

Report to Congressional Requesters

September 2015

BIOSURVEILLANCE

Challenges and Options for the National Biosurveillance Integration Center

Highlights of GAO-15-793, a report to congressional requesters

Why GAO Did This Study

A biological event, such as a naturally occurring pandemic or a terrorist attack with a weapon of mass destruction, could have catastrophic consequences for the nation. This potential threat underscores the importance of a national biosurveillance capabilitythat is, the ability to detect biological events of national significance to provide early warning and information to guide public health and emergency response. The 9/11 Commission Act of 2007 addresses this capability, in part, by creating NBIC within the Department of Homeland Security (DHS); it was tasked with integrating information from human health, animal, plant, food, and environmental monitoring systems across the federal government, to improve the likelihood of identifying a biological event at an earlier stage. In recent years, NBIC's budget has ranged from \$10 million to \$13 million annually.

GAO was asked to evaluate NBIC. This report discusses the (1) extent to which NBIC is implementing its roles as a biosurveillance integrator, and (2) options for improving such integration. To conduct this work, GAO reviewed NBIC products and activities; conducted interviews and surveyed 19 federal partners, 11 of which have key roles in biosurveillance; interviewed NBIC officials; and analyzed the 9/11 Commission Act, NBIC Strategic Plan, and National Strategy for Biosurveillance.

What GAO Recommends

GAO is not making recommendations. GAO provided this draft to DHS and its federal partners who provided technical comments which were incorporated, as applicable.

View GAO-15-793. For more information, contact Chris Currie at (404) 679-1875 or curriec@gao.gov.

September 2015

BIOSURVEILLANCE

Challenges and Options for the National Biosurveillance Integration Center

What GAO Found

The National Biosurveillance Integration Center (NBIC) has activities that support its integration mission, but faces challenges that limit its ability to enhance the national biosurveillance capability. In the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) and *NBIC Strategic Plan*, GAO identified three roles that NBIC must fulfill to meet its biosurveillance integration mission. The following describes actions and challenges in each role:

- Analyzer: NBIC is to use technology and subject matter expertise, including using analytical tools, to meaningfully connect disparate datasets and information for earlier warning and better situational awareness of biological events. GAO found that NBIC produces reports on biological events using open-source data, but faces challenges obtaining data and creating meaningful new information. For example, most of the federal partners with key roles in biosurveillance (8 of 11) stated that NBIC's products help their agencies identify biological events to little or no extent, generally because they already obtain such information directly from other federal partners more quickly. In addition, data that could help to identify and characterize a biological event may not exist or are not in a usable form. Further, few federal partners (5 of 19) reported that they share the data they do have with NBIC, citing legal and regulatory restrictions, among other reasons..
- Coordinator: NBIC is to bring together partners across the federal biosurveillance community to enhance understanding of biological events. NBIC has developed procedures and activities to coordinate with partners, such as daily and biweekly calls, but faces challenges related to the limited partner participation in the center's activities, lack of partner personnel detailed to NBIC, and competing structures for convening federal partners. For example, although NBIC would like to obtain liaisons from each of its federal partners, only 3 of 19 partners provided NBIC with dedicated liaisons.
- Innovator: NBIC is to facilitate the development of new tools to address gaps in biosurveillance integration. GAO found that NBIC has efforts underway to develop some tools, such as pilot projects examining the use of social media data to identify health trends, but faces challenges prioritizing developmental efforts. For example, partners noted limitations in NBIC's ability to address gaps, like limited resources and the difficulty in prioritizing the center's innovation efforts because its partners have diverse needs.

GAO identified various options that could address these challenges, ranging from strengthening the center's ability to implement its current roles to repealing NBIC's statute. GAO also identified potential benefits and limitations with each option. For example, one option would be to provide NBIC with additional authorities to obtain data to better develop meaningful information; however this may also require additional investments. Another option is to not pursue national biosurveillance integration through NBIC and to consider designating one of the other federal partners with key roles in biosurveillance as the federal integrator. The options identified are not exhaustive, and some could be implemented together or in part. GAO did not evaluate the financial implications of each option, but acknowledges some options may require additional investment or shifting of resources or priorities to result in significant long lasting change.

United States Government Accountability Office

Contents

Letter		1
	Background NBIC Has Activities That Support Integration, but Faces	6
	Challenges That Limit Its Ability to Enhance the National Biosurveillance Capability There Are a Range of Options for Addressing Biosurveillance Integration Challenges, and Each Has Associated Benefits and	15
	Limitations Agency Comments	36 44
Appendix I	Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners	47
Appendix II	Biosurveillance Agencies' Sources for Information that Enhances Situational Awareness of Biological Events	56
Appendix III	Comments from the Department of Homeland Security	60
Appendix IV	GAO Contacts and Staff Acknowledgments	62
Tables		
	Table 1: Elements of Situational Awareness in the Biosurveillance Context Table 2: Examples of the National Biosurveillance Integration	7
	Centers' (NBIC) Responsibilities from the 9/11 Commission Act of 2007 Organized by Biosurveillance Integrators Roles Identified by GAO	9
	Table 3: Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners	48
Figures		
	Figure 1: Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners	14

Figure 2: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Enhances	
Their Perception of Biological Events	17
Figure 3: Sources for Information That Enhances Situational	
Awareness within the National Biosurveillance Integration	
System	19
Figure 4: National Biosurveillance Integration System (NBIS)	
Partner Views on the Extent to Which the National	
Biosurveillance Integration Center (NBIC) Enhances	
Their Comprehension of Biological Events	21
Figure 5: National Biosurveillance Integration System (NBIS)	
Partner Views on the Extent to Which the National	
Biosurveillance Integration Center (NBIC) Enhances	
Their Agency's Ability to Carry Out Its Biosurveillance	
Roles	22
Figure 6: National Biosurveillance Integration System (NBIS)	
Partner Views on the Extent to Which the National	
Biosurveillance Integration Center (NBIC) Enhances	
Their Understanding of How Biological Events Are Likely	
to Progress (i.e., Projection)	22
Figure 7: National Biosurveillance Integration System (NBIS)	
Partners That Reported Participating in the National	
Biosurveillance Integration Center's (NBIC) Daily and	-00
Weekly Calls	29
Figure 8: National Biosurveillance Integration System (NBIS)	
Partner Views on the Extent to Which the National	
Biosurveillance Integration Center (NBIC) Is Achieving Its	40
Biosurveillance Integration Mission	43
Figure 9: Primary and Support Biosurveillance Agencies' Sources	EO
for Information that Enhances Situational Awareness	58

Abbreviations:

9/11

Commission Act Implementing Recommendations of the

9/11 Commission Act of 2007

AFHSC Armed Forces Health Surveillance Center
APHIS Animal and Plant Health Inspection Service
ASPR Assistant Secretary for Preparedness and

Response

BATR Biological Assessment and Threat Response

CBP Customs and Border Protection

CDC Centers for Disease Control and Prevention

DHS Department of Homeland Security

DOD Department of Defense
DOE Department of Energy
DOI Department of the Interior
DOS Department of State

DOT Department of Transportation EPA Environmental Protection Agency

EVD Ebola virus disease

FDA Food and Drug Administration
FSIS Food Safety Inspection Service
HHS Health and Human Services
HPAI highly pathogenic avian influenza
I&A Office of Intelligence and Analysis

IT information technology

NBIC National Biosurveillance Integration Center
NBIS National Biosurveillance Integration System
NCMI National Center for Medical Intelligence

NOAA National Oceanic and Atmospheric Administration
ODNI Office of the Director of National Intelligence

PEDv porcine epidemic diarrhea virus

S&T Roadmap National Biosurveillance Science and

Technology Roadmap

USDA Department of Agriculture
USGS U.S. Geological Survey
USPS U.S. Postal Service

VA Department of Veterans Affairs WHO World Health Organization

	This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.
·	

September 24, 2015

Congressional Requesters:

A biological event, such as a naturally occurring pandemic or a terrorist attack with a weapon of mass destruction, could have catastrophic consequences for the nation. Although Ebola did not cause many U.S. casualties, the outbreak in West Africa from 2013 through 2015 underscored the importance of developing and maintaining a national biosurveillance capability—that is, the ability to detect biological events of national significance with the aim of providing early warning and better information to guide public health and other types of emergency response. Further, because the data needed to detect an emerging infectious disease or bioterrorism threat may come from a variety of sources, the ability to share and analyze data from multiple sources may help officials better collaborate to analyze data and quickly recognize the nature of a disease event and its scope.

The Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) established the National Biosurveillance Integration Center (NBIC) within the Department of Homeland Security (DHS); it was specifically tasked with integrating and analyzing information from human health, animal, plant, food, and environmental monitoring systems across the federal government and supporting the interagency biosurveillance community. In analyzing this act, as well as the August 2012 *NBIC Strategic Plan*, we identified three general roles that NBIC, as a federal-level biosurveillance integrator, must carry out to achieve the duties and outcomes described by NBIC's authorizing legislation: (1) Analyzer, (2) Coordinator, and (3) Innovator.

 As an Analyzer, NBIC is to use technological tools and subject matter expertise to develop shared situational awareness by creating

¹6 U.S.C. § 195b.

²Senior NBIC officials agreed that these three roles are consistent with the center's responsibilities.

meaningful new insights from disparate datasets and information that could not be gleaned in isolation.³

- As a Coordinator, NBIC is to bring together multi-disciplinary partners
 across interagency organizations to enhance understanding of new or
 potential biological events, such as through the collaborative
 development of products and services.
- As an Innovator, NBIC is to facilitate the development of new tools, technology, and approaches to address gaps in biosurveillance integration.

In December 2009, we reported that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel from its partner agencies, which may have been at least partially the result of collaboration challenges it faced.⁴ For example, some partners reported that they did not trust NBIC to use their information and resources appropriately, while others were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated. In order to help NBIC enhance and sustain collaboration, including the provision of data, personnel, and other resources, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. As previously noted, in August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, articulate the value that NBIC seeks to provide to its partners, and lay the groundwork for setting interagency roles, responsibilities, and procedures. Further, in November 2014, NBIC completed its first biannual NBIC Federal Stakeholder Survey, which NBIC uses to assess the usefulness of its products and activities and to

³For the purposes of this report, we use the definition of situational awareness that the *NBIC Strategic Plan* uses in the articulation of its mission. According to the plan, the definition has its basis in the work of Mica Endsley, a former Chief Scientist of the U.S. Air Force who has written extensively on situational awareness. Endsley described situational awareness as having three elements: (1) perception that a situation has occurred, (2) comprehension of the situation's meaning, and (3) projection of the event's likely course in the near future. Further, the strategic plan notes that shared situational awareness is a common picture or understanding achieved cooperatively by entities that integrate mission essential, overlapping portions of their individual situational awareness for a unified purpose.

⁴GAO, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

determine what improvements should be made on the basis of those results. We believe these actions addressed the recommendations in our prior report.

You expressed interest in determining what progress NBIC has made in contributing to the national biosurveillance capability. This report's objectives are:

- 1. To what extent is NBIC implementing its roles as a biosurveillance integrator?
- 2. What are options for improving federal biosurveillance integration, and what are their benefits and limitations?

To determine the extent to which NBIC is implementing its role as a biosurveillance integrator, we conducted structured interviews with 19 federal departments and their component agencies across 13 of the 14 departments and agencies that compose the National Biosurveillance Integration System (NBIS)—the federal partners that NBIC is responsible for coordinating because they have missions and resources that can contribute to earlier detection and shared situational awareness for biological events of national significance. Although NBIC has interaction with other stakeholders, we selected these 19 federal agencies based on their biosurveillance roles and responsibilities and because they were federal departments or components within federal departments that have signed the NBIC Advisory Board charter—signifying their participation in the NBIS.5 Prior to conducting our structured interviews, we provided a list of these agencies to NBIC and senior NBIC officials agreed that the agencies we identified represented the partners with which the center had the most interaction and collaboration. 6 We discussed with these NBIS partners the extent to which NBIC has enhanced the national biosurveillance capability by carrying out its national integrator roles and

⁵We identify these agencies and describe their biosurveillance responsibilities later in this report, as well as in Appendix I.

⁶Our list initially included 25 agencies, but we later removed 6 of these agencies because we learned that the agency had relatively little direct interaction with NBIC, among other reasons. For example, we initially identified DOI's Fish and Wildlife Service and National Park Service as potential NBIS partners. However, according to DOI officials, these agencies have relatively little direct interaction with NBIC because DOI's Office of Emergency Management, which we did interview, collects information from both agencies and filters it to NBIC.

any challenges the center has faced in doing so, including the extent to which NBIC's products and activities enhance the agency's situational awareness of biological events. Within these agencies, we interviewed officials who serve on NBIC's Advisory Board or its Interagency Working Group, as well as other relevant officials that regularly interact with NBIC, review the center's products, or participate in the center's activities. As part of this review, we did not interview or survey NBIC's nonfederal stakeholders, such as state, local, tribal, or territorial agencies.

We also conducted a Web-based survey of the 19 agencies to identify the federal agencies from which they obtain information that contributes to their agency's situational awareness of biological events, the methods through which they share information from NBIC, and the extent to which they participate in NBIC activities. We obtained a 100 percent response rate on this survey. In the survey, we asked each agency whether it obtains information from each of the other agencies in our population, as well as which types of information it obtains from them (perception-, comprehension-, or projection-related information). We performed a network analysis of these survey data, which is a quantitative and graphical technique for identifying the underlying patterns in a complex system of relationships among entities of interest.⁸ Additional information on our survey methodology can be found in Appendix II.

Further, we reviewed NBIC products, such as its daily Monitoring List e-mail and Biosurveillance Event Reports, and observed some NBIC activities, such as its daily and bi-weekly calls. We reviewed key documents that guide NBIC's activities and products, such as the August 2012 NBIC Strategic Plan, the July 2012 National Strategy for Biosurveillance, and the White House's Office of Science and Technology Policy's June 2013 National Biosurveillance Science and Technology

⁷The Advisory Board serves as the assistant secretary–level body for coordination and communication regarding integrated biosurveillance among NBIC's federal partners. The NBIC Interagency Working Group is to provide support and respond to taskings from the Advisory Board to assist in addressing NBIC operational, programmatic, and scientific issues.

⁸Our survey data were processed into a matrix form readable in the UCINet network analysis package and transformed into a prototype graphic using a set of automated and manual techniques. This prototype was then refined using graphical software such as Adobe Illustrator.

