United States Government Accountability Office

Report to Congressional Addressees

June 2022

COVID-19

Pandemic Lessons Highlight Need for Public Health Situational Awareness Network

Accessible Version

GAO Highlights

COVID-19

PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK

Why GAO Did This Study

The COVID-19 pandemic has drawn attention to the urgent need for public health officials to access real-time information about emerging threats to enable them to make timely, responsive decisions. For over a decade, federal law has mandated that HHS improve the nation's situational awareness of these threats.

The most recent mandate, enacted in 2019, included a provision for GAO to report on HHS's efforts to implement these improvements. The CARES Act also included a provision for GAO to conduct monitoring and oversight of the federal response to the pandemic.

This report examines (1) the extent to which HHS has made progress toward implementing the requirements in the 2019 act; and (2) the challenges and lessons learned from COVID-19 that HHS could incorporate in planning for a situational awareness and biosurveillance network.

GAO reviewed HHS documentation, such as grants provided to states, technical and reporting standards, and adoption plans. It also analyzed documentation and compared it to requirements in the act.

In addition, GAO surveyed public health officials from 50 U.S. states, the District of Columbia, and five U.S. territories. Thirty-nine states, the District of Columbia and three U.S. territories (hereinafter collectively referred to as states) responded to the survey, for a response rate of 77 percent. GAO assessed these responses to identify COVID-19 challenges and

View GAO-22-104600. For more information, contact Jennifer R. Franks at (404) 679-1831 or franksj@gao.gov.

What GAO Found

Since 2006, multiple federal laws have mandated that the Department of Health and Human Services (HHS) take steps to improve the nation's situational awareness of threats related to public health emergencies, such as the COVID-19 pandemic. Specifically, HHS was required to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems. This network was to be used to facilitate early detection of and rapid response to potentially catastrophic infectious disease outbreaks.

More than 15 years after the law initially mandated it, the federal government does not yet have this needed situational awareness network capability. If this network had been available, it could have been used to provide vital information to better manage a timely COVID-19 response.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 reiterated the need for HHS to improve situational awareness capabilities. The following summarizes key requirements in the act and the extent to which HHS has implemented them as of March 2022.

Summary of statutory requirements related to the improvement of situational awareness for public health emergencies and the extent to which HHS has implemented them as of March 2022

Summary of requirements	Implementation status
Adopt technical and reporting standards.	Full
Provide grants to establish integrated systems.	Partial
Develop a plan for sharing and securing information.	N/A
Establish a near real-time electronic nationwide public health situational awareness and biosurveillance capability.	N/A
Facilitate coordination among relevant agencies.	N/A
Conduct a public meeting with experts in public health by December 21, 2019.	N/A
Utilize applicable interoperability standards and define minimal data elements.	N/A
Develop a strategy and implementation plan by December 24, 2020.	N/A
Conduct a review of the data and information transmitted by the network by June 24, 2021 and every 6 years thereafter.	N/A
Develop a budget plan by June 24, 2021, and on an annual basis thereafter.	N/A

Legend:
Full = Requirement is fully implemented; **Partial** = Requirement is partially implemented; **N/A** = Requirement is not implemented
Source: GAO analysis of The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and other related laws, and Department of Health and Human Services (HHS) data. | GAO-22-104600

The lack of significant progress in implementing the requirements in the act is due, in part, to the department failing to prioritize the requirements of the act and not establishing an appropriate management and governance structure. Such a structure would include a lead operational division with defined roles and responsibilities for implementation of statutory requirements, and an organization to provide oversight of these efforts. During GAO's review, HHS began drafting a work plan intended to address the requirements of the 2019 act. However, HHS has not provided a time frame for completing the work plan.

United States Government Accountability Office

lessons learned. Further, GAO interviewed representatives from eight public health organizations representing state and local levels, such as the National Governors Association and National Association of County and City Health Officials, as well as HHS officials.

What GAO Recommends

GAO is making 12 recommendations to HHS to prioritize the development of the public health situational awareness and biosurveillance network. Among these recommendations are that HHS should:

- designate a lead operational division for implementation of statutory requirements and clearly define its roles and responsibilities;

- identify the office responsible for overseeing the completion of the activities performed by the lead operational division and clearly define its roles and responsibilities;

- commit to a deadline for finalizing the work plan to implement the 2019 act requirements and ensure that the work plan is fully implemented;

- identify and document information-sharing challenges and lessons learned from the COVID-19 pandemic;

- share the lessons learned from the COVID-19 pandemic with relevant stakeholders, such as state, territorial, and local public health officials; and

- incorporate lessons learned from the COVID-19 pandemic into plans for implementing the situational awareness and biosurveillance network.

HHS concurred with 10 of the 12 recommendations. The department stated that the remaining two were under review. The two under review related to identifying the office responsible for overseeing the completion of the activities performed by the lead operational division and identifying and documenting information-sharing challenges and lessons learned from COVID-19.

COVID-19

Pandemic Lessons Highlight Need for Public Health Situational **Awareness Network: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network**

In January 2022, GAO designated HHS leadership and coordination of a range of public health emergencies as high risk. For more than a decade, GAO has reported on HHS's execution of its lead role in preparing for, and responding to, public health emergencies and have found persistent deficiencies in its ability to perform this role. Similarly, HHS has not provided the leadership necessary to carry out its required responsibilities in the 2019 act.

Public health entities experienced a variety of challenges and identified lessons learned from the COVID-19 pandemic that could better inform HHS in developing and implementing the public health situational awareness and biosurveillance network. Specifically, state survey respondents identified a number of information-sharing challenges that they experienced in the management of public health information. The following summarizes the top four challenges state survey respondents most often rated as challenging.

State Reported Challenges in Managing Public Health Information during COVID-19
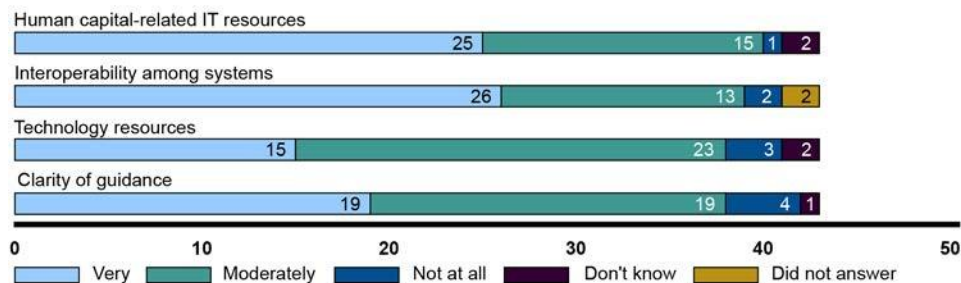
Source: GAO survey data. | GAO-22-104600

Additional challenges—limitations on data collected, increased reporting requirements, and impediments to health-related data sharing and collaboration—were identified by public health organizations at the national, state, and local levels. Thirty states identified lessons that HHS could use in planning for the network. The three lessons that states identified most often were

1) **improve public health reporting** by, for example, standardizing and sharing data among federal entities and states to improve surveillance needs;
2) **collaborate early with stakeholders** by, for example, involving state and local stakeholders throughout the entirety of emergency reponse activities; and
3) **establish a public health infrastructure to enable data sharing** by, for example, implementing the network required by the 2019 act.

After having over two years of experience in responding to COVID-19, HHS had not taken steps, as of March 2022, to identify, document, and share all of the challenges and lessons learned from the pandemic. These challenges and lessons could be incorporated into the planning and implementation of the public health situational awareness and biosurveillance network. Until HHS takes steps to identify, document, share, and incorporate lessons learned from the COVID-19 pandemic, opportunities to improve the response to future and ongoing public health emergencies by learning from past challenges will likely be missed.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
HHS	Department of Health and Human Services
OCIO	Office of the Chief Information Officer
ONC	Office of the National Coordinator for Health Information Technology
PAHPA	Pandemic and All-Hazards Preparedness Act
PAHPAIA	Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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June 23, 2022

Congressional Addressees

Catastrophic public health events—such as the COVID-19 pandemic—
can threaten our national security, weaken our economy, cause hundreds
of thousands of casualties, and damage public morale and confidence.
The pandemic drew attention to the urgent need for public health officials
to access real-time information about emerging threats to enable them to
make timely, responsive decisions.

Public health officials rely on information from a number of key sources to
create the situational awareness they need to prepare for and respond to
a variety of public health emergencies. This information includes critical
response resources, medical care capacity, environmental threats, and
the preparedness status of the many public health jurisdictions across the
country. In addition, public health officials need information about health-
related events from data collection and analysis conducted through
biosurveillance.[1] Biosurveillance supports early detection of disease
outbreaks, thus enabling more efficient and effective emergency
preparedness and response.

Since 2006, federal laws have mandated that the Department of Health
and Human Services (HHS) take steps toward improving the nation's
situational awareness of threats related to public health emergencies.[2]
Specifically, HHS was required to establish a near real-time electronic
nationwide public health situational awareness capability. This capability
was to be based on an interoperable network of systems to facilitate
sharing data and information to enhance early detection of and rapid
response to potentially catastrophic infectious disease outbreaks and
other public health emergencies. The nationwide public health situational

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[1]Biosurveillance is the process of gathering near real-time biological data that relates to
human and zoonotic disease activity and threats to human or animal health in order to
achieve early warning and identification of such health threats, early detection and prompt
ongoing tracking of health events, and overall situational awareness of disease activity.

[2]Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831
(2006); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No.
113-5, 127 Stat. 161 (2013); Pandemic and All-Hazards Preparedness and Advancing
Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019).

awareness network was to be built on existing state situational awareness systems or enhanced systems that enable such interoperability.

The most recent of these laws—the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA)—reiterated the need for HHS to improve situational awareness capabilities by establishing the near real-time electronic nationwide public health situational awareness capability, among other things.[3] PAHPAIA also includes a provision for GAO to report on HHS's efforts to implement the legal requirements.

In addition, the CARES Act includes a provision for us to report regularly on the federal response to the pandemic. Specifically, the act requires us to conduct monitoring and oversight of the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic.[4]

Our specific objectives for this review were to determine (1) the extent to which HHS has made progress toward establishing systems of public health communications and surveillance, and modernizing public health situational awareness and biosurveillance in accordance with the requirements in PAHPAIA; and (2) the challenges and lessons learned from the COVID-19 pandemic that states, territories, and HHS could incorporate in the planning and implementation of the public health situational awareness and biosurveillance network.

To address the first objective, we identified PAHPAIA requirements aimed at establishing systems of public health communications and surveillance, and modernizing public health situational awareness and biosurveillance. We then reviewed available HHS documentation, such as grants, contracts, and cooperative agreements provided by the department to states for the establishment of systems of public health alert communications and surveillance. We also reviewed HHS's technical and reporting standards for interoperability and the department's plans for the adoption of the standards. We compared these documents against the act's requirements we identified. Further, we reviewed HHS's draft work

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[3]Pub. L. No. 116-22, § 205(a)(4)(A), 133 Stat. at 919 (2019).

[4]Pub. L. No. 116-136, § 19010, 134 Stat. at 579–81. We regularly issue government-wide reports on the federal response to COVID-19. These reports are available on GAO's website at https://www.gao.gov/coronavirus.

plan and summarized the progress HHS had made, as of April 2022, in developing the plan.

We also interviewed relevant HHS officials in the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Chief Information Officer (OCIO), and the Centers for Disease Control and Prevention (CDC). We interviewed these officials to, among other things, discuss the actions the department had taken or planned to take to implement the legal requirements. We also conducted interviews with officials in the Office of the National Coordinator for Health Information Technology (ONC) to determine their actions to coordinate with ASPR and CDC to adopt technical and reporting standards for interoperability.

To address the second objective, we administered a web-based survey to a relevant public health official in each of the 50 states, the District of Columbia, and five U.S. territories (hereinafter collectively referred to as states).[5] The survey included questions that solicited state officials' views on any COVID-19 challenges they have faced and lessons they have learned that could inform HHS's work to develop and implement a nationwide public health situational awareness and biosurveillance network. Also included on the survey were questions related to state systems that support pandemic response. Further, the survey solicited state officials' views on HHS coordination and guidance that could help support states if a near real-time nationwide public health situational awareness and biosurveillance network was implemented, among other things.

We administered the survey from September 2021 through December 2021; therefore, the corresponding responses reflected information and views as of that time period. We received responses from 43 states, for a 77 percent response rate. We assessed the completed or partially completed responses to the survey questions received from 39 states, the District of Columbia, and three territories. See appendix I for a copy of the survey administered to states and the responses for each question.

To supplement the survey information we obtained from the states, we also interviewed representatives from selected national public health

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[5]The five U.S. territories are Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands. At times, the public health officials we administered the survey to forwarded the survey to other officials they felt were more appropriate to answer the questions. These officials included emergency preparedness and response and IT staff.

organizations that collectively represent state and local levels and have key roles in responding to public health emergencies. We also interviewed representatives from a selected state association. We used these interviews to identify common information management challenges and lessons learned from the COVID-19 pandemic among these organizations. The organizations we interviewed are the:

- Association of State and Territorial Health Officials,
- National Governors Association,
- Council of State and Territorial Epidemiologists,
- American Immunization Registry Association,
- National Rural Health Association,
- National Association of County and City Health Officials,
- National Community Pharmacists Association, and
- Community Health Care Association of New York State.

In addition, we interviewed relevant HHS officials at ASPR, OCIO, and CDC to discuss any efforts planned or underway to identify, document, and share challenges and lessons learned from the response to the COVID-19 pandemic. We compared these efforts against criteria we identified in a prior GAO report that defined best practices for developing and disseminating lessons learned for IT investments.[6] Lastly, we reviewed prior GAO reports, such as those issued as part of the CARES Act provision that requires us to regularly report on the federal response to the pandemic. We also reviewed relevant reports issued by the HHS Office of Inspector General. We reviewed these reports to summarize any lessons learned that we have previously identified. A full description of our objectives, scope, and methodology can be found in appendix II.

We conducted this performance audit from November 2020 to June 2022 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.

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[6]GAO, *Information Technology Investment Management: A Framework for Assessing and Improving Process Maturity,* Version 1.1, GAO-04-394G (Washington, D.C.: March 2004).

Background

Public health officials from 59 state and territorial health departments conduct a variety of public health functions in the United States and its territories.[7] These functions include disease detection, vaccine administration, and emergency preparedness and response. In addition, approximately 3,000 county, city, and tribal health departments; about 200,000 public and private clinical laboratories; and multiple federal agencies also conduct these functions.

