaches; and (4) differing priorities and other partnership issues. Many of the challenges that state and city officials identified are similar to issues we reported regarding biosurveillance at the federal level. We noted that many of the challenges like these that face the biosurveillance enterprise are complex, inherent to building capabilities that cross traditional boundaries, and not easily resolved. We recommended in June 2010 that a leadership mechanism, such as a focal point, and a strategy could help define the scope of the problems to be addressed, in turn leading to specific objectives and activities for tackling those problems, better allocation and management of resources, and clarification of roles and responsibilities.

In our follow-up questionnaires, by far the single most-commonly reported challenge was funding instability and insecurity, with 25 of 27 questionnaire respondents identifying it as a challenge that has not been adequately addressed. Among those, 23 ranked it as one of the top three challenges and 16 of those ranked it as their top challenge. In interviews, officials in both the human- and animal-health communities noted that they receive little or no support from state budgets for surveillance activities, leaving them largely reliant on federal funding for this type of activity. Moreover, two agriculture officials noted that it is difficult for states to develop long-term plans for building and maintaining capabilities because they do not know how much funding they will receive from year to year. For example, three of the nine visits we made to state publichealth departments occurred near the application deadline for the new

PHEP cooperative agreements. All three sets of public health officials reported receiving news of a last minute reduction in funding—which according to CDC officials equaled 12 percent—that resulted in the need to significantly revise their PHEP application and accompanying plan for building and maintaining capabilities, in a short time frame.

In interviews, agriculture officials in three of the seven states we visited said they receive little or no funding in their state budgets to support biosurveillance activities and depend on federal funding, which they say has been decreasing. Because of the decreases in funding, the agriculture officials from one state said that their department has decreased its staff level by half over the past 6 years, and these officials noted that without federal funding the department's biosurveillance capabilities would be minimal. Likewise, wildlife officials in five of the seven states we visited said that they receive little or no funding for surveillance from their state budgets and rely on federal programs to support surveillance.

Federal officials agreed that funding insecurity and instability is a serious challenge affecting states' ability to plan for and execute capability-building efforts. In October 2010, CDC's Advisory Committee to the Director—recognizing much of CDC's effect results from the funds it provides state, tribal, local, and territorial public-health departments—charged its State, Tribal, Local and Territorial Workgroup to produce recommendations to maximize resources and develop capacity throughout this nonfederal community.<sup>30</sup> A subworkgroup was created specifically to consider issues arising from the fiscal challenges facing states and localities.

According to CDC officials, the workgroup has discussed moving cooperative agreements like PHEP and ELC to a 2-year cycle to give

<sup>&</sup>lt;sup>30</sup>CDC's Advisory Committee to the Director is to advise the CDC Director on policy issues and broad strategies in pursuit of CDC's mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC's activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private- and public-sector constituents. The State, Tribal, Local, and Territorial Workgroup was created to provide input to the advisory committee on state, tribal, local, and territorial public-health policies and priorities; to provide input as requested regarding other CDC programs; and to provide public-health practice input from the state, tribal, local, and territorial public-health community.

state and local public-health departments more time to work within state-imposed restrictions, but they cannot make such a change without legislative action. In addition, CDC officials stated that they attempt to communicate budget decisions to their nonfederal partners in a timely manner. For example, they said that they provided guidance to PHEP applicants to help them plan around funding uncertainty by communicating the minimum funding available and advising them to plan for the next fiscal year using the current year's funding level with the expectation that it will likely be reduced. However, these officials also noted that when federal agencies have to operate on a continuing resolution, it restricts their ability to plan and obligate funds, which in turn can result in reductions and delays in funding activities at the state and local level.

An official from DOI's USGS National Wildlife Health Center also attributed funding instability and insecurity to the annual appropriations cycle, because federal agencies also do not know what the budget will be from year to year. Like CDC officials, he said that multiyear appropriations would allow for more long-term planning. USDA officials also acknowledged that their nonfederal partners face challenges planning for and developing capabilities because of funding uncertainty. Officials from USDA's Animal and Plant Health Inspection Service's Veterinary Services said they are working to streamline the cooperative agreement process to provide additional flexibility to the states by producing fewer but broader agreements that would allow the states to better prioritize their needs.

Twenty-one of the 27 state and city officials who responded to our follow-up questionnaire reported that the common federal approach of funding capabilities in response to specific diseases or initiatives—for example, West Nile virus—limited their ability to develop core capabilities that could provide surveillance capacity that cut across health threats and for emerging-disease threats. Along these lines, one of the respondents who rated this challenge among the top three said that broad-based surveillance activities are crucial for detecting new and emerging diseases, but funding targeted for specific diseases does not allow for focus on a broad range of causes of morbidity and mortality.

Federal officials agreed that the disease-specific nature of funding is a challenge to states' ability to invest in core capabilities. CDC officials said this long-standing issue stems from the way CDC receives funding, which is disease-specific and, in turn, awarded to the states that way. According to officials, funding authorized under the Patient Protection and Affordable Care Act (PPACA) has recently offered some authority for flexible

biosurveillance capability investments.<sup>31</sup> For example, they said the PPACA program supports additional epidemiologists and laboratory support staff and infrastructure improvements, among other things, at the state and local level. Additionally, CDC officials noted that the all-hazards nature of PHEP grants supports states' ability to invest in crosscutting core capabilities.

An official from DOI's USGS National Wildlife Health Center similarly noted that the structure of funding is a challenge for agencies at all levels, and said he would like to see more broad-based funding to allow for long-term investments to retain and develop capacity to address disease issues. USDA officials also acknowledge that stovepiped, or disease-specific, funding presents a challenge for their nonfederal partners when planning for and investing in crosscutting capabilities. Within USDA's Animal and Plant Health Inspection Service, officials from Veterinary Services said that they are moving away from funding disease- and program-specific items and toward a new funding approach, intended to reduce stovepiping and provide for additional flexibility. USDA's Wildlife Services officials also find stovepiped funding challenging, but said that they have little control over the issue.

In interviews and follow-up questionnaires, city and state officials also reported challenges with the leadership and planning for integrated biosurveillance approaches. Sixteen of 27 respondents to our follow-up questionnaires reported a lack of leadership and mechanisms to support regional approaches to disease surveillance. Similarly, 17 of 27 respondents reported that integrating information across disease domains is a challenge because of a lack of leadership and mechanisms to facilitate information sharing and data integration among public-health, agriculture, and wildlife disease-control functions. One respondent who ranked integrating human and animal surveillance information among the top three challenges said that the lack of leadership and mechanisms to do so is a barrier to effective and efficient disease response.

Federal agencies with biosurveillance roles have acknowledged that attention to integrated biosurveillance approaches is needed. In response to HSPD-21, CDC created the National Biosurveillance Strategy for

<sup>&</sup>lt;sup>31</sup>Pub. L. No. 111-148, § 4304, 124 Stat. 119, 584 (2010) (codified at 42 U.S.C. § 300hh-31).

Human Health, collaborating with federal and nonfederal partners, to provide a foundation for a long-term effort to improve a nationwide capability to manage human health-related data and information. The strategy lays out six priority areas for attention to address critical gaps and opportunities for improvement. Among the six is integrated biosurveillance, about which the strategy states that, because the responsibility for public health is shared across multiple levels of government, professional practice, and scientific disciplines, the timely exchange of reliable and actionable information is essential. Although the strategy includes goals for enhancing integration of human-health data, these goals have not yet been the central focus of implementation plans for the strategy. However, according to CDC officials, the efforts to establish objectives for enhancing management of human-health information as part of the strategy has been important for larger HHS efforts, such as implementing the National Health Security Strategy. 32 Officials also said these activities are important to the efforts the National Security Staff has underway to guide the biosurveillance enterprise. In addition. CDC officials stated that the BioSense program is being redesigned to improve the ability for jurisdictions to share data with each other during specific events, which could foster more regional data sharing.33

<sup>&</sup>lt;sup>32</sup>HHS's Office of the Assistant Secretary for Preparedness and Response issued the National Health Security Strategy in December 2009. The strategy is designed to achieve two goals: build community resilience and strengthen and sustain health and emergency-response systems. One of the strategy's 10 strategic objectives is to ensure the nation has a situational awareness capability. Under this objective, the strategy and its accompanying interim implementation plan emphasize the need for situational awareness obtained through epidemiological and animal-disease surveillance as well as monitoring agricultural and food supplies for contamination.

<sup>&</sup>lt;sup>33</sup>The objective of the BioSense program is to collect electronic data that are voluntarily shared by participating state, local, and other federal public-health entities, including data related to infections, injuries, and chronic diseases, to provide a more-complete picture of potential and actual health events both locally and across jurisdictional boundaries. According to CDC officials, they have been actively working over the past year to redesign BioSense. Officials say the redesigned BioSense—known as BioSense 2.0 is the focal point of their efforts to provide support and guidance to states in preparation for receipt of additional data that will be available to them as a result of certain provisions in PPACA. They say they have been working with the International Society for Disease Surveillance, Council of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials, among others, to help reach out to their state partners about the rollout of BioSense 2.0, which is scheduled for November 2011.

An official from DOI's USGS National Wildlife Health Center said it would be helpful to have a national strategy or framework to guide all of those involved in wildlife health to respond in a coordinated, appropriate, and proportionate way to wildlife disease issues. In addition, he said the framework is needed to outline the shared responsibilities related to threat detection and assessment, policy development, and management actions. According to the official, DOI plans to begin working on such a framework for wildlife surveillance with its partners in the near future. USDA officials also acknowledged that nonfederal partners have faced challenges with leadership and planning for integrated biosurveillance approaches. USDA officials from Animal and Plant Health Inspection Service's Wildlife Services said they could enhance the integration of biosurveillance capacities for their nonfederal partners by providing access to their existing networks. However, the officials said they would need a source of funding for the increased efforts required to meet the needs of nonfederal partners. Officials from Veterinary Services stated that to address integration challenges, they try to engage their nonfederal partners in planning activities, but are looking to the National Security Staff's work on the national biosurveillance strategy to help address larger challenges.

Some challenges identified by state and local officials reflected an opportunity for better partnerships between the federal and the state and local governments. Fourteen of 27 respondents to our follow-up questionnaires indicated that competing federal priorities present challenges. For example, in one interview, state officials said that grant guidance can be contradictory with regards to funding streams, and one grant may recommend focusing on a certain priority and then other grants recommend other priorities that do not complement the other grant's guidance. In addition, 12 of 27 questionnaire respondents reported having vague or insufficient guidance. In interviews, state and local officials who identified this issue noted that there is no user-friendly central repository of best practices for maintaining and enhancing capabilities and that quidance lacks concrete examples for things like developing state planning documents or fostering integrated biosurveillance efforts. Finally, 12 of 27 questionnaire respondents reported federalism challenges, such as conflict between national and local priorities, philosophies, and approaches to conducting biosurveillance. For example, in an interview, public-health officials in one state told us that they have to spend valuable time and resources convincing their federal partners not to overreact to electronic laboratory results of disease that are considered dangerous, such as plague, but are also endemic in low levels within their iurisdictions

Officials from CDC stated that they are aware of these kinds of challenges facing their nonfederal partners and of the need to improve federal and nonfederal coordination among programs. These officials said states may have different priorities than those at the federal level due the need to balance their state responsibilities to address health concerns of the state with their other activities conducted with varying federal agencies and programs. According to the officials, they are committed—in national strategy efforts—to building on current capabilities at all levels of government and will take into consideration the issues and challenges states experience in working with their federal biosurveillance partners. They also noted that as they developed guidance for PHEP recipients for the most recent round of cooperative agreements—Public Health Preparedness Capabilities: National Standards for State and Local Planning—they involved approximately 200 stakeholders and experts to help public-health departments better organize their work and determine whether they have the resources to build and sustain all the capabilities. Additionally, they said that they attempted to ensure that their nonfederal partners do not experience continual shifts in PHEP priorities by implementing a new process for reviewing and approving proposed changes to PHEP guidance.

They also described several efforts to coordinate grant guidance within CDC and with other federal partners to improve effectiveness and reduce conflicting activities or redundant reporting. Among these efforts were multiple workgroups and other activities to engage with federal and nonfederal partners, as well as a Memorandum of Understanding with multiple federal departments that fund preparedness activities. According to CDC officials, the memorandum establishes a formal framework that supports joint federal planning and better coordinates emergency public health and health care preparedness consistent with national strategies and priorities.

An official from DOI's USGS National Wildlife Health Center agrees that partners throughout the biosurveillance enterprise experience federalism challenges. He said that a national strategy or framework that clearly outlines roles and responsibilities could help alleviate these issues. USDA officials also acknowledged that their nonfederal partners have faced these kinds of challenges. Officials from USDA Animal and Plant Health Inspection Service's Wildlife Services said that they recently created a plan to achieve a more unified cross-program approach to addressing wildlife-disease issues that will affect the agency and its stakeholders. These officials stated that enhanced integration of the USDA resources, expertise, personnel, and infrastructure needed to address issues of

wildlife-disease surveillance—among other things—should help their nonfederal partners to mitigate this challenge. Officials from Veterinary Services stated that to address federalism challenges, they seek to proactively engage their nonfederal partners in planning activities, but are looking to the National Security Staff's work on the national biosurveillance strategy to help address the larger challenge.

In our June 2010 report, we called for a national strategy that could begin to address the difficult but critical issues of who pays for biosurveillance capabilities and how a national capability will be sustained in the future.<sup>34</sup> Our findings about the challenges with planning and investing in core capabilities, while not generalizable to all nonfederal jurisdictions, suggest that there may be some common issues with the structure of funding that affect longer-term planning and investments in core biosurveillance capabilities. We also reported in June 2010 that clarifying the numerous governmental and private-sector entities' roles and responsibilities for leading, partnering, or supporting biosurveillance activities could help ensure timely disease detection and situational awareness across multiple domains.<sup>35</sup> Our findings similarly suggest that there may be some common issues with promoting integrated biosurveillance approaches at the nonfederal level. As part of a national biosurveillance strategy, considering challenges like these may help partners across the enterprise find shared solutions as they strive to build and maintain an integrated national biosurveillance capability.

<sup>&</sup>lt;sup>34</sup>GAO-10-645.

<sup>&</sup>lt;sup>35</sup>GAO-10-645.

Federal Agencies
Provide Some
Support, but
Biosurveillance
Capabilities in Tribal
and Insular Areas Are
Limited by Resources
and Infrastructure

As with the state and local jurisdictions, the federal government does not have efforts designed specifically to build and maintain tribal or insular biosurveillance capabilities to support a national biosurveillance capability. However, tribal and insular jurisdictions also receive certain cooperative agreements and technical assistance that federal officials say can help support biosurveillance capacity. At the same time, federal officials reported that limited resources and infrastructure in tribal and insular jurisdictions present challenges to building their capacity.