Roadmap (S&T Roadmap). We also reviewed other relevant documents, such as NBIC's Advisory Board's charter, standard operating procedures for the center's activities and protocols, memorandums of understanding and interagency agreements between NBIC and its federal partners, the results of NBIC's Federal Stakeholder Survey, and evaluations of NBIC's pilot projects. We also interviewed NBIC officials to obtain their opinions on the extent to which NBIC is implementing its roles as a biosurveillance integrator and enhancing the national biosurveillance capability.

To identify options for improving federal biosurveillance integration, as well as their benefits and limitations, we examined the 9/11 Commission Act to identify tasks and responsibilities that NBIC, as a federal-level biosurveillance integrator, is to carry out. We analyzed documents that identify potential gaps and needs in biosurveillance integration, including the *National Strategy for Biosurveillance* and the *S&T Roadmap*. We also obtained information from our structured interviews with NBIC's federal partners on their views about what else, if anything, the center could be doing to better enhance the national biosurveillance capability. Given the challenges described by NBIC's federal partners, we identified options for policy or structural changes. Although these options are not exhaustive, they represent a range of potential actions that could be taken to better fulfill the biosurveillance integration mission described in the 9/11 Commission Act.

We conducted this performance audit from July 2014 to September 2015 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.

⁹See U.S. Department of Homeland Security, *National Biosurveillance Integration Center Strategic Plan*, Washington, D.C.: Aug. 2012; White House, *National Strategy on Biosurveillance*, Washington, D.C.: July 31, 2012; and Executive Office of the President, National Science and Technology Council, *National Biosurveillance Science and Technology Roadmap*, Washington, D.C.: June 14, 2013.

Background

Biosurveillance Integration

According to the July 2012 *National Strategy for Biosurveillance*, biosurveillance is the ongoing process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health, for the purpose of (1) achieving early detection and warning, (2) contributing to overall situational awareness of the health aspects of the incident, and (3) enabling better decision making at all levels. As defined in the *NBIC Strategic Plan*, biosurveillance integration is combining biosurveillance information from different sources and domains (e.g., human, animal, and plant health; food and environmental safety and security; and homeland security) to provide partners and stakeholders with a synthesized view of the information, and what it could mean. The goal is to create new meaning—that is, to provide insights that cannot be gleaned in isolation, leading to earlier warning of emerging events and shared situational awareness.

According to the *NBIC Strategic Plan*, biosurveillance, at a national level, is an important part of the process for achieving shared situational awareness of a biological event of national concern. Situational awareness, which is composed of three related elements that are described in table 1, plays a critical role in enhancing common understanding and decision making. Emerging biological events often require that decisions be made based upon preliminary, incomplete, and often inconclusive information across multiple domains. Each department and agency in the biosurveillance community has a primary mission that is often focused on a single domain, yet decisions and actions must be

¹⁰The *NBIC Strategic Plan* specifically identifies the human, animal, plant, food, and environmental domains. However, because the 9/11 Commission Act states that NBIC is to receive and consider other relevant homeland security information, we also include homeland security as one of the domains. The Homeland Security Act of 2002, defines homeland security information as any information possessed by a federal, state, or local agency that—(a) relates to the threat of terrorist activity; (b) relates to the ability to prevent, interdict, or disrupt terrorist activity; (c) would improve the identification or investigation of a suspected terrorist or terrorist organization; or (d) would improve the response to a terrorist act. 6 U.S.C. §§ 195b(j)(3), 482(f)(1).

¹¹Per the 9/11 Commission Act, the term "biological event of national concern" means an act of terrorism involving a biological agent or toxin, or a naturally occurring outbreak of an infectious disease that may result in a national epidemic.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Since first recognized in September 2012 in Saudi Arabia, MERS-CoV has been detected in nearly 30 countries, including the United States. As of July 2015, there have been more than 1,300 confirmed cases and over 500 deaths, the vast majority of which have been in Saudi Arabia. Two cases have been detected in the United States from patients who had recently travelled to Saudi Arabia.

MERS-CoV is characterized as a potentially severe respiratory illness and symptoms may include fever, cough, shortness of breath, congestion of the nose and throat, and diarrhea. Camels are considered the likely source for human infections. As of June 2015, human-to-human transmission has been limited and the risk of infection to travelers visiting the Arabian Peninsula is considered to be low.



Source: National Biosurveillance Integration Center, Centers for Disease Control and Prevention (photo) | GAO 15-793

made in a shared risk environment that considers all domains. According to the *NBIC Strategic Plan*, shared situational awareness across the biosurveillance community is achieved cooperatively by entities that integrate mission essential, overlapping portions of their individual situational awareness for a unified purpose, leading to a common picture or understanding of potential and ongoing biological events. Further, the plan notes that shared situational awareness of the broader biological domain may provide insights that cannot be gleaned in isolation, and thus enhance the likelihood of identifying an event earlier and with more certainty.

Table 1: Elements of Situational Awareness in the Biosurveillance Context

Element	Definition
Perception	The identification that a situation has occurred, such as the detection of a biological condition that differs from the norm. When such information is shared from one biosurveillance agency to another, it can help identify signals that a biological event with significance for an agency's mission might be occurring.
Comprehension	The understanding of the situation's meaning, such as the characterization of the nature and scope of the biological event. Shared information among biosurveillance agencies could help characterize and contextualize the nature and scope of an emerging biological event, which can help shape appropriate preparedness and response actions.
Projection	The determination of the event's likely course in the near future, such as how its nature and scope will evolve and the decision implications of that evolution. Such shared information among biosurveillance agencies could help understand how emerging and ongoing biological events are likely to progress in the near future, which can help subsequent decisions as to appropriate courses of action.

Source: GAO analysis of the Endsley Model of Situational Awareness and the NBIC Strategic Plan | GAO-15-793

Note: For the purposes of this report, we use the definition of situational awareness that the *NBIC Strategic Plan* uses in the articulation of its mission. The definition has its basis in the work of Mica Endsley, a former Chief Scientist of the U.S. Air Force who has written extensively on situational awareness. For example, see Mica Endsley, "Toward a Theory of Situation Awareness in Dynamic Systems," Human Factors, vol. 37, no. 1 (1995), and Mica Endsley and Debra G. Jones, Designing for Situation Awareness: An Approach to User-Centered Design. 2nd ed., (Boca Raton, FL) CRC Press, 2011.

Highly pathogenic avian influenza (HPAI)

Since December 2014, the U.S. Department of Agriculture has confirmed 223 detections of HPAI in backyard and commercial poultry in 15 states. Over 48 million birds have been affected in the United States as of July 2015, making it the largest outbreak in the country's history. The export market for poultry products contributes billions of dollars to the U.S. economy annually. Import restrictions against U.S. poultry and poultry products by 52 countries and the European Union have resulted in decreases in some exports and local economic impacts, such as increases in egg prices and limited-scale layoffs.

HPAI is an infectious viral disease of wild birds and domestic poultry (e.g., chickens, turkeys, ducks, geese). Signs in birds include coughing, decreased egg production, and sudden death. Although some sub-types of HPAI can be transmitted to humans, no human infections in the United States have been recognized in association with the recent outbreak.



Source: National Biosurveillance Integration Center, U.S. Department of Agriculture (photo) | GAO 15-793

The importance of biosurveillance integration has also been described by key national planning documents. In July 2012, the White House issued the National Strategy for Biosurveillance, which describes the U.S. government's approach to strengthening biosurveillance. Although the strategy does not specifically identify roles for NBIC, it does emphasize the need for integration across disparate information sources, including data derived from intelligence, law enforcement, environmental, plant, animal, and other relevant areas. In June 2013, the White House's Office of Science and Technology Policy issued the S&T Roadmap. Building upon the National Strategy for Biosurveillance, the Roadmap identifies biosurveillance capability needs and key research and development priorities, including those related to integration. For example, the roadmap proposes the development of a national, interagency biosurveillance datasharing framework that integrates data and information from disparate sources, as well as the development of tools that enhance the efficient manipulation of large data sets, including social media.

NBIC's Roles, Responsibilities, and Governance

As shown in table 2, the 9/11 Commission Act outlines certain requirements for NBIC. Drawing upon these requirements as well as the July 2012 *NBIC Strategic Plan*, we identified three main roles that NBIC, as a federal-level biosurveillance integrator, must carry out to achieve the duties and outcomes described by NBIC's authorizing legislation. Senior NBIC officials agreed that these three roles are consistent with the center's responsibilities. These roles are not mutually exclusive and can reinforce one other. For example, NBIC's efforts as an Innovator might result in the in the development of data that could enhance its role as an Analyzer by providing the center with another dataset to review.

Ebola virus disease (EVD)

Since late 2013, the World Health Organization (WHO) has reported a cumulative over 27,000 suspected, probable, and confirmed cases of EVD and over 11,000 related deaths as of June 2015. The vast majority of cases have been in West Africa, but there have also been cases in the United States. Eleven cases of EVD have been treated in the U.S., of which 9 recovered and 2 patients died. Of the 11 cases, 9 were presumed to have been contracted in West Africa and 2 were presumed to have been contracted at a Texas hospital by nurses treating an infected patient.

EVD symptoms typically develop 2 to 21 days after exposure to Ebola virus. Symptoms include fever, headache, joint and muscle aches, impaired liver and kidney function, stomach pain, and death. Although the WHO has classified the West African EVD epidemic as a Public Health Emergency of International Concern, the outbreak is considered to be unlikely to significantly affect U.S. public health



Source: National Biosurveillance Integration Center, Centers for Disease Control and Prevention (photo) | GAO 15-793

Table 2: Examples of the National Biosurveillance Integration Centers' (NBIC) Responsibilities from the 9/11 Commission Act of 2007 Organized by Biosurveillance Integrators Roles Identified by GAO

Examples of NBIC responsibilities from the 9/11

awareness or the overall performance of the center

Role **Commission Act** Consolidate data from all relevant surveillance Analyzer: Use technological systems maintained by member agencies across tools and subject matter human, animal, and plant domains expertise to develop shared situational awareness by Use an information technology (IT) system with the creating meaningful new best available statistical and other analytical tools to insights from disparate identify and characterize biological events of national datasets and information concern in as close to real time as practical that could not be gleaned in Receive and consider other relevant homeland isolation security information, as appropriate Oversee the development and operation of the Coordinator: Bring together National Biosurveillance Integration System (NBIS) multi-disciplinary partners across interagency Alert NBIS member agencies as well as public health organizations to enhance agencies of state, local, and tribal governments (in understanding of new or coordination with or through member agencies) of potential biological events, incidents that could develop into a biological event of such as through the national concern collaborative development Provide support for personnel from member agencies of products and services with sufficient expertise to analyze and interpret data Provide the infrastructure for integration, including IT Innovator: Facilitate the development of new tools, technology, and approaches. Seek private sources of surveillance when such to address gaps in sources would enhance coverage of gaps biosurveillance integration Monitor the availability and appropriateness of surveillance systems used by the center and those systems that could enhance biological situational

Source: GAO analysis of the 9/11 Commission Act and the NBIC Strategic Plan | GAO-15-793

NBIC is governed by the NBIC Advisory Board, which serves as the Assistant Secretary–level body for coordination and communication regarding integrated biosurveillance among the interagency biosurveillance community. ¹² According to the board's November 2013 charter, the Advisory Board is to ensure input on and timely resolution of NBIC operational, programmatic, and scientific issues affecting the broader biosurveillance community, and to provide recommendations to

¹²According to the board's charter, the Advisory Board replaced the NBIS Interagency Oversight Council in November 2013 and expanded NBIC's governance to the broader federal biosurveillance community.

Measles in the United States

From December 2014 through February 2015, state and local health departments reported 171 measles cases across 20 states and the District of Columbia. Most of these cases had been associated with an ongoing outbreak associated with Disneyland theme parks in California.

Measles is a highly contagious viral illness that can spread rapidly in communities without proper vaccination. Symptoms include high fever, cough, runny nose, watery eyes, rash, and death. Measles was officially declared eliminated in the U.S. in 2000 and cases in the U.S. have primarily the result of international travel to countries experiencing outbreaks. Outbreaks in the U.S. have persisted mainly due to the increase in unvaccinated people.



Source: National Biosurveillance Integration Center, Centers for Disease Control and Prevention (photo) | GAO 15-793

DHS to assist in achieving NBIC goals. The board is to meet at least twice a year and is to be chaired by DHS's Chief Medical Officer, with a cochair that is to be rotated annually among the federal partners by a majority vote. The NBIC Advisory Board members are to provide formal recommendations to the Advisory Board Chair and Cochair on: (1) identifying, prioritizing, and addressing NBIC and other appropriate operational and programmatic needs; (2) reviewing draft guidance and other supporting documents related to national biosurveillance strategy and policy, as appropriate; and (3) improving communications and collaboration among local, state, tribal, territorial, and federal interagency partners. The NBIC Interagency Working Group is to provide support and respond to taskings from the Advisory Board to assist in addressing NBIC operational, programmatic, and scientific issues. The working group is to consist of senior-level federal officials from NBIS member departments and agencies and the Executive Office of the President who are authorized to make recommendations on behalf of their organizations. Each agency is to have at least one working group member, but can have more based on the relevance to their missions of the topics to be covered by the working group or subworking groups. The working group is to meet as needed, but generally more frequently than the Advisory Board, according to NBIC officials.

Interagency Biosurveillance Community

The NBIS is a consortium of federal partners that was established to rapidly identify and monitor biological events of national concern and to collect; analyze; and share human, animal, plant, food, and environmental biosurveillance information with NBIC. 13 The NBIS community predated the enactment of the 9/11 Commission Act. Beginning in 2004, DHS coordinated the NBIS community and developed an information technology (IT) system to integrate other agencies' biosurveillance information, an effort that was moved among several DHS directorates, including DHS's Science and Technology Directorate. In 2007, DHS created the Office of Health Affairs, headed by the DHS Chief Medical Officer, to lead DHS's biodefense activities and provide timely incidentspecific guidance for the medical consequences of disasters. At that time, DHS placed the responsibility for coordinating the NBIS in the Office of Health Affairs. Shortly after that, the 9/11 Commission Act created NBIC and gave it responsibility for coordinating the NBIS. NBIC has remained in the Office of Health Affairs since that time.