Health care providers at the county, city, or tribal level are often the first to detect a potential public health concern or event. As such, these health care providers and local public health officials are expected to report certain events or symptoms of diseases to the state health department and other designated parties for situational awareness. In many cases, states may provide supporting personnel, financial resources, laboratory capacity, and other assistance to local responders when needed. When a public health event occurs that exceeds or is anticipated to exceed state, local, or tribal resources, like the COVID-19 pandemic, state governors may request that the federal government provide resources to assist the state in its response efforts.

For public health events involving primarily federal jurisdictions or authorities (e.g., military bases, federal facilities, or federal lands), federal departments and agencies may be the first responders and first line of defense in coordinating activities with state, local, and tribal partners. Along with HHS, several other federal agencies play a role in supporting public health functions, including the Departments of Agriculture, Homeland Security, Defense, and Veterans Affairs. Among these, HHS is the department with primary responsibility for supporting public health emergency preparedness and response through ASPR, which is to serve as the federal focal point for coordinating response support for public health and medical services. Figure 1 provides an illustration of the types of entities that have a role in sharing information to support nationwide public health situational awareness.

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[7]These health departments are in the 50 states, District of Columbia, and five U.S. territories. The remaining three health departments are in three freely associated states: the Marshall Islands, the Federated States of Micronesia, and Palau.

Figure 1: Illustration of the Types of Entities That Are to Share Information to Support Nationwide Public Health Situational Awareness
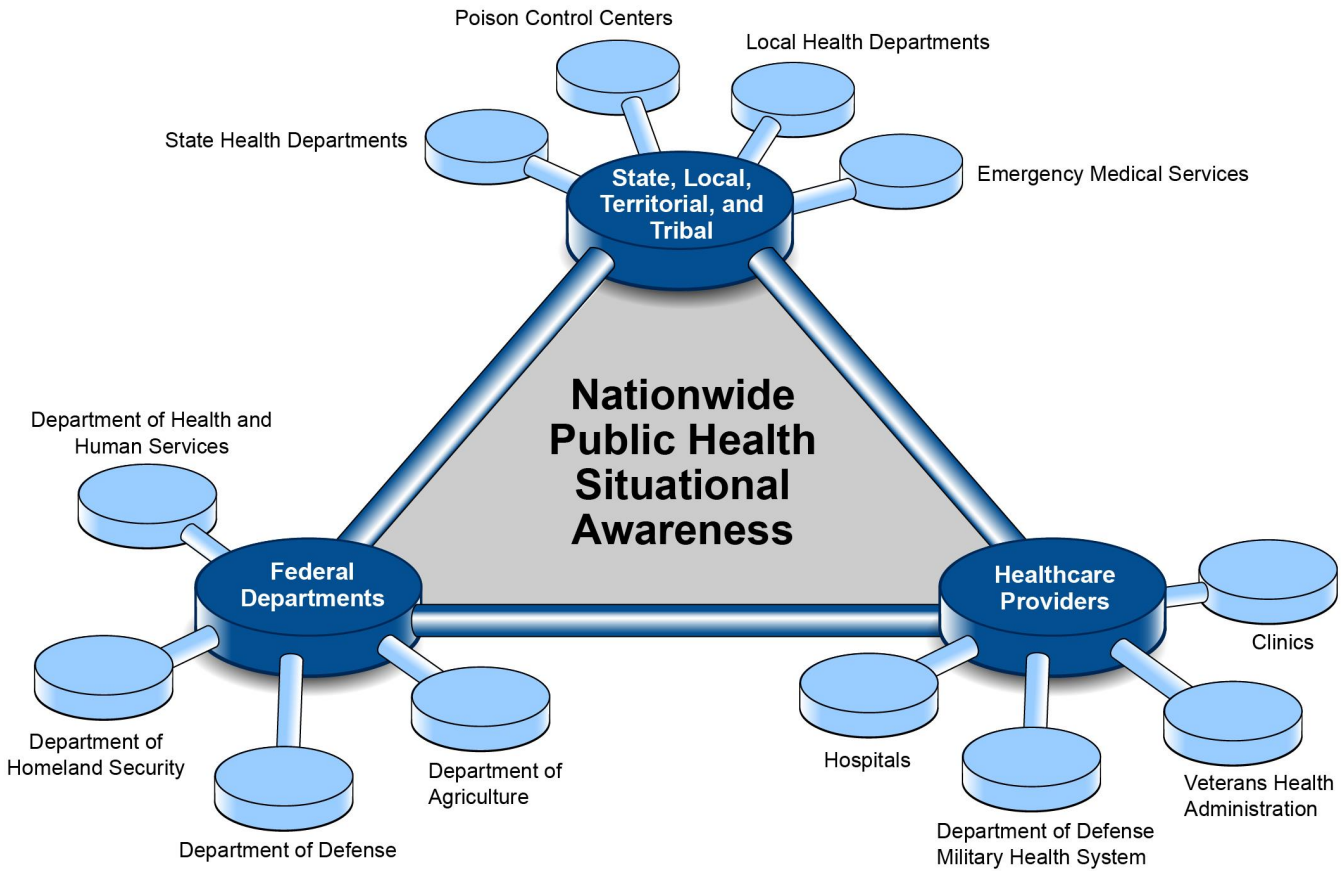
Source: GAO analysis of Department of Health and Human Services data. | GAO-22-104600

Because of the many entities involved, the identification and management of a public health emergency call for effective communication and collaboration across all levels of government and the public health community. In this regard, efficient information sharing among these entities is essential to create and maintain the situational awareness needed to effectively prepare for, respond to, and manage a public health emergency.

History of Congressional Efforts to Improve Public Health Situational Awareness and Biosurveillance

Congress has long recognized the importance of HHS's role in supporting the nation's ability to prepare for and respond to health emergencies through improved situational awareness and biosurveillance. In that regard, Congress and the President enacted three laws over the last 15 years that required HHS to improve the nation's public health situational awareness capability through an interoperable network of systems.[8] For example, the laws require improvements in early detection and rapid response to potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad.

Pandemic and All-Hazards Preparedness Act

In December 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) was enacted, and through provisions of the law, established the Office of ASPR in HHS.[9] Among other things, ASPR is to serve as the principal advisor to the Secretary of HHS on matters of public health and medical preparedness and response for public health emergencies. This official is also responsible for coordinating with state, local, tribal, and territorial officials to ensure effective management of federal public health and medical assets in the event of an emergency, among other duties. In addition, PAHPA established the National Biodefense Science Board.[10] This board is to provide expert advice and guidance to the Secretary on scientific, technical, and other matters regarding current and future chemical, biological, nuclear, and radiological agents.

Importantly, PAHPA required the Secretary of HHS to develop and submit a strategic plan to the appropriate committees of Congress by June 16, 2007. The strategic plan was to describe the steps the department would take to develop, implement, and evaluate an electronic network of

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[8]Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, 127 Stat. 161 (2013); Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019). The 2013 act added biosurveillance activities to the measurable steps that HHS was to include in the implementation plan required to develop the network.

[9]Pub. L. No. 109-417, § 102, 120 Stat. at 2832 (2006).

[10]Pub. L. No. 109-417, § 402, 120 Stat. at 2872 (2006), codified at 42 U.S.C. § 247d-7g.

interoperable systems. The network was to be made up of interoperable systems that would enable the simultaneous sharing of information needed to enhance situational awareness at the federal, state, local, and tribal levels of public health. The law required the department to establish such a network by December 19, 2008. The Secretary subsequently designated ASPR to be responsible for developing the public health situational awareness strategy.

However, in December 2010, we reported that the Secretary of HHS had not met the requirements set forth in PAHPA.[11] In particular, we found that the department had not developed a strategic plan for establishing the network, among other things.

Thus, we made three recommendations to the Secretary of HHS aimed at assisting the department in making progress to develop and implement a comprehensive strategic plan. Specifically, we recommended that the department develop a strategic plan that (1) defines goals, objectives, and priorities; (2) includes performance measures for evaluating capabilities of existing and planned information systems; and (3) integrates related strategies to achieve unified electronic public health situational awareness capabilities.

The department neither agreed nor disagreed with the recommendations but stated that a complete strategy for public health situational awareness would be developed and incorporated into other relevant strategies within two years. HHS subsequently implemented two of the three recommendations by 2015 by developing a strategic plan and implementation plan for the nationwide public health situational awareness network. HHS did not implement the third recommendation to identify within the strategic plan steps and performance measures for evaluating the capabilities of existing and planned information systems to establish the network.

Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

PAHPA was reauthorized by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). PAHPRA supports HHS in the awarding of grants, contracts, or cooperative agreements for

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[11]GAO, *Public Health Information Technology: Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities*, GAO-11-99 (Washington, D.C.: Dec. 17, 2010).

establishing integrated systems of public health alert communications and surveillance between public and private health-related entities.

In addition, the law reiterated the mandate for HHS to develop a strategy and implementation plan for establishing a near real-time nationwide public health situational awareness capability through an interoperable network of systems. The 2013 law added a requirement that HHS include in its strategy and implementation plan the measurable steps that the department will take to modernize and enhance biosurveillance activities. The strategy was to also identify actions for improving information sharing, coordination, and communication among disparate biosurveillance systems supported by HHS. PAHPRA required that the Secretary of HHS submit the strategy and implementation plan to the appropriate committees of Congress no later than September 9, 2013. The act required the nationwide public health situational awareness network to be established by March 13, 2015.

In May 2014, the Secretary of HHS submitted the *Public Health and Medical Situational Awareness Strategy* to Congress. The department later submitted the accompanying implementation plan in September 2015. In September 2017, we reported that the actions identified in the implementation plan did not address all of the activities required in PAHPRA.[12] We further reported that HHS did not define the measureable steps it would take to complete and track the status of activities required by the law.

We made three recommendations to HHS to (1) task an integrated project team with including within the implementation plan specific actions for conducting all activities required to establish and operate the network; (2) develop a project plan that includes measureable steps that can be used to guide and monitor HHS's actions to establish the network; and (3) conduct oversight of the establishment of the network under the leadership of the HHS CIO. HHS provided no comment on the report's findings or recommendations. All of the recommendations made in 2017 remained unaddressed as of March 2022.

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[12]GAO, *Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377 (Washington, D.C.: Sept. 6, 2017).

Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019

In June 2019, Congress and the President enacted the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). The act included statutory requirements for HHS related to supporting the establishment of systems of public health communications and surveillance. For example, PAHPAIA requires HHS to develop a plan to ensure that systems of public health communications and surveillance allow for the timely sharing and secure dissemination of essential information concerning bioterrorism or other public health emergencies.

The act further included statutory requirements for HHS related to modernizing public health situational awareness and biosurveillance. Notably, HHS was required to establish a near real-time nationwide public health situational awareness capability through an interoperable network of systems.

PAHPAIA also includes specific implementation dates for certain requirements. We discuss HHS's progress against these requirements later in this report. Specifically,

- **Conduct Public Meeting by December 21, 2019.** HHS was to conduct a public meeting for the purposes of discussing and providing input on the goals, functions, and uses of the public health situational awareness and biosurveillance network. The meeting was to include relevant federal agencies, as well as state, tribal, territorial, and local public health officials, and experts in the fields of informatics and data analytics, among others.

- **Adopt Technical and Reporting Standards by June 24, 2020.** HHS was to adopt technical and reporting standards—such as those for interoperability—for integrated systems of public health alert communications and surveillance. The department was to do so in cooperation with relevant federal agencies, including ONC and the National Institute for Science and Technology. As part of this requirement, HHS was to define minimal data elements for the network; collaborate with state, local, and tribal public health entities to integrate and build upon existing capabilities for data sharing; and develop procedures and standards for data collection.

- **Develop Strategy and Implementation Plan by December 24, 2020.** HHS was to develop and submit to appropriate congressional committees a coordinated strategy and implementation plan for

establishing the public health situational awareness and biosurveillance network.

- **Conduct Network Review by June 24, 2021 and every 6 years thereafter.** HHS was to conduct a review of the elements of the network, including elements added to advance new technologies that increase public health situational awareness. HHS was also to provide the results of the review to its congressional committees of jurisdiction. Further, the HHS Secretary was to submit a budget plan for the implementation of the network. The budget plan was to include (1) a summary of resources previously expended to establish, improve, and utilize the public health situational awareness and biosurveillance network; (2) estimates of costs and resources needed to establish the network; and (3) the identification of gaps in current capabilities.

In developing the network, the Secretary is required to consult with multiple entities. For example, the National Biodefense Science Board is to provide expert advice, including recommendations regarding the measurable steps the HHS Secretary should take to modernize and enhance biosurveillance activities. PAHPAIA also requires HHS to, on a periodic basis, meet with the Director of National Intelligence to inform on the development and capabilities of the network. Figure 2 provides an overview of the PAHPA, PAHPRA, and PAHPAIA requirement time frames and actual delivery dates.

Figure 2: Key Legislation on Public Health Situational Awareness and Biosurveillance and Health and Human Services (HHS) Delivered Requirements to Date

Pandemic and All-Hazards Preparedness Act	● **DECEMBER 19, 2006**
Strategy due to Congress - 180 days	**JUNE 16, 2007** ○
Network capability due - 2 years	**DECEMBER 19, 2008** ○
Pandemic and All-Hazards Preparedness Reauthorization Act	● **MARCH 13, 2013**
Strategy and implementation plan due to Congress - 180 days	**SEPTEMBER 9, 2013** ○
	● **MAY 2014** Strategy submitted to Congress
Network capability due - 2 years	**MARCH 13, 2015** ○
	● **SEPTEMBER 2015** Implementation Plan submitted to Congress
Pandemic and All-Hazards Preparedness and Advancing Innovation Act	● **JUNE 24, 2019**
Public meeting required – 180 days	**DECEMBER 21, 2019** ○
Adopt technical and reporting standards – 1 year	**JUNE 24, 2020** ○
Strategy and implementation plan due – 18 months	**DECEMBER 24, 2020** ○
Conduct review of the network capability – 2 years Budget plan due – 2 years	**JUNE 24, 2021** ○

● Effective date   ○ Due date   ● Actual delivery date

Source: GAO analysis of relevant legislation and Department of Health and Human Services data. | GAO-22-104600

Impact of COVID-19 on Public Health Situational Awareness

Beginning in December 2019, COVID-19 spread rapidly across the United States and other parts of the world.[13] Over time, the impacts of COVID-19 were widespread, including catastrophic loss of life and damage to the economy, security, and stability of the nation. In response, Congress and the President enacted the CARES Act, which among other things, directed GAO to conduct monitoring and oversight of the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic.[14] We are also to periodically report on, for example, the effect of the pandemic on public health and the economy.