Federal Agencies Have Provided Financial and Technical Assistance That Can Support Tribal and Insular Capabilities

### The Pacific Public Health Surveillance Network

Created by the Secretariat of the Pacific Community and the World Health Organization in 1996, the goal of Pacific Public Health Surveillance Network is to improve public-health surveillance and response in the Pacific Islands in a sustainable way. PIHOA officials said the U.S.-Affiliated Pacific Islands relies on two of the network's services-PacNet and EpiNet—to provide them with an awareness and updates concerning disease outbreaks or emerging diseases in the region. PacNet is an online listserv for health practitioners to share information regarding epidemic threats. EpiNet consists of multidisciplinary national/territorial outbreak-response teams. In addition to updates concerning disease outbreaks and outbreak-response information, district hospitals can also obtain expert technical assistance by linking in to either PacNet or EpiNet.

Source: GAO analysis of HHS data.

According to federal and professional association officials that work with tribal and insular jurisdictions, federal agencies provide disease-specific funding and cooperative agreements, as well as training and technical assistance, to support public-health and animal-health surveillance capacity.

Insular areas are eligible for the PHEP and ELC cooperative agreements from CDC. PHEP funds public-health preparedness projects in American Samoa, Guam, U.S. Virgin Islands, Northern Mariana Islands, Puerto Rico, Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau. In addition, ELC—which builds epidemiological and laboratory capacity—is awarded to Puerto Rico and the Republic of Palau.

According to officials from PIHOA, federal agencies also provide specimen testing for Pacific insular areas—which have no reference laboratory capacity of their own—for disease agents that the islands' clinical laboratory network is not equipped or certified to handle. PIHOA developed the Regional Lab Initiative for the transportation of human specimens, and PIHOA serves as a steward for the specimen transportation network by negotiating specimen-transportation contracts with commercial airlines, developing shipping standards for laboratory specimens, and overseeing the Regional Lab Initiative budget. PIHOA officials said that federal funding for this initiative is critical to enable Pacific insular areas to transport specimens for testing to those laboratories with greater capabilities.

According to CDC officials, their Division of Global Migration and Quarantine also works with the insular areas to enhance crosscutting

public-health initiatives, with a focus on disease surveillance and help public-health departments tie into various CDC programs. For example, the division has been working with Guam since late 2009 to move towards electronic data sharing of health information to improve timeliness and response to catastrophic events, including better linkages to the National Notifiable Disease Surveillance System. During a 2010 mumps outbreak in Guam and the Federated States of Micronesia, the division also played a coordination role and facilitated the shipment of lab specimens. Officials said that the Guam mumps outbreak helped identify gaps in their surveillance capacity, and the division followed up with targeted training to address the gaps. The division is also working to enhance the quality of American Samoa's public-health records to enhance its ability to submit electronic public-health data into the World Health Organization's syndromic surveillance system for the Pacific Islands region.

For animal health in the insular areas, USDA has employees and offices in some insular areas. USDA Veterinary Medical Officers in the field interact with producers, respond to reports of potential Foreign Animal Diseases, help administer disease eradication and control and surveillance activities, and assist with export certification out of these field-office sites. DOI provides diagnostic service to determine causes of mortality in wildlife. For example, in American Samoa and Palau, DOI performs necropsy surveys of free-ranging wildlife (both terrestrial and marine) to determine the cause of death. The agency reported that all bird carcasses necropsied are routinely tested for avian influenza.<sup>36</sup> The agency also reported that the ability to ship samples from American Samoa and Palau to Honolulu, Hawaii, has allowed the agency to gain a greater understanding of causes of wildlife mortality in those regions. In case of catastrophic mortality, DOI officials said the agency would probably send someone out to the area to provide on-site assistance and collaborate with local agencies to deal with the issue and resolve it to its logical conclusion. For example, DOI officials have offered response assistance to Palau to help with unusual poultry mortality events in efforts to effect early detection of avian influenza. DOI also provides annual workshops to agencies to communicate findings and provide on-site training on wildlife disease response.

<sup>&</sup>lt;sup>36</sup>A necropsy is one of the basic tools used to determine why an animal dies. It involves the thorough examination of a carcass externally and internally for any indications of causes of death.

Tribal nations are not eligible for PHEP or ELC funding, but CDC advises states to include tribes in their required all-hazards public-health capability planning for PHEP funding. In addition, IHS has cooperative agreements with Tribal Epidemiology Centers, to support local public health and provide data analyses for the tribes. As shown in figure 4, there are 12 Tribal Epidemiology Centers located around the country. The 12 Tribal Epidemiology Centers typically serve 30-100 tribes in their region. Officials from IHS said that the Tribal Epidemiology Centers may offer a foundation for building tribal biosurveillance capabilities. However, biosurveillance is not the primary job or mission of the epidemiology centers. The priorities of the centers are driven by the needs of the tribes, and the centers help the tribes create a structure for intervention to prevent the major conditions affecting the tribal population.



Figure 4: Tribal Epidemiology Centers

Source: Indian Health Service.

Federal agencies also provide technical assistance and training to tribal jurisdictions. The Office for State, Tribal, Local and Territorial Support within CDC provides training and technical assistance to improve data and surveillance standards in tribal areas and work to foster public-health workforce development in tribal areas. In addition, IHS provides, without charge, software for automated electronic surveillance that can be implemented by IHS, tribal, and Urban American Indian and Alaska Native sites to help with automated reporting and information sharing. The initial project, IHS's Influenza Awareness System, focused on influenza-like illness, but according to IHS officials is currently expanding

to include other notifiable diseases. IHS also provides technical assistance to tribes, sometimes through the Tribal Epidemiology Centers, and also provides some training, which is available to any American Indian or Alaska Native. The primary focus of the training is not biosurveillance but basic public-health functions, but federal officials who work with these jurisdictions say that any effort to build public-health infrastructure increases biosurveillance capabilities over their existing levels.

Additionally, according to USDA officials, tribes can participate in the same disease-control and eradication programs (such as tuberculosis, brucellosis, scrapie, and chronic wasting disease) as states through grants and cooperative agreements. These officials said these cooperative agreements increase tribes' biosurveillance capability, particularly with tribes that have more-robust existing infrastructure, like Navajo Nation, which has a full-time veterinarian. USDA officials with responsibility for wildlife said they also provide cooperative agreements and training to support tribal wildlife disease surveillance.

Federal Working Groups and Outreach Efforts Can Help Support Biosurveillance Capabilities

To help build public-health and animal-health surveillance capacity, federal agencies have also created working groups and other outreach efforts to tribal and insular jurisdictions. For example, the Office for State, Tribal, Local and Territorial Support within CDC works with health departments to increase public-health capacity through a working group that helps build capacity across jurisdictions, for example between tribes and corresponding state or local health departments. CDC has developed Pacific working groups to address various issues in the Pacific insular areas, such as the Public Health Preparedness and Response Working Group and an epidemiology working group. According to officials, these working groups help coordinate activities between various CDC departments and the Pacific insular areas.

USDA's Native American Program Coordinator serves as a tribal liaison, providing assistance to tribes and has developed a relationship with the large land-owning tribes that participate in its programs. The officials said that the tribal liaison has built this relationship over the years by attending the Intertribal Agriculture Council's Meetings, a gathering of tribal agriculture producers. They noted that because of the tribal liaison's continuous outreach, they believe that the tribes know whom to call if unusual animal disease symptoms appear in animals on their lands.

### Federal Agencies Face Unique Challenges Supporting Tribal and Insular Jurisdictions

### **USDA's Traceability Program**

On February 5, 2010, USDA announced a new framework for animal-disease traceability in the United States.



Approximately 30 tribes receive funding for the Traceability Program, which according to a senior USDA official is at the core of surveillance efforts at the tribal level.

According to USDA, the program will

- (1) only apply to animals moved interstate,
- (2) be administered by the states and tribes to provide more flexibility,
- (3) encourage the use of lower-cost technology, and
- (4) be implemented transparently through federal regulations and the full rulemaking process.

Source: USDA (data); USDA, Stephen Ausmus (photo).

Federal officials, as well as officials from professional associations like the Council of State and Tribal Epidemiologists and PIHOA described infrastructure and demographic challenges they face in helping to build biosurveillance capabilities in tribal and insular jurisdictions. For example, CDC officials said that, overall, there is a low capacity to detect and report diseases in both tribal and insular jurisdictions, and that better assurance for detection of potentially catastrophic signs would require enhancement of basic systems and public-health functions. HHS officials said that tribes, insular areas, and states face similar public-health infrastructure challenges, but the challenges are more severe in tribal and insular areas. For example, IHS and CDC officials said some tribes have serious public-health infrastructure limitations—for example, some have minimal or no functioning health-department structure—so officials said the idea of building biosurveillance capabilities is not a realistic pursuit in these areas.

USDA and DOI officials also reported capacity challenges—such as few veterinary and wildlife personnel on the ground in tribal and insular areas—that limit biosurveillance capabilities. Additionally, officials said that the federal cooperative agreements offered by federal agencies do not always provide for the infrastructure enhancement needed for tribal and insular areas, because they assume a basic level of capacity that these jurisdictions often do not have. However, USDA, DOI, and HHS officials also cautioned that despite the limited infrastructure in some of the tribal and insular areas, it would not be practical from a cost-benefit standpoint to invest in complete biosurveillance systems for every tribe and insular area. For example, for small tribal nations and insular areas it may not make sense to expect them to support and maintain separate laboratory facilities, especially when there are other nearby state resources available that could support testing for those populations.

Along the same lines, HHS officials said that tribes and their federal and state partners have historically faced disease-reporting challenges. CDC officials noted that as sovereign nations, tribes typically prefer to work directly with federal agencies, rather than state governments, but because of the nature of public health, it often makes sense for tribes and states to share data or conduct joint investigations with the states. CDC officials said that data sharing between tribes in states is challenging, because tribes may have limited public-health capacity. The officials said that Tribal Epidemiology Centers offer some promise for facilitating information sharing, but some states have been reluctant to share health data with Tribal Epidemiology Centers, because until recently they lacked public-health authority—a legal designation that governs the ability of

### American Indian and Alaska Native Health Research Advisory Council

The Health Research Advisory Council was established to provide HHS a venue for consulting with tribes about health research priorities and needs in American Indian and Alaska Native communities and collaborative approaches in addressing these issues and needs. The Council serves three primary functions:

- obtaining input from tribal leaders on health research priorities and needs for their communities;
- (2) providing a forum through which HHS operating and staff divisions can better communicate and coordinate American Indian and Alaska Native health research activities; and
- (3) providing a conduit for disseminating information to Tribes about research findings from studies focusing on the health of American Indian and Alaska Native populations.

Source: GAO analysis of HHS data.

governmental entities to collect, receive, and share data for public-health purposes under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).<sup>37</sup> Tribal Epidemiology Centers are operated by nonprofit organizations that typically had no legal health authority to handle such data. However, in 2010, PPACA designated these centers public-health authorities under HIPAA.<sup>38</sup> This provision allows the IHS-funded Tribal Epidemiology Centers to access federal and state data sets for research purposes, just as state health departments do. However, these centers still are nonprofit organizations that are competitively selected on a periodic basis and there is no guarantee that the entire nation will continue to have center coverage. HHS officials said the designation of the centers as public-health authorities will likely facilitate more sharing among states and tribes, but it is a relatively new development, so it is too soon to determine the effect.

Federal officials also reported facing demographic and logistical challenges in working with tribal nations. Complications in data collection and reporting arise from the nature of tribal boundaries and populations. Specifically, tribes are not defined by geographic boundaries, tribal members may not live on tribal lands, and tribal lands may cross state boundaries. Officials also said population size and geography vary for tribes and many tribes are in remote locations, including about half of the more than 500 federally recognized tribes located in Alaska. An official from IHS noted that, in general, tribal communities do not have populations large enough to justify building complete, individual surveillance programs and that tribes generally do not have infrastructure or resources to support such an effort.

According to USDA officials, every tribe has a different relationship with the state it is located in and with the federal government. Some tribes have direct relationships with the state agriculture department because most tribes do not have veterinarians. In some cases, the states may take care of the surveillance needs for a tribe, and in other cases, the tribes may have their own surveillance capacity. In general, tribes do not have funding to establish and maintain laboratories. Tribes typically use the state labs that are part of the National Animal Health Laboratory Network

<sup>&</sup>lt;sup>37</sup>Pub. L. No. 104-191, 110 Stat. 1936 (1996).

<sup>&</sup>lt;sup>38</sup> Pub. L. No. 111-148, § 10221(a), 124 Stat. 119, 935 (codified at 25 U.S.C. § 1621m(e)).

(NAHLN), the facilities at Plum Island, the Ames, Iowa lab, or state labs that are not part of NAHLN. (For more information about laboratories, see app. II.) DOI officials said that tribes are interested in wildlife management and disease surveillance, but do not have the resources, as tribes need to build capabilities at the most basic level—like wildlife biologists and management expertise.

Federal agencies, as well as association officials, reported similar resource, demographic, and logistical challenges in insular areas. Officials at the Council of State and Territorial Epidemiologists, PIHOA, and CDC said the Pacific insular areas are challenged in identifying disease outbreaks and emerging diseases. According to PIHOA officials, this is due to workforce shortages for doctors, nurses, epidemiologists, and laboratory officials, and the limited laboratory capacity on the islands. Although the islands can currently depend on laboratories outside Pacific insular areas to conduct testing, and there are currently initiatives and programs in place to improve laboratory capacity on the islands, it may take several days to detect a disease.

CDC officials said timely reporting cannot be ensured in the Pacific insular areas and there is limited ability to build public-health infrastructure in the territories. For example, they said the public-health systems will have to transition to more formal mechanisms of information sharing, because currently events trigger regional partners to respond in an ad hoc and unsystematic way. To address some of these challenges, PIHOA developed the Public Health Infrastructure Initiative, partially funded by CDC's National Public Health Improvement Initiative, which is supported by PPACA's Prevention and Public Health Fund, to help improve Pacific insular areas' public-health systems at every level. Through this initiative, PIHOA is working with Pacific insular areas officials to develop public-health curricula to improve the epidemiological and surveillance capabilities of the islands.

According to DOI officials, aside from Guam, insular areas in the Pacific region have little to no existing veterinary capacity to deal with animal or zoonotic diseases. DOI officials said they would like to get more wildlife disease data from places like Guam and the Commonwealth of the Northern Mariana Islands, but the lack of reliable in-territory contacts there has made it difficult to establish those relationships.