NBIC officials identified 14 federal partners that compose the NBIS. These departments and agencies, which are all signatories to the November 2013 charter of the NBIC Advisory Board, are DHS; the Departments of Agriculture (USDA), Commerce, Defense (DOD), Energy, Health and Human Services (HHS), the Interior (DOI), Justice, State, Transportation (DOT), and Veterans Affairs (VA); the Environmental Protection Agency (EPA); the United States Postal Service; and the Office of the Director of National Intelligence (ODNI). The 9/11

¹³Although not within the scope of this review, the national biosurveillance capability also depends upon participation from state, local, and tribal governments, as few of the resources required to support the capability are wholly owned by the federal government. The responsibility and capacity for collecting most information related to plant, animal and human health, food, and environmental monitoring resides within state, local, and tribal governments, or private sector entities—such as hospitals and other private health care providers. For more information on nonfederal biosurveillance, see GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, GAO-12-55 (Washington, D.C.: Oct. 31, 2011).

Porcine epidemic diarrhea virus (PEDv)
Since Spring 2013, there have been 11,364
confirmed samples of PEDv from 35 states as
of April 2015. As a result, 5 countries and the
European Union issued trade restrictions
against U.S. swine imports, some of which
have since lifted those restrictions. Hog and
pig farming is a multi-billion dollar industry.
However, despite earlier predictions, the
economic decline due to PEDv has not been
as drastic as predicted.

PEDv is a highly infectious virus specific to swine and does not affect humans or other species. Symptoms in pigs include diarrhea, vomiting, and anorexia, and is particularly deadly to young pigs. In June 2014, the U.S. Department of Agriculture issued a Federal Order requiring mandatory reporting of all novel swine enteric coronavirus diseases, including PEDv.



Source: National Biosurveillance Integration Center, U.S. Department of Agriculture (photo) | GAO 15-793

Commission Act outlines a number of responsibilities for member agencies. ¹⁴ For example, the member agencies are to use their best efforts to integrate biosurveillance information into NBIC and connect their biosurveillance data systems to the NBIC data system under mutually agreed protocols. Further, per the act, member agencies are to provide personnel to NBIC under an interagency personnel agreement and consider the qualifications of such personnel necessary to provide human, animal, and environmental data analysis and interpretation support to NBIC.

We surveyed and interviewed officials from 19 federal departments and their component agencies across 13 of the 14 departments and agencies that compose the NBIS.¹⁵ On the basis of their roles and responsibilities related to biosurveillance, we categorized the NBIS partners agencies into three groups:

Primary biosurveillance agencies: Primary biosurveillance agencies have major biosurveillance mission responsibilities that include collecting or analyzing biosurveillance information for the purposes of detecting, monitoring, or responding to biological events. These agencies generate information and develop subject matter expertise in pursuit of their missions that is directly relevant to disease detection and monitoring. In addition, they consume information from multiple sources—including nonfederal sources—to help achieve their missions. Examples of primary biosurveillance agencies include HHS's Centers for Disease Control and Prevention (CDC) and USDA's Animal and Plant Health Inspection Service (APHIS). Eleven of the 19 NBIS partners we interviewed and surveyed are primary biosurveillance agencies.

¹⁴The 9/11 Commission Act does not specify any member agency that must participate in the NBIS, but defines a member agency as any federal department or agency that has entered a memorandum of understanding regarding participation in NBIC. 6 U.S.C. § 195b(j)(4). Seven of the 14 federal partners have or had memorandums of understanding or interagency agreements with NBIC or DHS's Office of Health Affairs as of July 2015. These agreements are generally for the provision of specific personnel or technology, or participation in a joint project.

¹⁵Although ODNI is represented on the NBIC Advisory Board, officials from NBIC, ODNI, and the Department of Homeland Security's Office of Intelligence and Analysis (I&A) noted that NBIC's relationship with the intelligence community is currently conducted through I&A. According to NBIC officials, the center's relationship with ODNI is new and they have not yet established direct relationships with ODNI. Therefore, we did not include ODNI among the NBIS partners we interviewed and surveyed.

- Support biosurveillance agencies: Support biosurveillance agencies do not have missions that directly involve disease detection and monitoring; however, they collect data and information or have subject matter expertise that may be useful to efforts to detect, monitor, or respond to biological events. For example, the Department of Commerce's National Oceanic and Atmospheric Agency collects meteorological data that may be used by NBIC to help inform the officials about progression of an outbreak based on weather patterns. Five of the 19 NBIS partners we interviewed and surveyed are support biosurveillance agencies.
- Biosurveillance information consumers: Biosurveillance information consumers generally do not have missions that directly involve disease detection and monitoring and generally do not produce information that is useful for biosurveillance. However, they consume such information because biological events can affect their main mission and they may have a particular role to play in responding to an event. For example, officials from DOT stated that their department consumes biosurveillance information because biological events can affect the national transportation system and transporting people and items through a contaminated area can further exacerbate a biological event. Three of the 19 NBIS partners we interviewed and surveyed are biosurveillance information consumers.

Figure 1 and appendix I describe the missions and biosurveillance responsibilities of the 19 NBIS partners we interviewed and surveyed.

Interactive graphic Figure 1: Biosurveillance Responsibilities of the National Biosurveillance Integration **System Partners**

Click on highlighted departments or agencies for more information. Click 🗵 to close. For a printer-friendly version, see app. I.













Assistant

Secretary for

Preparedness

and Response Food and Drug Administration





Department of Justice

Federal Bureau of Investigation







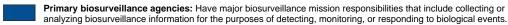


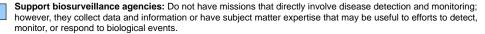




Office of the **Director of** National Intelligence^a

Legend





Biosurveillance information consumers: Generally do not produce information that is useful for biosurveillance, but consume such information because biological events can affect their main mission and they may have a particular role to play in responding to an event.

Source: GAO structured interviews with NBIS partners and GAO analysis of agency documents; Art Explosion (clip art). | GAO-15-793

^aThe Office of the Director of National Intelligence (ODNI) is represented on the National Biosurveillance Integration Center (NBIC) Advisory Board and NBIC Interagency Working Group. However, NBIC's relationship with the intelligence community is run through the Department of Homeland Security's Office of Intelligence and Analysis (I&A), according to our discussions with ODNI, NBIC, and I&A. In addition, NBIC's relationship with ODNI was new at the time of this review, and NBIC had not established direct relationships with ODNI. As a result, we did not include ODNI in additional interviews and the survey.

NBIC Has Activities
That Support
Integration, but Faces
Challenges That Limit
Its Ability to
Enhance the National
Biosurveillance
Capability

NBIC Compiles
Information on Key Global
Biological Events, but
Faces Challenges
Applying Statistical and
Analytical Tools to Create
New Meaningful
Information

To fulfill its Analyzer role, NBIC develops a variety of products to enable early warning and enhance situational awareness of biological events, but the center faces challenges related to its ability to develop products that contribute meaningful information and has difficulty obtaining biosurveillance data.

NBIC's Analyzer Role Products and Activities

NBIC's efforts to fulfill its Analyzer role include a variety of products and activities designed to enable early warning and shared situational awareness. As part of its daily analytic process, NBIC analysts review two main types of information: (1) open source, such as media reports, foreign, national, state, and local government agency websites, and industry and professional association reports and websites, and (2) partner-provided. First, to identify relevant open-source information, NBIC uses both automated and manual methods. For example, in addition to conducting manual searches of media, NBIC analysts also access commercial open source data feeds such as HealthMap and DOD's National Center for Medical Intelligence's (NCMI) Arkham data feeds, which provide open-source information in more than 80 languages that

National Biosurveillance Integration Center (NBIC) Daily Analytic Process with General Time Frames



- 24 hours a day: Department of Homeland Security's Office of Health Affairs Watch Desk evaluates opensource biosurveillance information using a variety of tools and sources, which will inform the development of future products. NBIC analysts review watch desk information and reports from federal partners to identify items of potential significance.
- <u>Late morning</u>: Analysts conduct a daily internal NBIC discussion to determine items of significance and decide additional actions that are required.
- Afternoon: The Daily Biosurveillance Review is distributed to internal recipients including agency liaisons, and serves as a tool that generates a record of what was known, at what time, and from what source.
- <u>Late afternoon</u>: Monitoring List is distributed via e-mail to federal partners and other domestic and international stakeholders to update them on items being monitored, as well as other reports published by NBIC.

Source: GAO analysis of National Biosurveillance Integration Center policies and procedures. | GAO 15-793

are translated automatically into English. ¹⁶ Second, NBIC also relies on finished analytical products from NBIS partners, which may be obtained directly from partners or are available publically on agency websites. These products are usually received or obtained as written reports that represent the agency's analysis and interpretation of the raw data that it collects on a routine basis or for a specific event. NBIC analysts may also make requests for information to NBIS partners for additional information.

NBIC produces a variety of regular products to enable early warning and enhance situational awareness, including its daily Monitoring List, Biosurveillance Event Reports, and Special Event Reports, as well as by responding to requests for information from its partners. NBIC's Monitoring List is a daily e-mail that contains brief summaries on acute, ongoing biological events of concern or interest to the NBIS partners. Biosurveillance Event Reports provide additional detail on specific events. For example, throughout 2015, NBIC produced such reports on the Middle East respiratory syndrome coronavirus, highly pathogenic avian influenza, Ebola virus disease, measles, and porcine epidemic diarrhea virus, among others. NBIC has also produced Special Event Reports at the request of state and local authorities in advance of mass gathering events, such as the Super Bowl and the Little League World Series. NBIC also responds to requests for information from the NBIS partners and other stakeholders.

¹⁶NBIC decommissioned its Biosurveillance Common Operating Network, an open-source search engine, in November 2013, an action that officials stated allowed NBIC to invest in more cost-effective technology. Officials stated that, as an interim measure, this system was replaced by acquiring access to other biosurveillance information feeds from other federal agencies, such as Arkham, and commercial sources. NBIC officials further added that the center is investing in additional capabilities to replace and improve upon the Biosurveillance Common Operating Network capabilities.

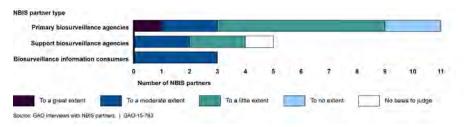
NBIC's Challenges as an Analyzer

According to agency officials we spoke with and strategic documents we reviewed, NBIC faces challenges in implementing its Analyzer role, including its limited ability to develop products that contribute meaningful information to its partners and difficulty obtaining biosurveillance data.

Products That Provide New Meaningful Information

Primary biosurveillance agencies generally reported that NBIC's products do not provide them with meaningful information because those products contain information that they either already generate themselves or could obtain directly from other NBIS partners more quickly. As illustrated in figure 2, during our structured interviews, 8 of 11 primary biosurveillance agencies reported that NBIC products and activities help their agency identify potential or ongoing biological events (i.e., perception) to little or no extent. For example, officials from 2 of these agencies stated that much of the information in NBIC's products related to their respective domains do not inform their biosurveillance activities because this information generally originates from reports that their agencies release publically.

Figure 2: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Enhances Their Perception of Biological Events



Further, officials from multiple agencies described information-sharing networks outside of their participation with NBIC that they use to pursue their missions, including integrating information across domains—such as animal and human health data. For example, officials from 10 of the 11 primary biosurveillance agencies reported during our structured interviews that they integrate biosurveillance information from both within and outside their respective domains. As illustrated by figure 3 and appendix II, the primary and support biosurveillance agencies reported that they directly obtain information that enhances their situational awareness (i.e., perception, comprehension, and projection) of biological events from many of the other federal agencies in the NBIS. As a result,

Analytic Products and Activities of the National Biosurveillance Integration Center (NBIC):



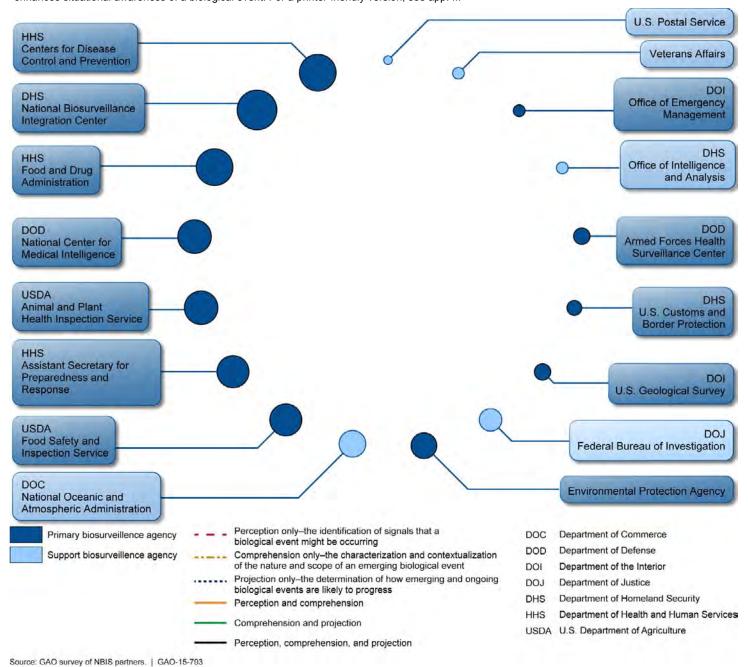
- NBIC Monitoring List: a daily e-mail to inform partners of new and ongoing events that NBIC is currently monitoring. These emails are sent to (1) federal; (2) state, local, tribal, and territorial; and (3) congressional users.
- Biosurveillance Event Report: a more detailed report focused on a specific event. These reports provide basic event details (e.g., pathogen, location, affected populations, and event progression) and describe interagency actions, among other things. These reports are distributed via e-mail as well as the Homeland Security Information Network, among others.
- Special Event Report: a report requested by government partners, such as state and local governments, to provide a public health assessment for a selected event.
- Requests for Information:
 biosurveillance information collection and
 gathering technique through analyst-to analyst communications that can be
 submitted through the Department of
 Homeland Security's National
 Operations Center, e-mail, phone calls,
 or a biosurveillance information-sharing
 portal known as Wildfire.

Source: National Biosurveillance Integration Center, GAO analysis | GAO 15-793

partners reported that NBIC's products contain much information of which they are already aware or could access regardless of their participation with NBIC. For example, as illustrated by figure 3, EPA officials reported that their agency obtains information that enhances all three elements of situational awareness from seven agencies, including APHIS, CDC, and NBIC, among others. Further, EPA officials reported that they obtain information that enhances their comprehension and projection of biological events from DOI's Office of Emergency Management and NCMI.