In September 2020, we noted the need for federal, state, and local public health officials to have access to adequate, reliable, and real-time information about the virus to drive future decisions.[15] Access to valuable information in near-real time can allow officials to make more informed decisions about public health, safety, and resource allocation.

HHS launched the HHS Protect platform in April 2020 to help integrate COVID-19 data and other types of health information collected by various federal, state, and local public health and commercial entities. However, we reported that some public health and state organizations raised questions about the completeness and accuracy of some of the HHS Protect COVID-19 data that were intended to support the federal government's response to the pandemic.[16] We noted that as HHS further develops its platform, it would be important to consider prior challenges the department has faced in developing and implementing information technology systems and data-sharing networks among federal, state, and local public health entities.

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[13]The outbreak of COVID-19 was first reported on December 31, 2019, in Wuhan, China. In the weeks that followed, the virus quickly spread around the globe. On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency for the United States, retroactive to January 27. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic.

[14]Pub. L. No. 116-136, § 19010(b), 134 Stat. at 580 (2020).

[15]GAO, *COVID-19: Federal Efforts Could be Strengthened by Timely and Concerted Actions*, GAO-20-701 (Washington, D.C.: Sept. 21, 2020).

[16]GAO-20-701.

In January 2021, we reported on the need for more complete and consistent COVID-19 data to inform health care indicators.[17] We noted that the lack of complete and consistent data limited the ability to monitor trends in the pandemic and assess the impact of public health actions to prevent and mitigate the spread of COVID-19. Additionally, we noted that incomplete and inconsistent data had limited the ability to prioritize the allocation of health resources in specific geographic areas or among certain populations most affected by the pandemic.

We recommended, among other things, that HHS immediately establish an expert committee comprised of knowledgeable health care professionals from the public and private sectors, academia, and nonprofits to systematically review and inform the alignment of ongoing data collection and reporting standards for key health indicators. HHS partially agreed with our recommendation and stated that it plans to consider ways to establish more permanent work groups to incorporate best practices for ongoing interagency data needs and to scale up as necessary during future public health emergencies. However, we maintained that immediately establishing an expert committee—not limited to federal agency officials—is an important and worthwhile effort to help improve the federal government's response to COVID-19 and its preparedness for future pandemics. We continue to monitor HHS's progress in implementing this recommendation.

HHS Made Minimal Progress toward Establishing a Public Health Situational Awareness and Biosurveillance Network

As of March 2022, HHS had not fully implemented most of the statutory requirements related to supporting the establishment of systems of public health communications and surveillance. Further, HHS had not implemented any of the PAHPAIA requirements related to modernizing public health situational awareness and biosurveillance. Consequently, more than 15 years after the law initially mandated it, the federal government does not yet have an interoperable network of systems for

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[17]GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, GAO-21-265 (Washington, D.C.: Jan. 28, 2021).

near real-time public health situational awareness.[18] Had the network been available, it could have been used to provide vital information to public health officials to better manage a timely COVID-19 response.

HHS Made Partial Progress toward Fulfilling Public Health Communications and Surveillance Requirements

As of March 2022, HHS had taken action to fulfill some, but not all, of the statutory requirements related to supporting the establishment of systems of public health communications and surveillance. Specifically, HHS implemented the requirement to adopt technical and reporting standards, but did not fully implement the remaining requirements related to providing for the establishment of systems of public health communications and surveillance. Table 1 summarizes the statutory requirements related to supporting the establishment of systems of public health communications and surveillance and the extent to which HHS has implemented them.

Table 1: Statutory Requirements Related to Supporting the Establishment of Systems of Public Health Communications and Surveillance and the Extent to Which HHS Has Implemented Them as of March 2022

Summary of requirements	Implementation status
Provide for the establishment of systems of public health communications and surveillance	
Adopt technical and reporting standards, including standards for interoperability, for integrated systems of public health alert communications and surveillance, and update such standards as necessary.	**Full**
Provide grants, contracts, or cooperative agreements for establishing integrated systems of public health alert communications and surveillance.	**Partial**
Develop a plan to, and ensure that integrated systems of public health alert communications and surveillance allow for the timely sharing and secure discussion of essential information.	**N/A**

Legend:

Full = Requirement is fully implemented

Partial = Requirement is partially implemented

N/A = Requirement is not implemented

Source: GAO analysis of The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) and Department of Health and Human Services (HHS) data. I GAO-22-104600

Adopt technical and reporting standards. PAHPAIA requires that HHS adopt technical and reporting standards, including standards for

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[18]Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, 127 Stat. 161 (2013); Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019).

interoperability, for integrated systems of public health alert communications and surveillance, and update the standards as necessary.[19] To that end, ONC has adopted various standards to promote public health system interoperability and health information exchange. According to ONC officials, the standards are developed through a consensus-based process by nationally recognized standards development organizations. In 2017, ONC established the Interoperability Standards Advisory. The Advisory includes all of the standards and implementation specifications that can be used by the U.S. health care industry to address specific interoperability needs for clinical, public health, and research purposes.

To illustrate, in February 2020, ONC released the *United States Core Data for Interoperability*—a standardized set of data elements intended for nationwide, interoperable health information exchange. According to ONC officials, the standards included in the Interoperability Standards Advisory are frequently updated to include improvements made based on recommendations received from public comments and feedback from subject matter experts. Version 3 of *the United States Core Data for Interoperability* is planned for July 2022. Other interoperability standards ONC has adopted relate to patient allergic reaction, COVID-19 vaccination, and patient medication data, among other things.

Provide grants to establish integrated systems. PAHPAIA supports HHS in the awarding of grants, contracts, or cooperative agreements for establishing integrated systems of public health alert communications and surveillance between various entities. These entities include federal, state, and local public health entities. CDC, a component of HHS, has provided funding to states for the establishment of various public health alert communications and surveillance systems.

According to CDC officials, the agency invests in a broad range of public health data and surveillance systems and capabilities, many of which play a role in the surveillance of public health threats at the federal, state, and local levels. However, according to these officials, there is not a clear way to define and distinguish CDC grants, contracts, or cooperative agreements to provide for, as required by law, the establishment of integrated systems of public health communications and surveillance. CDC officials stated that the agency does not categorize its surveillance

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[19]According to the National Institute of Standards and Technology, interoperability is the ability of one entity to communicate with another entity, whether the entities are people, devices, or processes.

activities and funding lines with specific situational awareness and biosurveillance objectives.

According to CDC, the agency supports activities related to situational awareness and biosurveillance by investing in individual system-specific investments through other funding mechanisms.[20] However, the funding CDC provided for these systems was not contingent on them being integrated between public health entities, as required by PAHPAIA and other related laws. Table 2 shows examples of the funding that CDC has provided for various systems using funds appropriated for the last 2 fiscal years, as well as through the CARES Act to support public health communications and surveillance activities.[21]

Table 2: Examples of Public Health Communications and Surveillance Systems Funded by the Centers for Disease Control and Prevention (CDC)

	Fiscal year 2020	Fiscal year 2021[a]	CARES Act funding[b]
National Syndromic Surveillance Program[c]	$23,000,000	$23,000,000	$11,000,000
National Respiratory and Enteric Virus Surveillance System	$1,320,000	$400,000	$11,300,000[d]
Flu Vaccine Effectiveness Network	$7,600,000	$5,335,572	$10,149,551
COVID-19 – Associated Hospitalization Surveillance Network	$20,000,000	$5,600,000	Not applicable for this funding source
New Vaccine Surveillance Network	$5,999,994	$2,500,000	$11,900,000[e]
National Healthcare Safety Network	$21,000,000	$21,000,000	$17,505,379

Source: Department of Health and Human Services data. I GAO-22-104600

Note: For a description of these systems, see appendix III.

[a]Fiscal year 2021 column notes funds from fiscal year 2021 appropriations that are not funds appropriated by the CARES Act.

[b]CARES Act column shows funding that was appropriated through the CARES Act, which was separate from other appropriations in fiscal years 2021 and 2022.

[c]The National Syndromic Surveillance Program is supported by CDC's BioSense platform that allows for the analysis of public health data gathered from hospitals, urgent care facilities, and laboratories. This program also involves collaboration among federal, state, local, academic, and private partners who share and analyze data to identify and monitor health events.

[d]This amount represents broader funding to build a Pan-Respiratory Surveillance System for tracking and assessing multiple respiratory pathogens. The Pan-Respiratory Surveillance System is intended

[20]According to CDC officials, the other funding mechanisms include, for example, CARES Act funding.

[21]CDC officials stated that the six systems listed in the table are examples of systems that CDC has provided funding for regarding public health communications and surveillance activities.

to integrate existing CDC respiratory surveillance systems and modernize specific State Public Health Laboratory data messaging systems.

eThis amount represents broader funding to electronically incorporate vaccine information from the immunization information systems into the integrated disease surveillance system, and support enhancement of a centralized hub for the exchange of vaccine and immunity data with state, tribal, local, and territorial immunization information systems.

Develop a plan for sharing and securing information. PAHPAIA requires that HHS develop a plan to ensure that integrated systems of public health alert communications and surveillance allow for the timely sharing and secure discussion of essential information among federal, state, and local health entities. However, HHS had not taken steps to develop such a plan.

HHS Took No Actions to Fulfill PAHPAIA Modernization Requirements

As of March 2022, HHS had not taken any action to fulfill the requirements in PAHPAIA related to modernizing public health situational awareness and biosurveillance, including those mandating that HHS plan for the public health situational awareness and biosurveillance network. Table 3 summarizes the PAHPAIA requirements related to modernizing public health situational awareness and biosurveillance and the extent to which HHS has implemented them.

Table 3: PAHPAIA Requirements Related to Modernizing Public Health Situational Awareness and Biosurveillance and the Extent to Which HHS Has Implemented Them as of March 2022

Summary of requirements	Implementation status
Modernize public health situational awareness and biosurveillance	
Establish a near real-time electronic nationwide public health situational awareness and biosurveillance capability through an interoperable network of systems to share data and information.	N/A
Facilitate coordination among relevant agencies and consult with the Secretaries of Agriculture, Commerce (and the Director of the National Institute of Standards and Technology), Defense, Homeland Security, Veterans Affairs, and the heads of other Federal agencies, as appropriate.	N/A
Conduct a public meeting with experts in public health, biosurveillance, and situational awareness by **December 21, 2019** to discuss and provide input on the potential goals, functions, uses, and elements of a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems.	N/A
In establishing and operating a public health situational awareness and biosurveillance network, utilize applicable interoperability standards; define minimal data elements; integrate and build upon existing state, local, and tribal capabilities; and develop procedures and standards for the collection, analysis, and interpretation of data, among other things.	N/A

Summary of requirements	Implementation status
Submit to Congress a coordinated strategy and implementation plan by **December 24, 2020** that includes a review and assessment of existing capabilities; measurable steps the department will carry out to develop and implement the network; and performance measures and target implementation dates for each measurable step.	**N/A**
Conduct a review of the data and information transmitted by the network by **June 24, 2021 and every 6 years thereafter**. The review is to include a discussion of any additional data sources and any challenges in the incorporation of standardized data from various sources.	**N/A**
Develop a budget plan by **June 24, 2021**, and on an annual basis thereafter, that includes resources previously expended to establish, improve, and utilize the public health situational awareness and biosurveillance network; estimates of costs and resources needed to establish the network; and the identification of gaps in current capabilities.	**N/A**
Consult with the National Biodefense Science Board in carrying out the requirements for the network. The board is to identify the steps needed to achieve a national biosurveillance system for human health, and identify any duplicative surveillance programs and gaps in the programs, among other things.	**N/A**
Periodically meet with the Director of National Intelligence to inform the development and capabilities of the public health situational awareness and biosurveillance network.	**N/A**

Legend:

Full = Requirement is fully implemented

Partial = Requirement is partially implemented

N/A = Requirement is not implemented

Source: GAO analysis of The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) and Department of Health and Human Services (HHS) data. I GAO-22-104600

In particular, HHS did not meet the four requirements that had specific delivery dates. For example, HHS was required to conduct a public meeting with stakeholders and experts on the potential goals and uses of a nationwide public health situational awareness and biosurveillance network by December 21, 2019. As of March 2022, HHS had not conducted the meeting. In another example, HHS was required to submit to Congress a coordinated strategy and implementation plan by December 24, 2020 that discussed the functions of the network, among other things. HHS had developed a strategy in 2014 and an implementation plan in 2015 in response to PAHPRA—the predecessor to PAHPAIA. However, ASPR officials stated in May 2021 that those plans were no longer valid. As of March 2022 and over a year after they were due to Congress, HHS had not developed a new strategy and implementation plan. Further, HHS had not defined how it would use applicable interoperability standards when establishing and operating the public health situational awareness and biosurveillance network.

It is important for HHS to define how new or existing standards for interoperability will be used for the network because many states reported that they are planning to modernize their systems. Specifically, 33 of 43 states responding to the survey reported that they planned on modernizing their systems that support public health situational

awareness and biosurveillance activities. The states noted that their modernization plans include the capability to interface with federal and other state systems to share data for common reporting or analysis to effectively respond to pandemics. As many states prepare for system modernization, a federal plan that demonstrates how new or existing standards for interoperability will be used for the network once implemented would better prepare states for future needs.

HHS officials stated that while the various implemented medical and public health surveillance systems may not yet be the fully integrated capability that PAHPAIA requires, the process of creating an interoperable, real-time system is iterative. For example, CDC stated that the Data Modernization Initiative and HHS Protect are examples of efforts that had been initiated. CDC believes that these efforts at least partially satisfy the requirement to establish a near real-time electronic nationwide public health situational awareness and biosurveillance network. The officials added that HHS Protect aimed to integrate health information collected by different entities to support the COVID-19 response. They further added that the systems implemented for COVID-19 could be used for a broader scope if budgeted.

We agree that HHS has implemented several systems related to public health situational awareness and biosurveillance, as discussed in appendix III. However, the law called for a near real-time electronic nationwide public health situational awareness and biosurveillance capability through an interoperable network of systems to share data and information. This capability was to be made up of interoperable systems that would enable the simultaneous sharing of information needed to enhance situational awareness at the federal, state, local, and tribal levels of public health. This capability does not exist today.

The Lack of a Management and Governance Structure for Oversight of PAHPAIA Implementation Has Hindered Progress

The minimal progress in establishing systems of public health communications and surveillance and modernizing public health situational awareness and biosurveillance is due, in part, to HHS not prioritizing the development and implementation of the network. To demonstrate, HHS had not established a management and governance structure. Specifically, HHS did not have a lead operational division with defined roles and responsibilities, or an organization to provide oversight

of the implementation of the activities required by PAHPAIA and other related laws. According to CDC officials, ASPR facilitates the coordination and strategy for medical situational awareness activities, and shares responsibility with HHS OCIO, CDC, and other agencies for the implementation of those capabilities. However, HHS officials were often unsure who was responsible for answering specific questions we asked related to the progress they had made in meeting the requirements in PAHPAIA and other related laws—indicative of the lack of clear roles and responsibilities.