The Federal Government Has Not Comprehensively Assessed Nonfederal Biosurveillance Capabilities Various federal agencies and professional associations with public-health missions have assessed some aspects of nonfederal biosurveillance capabilities, such as the evaluation of laboratory, epidemiology, surveillance, and other capacities, but the federal government has not systematically or comprehensively assessed state and local governments' ability to contribute to a national biosurveillance capability. An assessment of capabilities that support biosurveillance is called for in HSPD-10, which states 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.<sup>39</sup> We have previously reported that a national biosurveillance capability depends upon participation from nonfederal jurisdictions and that few of the resources required to support the capability are wholly owned by the federal government.<sup>40</sup> Therefore, assessing the baseline and identifying investment needs for a national biosurveillance capability necessarily involves assessing nonfederal entities' ability to support a national capability.

No federal, state, local, or association official we spoke to was able to identify a systematic approach—planned or underway—to assessing state and local biosurveillance capabilities and identifying strengths, weaknesses, and gaps across the biosurveillance enterprise. However, certain aspects of public-health capabilities have been assessed by federal agencies and professional associations. For example, CDC's most-recent round of guidance associated with the PHEP cooperative agreements has begun to define elements, priorities, resource considerations, and metrics for building and assessing public-health surveillance, epidemiology, and laboratory capabilities. According to CDC officials, these national standards are designed to assist states and localities in self-assessing their ability to address the prioritized planning resource elements of each capability and then to assess their ability to demonstrate the functions and tasks within each capability. CDC officials stated that this self-assessment enables states and localities to identify their gaps in preparedness, determine their specific jurisdictional goals and priorities, develop plans for building and sustaining capabilities, and prioritize preparedness investments. CDC officials noted that these data

<sup>&</sup>lt;sup>39</sup>Homeland Security Presidential Directive 10: Biodefense for the 21<sup>st</sup> Century.

<sup>&</sup>lt;sup>40</sup>GAO-10-645.

and data collected through the ELC could, with the right attention and resources, offer an opportunity to provide more-cohesive information for a national assessment in the future.

In addition, for the past 4 years the Association of Public Health Laboratories has conducted an assessment of the District of Columbia and the 50 state public-health laboratories' capacity to respond to biological, chemical, radiological, and other threats, such as pandemic influenza. Similarly, the Council of State and Territorial Epidemiologists has conducted four assessments since 2001 to assess the epidemiology capacity of state, local, and territorial health departments in the United States. Further, CDC funded a survey of state, local, and territorial syndromic surveillance capabilities that was conducted by the International Society of Disease Surveillance.

According to several federal and state officials, a comprehensive assessment of the biosurveillance enterprise may identify a baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise and improve the nation's ability to conduct biosurveillance, but state officials also noted that states would need additional funding to overcome any gaps identified by a federal assessment. For example, officials from one federal agency said that a comprehensive assessment of state and local biosurveillance capabilities would help identify vulnerabilities in the enterprise, assess needs, and help target resources to those areas. Similarly, another federal official who oversees programs for tribal entities noted that knowing more about tribes' strengths, weaknesses, and gaps would enable their division to better understand where they need to provide additional assistance or focus resources during an event.

State officials we interviewed also discussed how a national assessment could identify best practices in biosurveillance and inform states and federal resource decisionmaking. For example, public health officials from one state said that information about the capability needed to support a national biosurveillance capability would be helpful to support lessons learned and identify best practices. Similarly, wildlife officials from one state said they lack knowledge about the types of wildlife surveillance conducted by other states and other states' baseline capabilities. They said an assessment of capabilities could determine how their efforts compare to other states, which would provide information to state decision makers to guide resource decisions. According to public-health officials from another state, some gaps in biosurveillance are already fairly well understood—such as electronic lab reporting and workforce

sufficiency. These officials said that a formalized national assessment would bring these gaps to the attention of federal agencies and hoped that federal agencies would address these gaps with additional funding, guidelines, and the prioritization of investments.

Although federal, state, and local officials we interviewed generally agreed that a comprehensive national assessment may improve the nation's ability to conduct biosurveillance, all the officials we interviewed acknowledged that such an assessment would be a complex undertaking. Federal, state, and local officials said the size, variability, and complexity of the biosurveillance enterprise—including federal, state, and local biosurveillance efforts—make it difficult to define precisely what should be measured and identifying the most appropriate assessment participants would be difficult. For example, public-health officials from one state said it would be important to identify definitions and create measurements with which to evaluate capacities, otherwise it would be difficult to maintain a narrow scope for the assessment. They also noted that the development of this type of assessment would require the input of multiple stakeholders. Other officials also noted that it may be difficult to identify the most appropriate parties to provide information for the assessment. For example, agriculture officials from one state said that identifying the most appropriate person to complete the assessment would be difficult, because a state veterinarian will have a different perspective from someone who regularly works in the field. The difficulty in conducting a comprehensive national assessment is exacerbated not only by the magnitude of the undertaking—assessing the capabilities of the states, tribes, insular areas, and the tens of thousands of localities in the United States—but also by the lack of a clear mission and a vision for the desired end state of a national biosurveillance capability. In our June 2010 strategy recommendation, we noted that the National Security Staff and its focal point should define the mission and desired end state.<sup>41</sup>

Until it conducts an assessment of nonfederal biosurveillance capabilities, the federal government will continue to lack key information about the

<sup>&</sup>lt;sup>41</sup>In August 2011, the National Security Staff reported that it had created a biosurveillance sub-Interagency Policy Committee, under the guidance of the Domestic Resilience Group, to serve as a focal point in order to coordinate the development of a National Strategy for Biosurveillance. They said the strategy, and the implementation guidance to it, will define the overall purpose of the U.S. government biosurveillance effort, and will pay particular attention to the assignment of roles and responsibilities.

baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise to guide development and maintenance of a national biosurveillance capability. Officials we interviewed at all levels, as well as federal guidance and directives like HSPD-21, acknowledge that a national biosurveillance capability necessarily rests on the cumulative capabilities of state and local agencies that constitute a large portion of the biosurveillance enterprise. A national strategy like the one we recommended in June 2010—one capable of guiding federal agencies and its key stakeholders to systematically identify risks, resources to address those risks, and investment priorities—may be better positioned to guide development and maintenance of the capability if it takes into account the particular challenges and opportunities inherent in partnering with nonfederal jurisdictions such as state, tribal, local, and insular governments. Moreover, efforts to build the capability would benefit from a framework that facilitates assessment of nonfederal jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise.

### Conclusions

A key component of preparedness for a potentially catastrophic biological event is the ability to detect a dangerous pathogen early and assess its potential spread and effect. Experts have noted, and our reviews of both federal and nonfederal government biosurveillance activities confirm, that the federal government has undertaken numerous efforts to support timely detection and situational awareness for potentially catastrophic biological events, but these efforts are not well integrated. As we reported in June 2010, current efforts lack a unifying framework and structure for integrating dispersed capabilities and responsibilities across the biosurveillance enterprise. Further we noted that without this unifying framework, it will be difficult to create an integrated approach to building and sustaining a national biosurveillance capability as envisioned in HSPD-21.

Officials at all levels of government, as well as HSPD-21's vision of a national biosurveillance capability, acknowledge that state and local capabilities are at the heart of the biosurveillance enterprise. 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. Therefore, to be most effective, a national biosurveillance strategy like the one we recommended in June 2010—one capable of guiding federal agencies and their key stakeholders to systematically identify risks, resources to address those risks, and investment priorities—would

address the particular challenges and opportunities inherent in partnering with state and local jurisdictions. Moreover, efforts to build the capability would benefit from a framework that facilitates assessment of jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise.

# Recommendations for Executive Action

In order to help build and maintain a national biosurveillance capability in a manner that accounts for the particular challenges and opportunities of reliance on state and local partnerships, we recommend the Homeland Security Council direct the National Security Staff to take the following action as part of its implementation of our previous recommendation for a national biosurveillance strategy:

Ensure that the national biosurveillance strategy (1) incorporates a
means to leverage existing efforts that support nonfederal
biosurveillance capabilities, (2) considers challenges that nonfederal
jurisdictions face in building and maintaining biosurveillance
capabilities, and (3) includes a framework to develop a baseline and
gap assessment of nonfederal jurisdictions' biosurveillance
capabilities.

# Agency Comments and Our Evaluation

We provided a draft of this report for review to the National Security Staff, DHS, HHS, DOI, USDA, the Department of Justice; and the state and city officials who contributed to our review. The National Security Staff acknowledged the accuracy of the information contained in the report but did not comment on the recommendation. DHS provided a written response to the draft report, which is summarized below and presented in its entirety in appendix V of this report. USDA provided an oral response that is summarized below. DHS, HHS, DOI, USDA, the Department of Justice, the North Carolina Division of Public Health, and the Utah Department of Agriculture and Food provided technical comments, which we incorporated where appropriate.

In written comments, DHS concurred with our findings. DHS noted that its National Biosurveillance Integration Center has key biosurveillance roles and responsibilities, and stated that to support the Center's mission, DHS is working with the National Security Staff on the Sub-Interagency Policy Committee on Biosurveillance. DHS further stated that it understands the importance of and supports the inclusion of nonfederal biosurveillance resources in the National Biosurveillance Strategy under development.

In oral comments, USDA concurred with our findings and recommendations. Overall,. Specifically, USDA's Animal and Plant Health Inspection Service's Veterinary Services and Wildlife Services supported our recommendation to leverage support, consider challenges, and develop a framework to understand the current capacity and conduct a needs assessment for nonfederal identities to conduct biosurveillance activities. USDA stated that it will continue to work with the National Security Staff in development of the National Biosurveillance Strategy. USDA noted that its Animal and Plant Health Inspection Service has an established national program—the National Wildlife Disease Program that is currently available to provide the infrastructure and leadership necessary to implement these recommendations, and should be incorporated into an integrated system. USDA noted that the program has a history of providing leadership for national surveillance during various outbreaks, which demonstrates its overall abilities to develop and maintain broad local, state, tribal and private efforts to conduct targeted biosurveillance activities.

We are sending copies of this report to the Special Assistant to the President for National Security Affairs; the Attorney General; the Secretaries of Homeland Security, Health Human and Services, Agriculture, and the Interior; and interested congressional committees. The report is also available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report please contact me at (202) 512-8777 or jenkinswo@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.

William O. Jenkins, Jr.

William offending

Director, Homeland Security and Justice Issues

# Appendix I: Objectives, Scope, and Methodology

To address our objectives, we reviewed key legislation and presidential directives related to biosurveillance, including the Homeland Security Act of 2002;<sup>1</sup> the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;<sup>2</sup> the Pandemic and All Hazards Preparedness Act of 2006;<sup>3</sup> and Homeland Security Presidential Directives (HSPD) 9, 10, and 21. This report focuses on surveillance efforts for zoonoses—diseases affecting animals and humans—and other emerging infectious diseases with the potential to cause catastrophic human-health effects.

Our work issued in June 2010 on biosurveillance efforts at the federal level explored surveillance for the following biosurveillance domains: human health, animal health, plant health, food, and the environment (specifically, air and water). Given further complexity arising from the number of and variation among states, localities, tribes, and insular areas, we narrowed the disease scope for this report. We focused on zoonotic disease agents, because of the particular threats associated with them and because threats from zoonotic disease agents clearly illustrate the potential benefits of an integrated biosurveillance capability. Given the focus on surveillance for zoonoses and other emerging infectious diseases in humans, certain federal efforts—for example, the Department of Homeland Security's air-monitoring system BioWatch—are not discussed. Similarly, certain types of waterborne, foodborne, plant, or animal diseases—for example Foot and Mouth Disease—that could have devastating economic consequences or dire human-health effects are not the focus of this report.

At the federal level, we consulted officials at the Departments of Agriculture, Homeland Security, Health and Human Services, and the Interior, which have key missions, statutory responsibilities, directives, or programmatic objectives for biosurveillance activities within the scope of this report, including protecting human and animal health and national security. We also discussed biosurveillance issues at the state and city level with officials from the Department of Justice's Federal Bureau of Investigation.

<sup>&</sup>lt;sup>1</sup>Pub. L. No. 107-296, 116 Stat. 2135 (2002).

<sup>&</sup>lt;sup>2</sup>Pub. L. No. 107-188, 116 Stat. 594 (2002).

<sup>&</sup>lt;sup>3</sup>Pub. L. No. 109-417, 120 Stat. 2831 (2006).

To develop background on and contextual understanding of the federal efforts that support state biosurveillance capabilities and the challenges officials face building and maintaining those capabilities, we interviewed officials from 10 professional associations and research organizations and asked for recommendations on factors to consider when selecting states for site visits. We interviewed officials from the following organizations:

- International Society for Disease Surveillance,
- Council of State and Territorial Epidemiologists,
- Trust for America's Health.
- National Association of State Public Health Veterinarians,
- American Phytopathological Society,
- Association of Public Health Laboratories,
- U.S. Animal Health Association,
- American Association of Veterinary Laboratory Diagnosticians,
- Association of State and Territorial Health Officials, and
- OneHealth.

On the basis of information collected during interviews with officials from professional associations and research organizations and a review of published reports and studies, we identified several factors that could be associated with variability in approaches, philosophies, and challenges faced by states in conducting biosurveillance. We selected seven states for site visits with the dual goals of capturing variation on each of these factors and accounting for each in commonalities identified across the states we visited. The factors we identified and their application to our site selection are shown in table 6.

Factor considered	Application of factor to selection
Geographic location / political culture	We visited coastal states in the eastern and western United States, as well as noncoastal states. We also visited states with large urban populations and states with more rural populations. In addition, we visited at least one state that has an international border.
State/local public-health organizational structure	We visited at least one state with a centralized public-health structure, at least one with a decentralized public-health structure, at least one with a shared or mixed relationship, and at least one with no local public-health departments. <sup>a</sup>
Strength of capabilities and programs (based on expert recommendations)	We visited at least one state identified by professional association officials as having strong public-health capabilities as a result of leadership and political will, connections between public and animal health or attention to health security as a public-health and national-security issue. We also visited at least one state that the professional association officials identified as part of a group of states that had chronically struggled with resource issues.
Presence and type of agriculture	According to association officials we interviewed, the extent to which a state has agricultural interest has a bearing on its animal-health resources and programs. We visited at least one state with a large industry presence for one or more of the following types of agriculture: commercial fishing, chickens, turkey, hogs, and cattle.
Public-health priorities	In 2007 and 2008, the Association of State and Territorial Health Officials surveyed the states for their State-by-State Profile of Public Health. As part of that effort, the association asked states to select from a list indicating their top five priorities. Within the list were two priorities particularly relevant to health preparedness generally and biosurveillance capabilities specifically. Respectively these are: (1) assuring preparedness for a health emergency and (2) focusing on early detection or population-protection measures. We selected at least one state that selected neither of the priorities and at least one state that selected one or both. There were no states that selected priority (2) but did not select priority (1) in our sample.

Source: GAO.