Interactive graphic Figure 3: Primary and Support Biosurveillance Agencies' Sources for Information That Enhances Situational Awareness of Biological Events

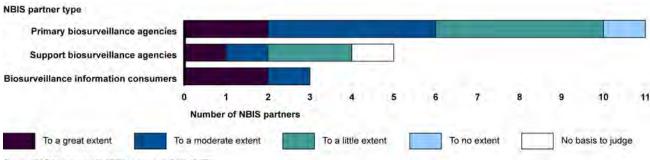
Move mouse over agency names to show the sources from which that agency obtains biosurveillance information. The size of the circle for an NBIS partner reflects the number of times other primary and support biosurveillance agencies identified that agency as an information source that enhances situational awareness of a biological event. For a printer-friendly version, see app. II.



However, agencies with more limited roles in biosurveillance, such as the biosurveillance support agencies and information consumers, had more favorable views on NBIC's products and activities. For example, as also illustrated by figure 2, 5 of the 8 biosurveillance support agencies and information consumers stated that NBIC's products and activities help their agencies identify potential or ongoing biological events (i.e., perception) to a moderate extent. Officials from some of these agencies reported that they leveraged NBIC products because their own agencies lacked time, capacity, or the infrastructure to regularly review disparate sets of information across multiple agencies and domains. For example, officials from a support biosurveillance agency reported that because the agency did not have the capacity to review all of the relevant biosurveillance information that it collected, NBIC's products filled a critical information gap in its intelligence. Some NBIS partners suggested that NBIC's reports might be useful for state and local entities that might not have access to the same breadth of information or the capacity to integrate biosurveillance information themselves.

Further, as illustrated by figure 4, 5 of the 8 biosurveillance support agencies and information consumers stated that NBIC's products and activities help their agencies understand the nature and scope of emerging biological events (i.e., comprehension) to a great or moderate extent. Officials from these agencies generally stated that NBIC's products were easy to understand and provided useful context for events outside their scope of expertise. For example, officials from a support biosurveillance agency praised one of NBIC's Biosurveillance Event Reports on the recent outbreak of highly pathogenic avian influenza, which included information from CDC, APHIS, and USDA's Food Safety and Inspection Service (FSIS) on how the disease will affect the food chain, if it could cross to the human population, and what information is known locally.

Figure 4: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Enhances Their Comprehension of Biological Events

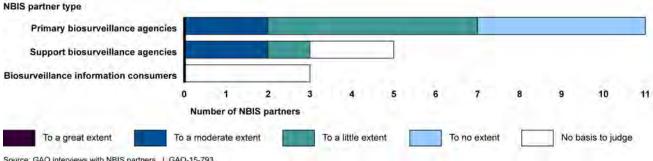


Source: GAO interviews with NBIS partners. | GAO-15-793

Regardless of their role in biosurveillance, partners noted that NBIC's products and activities do not generally contribute new meaning or analysis—that is, insights that cannot be gleaned in isolation. For example, as shown in figure 5, 10 NBIS partners stated that NBIC's products and activities enhance their agencies' ability to carry out their biosurveillance roles and responsibilities to little or no extent, 4 responded to a moderate extent, and 5 responded that they did not have a basis to judge. Generally, partners that responded to little or no extent noted that NBIC products and activities do not, for example, identify trends and patterns or describe potential impacts of a biological event. For example, officials from a primary biosurveillance agency stated that NBIC's products and activities do not "connect the dots" between dissimilar information, provide novel synthesis of information, or recommend possible courses of action.

¹⁷Generally, these 5 NBIS partners stated that they did not have a basis to judge because they are biosurveillance information consumers or they considered their role in biosurveillance to be relatively small.

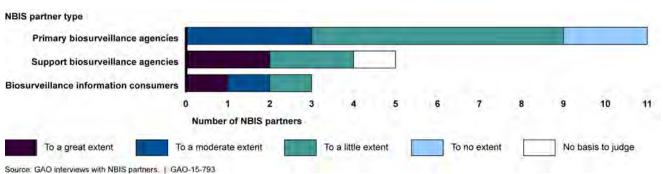
Figure 5: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Enhances Their Agency's Ability to Carry Out Its Biosurveillance Roles



Source: GAO interviews with NBIS partners. | GAO-15-793

Further, as shown in figure 6, 11 of the 19 NBIS partners stated that NBIC's products and activities help their agencies understand how emerging and ongoing biological events are likely to progress into the near future (i.e., projection) to little or no extent. Officials noted that forecasting and projection are inherently difficult, but suggested that NBIC could develop other kinds of analysis that would be useful for the projection element of situational awareness. For example, officials from a primary biosurveillance agency suggested that NBIC could integrate more data and information from other DHS components into its reports, which would help to provide a homeland security perspective on biological events. Officials from another agency stated that NBIC could combine information across multiple domains on a local disease outbreak with known travel and weather patterns to predict how a disease might spread.

Figure 6: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Enhances Their Understanding of How Biological Events Are Likely to Progress (i.e., Projection)



NBIC officials stated that the center is working to improve its products and its ability to contextualize the information it collects from open sources. and has sought partner input to do so. For example, beginning in late June 2015, partly on the basis of feedback the center received from its November 2014 Federal Stakeholder Survey, NBIC modified its daily Monitoring List to include an up-front summary that identifies the status of ongoing biological events as worsening, improving, unchanged, or undetermined. During our interviews with the NBIS partners, several agency officials suggested that the center make a similar change to this product because it would help them to more quickly scan the report to determine which events might be worth further examination. Although we are not able to analyze the effect this change had on partner views because the change took place after our interviews, it appears to be a positive step in response to one issue that partners raised. Further, NBIC officials noted that the center is also working to better integrate forecasts and projections into its products and activities. Specifically, NBIC is participating in a working group led by the Office of Science and Technology Policy to support the priorities articulated in the S&T Roadmap by developing a common interagency vision for specific federal capabilities and practical next steps leading to the application of reliable infectious disease forecasting models in decision-making processes.

Data Availability and Access

Data that NBIC could use to identify and characterize a biological event of national concern using statistical and analytical tools, as called for in the 9/11 Commission Act, are limited. Apart from searches of global news reports and other publically available reports generated by NBIS partners, NBIC has been unable to secure streams of raw data from multiple domains across the biosurveillance enterprise that would lend themselves to near-time quantitative analysis that could reveal unusual patterns and trends. NBIC acknowledged in its strategic plan that the data required to carry out its mission as envisioned in the 9/11 Commission Act either do not exist or are subject to a variety of information sharing challenges that make a large information technology-centered solution less feasible than originally imagined.

NBIC and NBIS partners noted that there were several kinds of data that could be useful for this kind of biosurveillance integration, but these data may not exist or may not be in a usable form. For example, EPA officials stated that under the existing statutory framework, the federal government does not collect real-time data on water quality and contamination from drinking water utilities. Instead, water systems report

violations of drinking water standards to EPA on a quarterly basis. In addition, officials from CBP and DOI's U.S. Geological Survey (USGS) reported that there is a significant gap in the availability of animal health data, particularly data on wildlife disease, which makes it difficult to fully understand the dynamics of zoonotic diseases. NBIC officials also noted that other kinds of data are maintained in formats that make them difficult to analyze, such as paper health records. Further, the *S&T Roadmap* noted that many livestock health records are held by private industry and are not broadly accessible or standardized in a manner that would make such data usable.

In our survey, few—5 of 19—NBIS partners reported that they shared raw data with NBIC, and during structured interviews NBIS partners discussed a variety of challenges they faced in sharing certain data with NBIC. 18 Some agencies are reluctant to share their data with NBIC because they are unsure how the information will be used. For example, officials from a primary biosurveillance agency stated that the agency does not share some data with NBIC because sharing such information too broadly might have substantial implications on agricultural trade or public perception of safety. Further, officials from another primary biosurveillance agency noted that there is sometimes reticence to share information and data with components of DHS because, given the department's roles in law enforcement and national security, the information might be shared outside of the health security community in a way that lacks appropriate context and perspective.

Other agencies stated that they are unable to share data for regulatory or legal reasons, or because appropriately protecting the data would take too long. For example, officials from HHS's Food and Drug Administration (FDA) stated that their agency is unable to share some of its data on food and drug contamination because this information is confidential commercial information that FDA is restricted from sharing outside the agency. According to CDC officials, their agency receives electronic data from state, territorial, local, and tribal sources for a variety of programs

¹⁸Specifically, these partners reported that they share raw structured data with NBIC through approved channels. Raw structured data include data that have been collected in an electronic format that can be automatically processed by a computer but have not been analyzed to reach conclusions about their meaning, such as whether the data are signs of a potentially catastrophic infectious disease outbreak. All 5 of the NBIS partners that reported sharing such data with NBIC are primary biosurveillance agencies.

and purposes that are covered by data use agreements that do not allow CDC to share the data outside the terms of those agreements and as allowed or required by applicable federal laws, such as the Privacy Act of 1974 and the Freedom of Information Act. 19 Pursuant to federal law and the terms of these agreements, CDC may share aggregated information as long as it protects an individual's privacy. However, according to CDC officials, some of these data cannot be shared without extensive, timeconsuming work to appropriately redact the data to ensure that individuals may not be identified and that privacy is protected, which results in the release of the data being postponed to the point that the data are no longer actionable. Further, officials from VA noted that the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations also restrict their ability to share some data because it requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.²⁰

Concerns over data are a long-standing issue with NBIC and the federal biosurveillance integration mission. We have previously reported that scant availability of data throughout the federal government, a lack of trust, and partners' concerns over sharing sensitive information with NBIC were major barriers in NBIC's ability to obtain the data and other information that it needed to support data integration. NBIC officials recognize that these barriers inhibit the ability of their partners to share some data with the center, but noted that they are trying to work with some of their partners to address these issues. For example, NBIC is currently developing a project with VA to determine how the center can use VA's data for biosurveillance purposes while ensuring that sensitive data are properly managed.

¹⁹5 U.S.C. § 552a; 552.

²⁰See Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021 (Aug. 21, 1996) (codified at 42 U.S.C. §§ 1320d–1320d-9); 45 C.F.R. Parts 160, 164.

²¹GAO-10-171.

NBIC Has Developed Procedures to Coordinate with Biosurveillance Partners, but Faces Limited Participation and Provision of Partner Personnel

To fulfill its Coordinator role, NBIC has established procedures that occur daily, weekly, and as emerging or significant biological event occur, but the center faces challenges related to participation of NBIS partners in the center's activities, the provision of partner personnel to NBIC, and competing structures for convening NBIS partners.

NBIC's Coordinator Role Products and Activities

NBIC's efforts to fulfill its Coordinator role with its partners includes a variety of interactions and established procedures that occur daily, weekly, and as emerging or significant biological events occur, including the NBIS Protocol, daily and weekly calls, by moderating an information sharing portal, and jointly developed products.

- NBIS Protocol: A mechanism that brings federal partners together to provide information sharing on an emerging or significant biological event through a short-notice teleconference, the protocol is meant to accelerate the ability to characterize an event as rapidly as possible and seeks to gather the scientific and medical communities of interest to assess the biological threat. The protocol is activated at the request of any federal NBIS partner, or the White House, when a situation meets one of the thresholds previously established by the NBIS partners.²² Participation in NBIS Protocol Calls is not mandatory, and an NBIS partner may choose to opt out based on the announced subject of the call. NBIC exercises the protocol two times a year. According to NBIC officials, the protocol has been activated once since fiscal year 2012, in April 2013 to discuss both the avian flu in China (H7N9) and Middle Eastern respiratory syndrome.
- Daily Calls: NBIC's Daily Analysts' Call is a daily internal teleconference in which NBIC analysts discuss information and

²²These thresholds are (1) any indications of biological events manifesting anomalous levels of death, illness, disease, or injury that surpasses agency specific thresholds for information sharing with NBIS; (2) any credible indication of an accidental or intentional misuse of any chemical, radiological, or biological agent that may adversely affect human, animal, or plant health or harm the food supply; (3) any non-routine request for assistance or information from one NBIS partner to another regarding a biological event that may have significance to the larger NBIS community; and (4) any biological event that could reasonably be assessed as being a "high visibility" event requiring awareness of senior leadership.

Coordinator Products and Activities of the National Biosurveillance Integration Center (NBIC):



- National Biosurveillance Integration System (NBIS) Protocol: a mechanism that brings federal partners together on a short-notice teleconference to provide information sharing on an emerging or significant biological event.
- Daily Analysts' Call: a daily teleconference in which NBIC analysts and other participants discuss newly identified potential and active hazards.
- Bi-weekly Reporting Call: NBIC hosts the Interagency Biosurveillance Presentation Series bi-weekly via teleconference with NBIS Partners presenting and discussing biosurveillance project findings of interest.
- Wildfire portal: an encrypted interagency information-sharing portal—housed within the National Center for Medical Intelligence—through which participating entities can request information among a trusted subset of interagency subject matter experts within the federal biosurveillance community.
- Jointly Developed Products: NBIC brings together its multidisciplinary partners to develop joint products that enhance understanding of new or potential biological events.

Source: GAO analysis of NBIC policies and procedures | GAO 15-793

- analytic insights from the previous day, but all NBIS partners may call in.
- Biweekly Calls: Until recently NBIC hosted a Weekly Reporting Call to present and discuss the most significant biosurveillance events from the previous week. In response to feedback the center received from its November 2014 Federal Stakeholder Survey, NBIC changed the format of the weekly call in January 2015 to a biweekly call with a rotating responsibility among the NBIS partners to provide a featured speaker on a relevant issue, as well as an opportunity to pose questions to NBIC and the other partners on ongoing or potential biological events.
- Wildfire Web-Based Information-Sharing Portal: Wildfire is a tool used and governed by the Biosurveillance Indications and Warnings Analytic Community, a self-governing interagency body composed of federal officials who are actively responsible for pursuing a biosurveillance mission.²³ The portal is housed within the National Center for Medical Intelligence. Federal officials who are actively responsible for pursuing a biosurveillance mission can share information about potentially significant biological events on Wildfire. According to NBIC officials, NBIC analysts routinely use the portal. In addition, as the moderator since August 2013, NBIC ensures that questions posed by officials across the interagency are answered in a timely manner.
- Jointly-Developed Products: NBIC also brings together its multidisciplinary partners to develop joint products that enhance understanding of new or potential biological events. For example, NBIC coordinated with APHIS to facilitate a study by DHS's Homeland Infrastructure Threat and Analysis Center that modeled the potential biological and economic impacts of the Kudzu bug, a pest that presents a potential risk to the U.S. soybean crop if pesticide applications failed. NBIC has also developed joint classified intelligence products developed by DHS's Office of Intelligence and Analysis by, for example, describing the scope and context of a biological agent in these products.

²³The agencies and departments represented in the Biosurveillance Indications and Warnings Analytic Community include APHIS, CDC, Department of State, DHS, DOD, HHS's Office of the Assistant Secretary for Preparedness and Response, and the intelligence community.