We have previously reported that clear roles and responsibilities during a pandemic have been a longstanding concern.[22] For more than a decade, we have reported on HHS's execution of its lead role in preparing for, and responding to, a range of public health emergencies and have found persistent deficiencies in its ability to perform this role. These deficiencies have hindered the nation's response to the current COVID-19 pandemic and a variety of past threats, including other infectious diseases—such as the H1N1 influenza pandemic, Zika, and Ebola—and extreme weather events, such as hurricanes. We have also reported that lessons from the initial COVID-19 response, as well as experience from past economic crises, disasters, and emergencies highlight the importance of having clear goals and defining roles and responsibilities among those responding to a crises.[23]

We have also reported that federal leadership roles and responsibilities, including those at HHS, need to be robust and rigorously tested as they evolve to ensure clarity in how relationships should work during emergencies. In January 2022, we added HHS's leadership and coordination of a range of public health emergencies to our High-Risk List to help ensure sustained executive branch and Congressional attention

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[22]GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies,* GAO-22-105291 (Washington, D.C.: Jan. 27, 2022).

[23]GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts,* GAO-20-625 (Washington, D.C.: June 25, 2020).

so that our nation is adequately prepared for future threats.[24] Without a management and governance structure, including defined roles and responsibilities, to oversee the activities required by PAHPAIA and other related laws, HHS and the federal government will continue to lack the comprehensive capabilities needed to allow for the timely and secure sharing of information to detect, manage, and respond to infectious disease outbreaks like COVID-19.

During our review, ASPR, CDC, and the OCIO began drafting a work plan that is intended to address PAHPAIA requirements. At the time of our review, ASPR did not have a time frame for completing and finalizing the work plan.

The draft work plan includes proposed roles and responsibilities for the governing and decision-making body, federal lead entity, and participating entities— including federal departments and agencies—for the public health situational awareness and biosurveillance network. According to HHS officials, the work plan will include an update of the 2014 strategy and 2015 implementation plan. They added that the work plan will also include measurable steps, a timeline of tasks, resource requirements, estimated costs, and performance metrics to guide and monitor HHS's actions to establish the public health situational awareness and biosurveillance network. Officials further stated that ASPR has recently hired a Chief Health Informatics Officer responsible for managing and coordinating health informatics strategies, and will focus on improving interoperability and innovation for ASPR.

Until HHS finalizes and implements the work plan, it will continue to lack any significant progress in implementing the various statutory requirements enacted over the last 15 years, including the establishment of a public health situational awareness and biosurveillance network.

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[24]GAO-22-105291. We designate federal programs and operations as "high risk" due to their vulnerabilities to fraud, waste, abuse, and mismanagement, or because they need transformation. We consider qualitative factors, such as whether the risk involves public health or safety. For information on how we determine which federal government programs and functions should be designated high risk, see GAO, *Determining Performance and Accountability Challenges and High Risks,* GAO-01-159SP (Washington, D.C.: November 2000). For more information on programs and operations on our High-Risk List, see https://www.gao.gov/high-risk-list.

Public Health Entities Identified Challenges and Lessons Learned from COVID-19 that Could Help HHS Establish a Situational Awareness Network

States and public health organizations experienced a variety of challenges and identified lessons learned from the COVID-19 pandemic that could be incorporated in the planning and implementation of a public health situational awareness and biosurveillance network. Specifically, states most often reported that the lack of human capital-related IT resources, interoperability among systems, technology resources, and clarity of guidance from the federal government were their top challenges related to the management of public health information during the pandemic. Public health organizations identified additional challenges, such as limitations on data collected, increased reporting requirements, and impediments to health-related data sharing and collaboration.

Furthermore, states and public health organizations identified lessons learned related to improving public health reporting, collaborating early with stakeholders, establishing a public health infrastructure, establishing a data management framework, and investing in an IT health-related workforce. However, as of March 2022, HHS had not identified, documented, shared, and incorporated its challenges or lessons learned from the COVID-19 pandemic into the planning and implementation of the public health situational awareness and biosurveillance network.
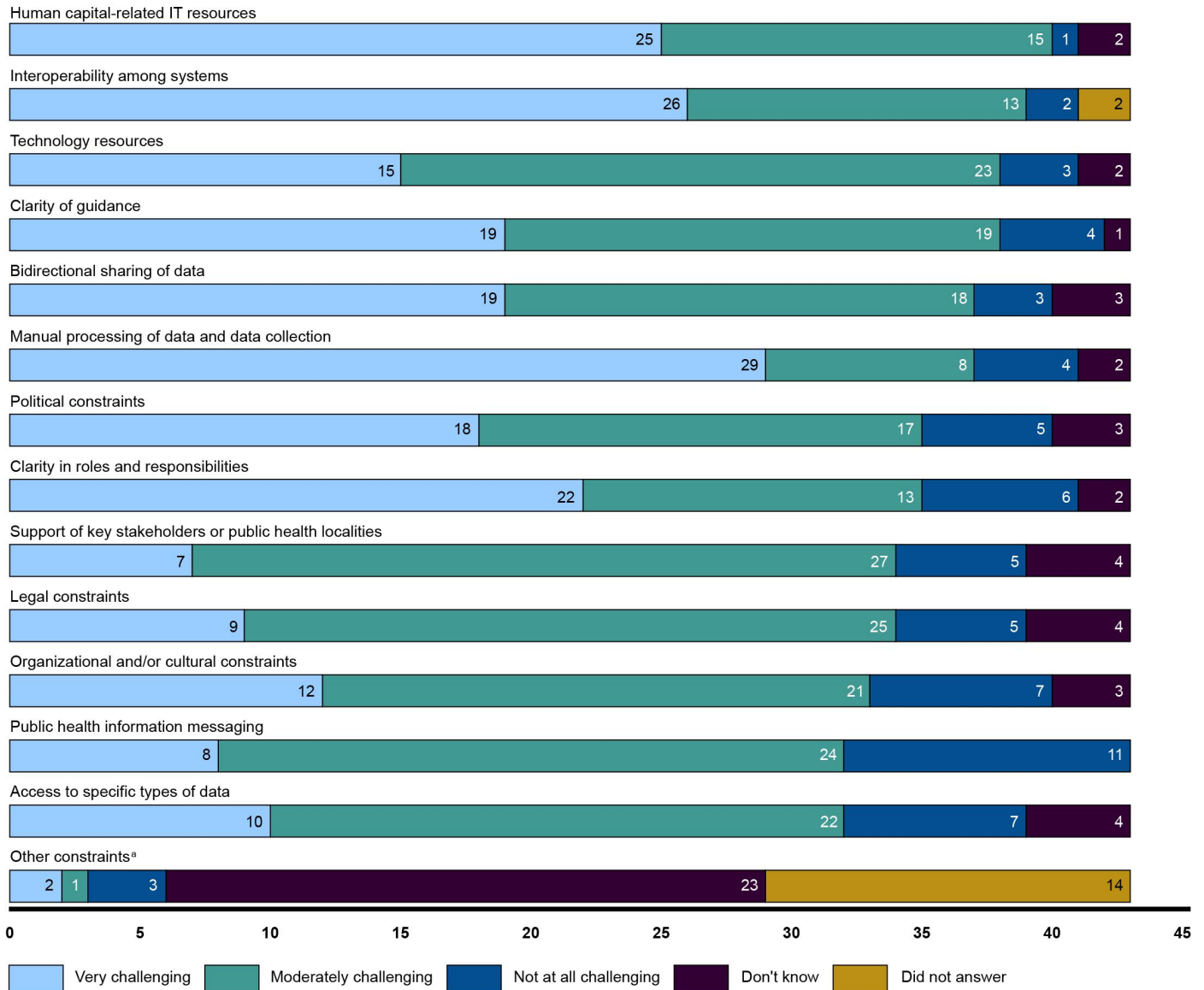
States Identified Challenges in Responding to COVID-19

States responding to our survey identified a number of challenges that they experienced in the management of public health information during the pandemic.[25] States varied in their views on the extent of each challenge. Figure 3 provides the views of the states for each reported challenge.

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[25]We administered a web-based survey to public health officials within the 50 states, the District of Columbia, and five U.S. territories. The territories are Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands. At times, the public health officials we administered the survey to forwarded the survey to other officials they felt were more appropriate to answer the questions. These officials included emergency preparedness and response and IT staff.

Figure 3: State Views of Challenges in the Management of Public Health Information during the COVID-19 Pandemic

Identified challenges

Challenge	Very challenging	Moderately challenging	Not at all challenging	Don't know	Did not answer
Human capital-related IT resources	25	15	1	2	
Interoperability among systems	26	13	2		2
Technology resources	15	23	3	2	
Clarity of guidance	19	19	4	1	
Bidirectional sharing of data	19	18	3	3	
Manual processing of data and data collection	29	8	4	2	
Political constraints	18	17	5	3	
Clarity in roles and responsibilities	22	13	6	2	
Support of key stakeholders or public health localities	7	27	5	4	
Legal constraints	9	25	5	4	
Organizational and/or cultural constraints	12	21	7	3	
Public health information messaging	8	24	11		
Access to specific types of data	10	22	7	4	
Other constraints[a]	2	1	3	23	14

Legend: Very challenging · Moderately challenging · Not at all challenging · Don't know · Did not answer

Source: GAO survey data. | GAO-22-104600

[a]Other constraints include managing communications in light of complex information resources and addressing an abundance of misinformation regarding pandemic response.

Challenge	Very challenging	Moderately challenging	Not at all challenging	Don't know
Human capital-related IT resources	25	15	1	2
Interoperability among systems	26	13	2	0
Technology resources	15	23	3	2
Clarity of guidance	19	19	4	1
Bidirectional sharing of data	19	18	3	3
Manual processing of data and data collection	29	8	4	2
Political constraints	18	17	5	3
Clarity in roles and responsibilities	22	13	6	2
Support of key stakeholders or public health localities	7	27	5	4
Legal constraints	9	25	5	4
Organizational and/or cultural constraints	12	21	7	3
Public health information messaging	8	24	11	0
Access to specific types of data	10	22	7	4
Other constraints	2	1	3	23

The following summarizes the challenges state survey respondents most often rated as challenging with regard to the management of public health information during the COVID-19 pandemic. In addition, representatives from public health organizations identified similar challenges.

- **Human capital-related IT resources.** Forty of 43 states rated human capital-related IT resources as challenging during the pandemic.[26] For example, one state reported that there were not enough trained IT staff across the state to support various public health IT initiatives due to funding and hiring limitations. Another state lacked staff with experience in public health and informatics to support needed improvements in electronic laboratory and case reporting. Additionally, representatives from a public health organization reiterated that a lack of human capital-related IT resources was a challenge. Specifically, the representatives stated that they have had difficulty in recruiting people with the right skill sets to manage health IT systems because of limited compensation and competition for similar skills within the federal and private sectors.

- **Interoperability among systems.** Thirty-nine of 41 states rated interoperability among systems as challenging. For example, in

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[26]Examples of human capital-related IT resources include inadequate staffing, training, and technical competence.

describing the challenge, one state noted that interoperability between its immunization information system and its surveillance system has yet to be achieved. Another state reported that because of the lack of interoperability among its health department systems, public health officials and stakeholders (e.g., hospitals, vaccination partners, and other state agencies) are required to manually input data into different systems.

Additionally, representatives from public health organizations stated that interoperability was also a challenge. The representatives reported difficulty in sharing data between states due to disparate, legacy systems, such as immunization information systems, that are not interoperable and in urgent need of an upgrade. The public health organization representatives also stated that many local health departments had to report data manually because their systems lacked interoperability. In contrast, laboratory and hospital emergency room data were more automated and complete based on systems and reporting processes already in place prior to the pandemic.

- **Technology resources.** Thirty-eight of 43 states rated technology resources as challenging. For example, one state described that its existing technologies and infrastructure were inadequate to address the response demands brought on by the pandemic. More specifically, this state noted that its disease surveillance system could only handle an average of a hundred concurrent users at any given time. As a result, the state had to rapidly adapt to handle the exponential increase in electronic laboratory reports by making system enhancements and increasing data storage and processing capabilities. Another state described the lengthy time frames and high costs for procuring vendors as a challenge when significant enhancements to health IT systems are needed quickly.

  Additionally, a report from a public health organization estimated that it would take approximately $7.8 billion over 5 years to modernize state, territorial, local, and tribal public health data, including modernizing public health systems. According to representatives from this organization, the state and local public health data infrastructure is severely underfunded, fractured, and outdated. The representatives also stated that the investments made as part of the Data Modernization Initiative at CDC was a positive step—$50 million in fiscal year 2020, $50 million in fiscal year 2021, $500 million in the CARES Act, and approximately $300 million in the American Rescue

Plan Act of 2021.[27] However, the representatives added that additional funding is needed at the state, local, tribal, and territorial levels to fully modernize a public health infrastructure, and to attract and retain a supporting workforce.

- **Clarity of guidance.** Thirty-eight of 43 states rated clarity of guidance also as challenging. For example, several states noted that federal guidance changed multiple times over the course of the early stages of the pandemic. Another state noted that in the initial stages of the COVID-19 pandemic, guidance from CDC, the White House, and HHS concerning personal protective equipment levels, effective treatment options, and masking were not always clear and easily understood, which led to confusion. Additionally, a representative from a public health organization agreed that this was a challenge and stated that guidance from HHS on data standards was needed to support states' efforts to build their technological infrastructure and provide for system interoperability.

Public Health Organizations Identified Challenges in Responding to COVID-19

Representatives from public health organizations identified similar challenges that the states faced during the COVID-19 pandemic response.[28] In addition, representatives from these organizations identified other common challenges. The following summarizes these challenges.

- **Limitations on data collected.** Representatives reported challenges with collecting complete demographic data for use in identifying trends

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[27]Launched in 2020, CDC's Data Modernization Initiative is a multi-year effort to modernize core data and surveillance infrastructure across the federal and state public health landscape. Section 2404 of the American Rescue Plan Act of 2021, Pub. L. No. 117-2, § 2404, 135 Stat. 4, 42 (2021) provides $500 million to CDC, available until expended, for activities to support public health data surveillance and analytics infrastructure modernization initiatives.