<sup>a</sup>As identified in the Association of State and Territorial Health Officials 2008 State-by-State Profile of Public Health.

The states selected were California, Colorado, Delaware, Mississippi, New Jersey, North Carolina, and Utah. In every state, we interviewed three groups of officials:

- Officials in public-health departments, including state epidemiologists, who had responsibility for infectious-disease control, disease monitoring, and emergency response in humans.
- 2. Officials, generally including the state veterinarian, in state agriculture departments who had responsibility for infectious-disease control and monitoring in livestock and poultry.

3. Officials in various departments that included wildlife infectiousdisease control and monitoring in their missions. For example, one of these was a State Department of Wildlife and Fisheries.

We also interviewed public-health officials with responsibility for human infectious-disease control and monitoring in two cities with an increased risk of bioterrorism—New York City and Washington, D.C.—that received direct funding from federal agencies to support preparedness capabilities.

We analyzed the information collected during state and city interviews and developed follow-up questionnaires to confirm and enhance information from the interviews about the federal programs and initiatives that support state and local biosurveillance capabilities and the challenges officials face. We sent follow-up questionnaires to publichealth departments in all seven states and two cities and to agriculture and wildlife officials in the seven states. Within each public-health department, we sent separate questionnaires to laboratory and epidemiology officials. In total, we distributed 32 questionnaires and received 27 responses. Of the 27 respondents, 7 were epidemiologists, 7 were public-health laboratory officials, 6 were state agriculture officials, and 7 were state wildlife officials. All of the public-health, agriculture, and wildlife departments represented by the 27 respondents had also been represented in our initial interviews. However, in 7 cases—6 laboratory directors and 1 state veterinarian—the lead officials to whom we directed the questionnaire had not been present at the initial interviews. We pretested the public-health questionnaire with a laboratory official who was not at the original interviews in order to ensue the questions could be understood outside of the context of the interview.

Each questionnaire had two sections: one on federal support to states and cities and one on challenges faced by states and cities. The content of the federal support section varied for human-health and animal-health respondents, but the challenges section was the same for both human-and animal-health respondents. The specific federal programs and challenges we asked about were based on initial interviews with the different groups of respondents. We asked respondents to consider federal efforts over the last 2 years. Because the states and cities in this report were not selected in a probability sample, neither the information derived from interviews with officials nor the questionnaire responses are generalizable across the 50 states or the tens of thousands of localities in the United States. Rather, both the interviews and the questionnaire results offer some perspective on the value of select federal activities to, and challenges faced by, a group of state officials who are actively

engaged in efforts to detect and respond to major disease events. In addition, although we interviewed officials responsible for public-health emergency management in most state public-health departments that we visited, we did not administer follow-up questionnaires to the officials responsible for planning and preparing for emergency response, because their response focus was generally not central to our scope. Because this report focuses on detection of and situational awareness of potentially catastrophic zoonotic and emerging infectious-disease events, certain federal efforts that federal agencies consider important in supporting state and local preparedness may not have been identified by state and city officials during our interviews and follow-up questionnaires.

To consider the relationship between our findings at the nonfederal level and our previous findings at the federal level about building and maintaining a national biosurveillance capability, we reviewed our June 2010 findings about the centrality of nonfederal capabilities to a biosurveillance enterprise. We also reviewed our June 2010 findings about the purpose of a national biosurveillance strategy and the benefits it could provide for guiding the effort to support a national biosurveillance capability. We determined that because the federal government relies on nonfederal resources to support a national biosurveillance capability, our June 2010 findings about using the strategy to determine how to leverage resources, weigh the costs and benefits of investments, and define roles and responsibilities were particularly germane to the federal government's efforts to partner with nonfederal biosurveillance enterprise partners to support a national biosurveillance capability.

To understand how the federal government supports biosurveillance in tribal and insular areas, we consulted officials from components of federal departments with responsibility for working with tribal or insular councils and governments, generally, or on health-related matters. These included: the Department of Health and Human Services's Indian Health Service; the Department of Health and Human Services's Centers for Disease Control and Prevention's (CDC) Office of State, Tribal, Local and Territorial Support; CDC's Office of Surveillance, Epidemiology, and Laboratory Services, CDC's National Center for Emerging and Zoonotic Infectious Diseases, the Department of Agriculture's Office of Tribal Relations and the Department of Agriculture's Animal and Plant Health Inspection Service; the Department of the Interior's Bureau of Indian Affairs; and the Department of the Interior's Office of Insular Affairs. In addition, to develop additional background and context about health infrastructure and surveillance in insular areas, we interviewed representatives from the Pacific Island Health Officers Association

(PIHOA), which works in the U.S.-Affiliated Pacific Islands to strengthen crosscutting public-health infrastructure, including health-workforce development, quality assurance, health data systems, public-health planning, and public-health laboratories. The findings in this report about insular areas focus on the U.S.-Affiliated Pacific Islands. With the exception of Puerto Rico and the U.S. Virgin Islands, all commonwealths, territories, possessions, and freely associated states of the United States fall within the U.S.-Affiliated Pacific Islands.

To evaluate the extent to which the federal government has assessed nonfederal governments' capacity to contribute to a national biosurveillance capability, we reviewed relevant presidential directives and federal-agency documents like the National Biosurveillance Strategy for Human Health, along with our prior work and recommendations on building and maintaining a national biosurveillance capability. We determined that such assessment is called for in HSPD-10 and CDC's National Biosurveillance Strategy for Human Health<sup>4</sup> and is a critical activity for developing an effective national strategy containing the elements we advocated in prior work on national strategies.<sup>5</sup> To determine what types of assessment activities had been undertaken and whether an enterprisewide assessment of biosurveillance of nonfederal capabilities had been conducted, we reviewed relevant assessments and federal documents like the Council of State and Territorial Epidemiologist's 2009 National Assessment of Epidemiology Capacity and CDC's Public Health Preparedness series. In addition, we interviewed federal officials at all five federal departments, state officials in each of the seven states, city officials in the two cities, and officials at 10 professional and research institutions that include public health, animal health, or laboratories in their missions about assessment efforts. including whether they had participated in or had any familiarity with an enterprisewide assessment of nonfederal capabilities.

<sup>&</sup>lt;sup>4</sup>In response to HSPD-21's charge for the Department of Health and Human Services to enhance biosurveillance for human health, CDC has created the National Biosurveillance Strategy for Human Health with input from federal and other partners.

<sup>&</sup>lt;sup>5</sup>See 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) and GAO, Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

Appendix I: Objectives, Scope, and Methodology

We conducted this performance audit from August 2010 to October 2011 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.

## Appendix II: Laboratories, Laboratory Networks, and Their Roles in Biosurveillance

Public-health and animal-health laboratories serve a critical role in both initial detection and ongoing situational awareness of biological events.

Table 7: Laboratories and Laborato	
Public-health laboratories	Role in biosurveillance  Public-health laboratories are state and local governmental health labs that conduct complex testing to protect the public from diseases and other health threats. Public-health laboratories serve as the nation's early warning system for diseases and other health hazards. They protect our health by monitoring continuously for diseases and other health hazards. Public-health laboratories work very closely with the Centers for Disease Control and Prevention (CDC) and other federal health agencies.
Veterinary diagnostic laboratories	Each state has a publicly funded veterinary diagnostic laboratory, but the sizes and diagnostic capabilities of these laboratories vary widely. Certain laboratories specialize by species, based on the local needs within a specified geographic area, but the majority of state laboratories cover a broad range of species and conditions. In most states, animal-health diagnostic laboratories are associated with state departments of agriculture and, depending on the state, are located at veterinary colleges, land-grant university departments of veterinary science, or state agencies for public health. These facilities handle or forward the majority of specimens for diagnosis and monitoring of disease.
National Veterinary Services Laboratories (NVSL)	The NVSL has two testing facilities located in Ames, Iowa, and the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York. These laboratories provide diagnostic services and serve as reference laboratories for certain infectious diseases. Additionally, NVSL oversee and conduct laboratory testing in conjunction with federally mandated eradication programs; screen samples for the presence of exotic diseases at the request of federal and state regulatory staff; assist in investigating unusual agricultural animal disease occurrence in the United States; conduct testing for routine support of national and state animal-health management; and help ensure the United States meets animal export requirements.
U.S. Geological Survey's National Wildlife Health Center	Headquartered in Madison, Wisconsin, with a field station in Honolulu, Hawaii, the National Wildlife Health Center is a Biological Security Level—Three laboratory (BSL-3) which allows investigators to determine causes of wildlife mortality and to work with highly infectious disease agents such as plague, West Nile virus, and other zoonoses. It also serves as a containment facility for the investigation of highly pathogenic, newly discovered disease agents for which little information exists. Other responsibilities include: research on the ecology of various diseases; public outreach and education.
Department of Health and Human Services / CDC's Laboratory Response Network (LRN)	LRN is charged with maintaining an integrated network of federal, military, state, local, and international laboratories that can respond to bioterrorism, chemical terrorism, and other public-health emergencies. The biological component of LRN provides network capacity to test for biological agents in a variety of formats including clinical specimens, and food and environmental samples. The laboratories in this component are classified as either reference, national, or sentinel laboratories, depending on the types of tests that the laboratory can perform and how it handles infectious agents. <sup>a</sup>
U.S. Department of Agriculture's Animal and Plant Health Inspection Service and the National Institute of Food and Agriculture's (NIFA) <sup>b</sup> National Animal Health Laboratory Network (NAHLN)	NAHLN is responsible for a functional national network of existing veterinary diagnosis laboratories to rapidly and accurately detect and report animal diseases of national interest. These laboratories include federal, state, and university laboratories. Federal laboratories include the NVSL, which serve as international reference laboratories and conduct tests and confirm tests for other laboratories for certain infectious diseases, such as foot-and-mouth disease.

Appendix II: Laboratories, Laboratory Networks, and Their Roles in Biosurveillance

#### Laboratory

#### Role in biosurveillance

Integrated Consortium of Laboratory Networks (ICLN)

The ICLN is a coordinated and operational system of laboratory networks that is designed to provide timely, high-quality, and interpretable results for early detection of acts of terrorism and other events that require integrated laboratory-response capabilities. The ICLN's individual laboratory networks focus on detecting biological threat agents that affect humans, animals, or plants and that contaminate the air, water, or food supply. The laboratory networks that constitute the ICLN are: LRN; NAHLN; U.S. Department of Agriculture's Animal and Plant Health Inspection Service and NIFA's National Plant Diagnostic Network; U.S. Department of Agriculture's Food Safety Inspection Service and Department of Health and Human Services's Food and Drug Administration's Food Emergency Response Network (FERN); and the Environmental Protection Agency's Environmental Response Laboratory Network (ERLN).

Source: GAO analysis of U.S. government data.

<sup>a</sup>Reference laboratories can perform tests to detect and confirm the presence of a threat agent and ensure a timely response. Sentinel laboratories are hospital-based facilities that are in direct contact with the public. If these laboratories detect suspicious specimens, they forward the suspect samples to reference laboratories. National laboratories have unique resources to handle highly infectious diseases and to identify and definitively characterize new strains and novel agents.

<sup>b</sup>NIFA is the former U.S. Department of Agriculture Cooperative State Research, Education, and Extension Service.

### Appendix III: Responses to Follow-Up Questionnaire Concerning Federal Programs and Initiatives That May Support Nonfederal Biosurveillance Capabilities

### Response Options on Follow-up Questionnaire for Federal Programs and Initiatives

Supports Core Capabilities: This federal support is essential to core biosurveillance capabilities. Without this support, it would not be possible to carry out core functions or those functions would be significantly diminished.

Supports Capability Enhancement: Without this support, core functions are adequately maintained, but enhanced biosurveillance methods and mechanisms cannot be built or maintained.

Not Used To Support Capabilities: The federal government provides this type of support to your jurisdiction, but it is not used to support or to enhance biosurveillance capabilities.

**Support Not Received:** Your jurisdiction does not receive this type of support from the federal government.

**Do Not Know:** You are not familiar with the federal support or its function falls too far outside your role and responsibilities to offer perspective on how it contributes to biosurveillance capabilities.

Source: GAO.

This appendix contains the results of our follow-up questionnaire for each of the four categories of federal programs and initiatives that state and city officials identified during interviews. Presented below are the questions and response totals to the follow-up questionnaires we sent to (1) state and city public-health epidemiology officials (called the Epidemiology group in this appendix), (2) state and city public-health laboratory officials (the Laboratory group), (3) state agriculture officials (the Agriculture group), and (4) state wildlife officials (the Wildlife group) by group, and descriptions of the federal programs and initiatives listed.

The content of the questionnaire varied for the different respondent groups. For example, public-health officials (the Epidemiology and Laboratory groups) were asked about some information sharing and analytical products, whereas animal-health officials (the Agriculture and Wildlife groups) were asked about others. This was based on earlier interviews with these different groups of officials. Of the 27 officials who responded to these questionnaires, 7 were from the Epidemiology group, 7 were from the Laboratory group, 6 were from the Agriculture group, and 7 were from the Wildlife group. For more detail on the method by which these questionnaires were administered, see appendix I.

Table 8 shows response from the public-health Epidemiology and Laboratory groups to the following question concerning <u>Information Sharing & Analytical Products</u>: How, if at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Information Sharing and Analytical Products—includes those federally-supported mechanisms used to share information and data regarding disease trends and patterns.)

Appendix III: Responses to Follow-Up Questionnaire Concerning Federal Programs and Initiatives That May Support Nonfederal Biosurveillance Capabilities

Table 8: Responses from the Epidemiology and Laboratory Groups Concerning Information Sharing and Analytical Products Number of respondents who selected each of the following options Not used to support capabilities / Information-sharing Supports Support not tools and analytical Supports core capability received / Do products Description Group capabilities enhancement not know CaliciNet To increase the quality of national Epidemiology 3 of 7 1 of 7 3 of 7 norovirus surveillance, the Centers for Laboratory 1 of 7 3 of 7 3 of 7 Disease Control and Prevention (CDC) has developed and implemented an electronic norovirus outbreak surveillance network, CaliciNet, with state and local public-health laboratories. This network compares norovirus sequences to be able to rapidly link norovirus outbreaks with a common food source as well as to identify emerging norovirus strains. CDC's Health Alert 0 of 7 The Health Alert Network is a nationwide 5 of 7 2 of 7 Epidemiology Network system serving as a platform for the 4 of 7 2 of 7 1 of 7 Laboratory distribution of health alerts. Among other things, the network is to provide early warning alerts and to secure capability to securely transmit surveillance, laboratory, and other sensitive data. 0 of 7 Conference calls with Some federal agencies conduct regular Epidemiology 4 of 7 3 of 7 federal agencies conference calls or organize calls during 3 of 7 3 of 7 1 of 7 Laboratory an event—such as a flu outbreak—to facilitate the sharing of information. Some national associations conduct Conference calls with Epidemiology 4 of 7 3 of 7 0 of 7 national associations in regular conference calls or organize calls 5 of 7 2 of 7 0 of 7 Laboratory which federal officials to address specific issues—such as the also participate updating of the national notifiable disease list—to facilitate the sharing of information. Direct information Some state and local officials have 4 of 7 3 of 7 0 of 7 Epidemiology sharing by individual developed relationships with individual 0 of 7 2 of 7 5 of 7 Laboratory federal officials federal officials with whom they may call or e-mail to discuss specific issues and share information.