NBIC's Challenges as a Coordinator

According to agency officials we spoke with and strategic documents we reviewed, NBIC faces challenges that affect its ability to implement its Coordinator role, including the limited participation of NBIS partners in NBIC activities, limited provision of partner personnel to NBIC, and competing structures for convening NBIS partners.

Limited Participation

Although NBIC has implemented its Coordinator role through a variety of interactions and procedures, partner participation in key NBIC activities has generally been limited. For example, as shown in figure 7, about half of the NBIS partners reported in our survey that they regularly participated in NBIC's Weekly Reporting Calls (9 of 19) during the time period between August 2012 and December 2014, and even fewer reported regularly participating in the Daily Analyst Calls (2 of 19). Some of the agencies that reported not regularly participating in the daily and weekly calls are primary biosurveillance agencies that are generally considered to be among the lead generators of biosurveillance information in their respective domains. Officials from one of these agencies noted that much of the information presented during the daily and weekly calls was already provided in the daily Monitoring List e-mail, and therefore provided relatively little new information.

Figure 7: National Biosurveillance Integration System (NBIS) Partners That Reported Participating in the National Biosurveillance Integration Center's (NBIC) Daily and Weekly Calls Since August 2012, how frequently has your agency participated in NBIC's Daily Analysts' Call? NBIS partner type Primary biosurveillance agencies Support biosurveillance agencies Biosurveillance information consumers Number of NBIS partners Since August 2012, how frequently has your agency participated in NBIC's Weekly Reporting Call? NBIS partner type Primary biosurveillance agencies Support biosurveillance agencies Biosurveillance information consumers 2 Number of NBIS partners Regularly Sometimes No response Source: GAO survey of NBIS partners. | GAO-15-793

Note: Because the format of weekly call changed in January 2015 during the course of our review, we asked survey respondents to identify the frequency with which they participated in the weekly call for the time period between August 2012 and December 2014.

The National Strategy for Biosurveillance notes that in a reduced resources environment, it is important to pursue activities that add value for all participants, and officials across the NBIS noted that the modification to the weekly call was a positive step. For example, officials from a primary biosurveillance agency stated that the change provided them with an opportunity to advertise the services their agency provides. Officials from another primary biosurveillance agency noted that the new presentation-focused format is more likely to benefit all partners across the NBIS. NBIC officials stated that they plan to request feedback from the partners in the future on the new format of these calls to determine what, if any, additional changes are needed.

Limited Provision of Partner Personnel

Another challenge faced by NBIC concerns its ability to obtain personnel from its partners as originally envisioned in the 9/11 Commission Act. NBIC officials told us that effective biosurveillance depends on subject

matter experts to interpret events and place them in context. Although all of the NBIS partners provide key points of contact for NBIC, few (3 of 19) partners currently provide a dedicated liaison as of July 2015. Officials across the NBIS partners provided various reasons for why their agencies did not provide a liaison. For example, officials from one primary biosurveillance agency stated that for their agency, and likely other agencies as well, it is difficult to provide personnel to NBIC on a full- or part-time basis because of their own resource constraints. Further, officials from a support biosurveillance agency noted that the lack of clarity about NBIC's value to its partners is a barrier to providing the center with detailees.

In order to obtain more personnel from its partners, NBIC has agreed to partially fund some of the liaisons. For example, according to NBIC officials, the center already funds liaisons from VA, DOI, and USDA's APHIS and is working to establish a liaison with CDC. .According to NBIC, liaisons have provided great benefit to the center such as by providing special knowledge of their agency's roles and areas of responsibility and providing NBIC with the critical ability to reach-back into their respective agency or department. According to the officials, NBIC would like to more fully leverage the capabilities of its partners and obtain a liaison from each NBIS partner; however, budget constraints currently prohibit NBIC from obtaining fully funded liaisons from each partner.

Competing Structures for Convening Partners

Federal partners noted that they were unclear about the differences between two of the major structures used for convening federal stakeholders to discuss emerging biological events. The NBIS Protocol, as previously identified, is managed by NBIC, while the other, the Biological Assessment Threat Response (BATR) Protocol, is managed by the White House's National Security Council Staff. According to the *NBIC Strategic Plan*, the BATR Protocol is a national-level interagency consultation process with mid-to-high level decision makers that is designed to achieve coordinated action and desired outcomes to prevent, protect from, and respond to high-consequence bioterrorism and biosecurity threats.²⁴ According to NBIC, each of the protocols is designed to serve a different purpose for a different set of participants

²⁴NBIC officials stated that the BATR is currently being restructured, but did not know when the National Security Council had intended to finalize it.

according to their respective roles in the recognition of, and response to, a biological event. The NBIS Protocol is a mechanism to bring together federal analysts and operators for information sharing early in a biological event's discovery and development phase; whereas the BATR Protocol is designed to enable the most senior level of federal leadership to achieve situational awareness to effectively coordinate available resources for incident response. However, although we did not ask a specific question about the two protocols in our structured interviews, about a quarter of the NBIS partners (5 of 19) we interviewed were unclear about the differences between the two protocols. For example, in structured interviews, officials from two of the agencies noted that the protocols appeared to serve the same purpose or were attended by the same officials.

NBIC Has Efforts Under Way to Develop New Biosurveillance Tools, but Faces Challenges Prioritizing Development Efforts in a Limited Resource Environment

To fulfill its Innovator role, NBIC has funded several pilot projects, sought new data sources, and made efforts to enhance its IT system, but faces challenges related to its limited resources and the varying needs of its partners.

NBIC's Innovator Role Products and Activities

NBIC's efforts to fulfill its role as an Innovator include conducting gap analyses, funding pilot projects that aim to develop new biosurveillance tools and technology, seeking new sources of data and information, and building its internal IT system. Beginning in September 2012, NBIC sought input from its federal partners to identify and prioritize biosurveillance capability gaps. According to NBIC officials, the gap analysis effort enabled NBIC to survey the biosurveillance community to identify any innovative pilot projects that NBIC could sponsor given its current resources and designed to provide broad support to the NBIS and other stakeholders, not only to NBIC. Specifically, NBIC requested that its partners identify existing capability gaps and suggest specific actions that would make progress toward a desired end state or outcome. In response, NBIC received 13 proposals from the NBIS partners, and then requested that partners prioritize the capability gaps for implementation. This prioritization was completed in April 2013. On the basis of the results, NBIC funded a pilot project to develop standardized methods of communicating the uncertainty of biosurveillance information. The project's aim was intended to help promote improved understanding when information is shared among biosurveillance analysts, leading to more

Innovator Products and Activities of the National Biosurveillance Integration Center (NBIC):



- National Collaborative for Bio-Preparedness (NCB-Prepared): a pilot project sponsored by NBIC and the University of North Carolina at Chapel Hill, among others. According to NBIC, a September 2014 prototype was capable of real-time analysis of health data in a geographic format, enabling users to search data, for example, on clinical symptoms and text within health records, using data from Emergency Medical Services, 911 phone calls, and Poison Control Centers. According to NBIC, this pilot program is intended to be offered to state and local governments and the private sector.
- Social Media pilot projects: NBIC has conducted several pilot projects to examine the extent that social media can augment existing biosurveillance detection and analysis. The pilot projects assessed the feasibility of using commercial and government off-the-shelf systems to aggregate social media information for biosurveillance. The most recent pilot, initiated in fiscal year 2012, funds the Department of Defense's Naval Surface Warfare Center to develop analytical techniques to improve the use of social media data for biosurveillance. NBIC plans to conclude the project at the end of fiscal year 2015, and transition the project's algorithms for operational use.

Source: National Biosurveillance Integration Center, GAO analysis | GAO 15-793

rapid characterization and mitigation of disease outbreaks. The resulting product, which was completed in October 2014, provides biosurveillance analysts with procedures for selecting and applying uncertainty methods as well as a standardized format for reporting information.

The 2012 *NBIC Strategic Plan* also identified a number of pilot projects designed to assess the extent to which such projects could be adopted full-scale. According to the plan, each pilot project is intended to improve collaboration or information sharing. According to NBIC, these pilots are routinely assessed and evaluated to determine what is most helpful and effective, and those that prove successful will be integrated into normal operations, while those that are not will be discontinued. For example, NBIC has jointly funded the National Collaborative for Bio-Preparedness pilot project to develop a comprehensive, state-level system to analyze public health trends and detect emerging biological incidents by using data analytics and anomaly algorithms. Further, NBIC has also funded three pilot projects examining the feasibility of using open-source data from various social media applications in order to identify possible health trends. NBIC has completed two of these pilots and one is ongoing.

NBIC has been seeking new sources of data and information in order to fulfill its mission for early warning and shared situational awareness of acute biological events, including data and information from other DHS components and NBIS partners, as well as classified information. First, in September 2013, NBIC analyzed the usefulness of department-wide absenteeism data from DHS's Office of the Chief Human Capital Officer. which could be an indicator of an emerging epidemic. Based on an analysis of 20 months of DHS workforce data from 2012 and 2013, the study concluded that absenteeism data could be a useful component in biosurveillance, as understanding differences between normal leave behavior and expected rises in leave behavior during peak flu seasons would help in establishing baseline values for comparison. In August 2014, NBIC, working with DHS's Science and Technology Directorate and Lawrence Livermore National Laboratory, evaluated the usefulness of DHS components' data systems as potential biosurveillance data sources. The assessment identified two Customs and Border Protection (CBP) databases as the most useful to NBIC's mission, and in June 2014. NBIC funded a part-time liaison to CBP's Office of Intelligence to determine the extent to which NBIC can use CBP databases for

biosurveillance purposes.²⁵ Second, NBIC has also sought to obtain new sources of data from NBIS partners and other stakeholders. For example, as of July 2011, VA has provided NBIC a liaison to, among other responsibilities, identify ways NBIC can use VA's patient healthcare information to support its early detection and situational awareness mission. Finally, according to NBIC officials, the center has enhanced its process for analyzing intelligence information and reviews various intelligence sources to supplement, corroborate, or provide additional context to the biosurveillance items identified through other sources. For example, an NBIC intelligence analyst reviews all source intelligence information to identify potential topics of interest, such as indications of novel infectious disease or terrorism, and if necessary, reaches back to partners in the intelligence community for further information.

NBIC officials noted that the center's recent focus is on building its internal IT infrastructure, rather than pilot projects. For example, through its current Biofeeds project with the Pacific Northwest National Laboratory, NBIC is seeking to build a visual and text analytics capability that to enable the center to more effectively and efficiently identify relevant information in open source data. Officials also noted that NBIC is partnering with the Defense Threat Reduction Agency on the Biosurveillance Ecosystem project to build a collaborative analytic workbench for the center. Further, officials stated that NBIC has obtained an IT program manager as a detailee from the Transportation Security Administration to help build the center's internal IT program.

NBIC's Challenges as an Innovator

According to agency officials we spoke with and strategic documents we reviewed, NBIC faces challenges that affect its ability to implement its Innovator role, including its limited resources and the varying needs of partners.

²⁵Out of 13 DHS component databases, the study identified 2 CBP systems as the most useful to NBIC. The Automated Targeting System is an enforcement and decision support system that compares passenger and cargo manifest information against intelligence and other law enforcement data. TECS (not an acronym) is an automated enforcement and antiterrorism database maintained by CBP that provides information for law enforcement and border security purposes.

Limited Resources

Although we did not ask a specific question about resource limitations, officials from 9 of the 19 NBIS partners identified it as a challenge NBIC faces in developing new biosurveillance tools and technology. From fiscal year 2012 through 2015, NBIC's budget ranged from \$10 million to \$13 million annually. 26 Officials from 2 primary biosurveillance agencies noted that NBIC's budget limits its ability to enhance its existing technology systems to invest in innovations such as disease event modeling. Further, officials from 3 primary biosurveillance agencies more generally expressed concerns regarding the imbalance between the size and nature of NBIC's mission, including its role as an innovator, and the resources that it had available to achieve it. NBIC officials stated they have never requested a budget increase, because their larger DHS office, the Office of Health Affairs, has experienced budget reductions, and an increase for NBIC would require a decrease for another program. However, NBIC officials noted that they would likely use any increase in its budget to help develop more analytical tools for itself and its partners.

Partners Have Varying Needs

Related to its limited resources, NBIC also faces challenges prioritizing its innovation efforts because its partners have diverse, and sometimes conflicting, needs. The S&T Roadmap noted that active collaboration for biosurveillance presents challenges because stakeholders have varying missions and roles. As previously noted, NBIC asked its partners to identify existing capability gaps. The 13 submissions covered a wide variety of biosurveillance issues and domains, such as wildlife disease surveillance, integration of pharmacy data, and analysis of Medicare claims data. However, although NBIC asked partners to prioritize the 13 submissions identified as existing capability gaps, the proposal that was selected had been ranked third by the partners, and officials from a primary biosurveillance agency stated that it was unclear why the higher ranking proposals were not selected. Further, officials from a primary biosurveillance agency suggested that NBIC conduct its own needs analysis to determine what tools and technology NBIC could invest in. NBIC officials noted that the third ranked proposal was selected because it was the highest ranked proposal that was "shovel ready", thereby

²⁶Officials reported that this includes funds from reprogramming, recessions, and transfers.

allowing funding to be applied when funding was available, whereas the top two proposals were not. According to NBIC officials, future investments will be informed by the *S&T Roadmap*.

Biosurveillance Partners Expressed Skepticism about the Feasibility of NBIC's Mission

Although 13 of the 19 NBIS partners stated in our structured interviews that the concept of having a federal entity whose mission is to serve as the integrator of national biosurveillance information across agencies and disease domains is very or moderately important, some also expressed doubts about the feasibility and practicality of this mission. Specifically, although we did not specifically ask a question about the practicality of NBIC's mission, about a third of the NBIS partners (7 of 19) expressed skepticism and doubts about the feasibility of NBIC's mission, including whether federal integration of biosurveillance information could actually achieve early warning and situational awareness of biological events. Among the specific reasons officials cited for the skepticism was their uncertainty that the current model of biosurveillance integration was the most effective investment for strengthening the national biosurveillance capability. For example, officials from one agency noted that while the concept makes sense intuitively, there is no reliable evidence, such as a peer-reviewed study, that has confirmed the viability of the concept, nor has there been a large-scale biological threat that has been detected through integration; moreover, such a system—by virtue of its being federally-based—would lack timely detection and response capabilities because events occur at the local level. Officials from another agency questioned the feasibility of NBIC's mission because the data and technology that are currently available do not provide for the accurate projection of biological events or facilitate the provision of early warning. Additionally, an NBIC official told us that the ability to achieve early detection of emerging events—especially unexpected or novel events—is dubious because most of the tools and techniques used in surveillance rely on contrasting current conditions with known baseline trends and patterns, but as an event emerges, surveillance practitioners are not necessarily going to be focused on those patterns and trends until something prompts their attention. Moreover, when a biological event is novel, its patterns and trends are not yet known.