[28]We interviewed representatives from selected public health organizations at the national, state, and local level that have key roles in responding to public health emergencies. These organizations were the Association of State and Territorial Health Officials, National Governors Association, Council of State and Territorial Epidemiologists, American Immunization Registry Association, National Rural Health Association, National Association of County and City Health Officials, National Community Pharmacists Association, and Community Health Care Association of New York State.

in COVID-19 vaccinations and the number of COVID-19 vaccine doses administered. Similar challenges were experienced in a prior public health emergency. For example, we reported in January 2021 that due to variations in states' immunization tracking systems and capabilities, limited information was available nationally on the number of H1N1 vaccine doses administered.[29] We further reported that according to a state immunization official, just one-quarter of states required patient-level reporting on H1N1 vaccine administration to state registries.

- **Increased reporting requirements.** Representatives described difficulty in managing the increasing demand for reporting health data to relevant authorities. Specifically, they stated that it was difficult for state and local health officials to manage the increase in the information that was expected to be reported to governors, legislators, health officials, and to the federal government during the rollout of COVID-19 vaccines by new providers and partners (e.g., medical clinics, hospitals, and pharmacies) to address the pandemic.

- **Impediments to health-related data sharing and collaboration.** Representatives stated that data sharing and collaboration is challenging because states and local jurisdictions have separate vaccination management systems and have limited visibility into other states' data and no visibility into vaccination data at the federal level. The representatives further added that they were not aware of the HHS Protect system and wished it had been promoted more as a tool states could use. Other representatives noted that improved collaboration is needed with external entities to better understand how rural health facilities are managed and how state and local public health entities coordinate with them.

States and Public Health Organizations Identified Lessons Learned That HHS Could Use in Planning for the Network

Thirty of 43 states noted that they had identified lessons learned from the COVID-19 pandemic related to the management of public health information. The following summarizes three lessons learned that states

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[29]GAO-21-265. In the spring of 2009, H1N1, a novel influenza A virus emerged and was detected first in the United States. Subsequently, this virus spread quickly across the United States and the world.

identified most often. In addition, representatives from public health organizations also identified similar lessons learned.

- **Improve public health reporting.** Sixteen of 30 states identified improving public health reporting as a lesson learned during the pandemic. For example, one state reported that data sharing should be established with surrounding states to ensure that early detection surveillance and planning needs are identified prior to a surge in local communities. This state noted that data sharing on bed capacity, ventilator usage, and hospitalization statistics in real-time would have been helpful in determining surveillance needs. Additionally, this state noted that specific state surveillance details that demonstrate, for example, how different age groups and health care workers are impacted by COVID-19 could have helped with pandemic response. Another state reported that standardized HHS reporting of data, such as in the reporting of COVID-19 cases, tests, or deaths, would be more beneficial for its needs. The state further noted that HHS developed various reports through the gathering of web-based health data from a university, which is not standardized, rather than from state health department data.

- **Collaborate early with stakeholders.** Seven of 30 states reported collaborating early with stakeholders as a lesson learned during the pandemic. For example, one state reported that state, territory, local, and tribal jurisdictions should be involved in the initial planning phase with federal public health officials before decisions are made that may impact them. Another state reported that public health stakeholders, including those at the state and local level, should be engaged not only at the beginning, but throughout the entirety of public health emergency response activities.

  A representative from a public health organization agreed with the need for stakeholder collaboration, stating that rural health partners, in particular, need to be included as stakeholders and collaborate more with federal and state public health officials in order to more effectively support a public health situational awareness system. One state noted a positive experience with collaboration and stated that various departments within the state collaborated to understand how COVID-19 was being spread in order to respond to it. This state also reported sharing resources including workers and volunteers, as well as equipment, vehicles, and supplies from different departments during the COVID-19 response.

  Representatives from public health organizations also noted that during the implementation of HHS Protect, states, territories, and local

and tribal entities were often not involved as stakeholders. This resulted in challenges associated with duplicative and inefficient processes. For example, the representatives stated that some of the data HHS requested be reported from hospitals were already being reported as part of electronic case reporting at the state and local level.[30] However, those already established reporting mechanisms were not being used. The representatives also cited an example of a hospital staff member being solely responsible for reporting HHS Protect data to CDC when the data was easily available through electronic case reporting.[31]

- **Establish a public health infrastructure.** Five of 30 states reported establishing a public health infrastructure as a lesson learned during the pandemic. For example, a state reported that a technological infrastructure or backbone is needed to enable data sharing with state agencies and departments, including private and federal partners. Such a technological infrastructure or backbone could be achieved by establishing the network required by PAHPAIA and other relevant laws. The official explained that during the COVID-19 pandemic, the state was manually collecting, processing, and transferring data from one place to another. More specifically, the official described having to fax documents, make copies, and transport documents via vehicles to get information where it was needed. The state added that by establishing this infrastructure, errors would be reduced from manually inputting data and the loss of documents from manually transporting them would be avoided. The state further added that establishing a redundant network connection would also provide continuity of operations when a portion of the network fails. In another example, a state highlighted the importance of having a well-built, comprehensive, and integrated disease surveillance system.

In addition to the lessons learned identified by the states through the survey, representatives from public health organizations described lessons learned from the COVID-19 pandemic. The following summarizes these lessons learned.

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[30]Electronic case reporting is the automatic submission of disease reports directly from electronic health records at clinical care organizations to state, local, tribal, and territorial public health departments.

[31]We examined HHS Protect hospital capacity reporting requirements and the challenges experienced by reporting entities, among other things. See GAO, *COVID-19: HHS's Collection of Hospital Capacity Data*, GAO-21-600 (Washington, D.C.: Aug. 5, 2021).

- **Establish a data management framework.** Representatives from public health organizations said that COVID-19 has demonstrated the need for a national data management framework. They stated that HHS needed to engage with state and local public health entities to define and agree on common terminology and data elements. One example they cited was that core data elements for an HIV surveillance system should be the same core data elements, or use the same terminology, as the system used for tracking Hepatitis, as these diseases have common characteristics that are tracked for public health surveillance. However, data for tracking HIV and Hepatitis diseases are collected in different surveillance systems, creating redundancy.

  Representatives from public health organizations reiterated the need for HHS to define the purpose of the public health situational awareness and biosurveillance network required by PAHPAIA and other relevant laws. In addition, they added that HHS should coordinate with state, local, and territorial public health entities to define common data elements, a data strategy, the type of data that will be required for the network, and the ownership of the data.

- **Invest in an IT health-related workforce.** A representative from a public health organization described the need for greater investments in the IT health-related workforce because health departments do not have all the technical and health care-related skillsets necessary to address their needs. More specifically, the representative stated that there needs to be a better understanding of public health by the IT workforce because they may not have a full understanding of the specific IT needs of public health practitioners.

HHS Did Not Identify and Document Challenges and Lessons Learned from COVID-19 for the Situational Awareness and Biosurveillance Network

GAO's *IT Investment Management Framework* stresses the importance of identifying lessons learned to support future investment decisions.[32] Lessons learned can be leveraged from an event to inform future efforts and limit the chance of recurring challenges. We have previously reported that mechanisms for documenting, sharing, and disseminating lessons learned serve to communicate acquired knowledge more effectively and

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[32]GAO-04-394G.

ensure that beneficial information is incorporated into planning, work processes, and activities. Lessons learned provide a powerful method of sharing good ideas for improving work processes, quality, safety, and cost-effectiveness. They can be based on positive experiences or on negative experiences that result in undesirable outcomes. The framework notes that gathering lessons learned should be ongoing because stakeholders' perspectives can be lost or forgotten over time. Additionally, it is important to disseminate lessons learned since lessons are of little benefit unless they are distributed and used by people who will benefit from them.

In July 2021, the Public Health Data Systems Task Force provided ONC a set of recommendations to help inform HHS's response to an executive order on ensuring a data-driven response to COVID-19 and future high-consequence public health threats.[33] The task force's recommendations focused on the challenges, gaps, and the ideal future state for data sharing between public health systems and clinical data sources (such as electronic health records, laboratory systems, immunization information systems, syndromic surveillance, and case reporting). The task force provided ONC with 52 recommendations including those related to public health data systems infrastructure. The recommendations were also related to situational awareness data; standards development and adoption; and improving engagement between public health authorities, healthcare organizations, practitioners, and governing bodies at the federal, state, and local levels. According to ONC, the White House will determine whether the recommendations should be implemented.

While these recommendations are a positive step toward recognizing improvements are needed in public health situational awareness, it is unclear whether HHS is taking action to implement them. Further, the scope of the review was narrowly focused. At the time of our review, HHS had not taken steps to identify, document, and share challenges and lessons learned in the management of public health information that it, states, and public health organizations experienced as a result of the pandemic. These challenges and lessons learned could be incorporated into the planning and implementation of the public health situational

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[33]The White House, Executive Order 13994, *Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats*," (January 21, 2021). Among other things, the order tasked HHS with reviewing the effectiveness, interoperability, and connectivity of public health data systems supporting the detection of and response to high-consequence public health threats, such as the COVID-19 pandemic.

awareness and biosurveillance network required by PAHPAIA and other related laws. We reported in November 2021 that CDC officials planned to develop an agency-wide COVID-19 after action review that included a formal process for identifying lessons learned within HHS.[34] However, this after action review had not taken place as of March 2022 and would not include lessons learned from other federal, state, and local public health agencies.

According to HHS officials in ASPR and CDC, the department had not taken steps to identify and document lessons learned from COVID-19—including those related to IT and system challenges—because they viewed the lessons learned process as ongoing. ASPR officials also stated that HHS is still responding to the pandemic and has been integrating lessons learned during real-time response throughout this time period. The officials added that they were working to establish a COVID lessons learned portal but did not provide a timeframe for completing that activity. However, HHS officials could not demonstrate that they had integrated lessons learned during the COVID-19 response.

While we agree that an ongoing, iterative lessons learned process can be beneficial, important lessons can be identified and documented from over two years of continual COVID-19 response activities. For example, representatives from public health organizations told us that they were not able to access HHS Protect information at a useful, granular level because it was summarized. As a result, these officials stated that they were not able to obtain, for example, all the necessary data from HHS regarding COVID-19 vaccination dose allocations in their jurisdictions to assist them in determining what additional vaccination supplies may be needed.

Given the state challenges we identified earlier, obtaining stakeholder perspectives on lessons learned and sharing these lessons with other stakeholders could provide invaluable information for future pandemic system implementation efforts. Also, incorporating these lessons learned into future plans for developing the network would increase its chances for successful implementation. Until HHS takes steps to identify, document, share, and incorporate lessons learned from the COVID-19 pandemic, opportunities to improve the response to future and ongoing

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[34]GAO, *COVID-19: HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives*, GAO-22-104457 (Washington, D.C.: Nov. 4, 2021).

public health emergencies by learning from past challenges will likely be missed.

In commenting on a draft of this report, HHS stated that the department continues to incorporate lessons learned early in the current response efforts. For example, officials stated that HHS responded to stakeholder input about the burden of COVID-19 hospital data reporting in its COVID-19 hospital reporting requirement guidance updates by decreasing the number or required data elements and flexibility in reporting data from weekends and holidays to the next business day. While this is a positive step, as discussed earlier, HHS had not taken steps, at the time of our review to identify and document lessons learned from COVID-19 and could not provide information related to lessons learned.

Conclusions

In the over 15 years since the enactment of the first of three laws aimed at improving pandemic-related information sharing, the federal government remains without a near real-time electronic nationwide public health situational awareness and biosurveillance network. By March 2022, HHS completed minimal actions required by PAHPAIA. While it provided grants to states for situational awareness and biosurveillance systems and adopted standards for interoperability, it is not clear how these efforts directly contribute to establishing the public health situational awareness and biosurveillance network required by law. The department has also not taken any action to complete the remaining requirements in PAHPAIA, including establishing the network. While HHS has begun drafting a work plan that is intended to address PAHPAIA requirements, the department could not provide a time frame for when the plan would be completed and finalized. The minimal progress that HHS has made in fulfilling PAHPAIA requirements is due, in part, to the lack of an established management and governance structure, such as a lead operational division, to oversee the activities required by PAHPAIA and other related laws. Without a management and governance structure to oversee the activities required by law, HHS and the federal government will likely continue to lack the comprehensive capabilities needed to allow for the timely response to infectious disease outbreaks like COVID-19.

While HHS had over 2 years of experience in responding to COVID-19, the department had not taken steps to identify, document, and share challenges and lessons learned from the pandemic that could be incorporated into the planning and implementation of the public health

situational awareness and biosurveillance network. Further, while officials planned to develop an agency-wide COVID-19 after action review that included challenges and lessons learned, as of March 2022, HHS had not done so. Until the department takes these steps, it will likely miss opportunities to improve the response to the ongoing and future public health emergencies.

Recommendations for Executive Action

We are making the following 12 recommendations to HHS:

The Secretary of HHS should prioritize the development of the public health situational awareness and biosurveillance network by designating a lead operational division for PAHPAIA implementation. (Recommendation 1)

The Secretary of HHS should clearly define the roles and responsibilities for the lead operational division responsible for PAHPAIA implementation. The roles and responsibilities should include the specific activities required in PAHPAIA. (Recommendation 2)

The Secretary of HHS should identify the office responsible for overseeing the completion of the activities performed by the lead operational division and clearly define its roles and responsibilities. (Recommendation 3)

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes the steps to be taken to address all of the required actions in PAHPAIA. (Recommendation 4)

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes specific near-term and long-term actions that can be completed to show progress in developing the network. (Recommendation 5)

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes time frames for implementing the near-term and long-term actions. (Recommendation 6)

The Secretary of HHS should ensure that the PAHPAIA work plan includes specific steps the department will take to oversee the progress of

the actions the lead operational division takes to implement PAHPAIA requirements. (Recommendation 7)

The Secretary of HHS should commit to a deadline for finalizing the work plan to implement PAHPAIA requirements and ensure that the work plan is fully implemented. (Recommendation 8)

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation identifies and documents the IT- and information sharing-related challenges and lessons learned from the COVID-19 pandemic. (Recommendation 9)

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation shares the lessons learned from the COVID-19 pandemic with relevant stakeholders, such as state, territorial, and local public health officials. (Recommendation 10)

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation request that state, territory, and local public health officials share their lessons learned from the COVID-19 pandemic with HHS. (Recommendation 11)

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation incorporates lessons learned from the COVID-19 pandemic into its plans for implementing the situational awareness and biosurveillance network. (Recommendation 12)

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in appendix IV. In its comments, the department concurred with 10 of the 12 recommendations and stated that the remaining two were under review. The department stated that it remains committed to the full implementation of PAHPAIA. HHS added that our report provides important information that can assist the department's ongoing efforts to fulfill their PAHPAIA responsibilities. For example, according to HHS, it is currently working to enhance its public health situational awareness network by defining roles and responsibilities for PAHPAIA implementation, and sharing lessons learned from the COVID-19 pandemic with relevant stakeholders. The department added that HHS is making strides and working toward improving the U.S. government's medical countermeasures enterprise, building early warning systems with

improved data analytics and forecasting capability, strengthening the U.S. public health system, and addressing health disparities. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Assistant Secretary for Preparedness and Response, Director of CDC, HHS OCIO, and interested congressional parties. 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 Jennifer R. Franks at (404) 679-1831 or franksj@gao.gov. GAO staff who made key contributions to this report are listed in appendix V.