Appendix III: Responses to Follow-Up Questionnaire Concerning Federal Programs and Initiatives That May Support Nonfederal Biosurveillance Capabilities

1			Number of respondents who selected each of the following options			
Information-sharing tools and analytical products	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities / Support not received / Do not know	
Electronic Laboratory	eLEXNET provides a web-based system for real-time sharing of food-safety laboratory data among federal, state, and local agencies. It allows public-health officials at multiple government agencies engaged in food-safety activities to compare and coordinate laboratory analysis findings in a secure setting. eLEXNET captures food-safety sample and test-result data from participating laboratories and uses them for risk-assessment and decision-support purposes, improving the early detection of problem products.	Epidemiology	1 of 7	1 of 7	5 of 7	
Exchange Network (eLEXNET)		Laboratory	1 of 7	3 of 7	3 of 7	
Environmental	ERLN provides federal, state, and local	Epidemiology	1 of 7	1 of 7	5 of 7	
Response Laboratory Network (ERLN)	decision makers with reliable analytical data used to identify chemical, biological, and radiological contaminants collected in support of response and clean-up activities. ERLN goals include providing laboratory testing capability and capacity to meet the Environmental Protection Agency's responsibilities for surveillance, response, decontamination, and recovery from incidents involving the release of chemical, biological, or radiological contaminants; facilitating the coordination of labs capable of responding efficiently and effectively to incidents; and establishing relationships and priorities with other federal laboratory networks.	Laboratory	2 of 7	2 of 7	3 of 7	
Epidemic Information Exchange (Epi-X)	Epi-X connects state and local publichealth officials so that they can share information about outbreaks and other acute health events, including those possibly related to bioterrorism. It is intended to provide epidemiologists and others with a secure, web-based platform that can be used to provide emergency notification of outbreaks and requests for CDC assistance. Epi-X provides tools for searching, tracking, and reporting on diseases.	Epidemiology	2 of 7	5 of 7	0 of 7	
		Laboratory	1 of 7	4 of 7	2 of 7	

Appendix III: Responses to Follow-Up Questionnaire Concerning Federal Programs and Initiatives That May Support Nonfederal Biosurveillance Capabilities

		Group	Number of respondents who selected each of the following options		
Information-sharing tools and analytical products	Description		Supports core capabilities	Supports capability enhancement	Not used to support capabilities / Support not received / Do not know
FluView	CDC collects, compiles, and analyzes information on influenza activity year round in the United States and produces FluView, a weekly influenza surveillance report, from October through mid-May. The collection of these data enables CDC to: find out when and where influenza activity is occurring, track influenza-related illness, determine what influenza viruses are circulating, detect changes in influenza viruses, measure the effect influenza is having on deaths in the United States.	Epidemiology	3 of 7	4 of 7	0 of 7
		Laboratory	1 of 7	2 of 7	4 of 7
Food Emergency Response Network (FERN)	FERN integrates the nation's food-testing laboratories at the federal, state, and local levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The network also seeks to strengthen laboratory capacities and capabilities, as well as act as surge capacity.	Epidemiology	2 of 7	1 of 7	4 of 7
		Laboratory	4 of 7	1 of 7	2 of 7
Foodborne Disease	FoodNet provides a network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne disease, and identifying the sources of specific foodborne diseases. It consists of active surveillance and related epidemiological studies, which help publichealth officials better understand the epidemiology of foodborne diseases in the United States. Participating FoodNet sites may also be employed to coordinate enhanced surveillance and epidemiologic investigation if a novel foodborne disease threat is suspected in order to more rapidly identify the source and extent of the threat.	Epidemiology	2 of 7	2 of 7	3 of 7
Active Surveillance Network (FoodNet)		Laboratory	2 of 7	2 of 7	3 of 7
Graphs and maps produced from the National Electronic Disease Surveillance System (NEDSS) <sup>a</sup> and other nationally notifiable data	CDC publishes graphs depicting disease trends, and disease incidence rates, as well as maps of the United States that identify the locations of disease incidence, which are based on data collected through NEDSS and other systems.	Epidemiology	3 of 7	3 of 7	1 of 7
		Laboratory	0 of 7	4 of 7	3 of 7

			Number of resp the	ondents who se following option	lected each of is
Information-sharing tools and analytical products	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities / Support not received / Do not know
Homeland Security	The Homeland Security Information	Epidemiology	1 of 7	1 of 7	5 of 7
Information Network	Network is a national secure and trusted web-based portal for information sharing and collaboration between federal, state, local, tribal, territorial, private sector, and international partners engaged in the homeland security mission.	Laboratory	0 of 7	2 of 7	5 of 7
Influenza-like Illness	ILINet is an electronic reporting system	Epidemiology	4 of 7	3 of 7	0 of 7
Surveillance Program (ILINet)	developed by CDC to conduct surveillance for influenza-like illness. CDC is able to use the information collected from ILINet Providers to estimate influenza-like illness on a national and regional scale and to analyze data for trends in influenza-like illness prevalence.	Laboratory	3 of 7	0 of 7	4 of 7
Laboratory Response	LRN Results Messenger is a software solution created to provide LRN labs with the immediate ability to manage and share standard laboratory data. LRN Results Manager provides basic laboratory data management, including the ability to enter and share sample and results data.	Epidemiology	3 of 7	1 of 7	3 of 7
Network (LRN) <sup>8</sup> Results Messenger		Laboratory	6 of 7	1 of 7	0 of 7
Morbidity and Mortality	MMWR is a public-health bulletin	Epidemiology	3 of 7	3 of 7	1 of 7
Weekly Report (MMWR)	published by CDC. The MMWR includes reports on disease epidemics, trends, prevention and control of illness, injuries, and deaths. This information represents the primary manner that state and local public-health officials, the media, and the public are informed of public-health issues from CDC. The MMWR publishes data from the National Notifiable Disease Surveillance System each week and in an annual Summary of Notifiable Diseases. These data are the official statistics, in tabular and graphic form, for the reported occurrence of nationally notifiable infectious diseases in the United States.	Laboratory	1 of 7	4 of 7	2 of 7

				oondents who se following option	
Information-sharing tools and analytical products	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities / Support not received / Do not know
PulseNet	PulseNet is an early warning system for	Epidemiology	7 of 7	0 of 7	0 of 7
	outbreaks of foodborne diseases. The network has participants from publichealth laboratories in all 50 states, federal regulatory agencies, and some state agricultural laboratories and is coordinated by CDC. PulseNet contributes to the identification and investigation of outbreaks of foodborne and bacterial diseases through comparison of the molecular "fingerprints" of foodborne pathogens from patients and their food, water, and animal sources.	Laboratory	7 of 7	0 of 7	0 of 7
TB Genotyping	TB GIMS is a secure web-based system	Epidemiology	4 of 7	0 of 7	3 of 7
Information Management System (TB GIMS)	designed to improve access and dissemination of genotyping information nationwide. The system stores and manages genotyping data on TB patients in the United States, provides immediate notification of genotyping results and updates to TB labs and programs, links isolate data to patient-level surveillance data, provides reports on genotype clusters, and provides national, state, and county maps of genotype clusters.	Laboratory	2 of 7	0 of 7	5 of 7
Working groups	Some federal agencies organize working	Epidemiology	2 of 7	5 of 7	0 of 7
organized by federal groups that bring together federal, state, and local officials to work on a specific issue—such as the State, Local, Territorial and Tribal Working Group <sup>c</sup> that helped CDC develop the National Biosurveillance Strategy for Human Health and the accompanying Concept Plan for Implementation.	Laboratory	3 of 7	2 of 7	2 of 7	

Source: GAO.

<sup>a</sup>NEDSS (National Electronic Disease Surveillance System) is an Internet-based infrastructure for public-health surveillance data exchange that uses specific PHIN (Public Health Information Network) and NEDSS Data Standards. NEDSS is not a single, monolithic application, but a system of interoperable subsystems, components and systems modules that include software applications developed and implemented by CDC; those developed and implemented by state and local health departments; and those created by commercial services and vendors.

<sup>b</sup>LRN is charged with maintaining an integrated network of federal, military, state, local, and international laboratories that can respond to bioterrorism, chemical terrorism, and other public-health emergencies. The biological component of LRN provides network capacity to test for biological agents in a variety of formats including clinical specimens, and food and environmental samples. The laboratories in this component are classified as either reference, national, or sentinel laboratories, depending on the types of tests that the laboratory can perform and how it handles infectious agents

<sup>c</sup>The State, Local, Territorial and Tribal Working Group members provided input regarding the development of a national biosurveillance capability from the state and local public-health and medical perspectives. This work group consisted of both governmental public-health and clinical-medicine entities. Several members were employed by state, tribal, territorial, or local government agencies. Others, although they do not officially represent their organizations, were employed by academic, private, and national professional institutions.

Table 9 shows responses from the Agriculture and Wildlife groups to the following question concerning <u>Information Sharing & Analytical Products</u>: How, if at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Information Sharing and Analytical Products—includes those federally-supported mechanisms used to share information and data regarding disease trends and patterns.)

Table 9: Responses from the Agriculture and Wildlife Groups Concerning Information Sharing and Analytical Products

				respondents w the following o	
Information sharing tools & analytical products	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Arboviral	ArboNet is an Internet-based national arboviral surveillance system developed by state health departments and CDC in 2000. ArboNet collects reports of arboviral diseases and other data from all states and three local districts (New York City; Washington, D.C.; and Puerto Rico). Data are reported by local health departments weekly for routine analysis and dissemination.	Agriculture	3 of 6	2 of 6	1 of 6
Surveillance System (ArboNet)		Wildlife	1 of 7	1 of 7	5 of 7
Direct information	Some state officials have developed relationships with	Agriculture	4 of 6	1 of 6	1 of 6
sharing by individual federal officials	individual federal officials with whom they may call or e- mail to discuss specific issues and share information.	Wildlife	3 of 7	4 of 7	0 of 7
Information and	SCWDS, which receives funding from the Department	Agriculture	1 of 6	4 of 6	1 of 6
reports of disease occurrence from the Southeastern Cooperative Wildlife Disease Study (SCWDS)	reports of disease of the Interior and the United States Geological Survey occurrence from the Southeastern Cooperative wildlife Disease of the Interior and the United States Geological Survey (USGS) National Wildlife Health Center, provides reports and coverage maps that identify disease occurrence for select diseases.		5 of 7	1 of 7	1 of 7

				respondents w	
Information sharing tools & analytical products	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Meetings and		Agriculture	5 of 6	1 of 6	0 of 6
conferences sponsored by professional associations	conferences, in association with federal partners. In addition to providing information about a specific topic, these events help foster information sharing between state and federal officials.	Wildlife	1 of 7	5 of 7	1 of 7
Morbidity and	CDC provides the MMWR on its website. The MMWR	Agriculture	1 of 6	2 of 6	3 of 6
mortality reports identifies cases of several diseases in humans, from CDC including zoonotic diseases such as brucellosis, V	including zoonotic diseases such as brucellosis, West Nile virus, and plague, and in some cases provides	Wildlife	1 of 7	5 of 7	1 of 7
National Animal	United States Department of Agriculture's (USDA) NAHRS is a comprehensive reporting system for World Organization for Animal Health (OIE)-reportable diseases in the United States. Under NAHRS, participating state animal-health officials report monthly on the occurrence of confirmed OIE-reportable diseases in U.S. livestock, poultry, and aquaculture species. States receive a monthly report from this system.	Agriculture	4 of 6	1 of 6	1 of 6
System (NAHRS) and associated reports		Wildlife	1 of 7	4 of 7	2 of 7
State-by-state	Federal agencies, such as USDA, provide state-by-	Agriculture	4 of 6	1 of 6	1 of 6
reports of disease occurrence for select diseases	state reports of disease occurrence for select diseases that include case counts. For example, USDA's Wildlife Services provides reports and coverage maps of select disease in wildlife that pose a risk to humans and livestock.	Wildlife	1 of 7	4 of 7	2 of 7
USDA Veterinary	State officials can submit and access disease data,	Agriculture	5 of 6	1 of 6	0 of 6
Service Laboratory Submissions website	such as avian influenza data, through the USDA Veterinary Services Laboratory Submissions site.	Wildlife	1 of 7	2 of 7	4 of 7
USGS National	The USGS National Biological Information	Agriculture	0 of 6	0 of 6	6 of 6
Biological Information Infrastructure	Infrastructure is a broad, collaborative program to provide increased access to data and information on the nation's biological resources. The USGS National Biological Information Infrastructure links diverse, high-quality biological databases, information products, and analytical tools maintained by partners and other contributors in government agencies, academic institutions, nongovernment organizations, and private industry.	Wildlife	1 of 7	2 of 7	4 of 7

Information sharing tools & analytical products	Description	Group	Number of respondents who selected each of the following options:			
			Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know	
USGS National	State officials can visit the USGS National Wildlife	Agriculture	0 of 6	2 of 6	4 of 6	
Wildlife Health Center website	Health Center website to obtain information about disease trends, learn about emerging diseases in wildlife, and obtain fact sheets on diseases. The National Wildlife Health Center also provides Wildlife Morbidity and Mortality Quarterly Reports on its website as well as online databases such as avian influenza surveillance data in wild birds.	Wildlife	3 of 7	4 of 7	0 of 7	

Source: GAO.

Table 10 shows responses from the public health Epidemiology and Laboratory groups to the following question concerning Nonfinancial Technical & Material Assistance: How, if at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Nonfinancial Technical & Material Assistance—includes those types of technical assistance [e.g., training and subject-matter expertise] and material assistance [e.g., supplies and equipment] that support the development and maintenance of biosurveillance capabilities.)