We have previously reported on skepticism on the part of some of the NBIS partners regarding the value of the federal biosurveillance mission as well as NBIC's role in that mission.²⁷ In our 2009 report, most of the NBIS partners we interviewed at that time expressed uncertainty about the value of participating in the NBIS or confusion about the purpose of NBIC's mission.²⁸ For example, officials from 1 of the partners stated that it was unsure whether NBIC contributed anything to the federal biosurveillance community that other agencies were not already accomplishing in the course of carrying out their biosurveillance-relevant missions. We, the NBIS partners, and other major stakeholders in the biosurveillance community acknowledge that no single problem limits NBIC's mission to integrate biosurveillance data. Rather, over the years, several long-standing problems have combined to inhibit the achievement of this mission as envisioned in the 9/11 Commission Act. Most notably, to operationalize the federal biosurveillance integration concept requires the simultaneous sharing and consideration of information from vastly disparate domains, including health, law enforcement, intelligence, and international partners. However, as noted in the S&T Roadmap, the sharing of this information is limited and is often not possible.

There Are a Range of Options for Addressing Biosurveillance Integration Challenges, and Each Has Associated Benefits and Limitations

The challenges previously described illustrate that NBIC faces significant obstacles in implementing its roles as a biosurveillance integrator as originally described in the 9/11 Commission Act. Below, we discuss options for policy or structural changes that could help better fulfill the biosurveillance integration mission. We identified these options and their benefits and limitations, on the basis of the roles of a federal-level biosurveillance integrator we identified in the 9/11 Commission Act, NBIC's strategic plan, and the perspectives of the NBIS partners obtained during our structured interviews. These options are not exhaustive, and some options could be implemented together or in part. In developing these options, we did not evaluate the financial implications of implementing each option, to the extent it is knowable, but we acknowledge they are likely to result in an increase, decrease, or shifting of funding based on the changes described.

²⁷GAO-10-171.

²⁸Specifically, we found that 12 of the 14 NBIS partners we interviewed at that time expressed uncertainty about the value of participating in the NBIS or confusion about the purpose of NBIC's mission. For more on the agencies we interviewed for that report, see GAO-10-171.

Option 1: Reinforce NBIC's Analyzer Role

Under this option, NBIC would be provided with new authorities and resources designed to access additional public and private data sources and statistical and modeling tools to develop meaningful information. Although NBIC would continue monitoring for signals of global disease outbreaks using open-source data, as the center currently does, it would shift attention from daily reporting on known disease outbreaks around the world to bringing together diverse datasets to create and improve forecasts and identify hypothesis-driven underlying connections in seemingly unrelated datasets. This option may require new statutory authorities to ensure NBIC can obtain all available data and also may require changes or clarification of key applicable provisions of existing statutes and regulations. For example, some partners have cited the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations related to protecting the privacy and security of personal health information as a reason for not sharing some biosurveillance information. To the extent that this option has the potential to result in a meaningful enhancement to the national biosurveillance capability, it may require significant new investments to do so-for example, to establish technology, systems, and legal frameworks that facilitate generation and sharing of data. Potential benefits and limitations of this option include the following:

Benefits

- Developing meaningful information not otherwise available: This option would address some of the challenges NBIC faces in implementing its Analyzer role, such as access to data from the NBIS partners, and would better position the center to develop meaningful information that could not be gleaned in isolation, potentially leading to earlier warning of emerging events and shared situational awareness.
- Capitalize on new data sources and analysis techniques:
 Focusing on providing the resources, infrastructure, and frameworks for data sharing may provide the foundation to capitalize on future advancements in data analytics, including big data analysis and electronic health records, to mine data for emerging patterns.

Limitations

- Uncertain need: The probability that a disease event with significant national consequences occurring in such a way that it would be detected more quickly by overlaying various data streams and applying statistical and analytical tools to them is not known.
- Uncertain data availability: There may not be a significant amount of meaningful data available that is not already being provided to facilitate advanced analytical techniques. For example, although

partners identified other potential data sources that could contribute to a more robust integration tool, such as water contamination and wildlife disease data, it is unknown whether such data could be collected and managed to make a meaningful contribution, and if they could, at what cost.

- whether a federal biosurveillance integrator would be able to identify patterns or connections that would lead to earlier warning of emerging events or reduce the time it takes to discover, prevent, or respond to a potentially catastrophic event, or that it would merit the associated costs. Finding patterns and trends without knowing specifically what to look for is challenging, and about a third of the NBIS partners (7 of 19) expressed skepticism and doubts about the feasibility of NBIC's mission, including whether federal integration of biosurveillance information could actually achieve early warning and situational awareness of biological events.
- Unknown impact of earlier detection: If NBIC were able to discern signals that gave warning of an emerging event, there is no guarantee that it would significantly decrease the amount of time it would take federal partners to confirm the warning and implement response actions.
- Increased costs: Creating the enterprise architecture both within NBIC and across the NBIS that would facilitate transfer and computeraided analysis of data would likely require a significant investment in technology, as well as skilled personnel with data analytic, legal, and regulatory expertise. Although we have not specifically assessed the costs of these options, such costs, at least in the near term, would likely exceed NBIC's current annual budget.

Option 2: Strengthen NBIC's Coordinator Role

Under this option, NBIC would be provided with greater authority for coordinating the federal biosurveillance enterprise. NBIC would be the operational agency accountable for overseeing the implementation of the *National Strategy for Biosurveillance*, drawing on the center's daily analytical capacity and the interagency governance infrastructure NBIC has already established. Responsibilities would include strategic oversight, such as helping to ensure consistency across the interagency for high-level policy and doctrine, and maintaining and creating the national strategy and related documents. Responsibilities could also include tactical coordination during national crises—drawing on the established NBIS Protocol and harmonizing it with parallel structures such as the BATR Protocol. Responsibilities could also include coordination to

build interagency connections that result in shared analytical capacity, for which NBIC could draw upon and enhance established structures like Wildfire moderation and Daily Analysts; Calls. Potential benefits and limitations of this option include the following:

Benefits

- Clear leadership: This option would create clear leadership across the interagency for developing and implementing biosurveillance policy in general and in response to specific biological events, which may also encourage partners to more fully participate in NBIC activities, such as regularly attending NBIC's Daily Analysts' and Biweekly Reporting calls.
- Better institutional connection: NBIC officials have stated that the
 current liaisons have provided great benefit to the center. Ongoing
 interaction among more dedicated liaisons from various agencies may
 strengthen biosurveillance subject matter expertise and could
 enhance communication across all the agencies.
- Routine, institutionalized channels to monitor for emerging trends and patterns: Clarifying the federal integrator's role in routinely convening and drawing on the analytical capacity of the various pockets of federal expertise across the NBIS could enhance the ability of NBIC to go beyond daily surveillance and monitoring activities to recognize connections and generate meaningful insights that may not be gleaned in isolation.
- Enhanced accountability for implementing the National Strategy for Biosurveillance: Formally vesting a federal entity with responsibility for leadership of the national biosurveillance enterprise would fill a longstanding need to institutionalize and create accountability for common goals and deliberate, results-driven, risk-based investment across the enterprise. Because the mission responsibilities and resources needed to develop a national biosurveillance capability are dispersed across a number of federal agencies, efforts could benefit from a focal point to provide sustained leadership that helps direct interagency efforts to invest in and implement new and existing programs in a way that ensures generation of meaningful data with the potential to discover emerging biological events with potentially catastrophic consequences.

Limitations

 Role conflict: Some of these responsibilities overlap with responsibilities that have historically been the purview of the National Security Council Staff, and legislative direction to assume these responsibilities could create more role conflict and confusion unless authority, roles, and responsibilities were very clearly designated. Authority and legitimacy: It may be difficult for an agency at NBIC's level to successfully influence decision making across the interagency. For example, discussions we had with some NBIS partners demonstrated that both DHS and NBIC have encountered and may continue to encounter issues with perceived legitimacy in the health security arena.

Option 3: Expand NBIC's Innovator Role

Under this option, NBIC would be provided with new authorities and resources to lead research and development investments of new tools and technology that would address gaps across the biosurveillance community. Responsibilities would include developing new analytical methods and IT systems, and seeking new sources of biosurveillance information, such as state, local, and private sources, including by developing new sources through systems like the National Collaborative for Bio-Preparedness. Efforts could be guided by the White House's *S&T Roadmap*, as well as other efforts to identify gaps in the national biosurveillance capability. For example, the *S&T Roadmap* identified 16 capability needs that are needed to strengthen biosurveillance, including those related to aberration detection; risk anticipation; threat identification and characterization; and information integration, analysis, and sharing. Potential benefits and limitations of this option include the following:

Benefits

- New tools and technology: NBIC could foster the development of tools and technology that benefit multiple federal partners and other members of the NBIS (e.g., state and local health agencies), thus enhancing the overall national biosurveillance capability. For example, the 2013 S&T Roadmap identified the need to strengthen detection by developing new modeling and ecological forecasting approaches that could enhance current ways of predicting disease outbreaks and determining likely impacts when a threat is detected. Specifically, this should be accomplished by developing methods that integrate traditional monitoring (i.e., pathogen, environmental, and health) with background data (i.e., meteorological and population dynamics).
- Coordinate research and development efforts: The S&T Roadmap notes that there are dozens, and possibly hundreds, of biosurveillance initiatives and pilot projects that have been implemented at local, state, regional, and national levels, NBIC would be well positioned to help coordinate and deconflict biosurveillance research and development across the interagency, which would help to avoid any unnecessary duplication, overlap, and fragmentation of effort. Further, the S&T Roadmap identifies 14 research priorities, many of which would benefit from coordination across the federal government, as

well as with state, local, and private entities. For example, one of the research priorities is to develop multilateral communication mechanisms among the various levels of government and the private sector to enable timely decision making. Effectively addressing such a research priority would likely require the collaboration of multiple federal and nonfederal partners, including HHS, USDA, and DHS, as well as healthcare providers and international partners, among others.

Limitations

- Increased costs: Although we have not specifically assessed the
 costs associated with the options, supporting the development of new
 tools and technology would likely exceed NBIC's current annual
 budget.
- More research and development expertise: Although NBIC has engaged in some pilot projects that develop tools and technology, a national integrator that focuses on innovation would likely need to acquire more expertise in research and development.
- **Significant restructuring:** In comparison with its other roles, NBIC's role as an Innovator is the least well defined in the 9/11 Commission Act, and NBIS partners noted that the center's current budget limits its ability to fulfill this role. Focusing attention on this role may represent a significant mission shift from the status quo, and may require very different sets of resources and procedures.

Option 4: Continue to Execute the 2012 NBIC Strategic Plan

In this option, NBIC would continue to implement the mission, goals, and objectives detailed in the August 2012 *NBIC Strategic Plan* or subsequent NBIS-approved updates. According to officials, NBIC is currently working on a mid-point review to assess progress made on meeting the goals described in the 2012 strategic plan and determine how best to accomplish priority activities and objectives by 2017, as identified by the NBIC Advisory Board and NBIC Interagency Working Group. Potential benefits and limitations of this option include the following:

Benefits

NBIC has made progress and may continue to do so: Although
most (10 of 19) federal partners stated that NBIC has limited impact
on their ability to carry out their biosurveillance roles and
responsibilities, 12 of 19 NBIS partners interviewed noted that NBIC
has made improvements in its products, outreach, coordination, and

other activities.²⁹ Further, in recent years, NBIC has been able to obtain or partially fund liaisons from other agencies. Establishing itself as a trusted and effective federal integrator with limited direct authority is a difficult task, and the center and its NBIS partners may merely need more time to evolve their roles and relationships to realize the full potential of the current NBIC as the federal biosurveillance integrator.

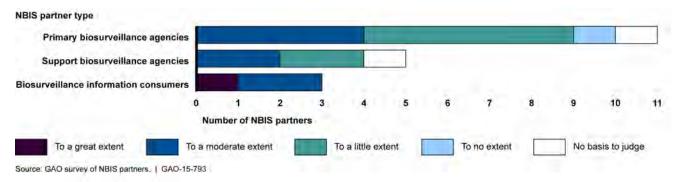
- Some agencies currently find value in NBIC's products: Agencies with more limited roles in biosurveillance, such as biosurveillance support agencies and information consumers, generally stated that they like NBIC's products because their own agencies do not have enough resources to review biosurveillance information across multiple agencies and domains. Further, NBIC officials noted that the center's products benefit some of their nonfederal stakeholders that have limited resources for biosurveillance, such as state, local, tribal, and territorial agencies. For example, as of July 2015, NBIC's daily Monitoring List e-mail is distributed to 338 individuals representing state, local, tribal, and territorial entities, including state departments of health and agriculture, fusion centers, and police departments.
- Data challenges: NBIC will likely continue to face challenges in obtaining all the biosurveillance data it needs to effectively apply statistical and analytical tools to identify and characterize biological events of national concern in as close to real time as practicable, per requirements in the 9/11 Commission Act.
- Partners remain skeptical of NBIC's value: NBIC has implemented our recommendation to create a strategy, in partnership with the NBIS agencies, that better defines its mission and focus on other collaborative practices. Nevertheless, NBIS partners remain skeptical of NBIC's value. As previously shown in figure 5, few of the NBIS partners (4 of 19) we interviewed stated that NBIC's products and activities enhanced their agency's ability to carry out their biosurveillance roles and responsibilities. Further, as illustrated in figure 8, 8 of 19 NBIS partners we interviewed stated that NBIC is achieving its mission to little or no extent. It is unclear whether additional time or what additional actions will improve partners'

Limitations

²⁹In our structured interviews, we did not specifically ask a question on the extent to which NBIC had improved its products, outreach, coordination, and other activities over time, so it is possible that officials from the other NBIS partners may have also agreed with this statement.

experience with NBIC's overall value to the national biosurveillance capability.