Jennifer R. Franks
Director, Information Technology and Cybersecurity

List of Addressees

The Honorable Patrick Leahy
Chairman
The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman
The Honorable Rob Portman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
Chair
The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman
The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

The Honorable Mitt Romney
United States Senate

Appendix I: Survey Questions Administered to States and Territories and the Responses for Each Question

We administered a web-based survey to 50 states, the District of Columbia, and five U.S. territories (hereinafter collectively referred to as states).[1] The survey was administered to solicit state officials' views on any COVID-19 challenges that they faced and lessons they have learned that could inform HHS's work to develop and implement a nationwide public health situational awareness and biosurveillance network. The following identifies the survey questions that we administered and the aggregated results from the responses under each question. Forty-three of 56 states responded to the survey. Not all 43 respondents to the survey answered each question. Some questions were only asked of a subset of respondents giving a qualifying answer to an earlier question. In addition, not all qualifying respondents may have answered a particular question. Narrative answers to open-ended text questions are not displayed below for brevity and to limit the possibility of identification of individual states.

Survey on the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Public Health Situational Awareness Capability

U.S. Government Accountability Office
Introduction
The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) reauthorized the mandate that the Department of Health and Human Services (HHS) develop a near real-time, electronic, nationwide public health situational awareness and biosurveillance capability through an interoperable network of systems based on information from various entities, including states and territories. According to the law, the purpose of the situational awareness capability

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[1]The U.S. territories are Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands. At times, the public health officials we administered the survey to forwarded the survey to other officials they felt were more appropriate to answer the questions. These officials included emergency preparedness and response and IT staff.

is to allow sharing of information and data among health partners to enhance the early detection of and rapid response to catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies. In accordance with the law, HHS is required to develop a plan to ensure that the network allows for the timely sharing of secure information concerning public health emergencies. PAHPAIA requires the network capability to include data and information from the following entities:

- state, local, and tribal public health entities, including public health laboratories;
- federal health agencies;
- zoonotic disease monitoring systems; and
- public and private sector health care entities, including hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, immunization information systems, community health centers, clinical laboratories, and public environmental health agencies.

According to PAHPAIA, the network capability should be built on existing state situational awareness systems or enhanced systems that enable interoperability. The law also included a provision for GAO to report on the progress of HHS efforts to implement the network capability.

To learn more about completing the questionnaire or printing your responses click here for help.

Thank you for your time and assistance.

Situational Awareness and Biosurveillance Capability

The following questions ask about your state's or territory's capabilities, as well as your state's or territory's involvement, if any, in HHS's efforts to implement a nationwide public health situational awareness and biosurveillance capability for public health emergencies.

1. Does your state or territory have any information system(s) in place to collect data from health care or local public health entities (ex: local health departments, hospitals, laboratories, private health care facilities, pharmacies, federal installations, etc.) that support or has the potential to support the early detection and response to pandemics, novel emerging threats, or other public health emergencies?

Number of Responses

Yes	41
No	1
Don't know	1

2. (Part 1) Please indicate if your state or territory has implemented one or more of the following types of information systems.

Number of Responses

State Implemented Information System	Does your state have this system?		
	Yes	No	Don't Know
Immunization Information System(s)	41	0	0
Infectious Disease Surveillance System(s)	40	0	1
Syndromic Surveillance System(s)	39	2	0
Zoonotic Disease Monitoring System(s)	21	13	6
Other System(s)	14	9	9

2. (Part 2) Then, for each system that has been implemented, select each type of entity that reports any amount of data to that system or systems. (For example, if some hospitals report data to an Immunization Information System and some do not, please check the box for hospitals for that system type.) If your state does not have this system or if you don't know whether your state has this system, please select Not Applicable for the reporting entity.

Number of Responses

	Immunization Information System(s)	Infectious Disease Surveillance System(s)	Syndromic Surveillance System(s)	Zoonotic Disease Monitoring System(s)	Other System(s)
Local Health Departments (including state or locally funded clinics)	37	35	8	18	7
Hospitals (including federal, state, and local hospitals)	39	37	38	16	8
Laboratories	11	37	8	19	5
Private Sector Health Care Entities (other than hospitals)	41	31	18	15	6
Pharmacies	38	16	7	3	2
Federal Agencies	9	13	4	7	1
State Agencies/Entities	23	24	6	15	3
Other	6	6	8	5	4
Not Applicable	0	0	0	1	1

2a. If you selected "Other" for one or more of the reporting entity, please explain below. (Note – open ended text responses deliberately omitted)

2b. If you selected "Yes" for Other system, please describe the other type(s) of system(s) that the above entities report data to. (Note – open ended text responses deliberately omitted)

3. If you indicated in question 2 that your state or territory has a syndromic surveillance system(s), does the system track symptoms and/or signs of disease in animals?

Number of Responses

Yes	2
No	33
Don't know	5

4. Please describe what your state or territory currently does in practice, in the absence of a system. (Note – open ended text responses deliberately omitted)

5. Aside from any required reporting through state and federal mandates, are any data from your state's or territory's system(s) that support or could support early detection and response to pandemics, novel emerging threats, or other public health emergencies voluntarily reported to any federal entity(ies)?

Number of Responses

Yes	23
No	10
Don't know	10

5a. Please provide an example(s) in the space below, including the federal entities and systems that your state or territory is voluntarily reporting the data to. (Note – open ended text responses deliberately omitted)

6. Does your state or territory have access to all the federal systems that house the data you have shared with federal entities?

Number of Responses

Yes	17
No	12
Don't know	14

6a. Please provide an example of a federal system you share data with but do not have access to. (Note – responses deliberately omitted)

7. Does your state or territory share any reported data with other states or territories?

Number of Responses

Yes	27
No	9
Don't know	7

7b. Please explain if data is being shared formally (e.g., data sharing agreements, memorandums of understanding, etc.), informally (e.g., periodic meetings), both formally and informally, or don't know. (Note – open ended text responses deliberately omitted)

8. Does your state or territory have plans to implement or modernize a system(s) that supports early detection and response to pandemics, novel emerging threats, or other public health emergencies?

Number of Responses

Yes	33
No	3
Don't know	7

8a. Please describe your state or territory's plans to implement or modernize a system(s) and include approximate timeframes for implementation. (Note – open ended text responses deliberately omitted)

8b. Will the plans to modernize the system(s) include the ability for the system to interact or be interoperable with other state or territorial systems to share data for common reporting or analysis?

Number of Responses

Yes	23
No	2
Don't know	7

8c. Will the plans to modernize the system(s) include the ability for the system to interact with federal systems to share data for common reporting or analysis?

Number of Responses

Yes	23
No	1
Don't know	8

Coordination

The Pandemic and All-Hazards Preparedness and Advancing Innovation
Act of 2019 (PAHPAIA) requires HHS to coordinate with states and
territories when developing the situational awareness and biosurveillance
network capability required by the law.

9. Has HHS (e.g., Office of the Assistant Secretary for Preparedness and
Response (ASPR), the Centers for Disease Control and Prevention
(CDC), Office of the Chief Information Officer (OCIO)) or any other federal
entity coordinated with your state or territory regarding providing
information and data that could support a situational awareness and
biosurveillance network capability for public health emergencies? This
would include information that supports the early detection of and
response to pandemics and public health emergencies, including COVID-
19.

Number of Responses

Yes	31
No	0
Don't know	11

10. Which of the following federal entities or their component agencies
coordinate with your state or territory? Please select "other" if the specific
agency or component is not listed.

Number of Responses

	Yes	No	Don't Know
10a. HHS Office of the Assistant Secretary for Preparedness and Response	25	3	1
10b. HHS Centers for Disease Control and Prevention	29	0	1
10c. HHS Office of the Chief Information Officer	4	6	17
10d. Food and Drug Administration	17	7	6
10e. Department of Defense	12	9	8
10f. Department of Homeland Security (e.g., Federal Emergency Management Agency (FEMA) and National Biosurveillance Integration Center)	20	4	5
10g. Department of Agriculture	13	8	8
10h. Environmental Protection Agency	13	6	9
10i. White House	17	7	5
10j. Other entity	1	5	13

10k. If you selected "Yes" to Other entity, please name the other entity/entities that apply. (Note – open ended text responses deliberately omitted)

10l. If you selected "Yes" to any of the items above, please provide examples of the coordination that took place. (Note – open ended text responses deliberately omitted)

11. Would your state or territory benefit from the types of coordination described below regarding HHS's (e.g., ASPR, CDC, OCIO) efforts to develop a network capability? If yes, please provide an example of how your state or territory would benefit. If no, please write N/A in the box. (Note – Examples deliberately omitted)

Number of Responses

Coordination Type	Benefit from this Type of Coordination		
	Yes	No	Don't Know
Integrating and building upon any existing system capabilities	35	3	5
Using a standardized data set and/or creating common data elements	34	5	4
Sharing of data and information	36	2	5
Developing procedures and standards for the collection and analyses of data that states, territories, regions, or other entities collect and report to HHS, ASPR, CDC, or other HHS entities	33	6	4
Piloting test standards and implementation specifications for the network capability	26	2	14
Other types of coordination	9	7	25

11a. If you selected "Yes" for Other types of coordination, please describe. (Note – open ended text responses deliberately omitted)

11b. If you selected "No" for all types of coordination, please explain why none of these types of coordination efforts would be beneficial to your state or territory. (Note – open ended text responses deliberately omitted)

Challenges and Lessons Learned

These questions ask about challenges and lessons learned from the COVID-19 pandemic that could be helpful to HHS in planning for the implementation of the public health situational awareness and biosurveillance network capability.

12. Overall, how challenging, if at all, were the following activities during the COVID-19 pandemic regarding the management of public health information, such as the data collected for monitoring the pandemic?

Number of Responses

	Very Challenging	Moderately Challenging	Not at all Challenging	Don't Know
12a. Clarity of guidance from the federal government on public health information management (e.g., inconsistent guidance, conflicting guidance, lack of definitions on the data necessary and the use of the data, lack of definitions of situational awareness or biosurveillance)	19	19	4	1
12b. Clarity in roles and responsibilities of federal entities and agencies such as the White House, ASPR, CDC, HHS OCIO, and FEMA (e.g., duplicative, overlapping, fragmented roles and responsibilities)	22	13	6	2
12c. Support of key stakeholders or public health localities. For example, this would include ineffective collaboration amongst stakeholders to implement a system (e.g., obtaining inadequate stakeholder requirements/input for systems)	7	27	5	4
12d. Manual processing of data and data collection for federal reporting	29	8	4	2
12e. Interoperability among systems (e.g., non-standardized data, incompatible systems, or legacy systems)	26	13	2	0
12f. Access to specific types of data for reporting and decision-making (e.g., not having access to local-level or other granular data in systems, such as Tiberius, HHS Community Profile Reports, or CDC COVID Data Tracker)	10	22	7	4

	Very Challenging	Moderately Challenging	Not at all Challenging	Don't Know
12g. Bidirectional sharing of data between state, territorial, federal, and public or private health care entities—such as hospitals or pharmacies—across multiple systems (e.g., sharing of immunization systems' data across states, territories, etc.)	19	18	3	3
12h. Public health information messaging (e.g., informing stakeholders on the importance of reporting COVID-19 data)	8	24	11	0
12i. Human capital-related IT resources (e.g., inadequate staffing, training, technical competence/skill set, etc.)	25	15	1	2
12j. Technology resources (e.g., funding or availability of systems and/or data warehouses, network connectivity)	15	23	3	2
12k. Legal constraints (e.g., privacy constraints)	9	25	5	4
12l. Organizational and/or cultural constraints	12	21	7	3
12m. Political constraints	18	17	5	3
12n. Other constraints	2	1	3	23

12o. Please describe the other constraint. (Note – open ended text responses deliberately omitted)

13. The following questions ask you to identify your state's or territory's top three challenges from question 12. After each selection, please provide an example of that challenge. (Note – open ended text responses deliberately omitted)

Number of Responses

	1st Top Challenge	2nd Top Challenge	3rd Top Challenge	Sum of the Top 3 Challenges
a. Clarity of guidance from the federal government on public health information management	8	1	2	11

	1st Top Challenge	2nd Top Challenge	3rd Top Challenge	Sum of the Top 3 Challenges
b. Clarity in roles and responsibilities of federal entities and agencies such as the White House, ASPR, CDC, HHS OCIO, and FEMA	7	3	5	15
c. Support of key stakeholders or public health localities	2	2	0	4
d. Manual processing of data and data collection for federal reporting	0	11	5	16
e. Interoperability among systems	8	6	1	15
f. Access to specific types of data for reporting and decision-making	1	0	3	4
g. Public health information messaging	1	1	2	4
h. Human capital-related IT resources	9	5	7	21
i. Bidirectional sharing of data between state, territorial, federal, and public or private health care entities—such as hospitals or pharmacies—across multiple systems	1	4	4	9
j. Technology resources	3	5	7	15
k. Legal constraints	0	0	1	1
l. Organizational and/or cultural constraints	0	0	1	1
m. Political constraints	2	3	3	8
n. Other challenge	1	2	2	5

14. Have you identified any lessons learned, positive or negative, from your experience with the COVID-19 pandemic that could be helpful to HHS in planning for the implementation of the public health situational awareness and biosurveillance network capability?

Number of Responses

Yes	30
No	4
Don't know	9

14a. Please describe any lessons learned, including successes that could be emulated or challenges that could be or were mitigated, which might assist HHS in planning for a situational awareness and biosurveillance network capability for public health emergencies. (Note – open ended text responses deliberately omitted)

HHS Guidance Related to General PAHPAIA Requirements

In establishing the public health situational awareness and biosurveillance network capability, PAHPAIA requires HHS to conduct activities, including utilizing interoperability standards, defining minimal data elements for the network, and collaborating with state and local public health officials to integrate and build upon existing state and local system capabilities to ensure the simultaneous sharing of data and information. These questions ask about general PAHPAIA requirements and any guidance HHS has provided to your state or territory regarding the systems that could potentially help support the public health situational awareness and biosurveillance network capability for public health emergencies.