			Number of respondents who selected each of the following options:			
Type of nonfinancial assistance	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know	
Conferences	Federal agencies and national associations sponsor	Epidemiology	2 of 7	4 of 7	1 of 7	
	conferences that state and local officials attend in order to, among other things, learn about new issues, share information, and make new connections with other officials.	Laboratory	5 of 7	2 of 7	0 of 7	
Exercises	Federal agencies sponsor exercises in which state or	Epidemiology	2 of 7	2 of 7	3 of 7	
	local officials participate to practice responding to a specific situation, such as a terrorist attack. These exercises enable state or local officials to then evaluate their response efforts and identify gaps.	Laboratory	4 of 7	2 of 7	1 of 7	
Expert	CDC provides support to state and local officials during outbreaks through conference calls, one-on-one discussions, and the provision of epidemiology aides to assist public-health departments with their investigations.	Epidemiology	6 of 7	1 of 7	0 of 7	
consultation for epidemiological investigation		Laboratory	3 of 7	2 of 7	1 of 7	
Expert	CDC provides expert information-technology	Epidemiology	2 of 7	2 of 7	3 of 7	
information- technology consultation	consultation to states and localities when they are developing new electronic systems, such as syndromic surveillance systems.	Laboratory	3 of 7	4 of 7	0 of 7	
Expert	CDC provides expert laboratory-consultation	Epidemiology	5 of 7	0 of 7	2 of 7	
laboratory consultation	services, such as advice about sampling methods, to state and local public-health officials to help improve testing capabilities.	Laboratory	6 of 7	1 of 7	0 of 7	
Laboratory	CDC supplies state public-health laboratories with	Epidemiology	6 of 7	0 of 7	1 of 7	
equipment	critical reagents and assays for a wide variety of laboratory tests to ensure laboratory tests are properly conducted.	Laboratory	7 of 7	0 of 7	0 of 7	
Laboratory	CDC provides laboratory testing support to states	Epidemiology	5 of 7	1 of 7	1 of 7	
testing of specimens with unusual characteristics	and localities, including the testing of specimens with unusual characteristics, which may be difficult for state or local laboratories to identify.	Laboratory	7 of 7	0 of 7	0 of 7	
Legal/Regulatory	Federal agencies may provide legal or regulatory	Epidemiology	1 of 7	3 of 7	3 of 7	
	support, such as model regulations, for states.	Laboratory	0 of 7	4 of 7	3 of 7	

				respondents w f the following o	
Type of nonfinancial assistance	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Personnel to enhance	CDC provides personnel, such as Epidemic Intelligence Service officers, to states to enhance their disease-investigation capacity. For example, the Epidemic Intelligence Service is a 2-year postgraduate on-the-job training program for health professionals interested in the practice of applied epidemiology. Epidemic Intelligence Service officers conduct epidemiologic investigations, research, and public-health surveillance and increase the epidemiologic capacity of the state.	Epidemiology	3 of 3	3 of 7	1 of 7
epidemiologic capacity		Laboratory	2 of 7	2 of 7	3 of 7
Secondary	CDC provides secondary laboratory confirmation- testing support to state and local public-health departments to confirm unusual diseases or to verify positive test results for select agents—biological agents and toxins that have the potential to pose a severe health threat.	Epidemiology	6 of 7	0 of 7	1 of 7
laboratory confirmation		Laboratory	7 of 7	0 of 7	0 of 7
Standards to	Federal agencies develop standards, such as the Public Health Information Network (PHIN), to improve disease reporting and information sharing. The PHIN is a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements.	Epidemiology	2 of 7	4 of 7	1 of 7
improve disease reporting		Laboratory	2 of 7	4 of 7	1 of 7
Systems to	CDC develops and provides systems, such as the	Epidemiology	1 of 7	3 of 7	3 of 7
enhance epidemiologic capacity	Early Aberration Reporting System, to enhance state and local epidemiologic capacity. The Early Aberration Reporting System assists state and local officials with their analysis of surveillance data.	Laboratory	0 of 7	2 of 7	5 of 7
Tools to support	CDC provides tools, such as Epi Info, to support	Epidemiology	5 of 7	2 of 7	0 of 7
epidemiologic investigations	state and local epidemiologic investigations. Epi Info provides public-health workers with a means to quickly create data-collection instruments, conduct data analysis, and report results during an epidemiologic investigation.	Laboratory	1 of 7	2 of 7	4 of 7
Training	Federal agencies provide various types of training	Epidemiology	4 of 7	3 of 7	0 of 7
	opportunities to state and local officials, including training that covers new sampling and testing methods, new reporting standards, or safety standards.	Laboratory	7 of 7	0 of 7	0 of 7

Source: GAO.

Table 11 shows responses from the Agriculture and Wildlife groups to the following question concerning Nonfinancial Technical & Material Assistance: How, if at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Nonfinancial Technical & Material Assistance—includes those types of technical assistance [e.g., training and subject-matter expertise] and material assistance [e.g., supplies and equipment] that support the development and maintenance of biosurveillance capabilities.)

				pondents who se following option	
Type of nonfinancial assistance	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Conferences	Federal agencies and national associations	Agriculture	2 of 6	3 of 6	1 of 6
	sponsor conferences that state and local officials attend in order to, among other things, learn about new issues, share information, and make new connections with other officials.	Wildlife	0 of 7	5 of 7	2 of 7
Disease guides	The USGS National Wildlife Health Center	Agriculture	3 of 6	3 of 6	0 of 6
describing clinical signs of diseases for easier identification, and other technical information	makes available guides on wildlife diseases, such as the Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds, and fact sheets on diseases, such as chronic wasting disease, that provide information on clinical signs, diagnosis, and management of wildlife diseases. In addition, USDA's Wildlife Services provides fact sheets on wildlife diseases and manuals for conducting surveillance for select wildlife diseases.	Wildlife	2 of 7	5 of 7	0 of 7
Equipment and	Federal agencies provide states with	Agriculture	5 of 6	0 of 6	1 of 6
supplies	equipment and supplies, such as sampling kits, assays, and personal protective equipment, to help states conduct outbreak investigations.	Wildlife	2 of 7	2 of 7	3 of 7
Exercises	Federal agencies sponsor simulations and	Agriculture	2 of 6	3 of 6	1 of 6
	drills in which participants practice responding to a specific situation, such as a terrorist attack. These exercises enable state or local officials to then evaluate their response efforts and identify gaps.	Wildlife	0 of 7	1 of 7	6 of 7
Field support	Federal agencies provide field support to	Agriculture	3 of 6	2 of 6	1 of 6
i f t	states to enhance their disease- investigation capacity. For example, federal agencies may send additional biologists to help collect samples during a disease outbreak.	Wildlife	1 of 7	3 of 7	3 of 7
Information	Federal agencies provide expert	Agriculture	2 of 6	3 of 6	1 of 6
technology expertise	information-technology consultation to states when they are developing new electronic systems, such as assistance for establishing or upgrading case- management systems.	Wildlife	0 of 7	2 of 7	5 of 7

				pondents who see following opti	
Type of nonfinancial assistance	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Laboratory testing	Several federal laboratories support states' efforts to diagnose a disease. For example, the National Veterinary Services Laboratory (NVSL) is a federal reference laboratory—a laboratory that conducts and confirms tests for other laboratories. The Foreign Animal Disease Diagnostic Laboratory tests for highly contagious diseases such as foot-and-mouth disease. The USGS National Wildlife Health Center is the only federal laboratory in the United States dedicated to wildlife-disease investigation and offers laboratory support to states for wildlife-disease diagnostics. USDA's Wildlife Services' National Wildlife Research Center also has the capacity to provide surge diagnostics for wildlife samples when large surveillance activities are activated, for example this center conducted most of the environmental screening for H5N1 during the avian influenza campaign.	Agriculture Wildlife	4 of 6 3 of 7	1 of 6 4 of 7	1 of 6 0 of 7
Personnel to enhance disease	Federal agencies provide personnel to states to enhance their disease-	Agriculture	4 of 6	2 of 6	0 of 6
investigation capacity	investigation capacity. For example, Veterinary Services Area Officers from USDA conduct disease surveillance and respond to emergency animal-disease outbreaks at the state level. USDA Wildlife Services's National Wildlife Disease Program has wildlife disease biologists across the country, often colocated with state agencies, to assist with planning and conducting surveillance to detect wildlife diseases that may threaten human health or agricultural resources. In addition, the Wildlife Disease Specialists from the USGS National Wildlife Health Center conduct disease-surveillance efforts in the field and provide expert disease knowledge with state officials to help diagnose diseases in wildlife.	Wildlife	2 of 7	4 of 7	1 of 7

Type of nonfinancial assistance	Description			Number of respondents who selected each of the following options:			
		Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know		
Subject-matter expertise for investigations, sampling, and testing	Federal agencies assist state animal- health officials with their disease investigations by providing subject-matter expertise for sampling, testing, and disease knowledge.	Agriculture	2 of 6	3 of 6	1 of 6		
		Wildlife	1 of 7	6 of 7	0 of 7		
Training	Federal agencies deliver or sponsor	Agriculture	3 of 6	2 of 6	1 of 6		
including training that cove sampling and testing meth	various training to state and local officials, including training that covers new sampling and testing methods, new reporting standards, or safety standards.	Wildlife	2 of 7	4 of 7	1 of 7		

Source: GAO.

Table 12 shows responses from the public-health Epidemiology and Laboratory groups to the following question concerning <u>Grants & Cooperative Agreements</u>: How, if at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Grants & Cooperative Agreements—refers to federal funding that may support the development and maintenance of biosurveillance capabilities.)

				spondents who ne following opti	
Grant or cooperative agreement	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Patient Protection and	CDC provides funding and capacity-building	Epidemiology	5 of 7	2 of 7	0 of 7
Affordable Care Act's (PPACA) Prevention and Public Health Fund Grants	assistance (including technical consultation, skills building / training, information, and technology-transfer assistance) through the PPACA Prevention and Public Health Fund Grants to help state, tribal, local, and territorial health departments improve: (1) the planning, coordination, and implementation of public health infrastructure investments; and (2) the evaluation (including dissemination of best practices) of public-health infrastructure investments.	Laboratory	2 of 7	2 of 7	3 of 7
City-Readiness	CDC provides funding to the 50 states and	Epidemiology	1 of 7	1 of 7	5 of 7
Initiative Program	four localities for the City-Readiness Initiative Program through the Public Health Emergency Preparedness (PHEP) cooperative agreement. CDC's Office of Public Health Preparedness and Response, Division of State and Local Readiness administers the PHEP cooperative agreement, provides annual guidance on preparedness activities that support the National Response Framework, and coordinates technical assistance.	Laboratory	0 of 7	0 of 7	7 of 7
Emerging Infections	CDC provides funding to Emerging Infections	Epidemiology	1 of 7	2 of 7	4 of 7
Program	Program participants to conduct active population-based surveillance and research for emerging infectious diseases of public health importance. The Emerging Infections Program is a network of CDC and 10 state health departments working with collaborators, including academic institutions and other federal agencies.	Laboratory	1 of 7	1 of 7	5 of 7

				spondents who le following opti	
Grant or cooperative agreement	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Epidemiology and	CDC supports public-health capacity by	Epidemiology	7 of 7	0 of 7	0 of 7
Laboratory Capacity for Infectious Diseases cooperative agreement (ELC)	seases through the ELC cooperative agreement to hire and train staff, buy laboratory equipment	Laboratory	7 of 7	0 of 7	0 of 7
Federal funding	Federal agencies, such as CDC, provide the states with funding and technical support to develop and enhance syndromic surveillance systems.	Epidemiology	4 of 7	1 of 7	2 of 7
specifically for the development or enhancement of syndromic surveillance systems		Laboratory	0 of 7	4 of 7	3 of 7
Food Emergency	USDA and the Department of Health and Human Services (HHS) provide laboratory funding for FERN, which integrates the nation's food-testing laboratories at the federal, state, and local levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The network also seeks to strengthen laboratory capacities and capabilities, as well as act as surge capacity.	Epidemiology	1 of 7	1 of 7	5 of 7
Response Network (FERN) funding		Laboratory	3 of 7	1 of 7	3 of 7
Hospital Preparedness		Epidemiology	1 of 7	3 of 7	3 of 7
Program	Preparedness and Response provides funding through the Hospital Preparedness Program to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public-health emergencies.	Laboratory	1 of 7	4 of 7	2 of 7
Immunization Grant	The federal government provides funding for	Epidemiology	6 of 7	0 of 7	1 of 7
Program (Section 317)	17) all states six sities territories and	Laboratory	2 of 7	1 of 7	4 of 7

				spondents who le following opti	
Grant or cooperative agreement	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
Public Health	CDC provides funding and technical	Epidemiology	7 of 7	0 of 7	0 of 7
Preparedness agreement for strengthening capabilities of PHEP award territories an localities.	assistance through the PHEP cooperative agreement for the development and strengthening of recipients' response capabilities during public-health incidents. PHEP awardees include 50 states, 8 territories and freely associated states, and 4 localities.	Laboratory	7 of 7	0 of 7	0 of 7
Public Health	The Supplemental Appropriations Act, 2009,	Epidemiology	5 of 7	1 of 7	1 of 7
appropriated funding for the "Public Health and Social Services Emergency Fund" to prepare for and respond to an influenza pandemic. CDC administered the grant to upgrade state and local pandemic-influenza preparedness and response capacity. The 62 awardees included 50 states, 8 territories and freely associated states, and 4 localities.	Laboratory	5 of 7	1 of 7	1 of 7	
State Homeland	The Department of Homeland Security's	Epidemiology	2 of 7	0 of 7	5 of 7
Security Grant Program	(DHS) State Homeland Security Grant Program provides funding to support the implementation of State Homeland Security Strategies to address the identified planning, organization, equipment, training, and exercise needs at the state and local levels to prevent, protect against, respond to, and recover from acts of terrorism and other catastrophic events.	Laboratory	1 of 7	1 of 7	5 of 7
Tuberculosis grants	CDC provides tuberculosis grants to help	Epidemiology	5 of 7	0 of 7	2 of 7
	state laboratories improve their testing ability and to support state tuberculosis surveillance and elimination efforts.	Laboratory	6 of 7	1 of 7	0 of 7
Urban Areas Security	UASI provides funding to address the unique	Epidemiology	2 of 7	1 of 7	4 of 7
Initiative (UASI)	planning, organization, equipment, training, and exercise needs of high-threat, high-density urban areas, and assists them in building an enhanced and sustainable capacity to prevent, protect against, respond to, and recover from acts of terrorism.	Laboratory	1 of 7	0 of 7	6 of 7

Source: GAO.

Table 13 shows responses from the Agriculture and Wildlife groups to the following question concerning Grants & Cooperative Agreements: How, if

at all, has each of the following items supported biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Grants & Cooperative Agreements—refers to federal funding that may support the development and maintenance of biosurveillance capabilities.)