Figure 8: National Biosurveillance Integration System (NBIS) Partner Views on the Extent to Which the National Biosurveillance Integration Center (NBIC) Is Achieving Its Biosurveillance Integration Mission



Option 5: Repeal the NBIC Statute

In this option, national biosurveillance integration would not be pursued through NBIC. Consideration could be given to designating one of the other primary biosurveillance agencies as the federal biosurveillance integrator. Potential benefits and limitations of this option include the following:

Benefits

Cost savings: Given that most federal partners stated that they
integrate some biosurveillance information themselves and that NBIC
has limited impact on their ability to carry out their biosurveillance
roles and responsibilities, the cost of operating NBIC may not be
worth its benefits.

Limitations

Officials report that a federal integrator is important: Although
federal partners generally thought that NBIC's products and activities
did not provide meaningful new information, they largely thought that
the concept of having a federal entity to integrate biosurveillance
information across the federal government was important. Specifically,
in our structured interviews, 13 of the 19 NBIS partners stated that the
concept of having a federal entity whose mission is to serve as the

integrator of national biosurveillance information across agencies and disease domains is very or moderately important.³⁰

- Potential loss of investment: As previously noted, 13 of 19 NBIS partners stated that NBIC has made improvements in its products, outreach, coordination, and other activities. Defunding NBIC could create a loss of investment, institutional learning, and progress made toward developing a federal biosurveillance integrator, which may need more time to evolve to become effective.
- Another integrator may experience similar challenges: Even if
 one of the other primary biosurveillance agencies were designated as
 the federal biosurveillance integrator, that entity may still find it difficult
 to overcome organizational boundaries and engender agency
 cooperation, given that multiple agencies have key biosurveillance
 responsibilities.

Agency Comments

We provided a draft of this report for review and comment to DHS and the 13 other departments and agencies that compose the NBIS—the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior, Justice, State, Transportation, and Veterans Affairs, as well as EPA, ODNI, and USPS. DHS provided written comments on September 16, 2015, which are summarized below and presented in their entirety in appendix III of this report. DHS, EPA, USPS, and the Departments of Agriculture, Interior, Health and Human Services, and Veteran's Affairs provided technical comments, which we considered and incorporated, where appropriate. The ODNI and the Departments of Commerce, Defense, Energy, Justice, State, and Transportation did not comment.

DHS expressed appreciation for our recognition of its progress fulfilling our prior recommendations, which were designed to enhance interagency collaboration. DHS also acknowledged the array of challenges detailed in this report, and noted some actions it is undertaking to try to address them. DHS noted that the report does not include nonfederal biosurveillance stakeholders in its scope, and posits that these stakeholders may find value in NBIC's current products. Although we

³⁰Of the 13 NBIS partners that stated that the concept is very or moderately important, 7 were primary biosurveillance agencies, 4 were support biosurveillance agencies, and 2 were biosurveillance information consumers.

cannot comment on the extent to which these nonfederal stakeholders value NBIC's current products, we have previously reported on the important role that nonfederal partners in the biosurveillance enterprise, particularly because most of the resources necessary to generate biosurveillance information are outside of the federal government.³¹ The federal departments and agencies with primary biosurveillance roles, as outlined in this report, have a variety of relationships and agreements with nonfederal partners to facilitate partnership and information sharing. We note that NBIC's authorizing legislation calls for NBIC to work with state and local entities in coordination with, and through when possible, its federal partners and these existing relationships.

We are sending copies of this report to the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, the Interior, Justice, State, Transportation, and Veterans Affairs; the Environmental Protection Agency; the United States Postal Service; and the Office of the Director of National Intelligence. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report please contact me at (404) 679-1875 or curriec@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 key contributions to this product are listed in appendix IV.

Chris Currie

Director, Homeland Security and Justice

³¹ See GAO *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*; GAO-12-55 (Washington, D.C.: Oct 31, 2011).

List of Congressional Requesters

The Honorable Michael T. McCaul Chairman The Honorable Bennie G. Thompson Ranking Member Committee on Homeland Security House of Representatives

The Honorable Martha McSally
Chairman
The Honorable Donald M. Payne, Jr.
Ranking Member
Subcommittee on Emergency Preparedness, Response, and
Communications
Committee on Homeland Security
House of Representatives

The Honorable Susan W. Brooks House of Representatives

Appendix I: Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners

We surveyed and interviewed officials from 19 federal departments and their component agencies across 13 of the 14 departments and agencies that compose the National Biosurveillance Integration System (NBIS). We refer to these 19 agencies as NBIS-partner agencies, and we categorized these into three groups:

- <u>Primary biosurveillance agencies:</u> Have major biosurveillance mission responsibilities that include collecting or analyzing biosurveillance information for the purposes of detecting, monitoring, or responding to biological events.
- <u>Support biosurveillance agencies:</u> Do not have missions that directly involve disease detection and monitoring; however, they collect data and information or have subject matter expertise that may be useful to efforts to detect, monitor, or respond to biological events.
- Biosurveillance information consumers: Generally do not produce information that is useful for biosurveillance, but consume such information because biological events can affect their main mission and they may have a particular role to play in responding to an event.

We developed these categories based on each partner's roles and responsibilities related to biosurveillance. Table 3 includes brief summaries of the NBIS partners, including agency type, mission, domains, and biosurveillance responsibilities.²

¹The Office of the Director of National Intelligence (ODNI) is represented on the National Biosurveillance Integration Center (NBIC) Advisory Board, and is therefore considered by NBIC to be a member agency of the NBIS. However, officials from NBIC, ODNI, and the Department of Homeland Security's Office of Intelligence and Analysis (I&A) noted that NBIC's relationship with the intelligence community is currently conducted through I&A. According to NBIC officials, the center's relationship with ODNI is new and they have not yet established direct relationships with ODNI. Therefore, we did not include ODNI among the NBIS partners we interviewed and surveyed.

² The *NBIC Strategic Plan* specifically identifies the human, animal, plant, food, and environmental domains. However, because the 9/11 Commission Act states that NBIC is to receive and consider other relevant homeland security information, we also include homeland security as one of the domains. The Homeland Security Act of 2002, defines homeland security information as any information possessed by a federal, state, or local agency that—(a) relates to the threat of terrorist activity; (b) relates to the ability to prevent, interdict, or disrupt terrorist activity; (c) would improve the identification or investigation of a suspected terrorist or terrorist organization; or (d) would improve the response to a terrorist act. 6 U.S.C. §§ 195b(j)(3), 482(f)(1).

Table 3: Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners

Agency: Animal and Plant Health Inspection Service (APHIS)						
Department: U.S. Department of Agriculture						
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To safeguard the health, welfare and value of American agriculture and natural resources, which includes issues related to animal and plant health, wildlife damage and disease management, regulation of genetically engineered crops and animal welfare and protection of public health and safety as well as natural resources that are vulnerable to invasive pests and pathogens.					
Main biosurveillance domains: Animal health Plant health	Biosurveillance roles and responsibilities: APHIS is responsible for implementing and conducting national measures to detect, control, or eradicate certain livestock and poultry diseases (such as diagnostic testing), as well as safeguard U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant pests. APHIS is also responsible for emergency response to an economically devastating or highly contagious animal disease—for example, by determining the veterinary and other expertise needed to respond.					
Agency: Armed Forces Hea	alth Surveillance Center (AFHSC)					
Department: Department of D	` '					
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To provide timely, relevant, actionable, and comprehensive health surveillance information to promote, maintain, and enhance the health of military and military-associated populations.					
Main biosurveillance domains: Human health	Biosurveillance roles and responsibilities: AFHSC coordinates surveillance activities by tracking and monitoring the health of the U.S. uniformed services. AFHSC is the central source for DOD-level medical surveillance data, including current and historical data on diseases and medical events (e.g., hospitalizations, laboratory tests, and immunizations) throughout service members' military careers. According to agency officials, AFHSC also monitors the health of military and civilian populations around the world for diseases that could affect the U.S. military.					

Agency: Centers for Disease Control and Prevention (CDC)						
Department: Department of Health and Human Services						
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To protect America from health, safety, and security threats; fight disease and support communities and citizens to do the same; and increase the health security of the nation.					
Main biosurveillance domains: Human health Animal health Agency: U.S. Customs and						
Department: Department of I	Homeland Security					
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To safeguard America's borders thereby protecting the public from dangerous people and materials while enhancing the Nation's global economic competitiveness by enabling legitimate trade and travel.					
Main biosurveillance domains: Human health Animal health Plant health Homeland security	Biosurveillance roles and responsibilities: CBP provides frontline personnel and assets at ports of entry in both U.S. and foreign ports where CBP performs hands-on inspections to determine that imports are free of pests and humans are free of disease, according to agency officials. CBP interacts with other agencies in this function, for example enforcing Department of Agriculture regulations on plants and animals or referring sick passengers to the Centers for Disease Control and Prevention. CBP also screens for chemical, biological, radiological, nuclear, and explosives, and maintains an ongoing mechanism to assess threats.					
Department: Department o	f Energy (DOE)					
Type of biosurveillance agency: Biosurveillance information consumer	Mission: To ensure America's security and prosperity by addressing its energy, environmental, and nuclear challenges.					
Main biosurveillance domains: Human health	Biosurveillance roles and responsibilities: According to officials, DOE largely uses biosurveillance information for occupational health reasons. However, DOE's National Laboratories can provide subject matter expertise to biosurveillance partners on an as-needed basis.					

Department: Department of State (DOS)						
Type of biosurveillance agency: Biosurveillance information consumer	Mission: To shape and sustain a peaceful, prosperous, just, and democratic world and foster conditions for stability and progress for the benefit of the American people and people everywhere.					
Main biosurveillance domains: Human health	Biosurveillance roles and responsibilities: DOS collects information from its medical units abroad to support its health preparedness and response activities, rather than as an early warning function, according to officials. DOS's Office of International Health and Biodefense focuses on global health security, pandemic preparedness, and emerging issues, such as new outbreaks of disease and how science and technology affect medicine and public health. Agency officials noted that DOS generally plays a policy and facilitation role, not a programmatic role.					
Department: Department o	f Transportation (DOT)					
Type of biosurveillance agency: Biosurveillance information consumer	Mission: To ensure a fast, safe, efficient, accessible and convenient transportation system.					
Main biosurveillance domains: Human health	Biosurveillance roles and responsibilities: DOT is a consumer of biosurveillance information because biological events can affect the national transportation system, according to officials. DOT provides information and guidance to stakeholders—state officials, private industry, transportation workers, and the travelling public—regarding biological events and epidemics. In addition to providing guidance when requested, DOT also has responsibility for ensuring the safe transporting of biohazardous waste and the highest-level biological agents.					
Department: Department o	f Veterans Affairs (VA)					
Type of biosurveillance agency: Support biosurveillance agency	Mission: To serve America's Veterans as their principal advocate to ensure that they receive medical care, benefits, social support, and lasting memorials, and to promote the health, welfare, and dignity of all veterans in recognition of their service to this nation.					
Main biosurveillance domains: Human health	Biosurveillance roles and responsibilities: VA patient health data can contribute to biosurveillance efforts, according to officials. In the event of an emergency, VA also can play a role in response by, for example, providing health care to the public through its infrastructure, which includes 167 VA Medical Centers.					

Agency: Environmental Protection Agency (EPA)							
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To protect human health and the environment. EPA's purpose includes ensuring that all parts of society—communities; individuals; businesses; and state, local and tribal governments—have access to accurate information sufficient to effectively participate in managing human health and environmental risks.						
Main biosurveillance domains: Environmental safety and security	Biosurveillance roles and responsibilities: EPA is developing guidance materials and training to promote the water sector's adoption of contamination warning systems based on lessons learned from five EPA-funded pilot projects, according to officials. EPA also runs the nationwide RadNet system that monitors the nation's air, precipitation, and drinking water to track radiation in the environment.						
Agency: Federal Bureau of	Investigation (FBI)						
Department: Department of	Justice						
Type of biosurveillance agency: Support biosurveillance agency	Mission: To protect and defend the United States against terrorist and foreign intelligence threats; to uphold and enforce the criminal laws of the United States; and to provide leadership and criminal justice services to federal, state, municipal, and international agencies and partners.						
Main biosurveillance	Biosurveillance roles and responsibilities:						
domains: Homeland security	As a member of the intelligence community, the FBI gathers, shares, and analyzes intelligence information on threats to the United States, including those involving biological agents.						
Agency: U.S. Food and Dru	ug Administration (FDA)						
Department: Department of I	Health and Human Services (HHS)						
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.						
Main biosurveillance domains: Food safety and defense Human health	Biosurveillance roles and responsibilities: FDA monitors events related to FDA-regulated products, such as vaccines, medicine, medical devices, food, tobacco products, and animal feed, according to agency officials. FDA's role is to ensure that its regulated products are safe and effective, but also to understand emerging threats that may require FDA to take action. For example, FDA can work with industry partners to increase vaccine production if a particularly virulent strain of influenza begins to spread.						

Agency: Food Safety and Inspection Service (FSIS)							
Department: U.S. Department of Agriculture							
Type of biosurveillance	Mission:						
agency: Primary biosurveillance agency	To ensure that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged.						
Main biosurveillance	Biosurveillance roles and responsibilities:						
domains: Food safety and defense Human health	In collaboration with federal, state, local and territorial public health officials, FSIS conducts surveillance by monitoring foodborne incidents, initiating foodborne illness investigations, and responding to consumer complaints.						
Agency: National Center fo	or Medical Intelligence (NCMI)						
Department: Department of I							
Type of biosurveillance	Mission:						
agency: Primary biosurveillance agency	To lead DOD activity for the production of medical intelligence and prepare and coordinate integrated, all-source intelligence for the DOD, other government agencies, and international organizations on foreign health threats and other medical issues to protect U.S. interests worldwide.						
Main biosurveillance	Biosurveillance roles and responsibilities:						
domains: Homeland security	As a member of the intelligence community, the Defense Intelligence Agency's NCMI analyzes intelligence to identify biological threats originating from outside the United States for DOD, according to agency officials. The center also assesses the extent to which foreign countries are able to address these threats and the impact that these threats may have on foreign militaries.						
Agency: National Oceanic	and Atmospheric Administration (NOAA)						
Department: Department of	Commerce						
Type of biosurveillance	Mission:						
agency: Support biosurveillance agency	To understand and predict changes in climate, weather, oceans, and coasts; share that knowledge and information with others; and conserve and manage coastal and marine ecosystems and resources.						
Main biosurveillance	Biosurveillance roles and responsibilities:						
domains: Environmental safety and security	NOAA provides information that might be relevant for those involved in monitoring and detecting biological events, such as situational awareness of weather events, according to agency officials. Warm temperatures, drought conditions, hurricane landings, and other weather events monitored by NOAA can influence biological events. For example, NOAA is working with other federal agencies to use NOAA's technical expertise in developing weather forecast models to help other agencies develop models to predict dengue epidemics.						