15. As HHS plans for the development and implementation of the public health situational awareness and biosurveillance network capability, would the following guidance from HHS (e.g., ASPR, CDC, or OCIO) be helpful to your state or territory for supporting the capability?

Number of Responses

	Yes	No	Don't Know
15a. Technical specifications	39	2	2
15b. Functional specifications or requirements	39	2	2
15c. Standards for interoperability	41	1	1
15d. Common operating picture	41	1	1
15e. Guidance on the development of the public health situational awareness and biosurveillance network capability	34	5	4
15f. Guidance on the type of information and data required by HHS from states and territories for the network capability	38	3	2
15g. Plans and guidance for integration of existing systems with the network capability	35	4	4

	Yes	No	Don't Know
15h. Guidance on performance measures and metrics to assess the performance of the network capability	33	5	4
15i. Other guidance	4	3	24

15j. Please describe the other guidance. (Note – open ended text responses deliberately omitted)

16. If you selected "Yes" to any of the above types of guidance, please identify the top 3 that would be most helpful to your state or territory and explain how the guidance will be helpful. (Note – explanations deliberately omitted)

Number of Responses

	Most Helpful	2nd Most Helpful	3rd Most Helpful	Total Helpful
16a. Technical specifications	7	5	6	18
16b. Functional specifications or requirements	5	11	5	21
16c. Standards for interoperability	12	6	7	25
16d. Common operating picture	7	5	6	18
16e. Guidance on the development of the public health situational awareness and biosurveillance network capability	0	4	2	6
16f. Guidance on the type of information and data required by HHS from states and territories for the network capability	1	7	4	12
16g. Plans and guidance for integration of existing systems with the network capability	6	2	6	14
16h. Guidance on performance measures and metrics to assess the performance of the network capability	3	1	3	7
16i. Other guidance	1	0	2	3

17. If you have any additional comments on any of the topics included in this questionnaire, please write them in the box below. (Note – open ended text responses deliberately omitted)

Appendix II: Objectives, Scope, and Methodology

Our objectives were to determine (1) the extent to which the Department of Health and Human Services (HHS) has made progress toward establishing systems of public health communications and surveillance, and modernizing public health situational awareness and biosurveillance in accordance with the requirements in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA); and (2) the challenges and lessons learned from the COVID-19 pandemic that states, territories, and HHS could incorporate in the planning and implementation of the public health situational awareness and biosurveillance network.

For the first objective, we reviewed 42 U.S.C. § 247d-4 (b) and (c) to identify and summarize requirements for establishing systems of public health communications and surveillance, and modernizing public health situational awareness and biosurveillance. We then assessed any actions HHS had taken against these requirements. Specifically, we reviewed available department documentation, such as grants, contracts, and cooperative agreements provided by HHS to states for the establishment of systems of public health alert communications and surveillance. We also reviewed HHS's technical and reporting standards for interoperability, including *the United States Core Data for Interoperability*. We compared these documents against the PAHPAIA requirements aimed at establishing systems of public health communications and surveillance. Further, we reviewed HHS's draft work plan and summarized the progress HHS had made, as of April 2022, in developing the plan.

We also interviewed relevant officials in the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Chief Information Officer (OCIO), and the Centers for Disease Control and Prevention (CDC). We interviewed these officials to discuss the actions the department had taken or planned to take to implement the legal requirements related to establishing systems of public health communications and surveillance and modernizing public health situational awareness and biosurveillance. We also interviewed the officials to understand each office's roles and responsibilities for establishing the public health situational awareness and biosurveillance

network. In addition, we conducted interviews with officials in the Office of the National Coordinator for Health Information Technology (ONC) to determine whether they had taken action to coordinate with ASPR and CDC to adopt technical and reporting standards for interoperability.

For the second objective, we administered a web-based survey to a public health official in each of the 50 states, the District of Columbia, and five territories (hereinafter collectively referred to as states).[1] We identified these contacts in a variety of ways, including our ongoing CARES Act public health-related work, emails to state public health entities, and state websites. The survey included questions that solicited state officials' views on the COVID-19 challenges they have faced and lessons they have learned that could inform HHS's work to develop and implement a nationwide public health situational awareness and biosurveillance network. The questions also related to state systems that support pandemic response. Further, the survey also solicited state officials' views on HHS coordination and guidance that could help support states if a network was implemented, among other things.

Before administering the survey, we pretested it with representatives from the Association of State and Territorial Health Officials and public health officials from the states of Oklahoma and New Mexico. The pretests were conducted to ensure that our survey questions were appropriate, skip patterns were clear and logical, and that the respondents could answer the questions without undue burden. We received survey responses from September 2021 through December 2021; therefore, the responses reflect information and views as of that time period. We received responses from 43 states, for a 77 percent response rate. We analyzed states' survey responses to summarize their views on challenges and lessons learned from the COVID-19 pandemic that HHS could consider in the planning and implementation of the public health situational awareness and biosurveillance network. See appendix I for a copy of the survey administered to states and responses for each question.

To supplement the survey information we obtained from the states, we also interviewed representatives from selected national public health organizations that collectively represent state and local levels and have

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[1]The U.S. territories are Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands. At times, the public health officials we administered the survey to forwarded the survey to other officials they felt were more appropriate to answer the questions. These officials included emergency preparedness and response and IT staff.

key roles in responding to public health emergencies. We also interviewed representatives from a selected state association. We used these interviews to identify common information management challenges and lessons learned from the COVID-19 pandemic among these organizations. The organizations we interviewed are the:

- Association of State and Territorial Health Officials,

- National Governors Association,

- Council of State and Territorial Epidemiologists,

- American Immunization Registry Association,

- National Rural Health Association,

- National Association of County and City Health Officials,

- National Community Pharmacists Association, and

- Community Health Care Association of New York State.

In addition, we interviewed relevant officials at HHS—ASPR, OCIO, and CDC—to discuss any efforts planned or underway to identify, document, and share challenges and lessons learned from the response to the COVID-19 pandemic. We compared these efforts against criteria we identified in a prior GAO report that defined best practices for developing and disseminating lessons learned for IT investments.[2] Lastly, we reviewed prior GAO reports, such as those issued as part of the CARES Act provision that requires us to regularly report on the federal response to the pandemic. We also reviewed prior HHS Office of Inspector General reports that identify the department's information management challenges. We reviewed these reports to summarize any lessons learned that we have previously identified.

We conducted this performance audit from November 2020 to June 2022 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.

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[2]GAO, *Information Technology Investment Management: A Framework for Assessing and Improving Process Maturity*, Version 1.1, GAO-04-394G (Washington, D.C.: March 2004).

Appendix III: Various State and Federal Entities Use IT to Support Public Health Situational Awareness and Biosurveillance Activities
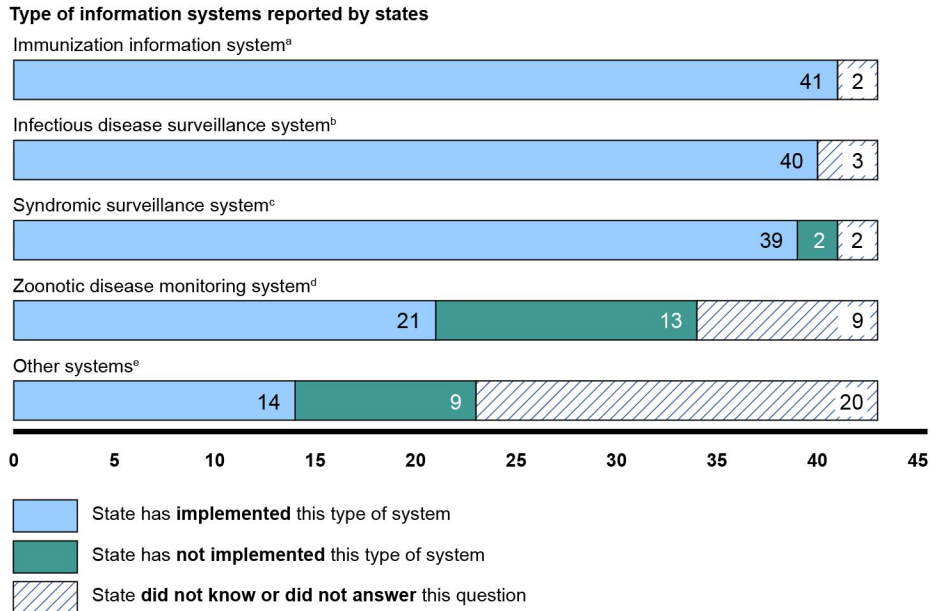
Maintaining a situational awareness capability involves an active, continuous, and timely exchange of information that enhances the ability of public health officials to make decisions related to emergency preparedness and response. Public health officials at state, local, tribal, territorial, and federal, levels rely on IT systems and tools to collect and share information in their day-to-day functions, such as tracking vaccinations and outbreaks of seasonal influenza. These officials also use IT systems to create the situational awareness needed to enable early detection of, and effective response to, emerging diseases and other public health events.

We administered a web-based survey to the 50 states, the District of Columbia, and five U.S. territories (hereinafter collectively referred to as states).[1] The survey included questions related to the systems the states have implemented to support public health situational awareness and biosurveillance, among other things. The responding states reported that they have implemented a number of systems, including immunization information systems, infectious disease surveillance systems, syndromic surveillance systems, and zoonotic disease monitoring systems, among others. Figure 4 identifies and describes the various types of systems that states reported that they have implemented to support public health situational awareness and biosurveillance activities.

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[1]The U.S. territories are Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands. At times, the public health officials we administered the survey to forwarded the survey to other officials they felt were more appropriate to answer the questions. These officials included emergency preparedness and response and IT staff.

Figure 4: Types of Information Systems States Reported Implementing to Support Public Health Situational Awareness and Biosurveillance

Type of information systems reported by states

Immunization information system[a]

| 41 | 2 |

Infectious disease surveillance system[b]

| 40 | 3 |

Syndromic surveillance system[c]

| 39 | 2 | 2 |

Zoonotic disease monitoring system[d]

| 21 | 13 | 9 |

Other systems[e]

| 14 | 9 | 20 |

0   5   10   15   20   25   30   35   40   45

State has **implemented** this type of system

State has **not implemented** this type of system

State **did not know or did not answer** this question

Source: GAO survey data. | GAO-22-104600

[a]Immunization information systems are confidential, population-based, computerized databases that record immunization doses administered by participating providers to persons residing within a given geopolitical area.

[b]Infectious disease surveillance systems monitor information about cases or a person diagnosed with a disease or condition to understand diseases and their spread and determine appropriate actions to control outbreaks.

[c]Syndromic surveillance systems use health-related data to identify patterns of disease symptoms prior to confirmed diagnoses. These systems may include real-time data from emergency departments, urgent and ambulatory care centers, inpatient health care settings, and laboratories.

[d]Zoonotic disease monitoring systems are intended to monitor diseases in humans or animals that are caused by germs that spread between animals and people.

[e]Other systems that were reported by states include prescription drug monitoring, infectious disease outbreak reporting, wastewater surveillance, and molecular surveillance.

Most of the states that responded to our survey indicated that various health entities, such as federal and state agencies, local health departments, and hospitals reported health-related data to the states' immunization information systems and infectious disease surveillance systems. In particular, at least 30 of the 43 states indicated that local health departments, hospitals, and private sector health entities reported data to these two types of state systems. Additionally, a large majority of state respondents indicated that laboratories also report data to infectious disease surveillance systems; hospitals report to syndromic surveillance

systems; and pharmacies report to immunization information systems (see appendix I, question 2 for more detailed information).

At the federal level, multiple agencies use numerous IT systems and tools as part of their efforts to collect, integrate, and share critical public health and medical information. For example, the Center for Disease Control and Prevention's (CDC) Red Sky tool is used to manage and share public health data about global events that may require CDC assistance or resources. CDC's BioSense platform supports the National Syndromic Surveillance Program and features the analysis of public health data gathered from hospitals, urgent care facilities, and pharmacies.

In response to COVID-19, in April 2020, the Department of Health and Human Services (HHS) created a data ecosystem—HHS Protect—to collect and share public health data related to the pandemic.[2] Following the Anthrax attacks of 2001, the Department of Homeland Security developed the BioWatch program to provide early indication of an aerosolized biological weapon attack.[3] Table 4 includes these and other examples of federal systems that provide information relevant to public health situational awareness and biosurveillance.

Table 4: Examples of Existing Federal Systems Relevant to Public Health Situational Awareness and Biosurveillance

Department	Subcomponent	System name	Description
Surveillance Systems and Dashboards Used to Monitor COVID-19			
Health and Human Services (HHS)	Centers for Disease Control and Prevention (CDC)	HHS Protect	Serves as the common operating picture and central hub to receive, integrate, and share COVID-19 data in near-real time for the U.S. government. HHS Protect also receives national and state data on COVID-19 cases, laboratory testing, COVID-19 deaths, hospital capacity, personal protective equipment, COVID-19 treatment, and COVID-19 vaccine administration in the U.S.

[2]HHS Protect includes the number of COVID-19 cases from more than 200 data sources (e.g. federal, state, and local governments and health care entities), supply chain data, inpatient bed utilization, intensive care unit bed utilization, percentage of inpatient beds occupied by COVID-19 patients, laboratory testing, COVID-19 deaths, COVID-19 vaccinations, and therapeutics.

[3]For more information on BioWatch and the Department of Homeland Security's efforts to replace the system, see GAO, *Biodefense: DHS Exploring New Methods to Replace BioWatch and Could Benefit from Additional Guidance*, GAO-21-292 (Washington, D.C.: May 20, 2021).