Table 13: Responses from the Agriculture and Wildlife Groups Concerning Grants and Cooperative Agreements

			Number of respondents who selected each o the following options:			
Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know		
DHS, through the National Center for	Agriculture	2 of 6	1 of 6	3 of 6		
Defense, provides funding to states participating in the Animal Health Network to help them develop their network. The Animal Health Network is a communication conduit for the state veterinarian and other officials to get vital animal disease alerts to noncommercial livestock and poultry	Wildlife	0 of 7	0 of 7	7 of 7		
USDA provides funding to states through cooperative agreements for expanded bird-monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.	Agriculture	6 of 6	0 of 6	0 of 6		
	Wildlife	5 of 7	1 of 7	1 of 7		
USDA provides states with funding to	Agriculture	1 of 6	2 of 6	3 of 6		
rucellosis operative preement USDA provides states with funding to conduct continued surveillance efforts for brucellosis and to support the cooperative federal-state-industry effort to eradicate brucellosis from livestock.	Wildlife	0 of 7	0 of 7	7 of 7		
USDA provides coordination and	Agriculture	3 of 6	1 of 6	2 of 6		
assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance programs.	Wildlife	6 of 7	1 of 7	0 of 7		
_	DHS, through the National Center for Foreign Animal and Zoonotic Disease Defense, provides funding to states participating in the Animal Health Network to help them develop their network. The Animal Health Network is a communication conduit for the state veterinarian and other officials to get vital animal disease alerts to noncommercial livestock and poultry owners.  USDA provides funding to states through cooperative agreements for expanded bird-monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.  USDA provides states with funding to conduct continued surveillance efforts for brucellosis and to support the cooperative federal-state-industry effort to eradicate brucellosis from livestock.  USDA provides coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance	DHS, through the National Center for Foreign Animal and Zoonotic Disease Defense, provides funding to states participating in the Animal Health Network to help them develop their network. The Animal Health Network is a communication conduit for the state veterinarian and other officials to get vital animal disease alerts to noncommercial livestock and poultry owners.  USDA provides funding to states through cooperative agreements for expanded bird- monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.  USDA provides states with funding to conduct continued surveillance efforts for brucellosis and to support the cooperative federal-state-industry effort to eradicate brucellosis from livestock.  USDA provides coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance	Description  DHS, through the National Center for Foreign Animal and Zoonotic Disease Defense, provides funding to states participating in the Animal Health Network to help them develop their network. The Animal Health Network is a communication conduit for the state veterinarian and other officials to get vital animal disease alerts to noncommercial livestock and poultry owners.  USDA provides funding to states through cooperative agreements for expanded bird-monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.  USDA provides states with funding to conduct continued surveillance efforts for brucellosis and to support the cooperative federal-state-industry effort to eradicate brucellosis from livestock.  USDA provides coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance.	Description  DHS, through the National Center for Foreign Animal and Zoonotic Disease Defense, provides funding to states participating in the Animal Health Network to help them develop their network. The Animal Health Network is a communication conduit for the state veterinarian and other officials to get vital animal disease alerts to noncommercial livestock and poultry owners.  USDA provides funding to states through cooperative agreements for expanded bird-monitoring programs, including the collection of samples from domesticated and wild birds for avian influenza testing.  USDA provides states with funding to conduct continued surveillance efforts for brucellosis and to support the cooperative federal-state-industry effort to eradicate brucellosis from livestock.  USDA provides coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information dissemination, education, and funding for state chronic wasting disease surveillance		

			Number of respondents who selected each the following options:			
Grant or cooperative agreement	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know	
Federal Aid in	The act provided that the proceeds of a tax	Agriculture	0 of 6	0 of 6	6 of 6	
Wildlife Restoration Act funds (Pittman- Robertson Act)	on certain ammunition and firearms used for sport hunting be distributed to the states and insular areas for wildlife restoration. States use the funds to buy, develop, maintain, and operate wildlife-management areas—such as conducting passive surveillance and disease-monitoring activities.	Wildlife	6 of 7	1 of 7	0 of 7	
Federal funding	In some instances, state public-health	Agriculture	1 of 6	1 of 6	4 of 6	
passed from public- health departments	departments collaborate with state agriculture or wildlife agencies on specific zoonotic disease efforts supported by federal cooperative agreements or grants that are received by state public-health departments. State public-health departments provide a portion of these funds to support the agriculture or wildlife agencies' animal-health monitoring efforts.	Wildlife	0 of 7	1 of 7	6 of 7	
Foreign animal	USDA's Veterinary Services provides	Agriculture	5 of 6	1 of 6	0 of 6	
disease cooperative agreement	states with funding and works cooperatively with the state veterinarians in an effort to accomplish the goals of the National Animal Health Surveillance System—to rapidly detect and conduct surveillance for foreign and emerging animal diseases and provide timely and accurate animal-health information. The states also quarantine any animals suspected of having a foreign animal disease and obtain and submit samples to USDA's Animal and Plant Health Inspection Service's NVSL for verification.	Wildlife	0 of 7	0 of 7	7 of 7	
Garbage feeder	USDA provides states with funding to	Agriculture	2 of 6	1 of 6	3 of 6	
cooperative agreement	conduct surveillance for pseudorabies virus and other diseases in garbage feeders—swine that eat food waste.	Wildlife	0 of 7	0 of 7	7 of 7	

			Number of resp the	ondents who se following option	
Grant or cooperative agreement	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know
National Animal	USDA's National Institute of Food and	Agriculture	3 of 6	2 of 6	1 of 6
Health Laboratory Network (NAHLN) funding	Agriculture (NIFA) provides funding to states that participate in the NAHLN for laboratory equipment, training, and staff. USDA's Animal and Plant Health Inspection Services provides operational support for the network as well as training, proficiency testing, reference materials, equipment, and equipment maintenance, and funding for testing. The NAHLN is a network of veterinary state and university laboratories conducting surveillance and diagnostic testing to protect the U.S. animal agricultural industries.	Wildlife	1 of 7	0 of 7	6 of 7
Scrapie cooperative	USDA provides states with funding to	Agriculture	1 of 6	2 of 6	3 of 6
agreement	conduct continued surveillance efforts for scrapie and to support efforts to eradicate scrapie from sheep and goats.	Wildlife	0 of 7	0 of 7	7 of 7
State Homeland	DHS's State Homeland Security Grant	Agriculture	3 of 6	1 of 6	2 of 6
Security Grant Program	Program provides funding to support the implementation of State Homeland Security Strategies to address the identified planning, organization, equipment, training, and exercise needs at the state and local levels to prevent, protect against, respond to, and recover from acts of terrorism and other catastrophic events.	Wildlife	0 of 7	0 of 7	7 of 7
Traceability	USDA provides funding through the	Agriculture	2 of 6	3 of 6	1 of 6
Cooperative Agreement	Traceability Cooperative Agreement to advance animal disease traceability by supporting the search ability of standardized animal disease traceability data within and among states, tribes, and territories.	Wildlife	0 of 7	0 of 7	7 of 7
Tuberculosis	USDA provides states with funding to	Agriculture	2 of 6	0 of 6	4 of 6
cooperative agreement	conduct continued surveillance efforts for tuberculosis and to support the cooperative federal-state-industry effort to eradicate bovine tuberculosis from cattle.	Wildlife	0 of 7	0 of 7	7 of 7

Grant or cooperative agreement			Number of respondents who selected each the following options:			
	Description	Group	Supports core capabilities	Supports capability enhancement	Not used to support capabilities/ Support not received/ Do not know	
U.S. Fish and	The State Wildlife Grant Program provides	Agriculture	0 of 6	1 of 6	5 of 6	
Wildlife Service's State Wildlife Grant Program	Wildlife Grant development and implementation of	Wildlife	3 of 7	3 of 7	1 of 7	
USDA's biosecurity	Various USDA components provide	Agriculture	1 of 6	0 of 6	5 of 6	
cooperative coop agreements resp gove deve anin deve	cooperative agreements for enhancing the $\frac{1}{\sqrt{1}}$	Wildlife	0 of 7	0 of 7	7 of 7	

Source: GAO.

Table 14 shows responses from public-health Epidemiology and Laboratory groups to the following question concerning Guidance: How useful, if at all, has each of the following items been in supporting biosurveillance capabilities in your area of responsibility over the last 2 years? (Note: This category—Guidance—refers to federal guidance that helps with the design of biosurveillance programs or with the implementation of activities that support biosurveillance capabilities.)

			Number of respondent	ondents who s following optio	
Type of guidance	Description	Group	Very useful	Moderately useful	Somewhat useful/ Not useful
Federal	Federal agencies provide guidance to help states	Epidemiology	3 of 7	3 of 7	1 of 7
guidance concerning industry information and privacy protection	ensure the security and privacy of industry information and individuals' health information—such as the Health Insurance Portability and Accountability Act (HIPAA)—during disease investigations.	Laboratory	2 of 7	5 of 7	0 of 7
Federal	Federal agencies have provided guidance	Epidemiology	1 of 7	4 of 7	2 of 7
guidance concerning information- systems security	concerning the protection and security of their information infrastructures.	Laboratory	1 of 7	5 of 7	1 of 7
guidance for assessing capabilities	Federal agencies may provide guidance to states and localities for assessing capabilities. For example, CDC's Public Health Preparedness Capabilities: National Standards for State and Local Planning includes performance metrics for some of the capabilities CDC expects states and localities to develop. The national standards for public-health preparedness help state and local public-health departments assess capabilities, identify gaps, determine specific jurisdictional priorities, and develop plans for building and sustaining capabilities.	Epidemiology	0 of 7	5 of 7	2 of 7
		Laboratory	2 of 7	2 of 7	3 of 7
Federal	Federal agencies provide states and localities with	Epidemiology	3 of 7	1 of 7	3 of 7
guidance for best practices for laboratory testing protocols	guides outlining the best practices for laboratory testing protocols.	Laboratory	6 of 7	1 of 7	0 of 7
Federal	Federal agencies develop disease-reporting	Epidemiology	5 of 7	1 of 7	1 of 7
guidance for disease- reporting requirements	requirements for state and local jurisdictions for those diseases posing a serious public-health, animal-health, or economic risk for which case reports would help inform prevention and control efforts.	Laboratory	2 of 7	3 of 7	2 of 7
Federal	Federal agencies provide states with guidance on	Epidemiology	4 of 7	1 of 7	2 of 7
guidance for sampling procedures for unusual or emerging disease agents	the appropriate methods for collecting and shipping samples for unusual or emerging diseases.	Laboratory	3 of 7	3 of 7	1 of 7

			Number of respondent	ondents who se following optio	
Type of guidance	Description	Group	Very useful	Moderately useful	Somewhat useful/ Not useful
Federal	Federal agencies provide guidance for	Epidemiology	5 of 7	1 of 7	1 of 7
guidance for standardized case definitions	standardizing case definitions to improve disease reporting and information sharing. For example, CDC published the Case Definitions for Infectious Conditions Under Public Health Surveillance, which provides uniform criteria for state health department personnel to use when reporting notifiable diseases to CDC.	Laboratory	4 of 7	2 of 7	1 of 7
Federal	Federal grants and cooperative agreements may	Epidemiology	1 of 7	3 of 7	3 of 7
guidance on how to execute projects that use federal funding	contain guidance that outlines specifically how certain funds should be used. For example, funding for specific surveillance efforts may contain sampling protocols or reporting requirements that states are expected to follow.	Laboratory	4 of 7	3 of 7	0 of 7
Federal	Federal agencies may provide guidance regarding	Epidemiology	2 of 7	1 of 7	4 of 7
guidance regarding methods and mechanisms for enhancing timely detection and situational awareness	methods and mechanisms for enhancing timely detection and situational awareness, for example, designing electronic reporting or syndromic surveillance systems.	Laboratory	1 of 7	3 of 7	3 of 7
Federal	Federal agencies provide states and localities with	Epidemiology	5 of 7	0 of 7	2 of 7
guidance regarding safety and security measures for specimen handling	guidance concerning the appropriate methods for handling, storing, and shipping specimens.	Laboratory	5 of 7	2 of 7	0 of 7
Federal	Federal grant and cooperative agreement	Epidemiology	2 of 7	4 of 7	1 of 7
priorities, goals, and objectives communicated through grant and cooperative agreement guidance	guidance generally provides instructions to state agencies about applying for and executing federal projects with funding, including federal priorities, goals, and objectives for the use of the funding.	Laboratory	4 of 7	3 of 7	0 of 7

Source: GAO.

Table 15 shows responses from the Agriculture and Wildlife groups to the following question concerning Guidance: How useful, if at all, has each of the following items been in supporting biosurveillance capabilities in your

area of responsibility over the last 2 years? (Note: This category—Guidance—refers to federal guidance that helps with the design of biosurveillance programs or with the implementation of activities that support biosurveillance capabilities.)

			Number of respondents who selected each of the following options:			
Type of guidance	Description	Group	Very useful	Moderately useful	Somewhat useful/ Not useful	
Federal guidance	Federal agencies provide guidance to help states	Agriculture	0 of 6	3 of 6	3 of 6	
concerning industry information and privacy protection	ensure the security and privacy of industry information and individuals' health information—such as the Health Insurance Portability and Accountability Act (HIPAA)—during disease investigations.	Wildlife	1 of 7	2 of 7	4 of 7	
Federal guidance	concerning concerning the protection and security of their information-systems information infrastructures. security	Agriculture	0 of 6	4 of 6	2 of 6	
concerning information-systems security		Wildlife	1 of 7	1 of 7	5 of 7	
	ssessing and localities for assessing capabilities. For	Agriculture	0 of 6	2 of 6	4 of 6	
assessing capabilities		Wildlife	1 of 7	2 of 7	4 of 7	
Federal guidance for	Federal agencies provide states and localities with	Agriculture	2 of 6	2 of 6	2 of 6	
best practices for laboratory testing protocols	guides outlining the best practices for laboratory testing protocols.	Wildlife	2 of 7	3 of 7	2 of 7	
Federal guidance for	Federal agencies develop disease reporting	Agriculture	2 of 6	4 of 6	0 of 6	
disease-reporting requirements for state and local jurisdictions for those diseases posing a serious public-health, animal-health, or economic risk for which case reports would help inform prevention and control efforts.	those diseases posing a serious public-health, animal-health, or economic risk for which case reports would help inform prevention and control	Wildlife	1 of 7	5 of 7	1 of 7	
Federal guidance for	Federal agencies provide states with guidance on	Agriculture	3 of 6	2 of 6	1 of 6	
sampling procedures for unusual or emerging disease agents	the appropriate methods for collecting and shipping samples for unusual or emerging diseases.	Wildlife	2 of 7	4 of 7	1 of 7	

			Number of each o		
Type of guidance	Description	Group	Very useful	Moderately useful	Somewhat useful/ Not useful
Federal guidance for	Federal agencies provide guidance for	Agriculture	1 of 6	5 of 6	0 of 6
standardized case definitions	standardizing case definitions to improve disease reporting and information sharing. For example, CDC published the Case Definitions for Infectious Conditions Under Public Health Surveillance, which provides uniform criteria for state health-department personnel to use when reporting notifiable diseases to CDC.	Wildlife	1 of 7	4 of 7	2 of 7
Federal guidance on how to execute projects that use federal funding funding for specific surveillance efforts may contain guidance that outlines specifically how certain funds should be used. For example, funding for specific surveillance efforts may contain sampling protocols or reporting requirements that states are expected to follow.		Agriculture	3 of 6	2 of 6	1 of 6
	Wildlife	2 of 7	2 of 7	3 of 7	
Federal guidance	Federal agencies may provide guidance regarding	Agriculture	1 of 6	3 of 6	2 of 6
regarding methods and mechanisms for enhancing timely detection and situational awareness	methods and mechanisms for enhancing timely detection and situational awareness, for example, designing electronic reporting or syndromic-surveillance systems.	Wildlife	1 of 7	3 of 7	3 of 7
Federal guidance	Federal agencies provide states and localities with	Agriculture	1 of 6	2 of 6	3 of 6
regarding safety and security measures for specimen handling	security measures — nandling, storing, and snipping specimens. for specimen	Wildlife	2 of 7	4 of 7	1 of 7
Federal priorities,	Federal grant and cooperative agreement	Agriculture	4 of 6	1 of 6	1 of 6
goals, and objectives communicated through grant and cooperative agreement guidance	guidance generally provides instructions to state agencies about applying for and executing federal projects with funding, including federal priorities, goals, and objectives for the use of the funding.	Wildlife	3 of 7	2 of 7	2 of 7

Source: GAO.