Agency: Office of Emergency Management					
Department: Department of the Interior (DOI)					
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To, among other responsibilities, coordinate prevention, planning, response, and recovery programs and policies for all types of hazards and emergencies that affect federal lands, facilities, infrastructure, and resources, as well as Tribal lands and insular areas.				
Main biosurveillance domains: Human health Animal health	Biosurveillance roles and responsibilities: According to agency officials, DOI's Office of Emergency Management monitors wildlife health through the Fish and Wildlife Service and the National Park Service. The Fish and Wildlife Service performs disease tests of birds and hunter-captured animals in its refuges. The National Park Service monitors the health of human visitors to the national parks as well as wildlife that live in the parks.				
Agency: Office of Intellige	nce and Analysis (I&A)				
Department: Department of	Homeland Security (DHS)				
Type of biosurveillance agency: Support biosurveillance agency	Mission: To equip federal, state, local, and tribal governments and the private sector with the intelligence and information they need to keep the homeland safe, secure, and resilient.				
Main biosurveillance domains: Homeland security	Biosurveillance roles and responsibilities: As a member of the intelligence community, I&A reviews all source intelligence, including biosurveillance information, to identify threats to the U.S., according to agency officials. I&A analysts look for threats, including terrorist threats aimed at agriculture and chemical, biological, radiological, nuclear, and high explosives threats. I&A develops analysis and information for DHS senior leadership, federal, state, and local government officials, and private stakeholders.				

Agency: Office of the Assis	stant Secretary for Preparedness and Response (ASPR)
Department: Department of H	Health and Human Services (HHS)
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters.
Main biosurveillance domains: Human health Animal health	Biosurveillance roles and responsibilities: ASPR tracks public health incidents and all-hazard incidents that potentially affect human health, such as hurricanes, earthquakes, and zoonotic diseases, according to agency officials. HHS collects and integrates such data through an around-the-clock operations center and disseminates this data to stakeholders both inside and outside of HHS. In addition, ASPR maintains the U.S. International Health Regulation's National Focal Point, which coordinates public health information from other countries as well as international organizations like the World Health Organization.
Agency: United States Geo	logical Survey (USGS)
Department: Department of t	he Interior
Type of biosurveillance agency: Primary biosurveillance agency	Mission: To provide reliable scientific information to describe and understand the Earth; minimize loss of life and property from natural disasters; manage water, biological, energy, and mineral resources; and enhance and protect quality of life.
Main biosurveillance domains: Animal health Environmental safety and security	Biosurveillance roles and responsibilities: USGS maintains the National Wildlife Health Center, which identifies, controls, and prevents wildlife losses from diseases as well as conducts research to understand the impact of diseases on wildlife populations, and devises methods to more effectively manage these disease threats. In addition, USGS monitors the environment. For example, according to agency officials, USGS is currently studying naturally occurring anthrax in top soil and looking at environmental drivers, such as drought, that can expose more topsoil and in turn expose more naturally occurring anthrax spores that can infect both animals and people.

Appendix I: Biosurveillance Responsibilities of the National Biosurveillance Integration System Partners

Agency: United States Postal Service (USPS)						
Type of biosurveillance	Mission:					
agency:	To provide prompt, reliable, and efficient postal services to					
Support biosurveillance agency	all areas of the nation.					
Main biosurveillance domains:	Biosurveillance roles and responsibilities:					
	USPS screens collection mail using biohazard detection					
Homeland security	units located in mail-processing plants to detect the presence of anthrax, according to agency officials. The U.S. Postal Inspection Service, a law enforcement agency within USPS, responds to suspicious packages and powders.					

Source: GAO structured interviews with NBIS partners GAO analysis of agency documents. | GAO-15-793

Appendix II: Biosurveillance Agencies' Sources for Information that Enhances Situational Awareness of Biological Events

We conducted a Web-based survey of the 19 National Biosurveillance Integration System (NBIS) partners to identify the federal agencies from which they obtain information that contributes to their agency's situational awareness of biological events.

Because this was not a sample survey, it has no sampling errors. However, the practical difficulties of conducting any survey can introduce errors, commonly referred to as nonsampling errors. We took steps in developing the questionnaire, collecting the data, and analyzing them to minimize such nonsampling errors. We conducted pretests with 3 agencies to help ensure that the questions were clear and unbiased, and that the questionnaire did not place an undue burden on respondents. An independent reviewer within GAO also reviewed a draft of the questionnaire prior to its administration. We made appropriate revisions to the content and format of the survey questionnaire based on the pretests and independent review. The survey was administered on the Internet from March 25, 2013, to May 15, 2013. To increase the response rate, we followed up with emails and personal phone calls to the experts to encourage participation in our survey. We received responses from all 19 agencies in our population (100 percent response rate). Based on comments we received from two agencies, we also conducted two followup phone calls with officials at these agencies who responded to our survey to verify their answers to survey questions about the federal agencies from which their agency obtains information that contributes to their agency's situational awareness of biological events. We made appropriate changes to the responses recorded on these officials' questionnaires to reflect the clarifications made during these phone calls. When we analyzed the data, an independent analyst verified all programs. Because this was a Web-based survey, respondents entered their answers directly into the electronic questionnaire, eliminating the need to key data into a database, minimizing error.

In the survey, we asked each agency whether it obtains information from each of the other agencies in our population, as well as which types of information it obtains from them (perception-, comprehension-, or projection-related information). For the purposes of this report, we use the definition of situational awareness that the *NBIC Strategic Plan* uses in the articulation of its mission. The definition has its basis in the work of Mica Endsley, who described situational awareness as having three elements: (1) perception that a situation has occurred, (2) comprehension

Appendix II: Biosurveillance Agencies' Sources for Information that Enhances Situational Awareness of Biological Events

of the situation's meaning, and (3) projection of the event's likely course in the near future. 1 We performed a network analysis of these survey data, which is a quantitative and graphical technique for identifying the underlying patterns in a complex system of relationships among entities of interest. Figure 9 illustrates the agency sources from which the primary and support biosurveillance agencies in our survey obtain data that enhances their situational awareness of biological events. For example, officials from the Environmental Protection Agency (EPA) reported that their agency obtains information that enhances all three elements of situational awareness from seven agencies, including the Animal and Plant Health Inspection Service, Centers for Disease Control and Prevention, and National Biosurveillance Integration Center, among others. Further, EPA officials reported that they obtain information that enhances their comprehension and projection of biological events from the Department of the Interior's Office of Emergency Management and the National Center for Medical Intelligence.

¹The definition has its basis in the work of Mica Endsley, a former Chief Scientist of the U.S. Air Force who has written extensively on situational awareness. For example, see Mica Endsley, "Toward a Theory of Situational Awareness in Dynamic Systems," Human Factors: The Journal of the Human Factors and Ergonomics Society, (vol. 37, no. 1) 1995; and Mica Endsley and Debra G. Jones, *Designing for Situation Awareness: An Approach to User-Centered Design.* 2nd ed., (Boca Raton, FL) CRC Press, 2011.

Figure 9: Primary and Support Biosurveillance Agencies' Sources for Information that Enhances Situational Awareness

Select an agency from the left-hand column and read across to see the sources from which that agency reported obtaining information that enhances situational awareness of a biological event.

Depar	tment and agency ^a	4FHSC	APHIS	ASPA	889	So	00/0cm	A.	IB.	No.	SIS	DHSIE	Welc .	NCMI	NA PROPERTY.	Sosy	Sos	72
HHS	Centers for Disease Control and Prevention (CDC)				Δ		Δ					Δ				Δ	0	Δ
HHS	Food and Drug Administration (FDA)		1															
DOD	National Center for Medical Intelligence(NCMI)	0								8			0					
USDA	Animal and Plant Health Inspection Service (APHIS)							0	0		Δ		Δ	Δ		Δ		
HHS	Assistant Secretary for Preparedness and Response (ASPR)	Δ	0				Δ	8	Δ	Δ	0		8				Δ	
USDA	Food Safety and Inspection Service (FSIS)						Ų T											
DOC	National Oceanic and Atmospheric Administration (NOAA) ^b																	
	Environmental Protection Agency (EPA)						A							_				
DOJ	Federal Bureau of Investigation (FBI)																	
DOI	U.S. Geological Survey (USGS)							9	*						A			
DHS	U.S Customs and Border Protection (CBP)	0					4		8		Δ							
DOD	Armed Forces Health Surveillance Center (AFHSC)														*			0
DHS	Intelligence and Analysis (I&A)			-	-													
DOI	Office of Emergency Management (OEM)		Δ					0		Δ	Δ				0			0
	Veterans Affairs (VA)						9			Δ	Δ							
	U.S. Postal Service (USPS)							3										
-	Primary biosurveillence agency				Δ	Perce	eption ar	nd com	prehen	sion	D	ос	Departn	nent of (Comme	rce		
	Support biosurveillence agency Perception only—the identification of signals that a biological event might be occurring Comprehension only—the characterization and contextualization of the nature and scope of an emerging biological event				Comprehension and projection Perception, comprehension, and projection					DOI Department of Defense DOI Department of the Interior DOJ Department of Justice								
0																		
\$												Departm				100	a dans	
-	Projection only—the determination of how emerging and ongoing biological events are likely to progress			R								Departn U.S. De					vices	

Source: GAO survey of NBIS partners. | GAO-15-793

Notes:

In the online interactive version of figure 9, the size of the circle for an NBIS partner reflects the number of times other NBIS partners identified it as an information source used to enhance situational awareness of a biological event. For the version above in this appendix, NBIS partners are listed down the left-hand column in order of the greatest to the least number of times other NBIS partners identified the agency as an information source that enhances their situational awareness.

Appendix II: Biosurveillance Agencies' Sources for Information that Enhances Situational Awareness of Biological Events

^aAlthough we obtained information from each NBIS partner identifying the other NBIS partners from which they obtain information that contributes to their situational awareness, we did not collect similar information from NBIC. According to NBIC, the agency relies heavily on products from NBIS partners, such as written reports of partners' analysis of specific events.

^bWe did not collect information from NOAA that identified which NBIS partners that contribute to its situational awareness of a biological event because unlike the other support biosurveillance agencies, officials from NOAA stated that situational awareness and early warning of biological events is of little importance to their agency's primary mission. Officials noted that although their agency can provide information that may be useful to efforts to detect, monitor, or respond to biological events, they maintain situational awareness of biological events only to the extent that it impacts NOAA operations.

Appendix III: Comments from the Department of Homeland Security



September 16, 2015

Chris P. Currie Director, Homeland Security and Justice U.S. Government Accountability Office 441 G Street, NW Washington, DC 20548

Re: Draft Report GAO-15-793, "BIOSURVEILLANCE: Challenges and Options for the National Biosurveillance Integration Center"

Dear Mr. Currie:

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 (GAO) work in planning and conducting its review and issuing this report.

DHS is pleased that the report recognizes the improvements the National Biosurveillance Integration Center (NBIC) has made in fulfilling recommendations from GAO's prior report on biosurveillance. The report also acknowledges the value NBIC provides in its roles as an analyzer and coordinator for its stakeholders, particularly those with little capacity to conduct biosurveillance activities themselves. NBIC is committed to continuing to advance its capabilities that provide shared situational awareness and early warning to its partners and the Nation to combat evolving threats to homeland security.

It is important to note, however, that while the report surveyed NBIC's federal partners, it did not address a significant number of state, local, tribal, and territorial stakeholders that also have access to NBIC products and who form a critical constituency as outlined in NBIC's statutory authorization. DHS believes that NBIC's products provide these stakeholders significant value, especially given the current constrained fiscal environment.

We also noted the report identifies challenges that remain in acquiring access to information sources and which hinder NBIC from realizing its full mission as envisioned in the authorization language. To create more shared value for contributing agencies, NBIC is tackling these issues through:

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

- piloting new data sharing models with partners such as U.S. Department of Veterans Affairs:
- 2. developing new collaboration tools with the Department of Defense; and
- 3. strengthening its interagency liaison program.

DHS believes these types of initiatives will continue the advancements NBIC has made toward fulfilling its mission of shared situational awareness, early warning, and robust analysis.

While the report does not offer recommendations, it does provide options for lawmakers to consider. Given the evolving threats that our Nation faces, both manmade and natural, greater coordination among federal, state, local, tribal, and territorial partners is required. NBIC is uniquely situated within DHS to provide a fusion of human health, animal health, and environmental data to develop a more comprehensive picture of the threat landscape and ensure our Nation's decision-makers have timely, accurate, and actionable information.

NBIC's evolving capability necessitates that it continue developing its role as outlined in these options. As the report states, integration of information ultimately goes to NBIC's role as 'coordinator' with its partners. NBIC is expanding its work as an 'innovator' to create collaborative platforms for information technology sharing, common situational awareness, and governance. In response to feedback from NBIC's stakeholder survey, NBIC is strengthening its capability of 'analyzer' by investing in new tools to meet the expectations of NBIC partners. Many of these challenges are inherent in any initiative that is so dependent on interagency coordination and action.

Again, thank you for the opportunity to comment on this draft report. Technical comments were previously provided under separate cover. Please contact me if you have any questions. We look forward to working with you in the future.

Sincerely

m H. Crumpacker, CIA, CFE

Director

Departmental GAO-OIG Liaison Office

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contact	Chris Currie, (404) 679-1875 or curriec@gao.gov
Staff Acknowledgments	In addition to the contact named above, Kathryn Godfrey (Assistant Director), Andrew Brown, David Dornisch, Lorraine Ettaro, Eric Hauswirth, R. Denton Herring, Tracey King, Erin O'Brien, Lerone Reid, John Vocino, Brian Wanlass, and Christopher Yun made key contributions to this report.

GAO's Mission	The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.					
Obtaining Copies of GAO Reports and Testimony	The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (http://www.gao.gov). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to http://www.gao.gov and select "E-mail Updates."					
Order by Phone	The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, http://www.gao.gov/ordering.htm .					
	Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.					
	Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.					
Connect with GAO	Connect with GAO on Facebook, Flickr, Twitter, and YouTube. Subscribe to our RSS Feeds or E-mail Updates. Listen to our Podcasts and read The Watchblog. Visit GAO on the web at www.gao.gov.					
To Report Fraud,	Contact:					
Waste, and Abuse in Federal Programs	Website: http://www.gao.gov/fraudnet/fraudnet.htm E-mail: fraudnet@gao.gov Automated answering system: (800) 424-5454 or (202) 512-7470					
Congressional Relations	Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548					
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548					