Department	Subcomponent	System name	Description
HHS	CDC/HHS Coordination Operations Response Element	Tiberius	Situational awareness platform that aggregates COVID-19 data, including vaccine data therapeutics data, and logistics data, from various U.S. stakeholders in support of Operation Warp Speed and later the HHS Countermeasures Acceleration Group and the HHS Coordination Operations Response Element.[a]
HHS	CDC	COVID-19 Vaccine Data Systems	System of systems used to track COVID-19 vaccine distribution and administration in the U.S.
HHS	CDC/Food and Drug Administration	Vaccine Adverse Event Reporting Systems	National system for health care professionals, vaccine manufacturers, and the public to report possible side effects or health problems after vaccination for investigation by scientists.
HHS	CDC	V-Safe COVID-19 Vaccine Pregnancy Registry	Smartphone-based, after-vaccination health checker for people receiving COVID-19 vaccines with additional data collection on pregnant vaccine recipients.
HHS	CDC	COVID-19-Associated Hospitalization Surveillance Network (commonly referred to as COVID-NET)	Collects demographic, clinical, and outcome data on laboratory-confirmed COVID-19 hospitalization data for children and adults through a network of acute-care hospitals in 14 states in the U.S.
HHS	CDC	Vaccine Administration Management System	Application used by vaccination clinics to register patients and record vaccination dose data.
HHS	CDC	National Wastewater Surveillance System	Tracks COVID-19 through wastewater testing data.
HHS	Multiple HHS subcomponents	Unified Hospital Data Surveillance System	Collects facility-level aggregated data from all hospitals in the U.S. on capacity and occupancy, pediatric and adult COVID-19 hospitalization, personal protective equipment inventory, and COVID-19 therapeutics inventory and utilization.
Public Health Surveillance Systems and Dashboards (Not COVID-19 Specific)			
HHS	CDC	Epidemic Information Exchange	The Epidemic Information Exchange provides 24/7 bi-directional electronic data and public health reporting between CDC, federal, state, and international public health agencies.
HHS	CDC	BioSense Platform	Platform that supports the National Syndromic Surveillance Program and allows for the analysis of public health data gathered from hospitals, urgent care facilities, and laboratories.[b]
HHS	CDC	Red Sky	Tool that gathers data and information about public health events and displays the data in a real-time dashboard and global map that is intended to track active health events and improve situational awareness.
HHS	CDC	National Notifiable Diseases Surveillance System	System that tracks data on nationally notifiable diseases from approximately 3,000 health departments across the U.S.
HHS	CDC	New Vaccine Surveillance Network	Network that conducts surveillance and data collection on use and impact of vaccines at seven U.S. study sites that collect population-based surveillance data.[c]

Department	Subcomponent	System name	Description
HHS	CDC	Flu Vaccine Effectiveness Network	Network that provides estimates of clinical influenza vaccines' effectiveness based on data from seven state study sites spread across the U.S.[d]
HHS	CDC	National Respiratory and Enteric Virus Surveillance System	Laboratory-based system that monitors circulation patterns of respiratory and enteric viruses.[e]
HHS	CDC	Laboratory Response Network	Integrated network of laboratories that can detect and respond to bioterrorism, emerging infectious diseases, chemical terrorism, and other public health emergencies.
HHS	CDC	National Outbreak Reporting System	Tracks U.S. reports of waterborne and foodborne disease outbreaks.
HHS	CDC	Chronic Disease Center Surveillance Systems	System of systems that monitors chronic diseases to understand the extent of risk behaviors, preventative practices, and the burden of chronic diseases.
HHS	CDC	Drug Overdose Surveillance and Epidemiology System	Analyzes data from other syndromic surveillance systems to identify outbreaks of drug overdoses.
HHS	CDC	National Vital Statistics System	Collects and analyzes data on vital events like births and deaths from all 50 states, two cities, and five territories.[f]
HHS	CDC	National Healthcare Safety Network	System that tracks health care-associated infections, antibiotic resistant infections, and antibiotic use across health care settings. Examples of these data include catheter-associated urinary tract infections, central-line associated bloodstream infections, and Methicillin-resistant *Staphylococcus aureus*.[g] This network was leveraged during the COVID-19 pandemic to collect and analyze COVID-19 data from all of the nation's nursing homes and dialysis clinics. Until HHS Protect was available, this system also collected COVID-19 hospitalization data.[h]
HHS	Office of the Assistant Secretary for Preparedness and Response (ASPR)	EMPortal Emergency Management Application	Knowledge management tool that provides all-hazards information, materials, and knowledge sharing to support emergency operations.
HHS	ASPR	GeoHEALTH	Interactive mapping application that collects public health incident and federal disaster information from open sources to create a visual environment for situational awareness capabilities.
HHS	ASPR	National Special Pathogen System	Nationwide systems-based network approach that builds on existing infrastructure and investments in preparing for infectious disease outbreaks. The system supports the urgent preparedness and response needs of hospitals, health systems, and health care providers related to treating patients with special pathogens.
HHS	ASPR	ASPR Ready	An ecosystem that is to streamline agency collaboration, information and data management, and provide the common operating picture for ASPR's preparedness and response missions.

Department	Subcomponent	System name	Description
Department of Homeland Security (DHS)	Countering Weapons of Mass Destruction Office	National Biosurveillance Integration System	Aggregates the collection and analysis of biosurveillance data, such as media reports, government agency websites, professional association reports, and data provided by National Biosurveillance Integration System partners.[i]
DHS	Countering Weapons of Mass Destruction Office	BioWatch	System that tracks pathogens in the air to identify early indications of aerosolized biological attacks. As of March 2022, this system was still in development.
DHS	Countering Weapons of Mass Destruction Office	Biological Detection for the 21st Century	System of sensor nodes that captures environmental data, camera images, and video to detect airborne bio-threats. As of March 2022, this system is still in development.
Department of Defense	Defense Applied Research Projects Agency	SIGMA+	Network of sensors that detects chemical, biological, radiological, nuclear, and high-yield explosive attacks.
Department of Defense	Defense Health Agency	Electronic Surveillance System for the Early Notification of Community-based Epidemics	Global military health system monitoring capability that detects imminent health threats impacting force readiness for active duty service members. The system is intended to monitor and provide alerts for rapid or unusual increases in the occurrence of infectious diseases and biological outbreaks.

Source: GAO analysis of Department of Health and Human Services, Department of Homeland Security, and Department of Defense data. I GAO-22-104600

[a]Operation Warp Speed—a partnership between the Departments of Health and Human Services (HHS) and Defense—aimed to help accelerate the development of a COVID-19 vaccine. In 2021, the Department of Defense transferred its responsibilities for Operation Warp Speed to HHS, and the operation was renamed to the Countermeasures Acceleration Group.

[b]The National Syndromic Surveillance program involves collaboration between federal, state, local, academic, and private partners who share and analyze data to identify and monitor health events.

[c]The seven study sites are Vanderbilt University Medical Center, Nashville, Tennessee; University of Rochester School of Medicine and Dentistry, Rochester, New York; Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; Texas Children's Hospital. Houston, Texas; Seattle Children's Hospital, Seattle, Washington; Children's Mercy Hospital, Kansas City, Missouri; and Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania.

[d]The seven study sites are located in California, Washington, Wisconsin, Michigan, Tennessee, Pennsylvania, and Texas in order to provide a representative sample of flu vaccine conditions across the U.S.

[e]Enteric viruses are a wide spectrum of viruses that invade and replicate in the mucosa of the intestinal tract and spread through fecal transmission.

[f]The two cities are Washington, DC and New York City and the five territories are Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

[g]Methicillin-resistant *Staphylococcus aureus* is a type of staph infection, typically of the skin, that is resistant to certain types of antibiotics.

[h]The National Healthcare Safety Network also allows health care facilities to track blood safety errors and important health care process measures such as health care personnel influenza and COVID-19 vaccination status and infection control adherence rates.

[i]The National Biosurveillance Integration System represents the federal departments and agencies with mission and resources that can contribute to earlier detection and situational awareness for nationally significant biological events.

Appendix IV: Comments from the Department of Health & Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES   OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

June 15, 2022

Jennifer R. Franks
Director, Information Technology and Cybersecurity
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Franks:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled,
***"COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness
Network"*** (GAO-22-104600).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT
ENTITLED — COVID-19: PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC
HEALTH NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK
(GAO-22-104600)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and
comment on the GAO draft report. HHS remains committed to the full implementation of the
Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019
(PAHPAIA), Public Law No. 116-22. GAO's report provides important information that can
assist HHS's ongoing efforts to fulfill this responsibility. For example, HHS is currently working
to enhance its public health situational awareness network by defining roles and responsibilities
for PAHPAIA implementation, and sharing lessons learned from the COVID-19 pandemic with
relevant stakeholders. HHS is also making strides and working toward improving the U.S.
government's medical countermeasures enterprise, building early warning systems with improved
data analytics and forecasting capability, strengthening the U.S. public health system, and
addressing health disparities.

While HHS agrees with the critical need to improve our nation's situational awareness of threats
related to public health emergencies, we continue to explore how best to implement PAHPAIA.
As HHS progresses in this work, we will describe these efforts in greater detail in the forthcoming
statement of actions, as well as through regular updates with GAO.

Recommendation 1

The Secretary of HHS should prioritize the development of the public health situational
awareness and biosurveillance network by designating a lead operational division for PAHPAIA
implementation.

HHS Response

HHS *concurs* with GAO's recommendation.

Recommendation 2

The Secretary of HHS should clearly define the roles and responsibilities for the lead operational
division responsible for PAHPAIA implementation. The roles and responsibilities should include
the specific activities required in PAHPAIA.

HHS Response

HHS *concurs* with GAO's recommendation.

Recommendation 3

The Secretary of HHS should identify the office responsible for overseeing the completion of the
activities performed by the lead operational division and clearly define its roles and

Page 1 of 4

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19: PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC HEALTH NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK (GAO-22-104600)

responsibilities.

HHS Response

Under review

Recommendation 4

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes the steps to be taken to address all of the required actions in PAHPAIA.

HHS Response

HHS *concurs* with GAO's recommendation.

Recommendation 5

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes specific near-term and long-term actions that can be completed to show progress in developing the network.

HHS Response

HHS *concurs* with GAO's recommendation.

Recommendation 6

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes time frames for implementing the near-term and long-term actions.

HHS Response

HHS *concurs* with GAO's recommendation.

Recommendation 7

The Secretary of HHS should ensure that the PAHPAIA work plan includes specific steps the department will take to oversee the progress of the actions the lead operational division takes to implement PAHPAIA requirements.

HHS Response

Page **2** of **4**

<u>**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT
ENTITLED — COVID-19: PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC
HEALTH NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK
(GAO-22-104600)**</u>

HHS *concurs* with GAO's recommendation.

<u>**Recommendation 8**</u>

The Secretary of HHS should commit to a deadline for finalizing the work plan to implement
PAHPAIA requirements and ensure that the work plan is fully implemented.

<u>**HHS Response**</u>

HHS *concurs* with GAO's recommendation.

<u>**Recommendation 9**</u>

The Secretary of HHS should ensure that the lead operational division for PAHPAIA
implementation identifies and documents the IT- and information sharing-related challenges and
lessons learned from the COVID-19 pandemic.

<u>**HHS Response**</u>

Under review

<u>**Recommendation 10**</u>

The Secretary of HHS should ensure that the lead operational division for PAHPAIA
implementation shares the lessons learned from the COVID-19 pandemic with relevant
stakeholders, such as state, territorial, and local public health officials.

<u>**HHS Response**</u>

HHS *concurs* with GAO's recommendation.

<u>**Recommendation 11**</u>

The Secretary of HHS should ensure that the lead operational division for PAHPAIA
implementation request that state, territory, and local public health officials share their lessons
learned from the COVID-19 pandemic with HHS.

<u>**HHS Response**</u>

HHS *concurs* with GAO's recommendation.

Page **3** of **4**

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT
ENTITLED — COVID-19: PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC
HEALTH NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK
(GAO-22-104600)**

Recommendation 12

The Secretary of HHS should ensure that the lead operational division for PAHPAIA
implementation incorporates lessons learned from the COVID-19 pandemic into its plans for
implementing the situational awareness and biosurveillance network.

HHS Response

HHS *concurs* with GAO's recommendation.

Page 4 of 4

Agency Comment Letter

Text of Appendix IV: Comments from the Department of Health & Human Services

June 15, 2022

Jennifer R. Franks
Director, Information Technology and Cybersecurity
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Franks:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network" (GAO-22-104600).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19: PANDEMIC LESSONS HIGHLIGHT NEED FOR PUBLIC HEALTH NEED FOR PUBLIC HEALTH SITUATIONAL AWARENESS NETWORK (GAO-22-104600)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the GAO draft report. HHS remains committed to the full implementation of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), Public Law No. 116-22. GAO's report provides important

information that can assist HHS's ongoing efforts to fulfill this responsibility. For example, HHS is currently working to enhance its public health situational awareness network by defining roles and responsibilities for PAHPAIA implementation, and sharing lessons learned from the COVID-19 pandemic with relevant stakeholders. HHS is also making strides and working toward improving the U.S. government's medical countermeasures enterprise, building early warning systems with improved data analytics and forecasting capability, strengthening the U.S. public health system, and addressing health disparities.

While HHS agrees with the critical need to improve our nation's situational awareness of threats related to public health emergencies, we continue to explore how best to implement PAHPAIA. As HHS progresses in this work, we will describe these efforts in greater detail in the forthcoming statement of actions, as well as through regular updates with GAO.

Recommendation 1

The Secretary of HHS should prioritize the development of the public health situational awareness and biosurveillance network by designating a lead operational division for PAHPAIA implementation.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 2

The Secretary of HHS should clearly define the roles and responsibilities for the lead operational division responsible for PAHPAIA implementation. The roles and responsibilities should include the specific activities required in PAHPAIA.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 3

The Secretary of HHS should identify the office responsible for overseeing the completion of the activities performed by the lead operational division and clearly define its roles and responsibilities.

HHS Response

Under review

Recommendation 4

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes the steps to be taken to address all of the required actions in PAHPAIA.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 5

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes specific near-term and long-term actions that can be completed to show progress in developing the network.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 6

The Secretary of HHS should ensure that the lead operational division, in developing the PAHPAIA work plan, includes time frames for implementing the near-term and long-term actions.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 7

The Secretary of HHS should ensure that the PAHPAIA work plan includes specific steps the department will take to oversee the progress of the actions the lead operational division takes to implement PAHPAIA requirements.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 8

The Secretary of HHS should commit to a deadline for finalizing the work plan to implement PAHPAIA requirements and ensure that the work plan is fully implemented.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 9

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation identifies and documents the IT- and information sharing-related challenges and lessons learned from the COVID-19 pandemic.

HHS Response

Under review

Recommendation 10

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation shares the lessons learned from the COVID-19 pandemic with relevant stakeholders, such as state, territorial, and local public health officials.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 11

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation request that state, territory, and local public health officials share their lessons learned from the COVID-19 pandemic with HHS.

HHS Response

HHS concurs with GAO's recommendation.

Recommendation 12

The Secretary of HHS should ensure that the lead operational division for PAHPAIA implementation incorporates lessons learned from the COVID-19 pandemic into its plans for implementing the situational awareness and biosurveillance network.

HHS Response

HHS concurs with GAO's recommendation.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Nicole Jarvis (Assistant Director), Freda Paintsil (Analyst-in-Charge), Gerard Aflague, Chris Businsky, Donna Epler, Christopher Gyra, Franklin Jackson, Grant Mallie, Kelly Rubin, Amber Sinclair, Andrew Stavisky, Walter Vance, Adam Vodraska, and AJ Yohn made key contributions to this report.

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