## Appendix IV: Responses to Follow-Up Questionnaire Concerning Challenges State and Local Officials May Face in Building and Maintaining Biosurveillance Capabilities

### Response options on follow-up questionnaire for challenges

Challenge that is not being adequately addressed: This is a current challenge, and the combination of resources, leadership, and organization is not currently adequate to address the challenge.

Challenge that is being adequately addressed: This is an ongoing challenge, but the current combination of resources, leadership, and organization is currently adequate to address the challenge.

Not a challenge: This is not a challenge.

**Do Not Know/No response:** Either you do not know if this item is a challenge in your area of responsibility or you decline to respond.

Source: GAO.

Table 16 shows the results of our follow-up questionnaire for the question concerning challenges that state and local officials may face in building and maintaining biosurveillance capabilities. Presented below are the question and response totals to the follow-up questionnaires we sent to (1) state and city public-health epidemiology officials, (2) state and city public-health laboratory officials, (3) state agriculture officials, and (4) state wildlife officials by group, and descriptions for the challenges identified.

Question: How do you classify the following challenges as they currently pertain to your area of responsibility?

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Table 16: Results of Responses to Questions Concerning Challenges
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Description	Group	Challenge that is not being adequately addressed	Challenge that is being adequately addressed	Not a challenge	Do not know/ No Response	
Working with multiple different federal	Epidemiology	5 of 7	0 of 7	1 of 7	1 of 7	
agencies may be a challenge, because they do not always have the same priorities, and conflict manifests in federal guidance, funding, or technical assistance.	Public Health Laboratory	2 of 7	2 of 7	2 of 7	1 of 7	
	Agriculture	4 of 6	2 of 6	0 of 6	0 of 6	
	Wildlife	3 of 7	3 of 7	1 of 7	0 of 7	
The division of roles and responsibilities across federal, state, and local jurisdictions may be a challenge, because federal, state, and local departments do not always share	Epidemiology	3 of 7	3 of 7	1 of 7	0 of 7	
	Public Health Laboratory	2 of 7	1 of 7	3 of 7	1 of 7	
	Agriculture	5 of 6	1 of 6	0 of 6	0 of 6	
priorities, philosophies, or approaches to conducting biosurveillance.	Wildlife	2 of 7	1 of 7	3 of 7	1 of 7	
The stability of funding may be a	Epidemiology	6 of 7	1 of 7	0 of 7	0 of 7	
uncertain whether, for what purpose,	Public Health Laboratory	7 of 7	0 of 7	0 of 7	0 of 7	
to build and maintain capabilities from	Agriculture	6 of 6	0 of 6	0 of 6	0 of 6	
year to year.	Wildlife	6 of 7	1 of 7	0 of 7	0 of 7	
	Working with multiple different federal agencies may be a challenge, because they do not always have the same priorities, and conflict manifests in federal guidance, funding, or technical assistance.  The division of roles and responsibilities across federal, state, and local jurisdictions may be a challenge, because federal, state, and local departments do not always share priorities, philosophies, or approaches to conducting biosurveillance.  The stability of funding may be a challenge, because state officials are uncertain whether, for what purpose, and how much funding will be available to build and maintain capabilities from	Working with multiple different federal agencies may be a challenge, because they do not always have the same priorities, and conflict manifests in federal guidance, funding, or technical assistance.  The division of roles and responsibilities across federal, state, and local jurisdictions may be a challenge, because federal, state, and local departments do not always share priorities, philosophies, or approaches to conducting biosurveillance.  The stability of funding may be a challenge, because state officials are uncertain whether, for what purpose, and how much funding will be available to build and maintain capabilities from  Epidemiology  Public Health Laboratory  Agriculture  Wildlife  Epidemiology  Public Health Laboratory  Agriculture  Wildlife	Description  Group  Group  Bepidemiology  5 of 7  Public Health Laboratory  The division of roles and responsibilities across federal, state, and local jurisdictions may be a challenge, because federal, state, and local departments do not always share priorities, philosophies, or approaches to conducting biosurveillance.  The stability of funding may be a challenge, because state officials are uncertain whether, for what purpose, and how much funding will be available to build and maintain capabilities from  Group  Epidemiology  5 of 7  Public Health Laboratory  Agriculture  4 of 6  Wildlife  3 of 7  Public Health Laboratory  Agriculture  5 of 6  Wildlife  2 of 7  Epidemiology  3 of 7  Public Health Laboratory  Agriculture  5 of 6  Wildlife  2 of 7  Agriculture  5 of 6  Agriculture  5 of 6  Agriculture  6 of 6	DescriptionGroupEpidemiology addressed5 of 7 of 7 of 7 of 7Working with multiple different federal agencies may be a challenge, because they do not always have the same priorities, and conflict manifests in federal guidance, funding, or technical assistance.Epidemiology of 5 of 7	DescriptionGroupthat is not being adequately addressedChallenge that is being adequately addressedNot a challenge because that is being adequately addressedWorking with multiple different federal agencies may be a challenge, because they do not always have the same priorities, and conflict manifests in federal guidance, funding, or technical assistance.Epidemiology5 of 70 of 71 of 7Public Health Laboratory2 of 72 of 60 of 6Wildlife3 of 73 of 71 of 7The division of roles and responsibilities across federal, state, and local jurisdictions may be a challenge, because federal, state, and local departments do not always share priorities, philosophies, or approaches to conducting biosurveillance.Epidemiology3 of 73 of 71 of 7The stability of funding may be a challenge, because state officials are uncertain whether, for what purpose, and how much funding will be available to build and maintain capabilities fromEpidemiology6 of 71 of 70 of 7Agriculture7 of 70 of 70 of 7	

Appendix IV: Responses to Follow-Up Questionnaire Concerning Challenges State and Local Officials May Face in Building and Maintaining Biosurveillance Capabilities

Challenge	Description	Group	Number of Respondents Who Selected Each of the Following Options:			
			Challenge that is not being adequately addressed	Challenge that is being adequately addressed	Not a challenge	Do not know/ No Response
Funding structure/ stovepiping	The structure of available funding may be a challenge because it tends to target specific diseases and does not allow for building and maintaining core capabilities for emerging disease threats.	Epidemiology	4 of 7	2 of 7	1 of 7	0 of 7
		Public Health Laboratory	6 of 7	1 of 7	0 of 7	0 of 7
		Agriculture	5 of 6	1 of 6	0 of 6	0 of 6
		Wildlife	6 of 7	1 of 7	0 of 7	0 of 7
Guidance for planning and developing biosurveillance capabilities	Assimilating existing knowledge to help plan and develop capabilities may be a challenge because guidance lacks specificity or there is no place to find best practices.	Epidemiology	4 of 7	2 of 7	1 of 7	0 of 7
		Public Health Laboratory	3 of 7	0 of 7	1 of 7	3 of 7
		Agriculture	3 of 6	1 of 6	1 of 6	1 of 6
		Wildlife	2 of 7	2 of 7	1 of 7	2 of 7
Laboratory capacity	Maintaining adequate laboratory capacity for biosurveillance purposes may be a challenge because it is difficult to maintain certifications or sufficient resources.	Epidemiology	4 of 7	1 of 7	0 of 7	2 of 7
		Public Health Laboratory	5 of 7	2 of 7	0 of 7	0 of 7
		Agriculture	4 of 6	2 of 6	0 of 6	0 of 6
		Wildlife	0 of 7	1 of 7	4 of 7	2 of 7
State policies	Using federal resources to build biosurveillance capabilities may be a challenge because state policies, rules or regulations create barriers for hiring personnel, attending national conferences and trainings, and/or participating in online training and discussions.	Epidemiology	2 of 7	4 of 7	1 of 7	0 of 7
		Public Health Laboratory	6 of 7	0 of 7	1 of 7	0 of 7
		Agriculture	5 of 6	1 of 6	0 of 6	0 of 6
		Wildlife	7 of 7	0 of 7	0 of 7	0 of 7
Support for integrating human and animal surveillance information	Integrating information across disease domains may be a challenge because of a lack of leadership and mechanisms to facilitate information sharing and data integration among public health, agriculture, and wildlife infectious disease control functions.	Epidemiology	3 of 7	3 of 7	0 of 7	1 of 7
		Public Health Laboratory	4 of 7	0 of 7	2 of 7	1 of 7
		Agriculture	5 of 6	1 of 6	0 of 6	0 of 6
		Wildlife	5 of 7	2 of 7	0 of 7	0 of 7
Support for regional approaches to surveillance	Sharing information and resources across state or other jurisdictional boundaries may be a challenge because leadership and mechanisms to facilitate regional approaches are inadequate.	Epidemiology	5 of 7	2 of 7	0 of 7	0 of 7
		Public Health Laboratory	4 of 7	1 of 7	1 of 7	1 of 7
		Agriculture	3 of 6	3 of 6	0 of 6	0 of 6
		Wildlife	4 of 7	2 of 7	1 of 7	0 of 7
Systems maintenance or enhancement	Maintaining or enhancing systems to support biosurveillance may be a challenge because of the fast rate of	Epidemiology	5 of 7	2 of 7	0 of 7	0 of 7
		Public Health Laboratory	4 of 7	3 of 7	0 of 7	0 of 7

Appendix IV: Responses to Follow-Up Questionnaire Concerning Challenges State and Local Officials May Face in Building and Maintaining Biosurveillance Capabilities

Challenge	Description change and ongoing upkeep associated with information technology.	Group	Number of Respondents Who Selected Each of the Following Options:			
			Challenge that is not being adequately addressed	that is being adequately	Not a	
		Agriculture	5 of 6	1 of 6	0 of 6	0 of 6
		Wildlife	1 of 7	2 of 7	1 of 7	3 of 7
Training availability	Ensuring adequate ongoing training and education for staff with biosurveillance responsibilities may be a challenge because training opportunities are limited.	Epidemiology	4 of 7	2 of 7	0 of 7	1 of 7
		Public Health Laboratory	3 of 7	2 of 7	2 of 7	0 of 7
		Agriculture	3 of 6	2 of 6	1 of 6	0 of 6
		Wildlife	6 of 7	1 of 7	0 of 7	0 of 7
Workforce competency	Maintaining the workforce may be a challenge, because staff lacks sufficient training and education.	Epidemiology	3 of 7	3 of 7	1 of 7	0 of 7
		Public Health Laboratory	4 of 7	2 of 7	1 of 7	0 of 7
		Agriculture	2 of 6	4 of 6	0 of 6	0 of 6
		Wildlife	5 of 7	0 of 7	2 of 7	0 of 7
Workforce sufficiency	Maintaining the workforce may be a challenge, because skilled professionals—i.e., epidemiologists, informaticians, statisticians, laboratory staff, animal health staff, or animal disease specialists - are not available in sufficient numbers.	Epidemiology	5 of 7	1 of 7	1 of 7	0 of 7
		Public Health Laboratory	6 of 7	1 of 7	0 of 7	0 of 7
		Agriculture	3 of 6	3 of 6	0 of 6	0 of 6
		Wildlife	5 of 7	0 of 7	2 of 7	0 of 7

Source: GAO.

# Appendix V: Comments from the Department of Homeland Security

U.S. Department of Homeland Security Washington, DC 20528



October 19, 2011

William O. Jenkins, Jr.
Director, Homeland Security and Justice
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Draft Report GAO-12-55, "BIOSURVEILLANCE: Nonfederal Capabilities Should be Considered in Creating a National Biosurveillance Strategy"

Dear Mr. Jenkins:

Thank you for the opportunity to review and comment on this draft report. The U.S. Department of Homeland Security (DHS) appreciates the U.S. Government Accountability Office's work in planning and conducting its review and issuing of this report.

Within DHS, the National Biosurveillance Integration Center's primary mission includes enhancing the capability of the Federal Government to:

- rapidly identify, characterize, localize, and track a biological event of national concern by integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems (both national and international); and
- disseminate alerts and other information to Member Agencies and, in coordination
  with Member Agencies, to agencies of state, local, and tribal governments, as
  appropriate, to enhance the ability of such agencies to respond to a biological
  event of national concern.

To effectively support this mission area, DHS is working in coordination with the National Security Staff's efforts to finalize the National Biosurveillance Strategy through its participation on the sub-Interagency Policy Committee on Biosurveillance. DHS understands the importance and supports the inclusion of nonfederal biosurveillance in the National Biosurveillance Strategy currently being developed.

Again, thank you for the opportunity to review and comment on this draft report. We note the report does not contain any recommendations for DHS. Technical comments were submitted under separate cover. We look forward to working with you on future homeland security issues.

Sincerely,

Jim H. Crumpacker

Director

Departmental GAO-OIG Liaison Office

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# Appendix VI: GAO Contact and Staff Acknowledgments

#### **GAO Contact**

William O. Jenkins, Jr., (202) 512-8777 or jenkinswo@gao.gov

#### Staff Acknowledgments

In addition to the contact named above, Edward George, Assistant Director; Amanda Jones Bartine; Michelle Cooper; Kathryn Godfrey; Susanna Kuebler; and Heather Romani made significant contributions to the work. Tina Cheng assisted with graphic design. Amanda Miller and Russ Burnett assisted with design, methodology, and analysis. Stuart Kaufman assisted with design and administration of the follow-up questionnaire. Tracey King provided legal support. Linda Miller provided communications expertise.

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