



August 2021

BIODEFENSE

After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness



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GAO@100 Highlights

Highlights of [GAO-21-513](#), a report to congressional committees

Why GAO Did This Study

The COVID-19 pandemic shows how catastrophic biological incidents can cause substantial loss of life, economic damage, and require a whole-of-nation response involving multiple federal and nonfederal entities. The 2018 National Biodefense Strategy outlines specific goals and objectives to help prepare for and respond to such incidents.

The CARES Act includes a provision for GAO to conduct monitoring and oversight of federal efforts to prepare for, respond to, and recover from COVID-19. This report addresses: (1) interagency plans key federal agencies developed, and exercises they conducted, to help prepare for biological incidents; and (2) the extent to which exercises and real-world incidents revealed opportunities to better achieve National Biodefense Strategy objectives.

GAO reviewed biological incident plans and after-action reports from exercises and real-world incidents from calendar years 2009 through 2019, including a non-generalizable sample of 19 reports selected based on threat scenario and other factors. GAO interviewed federal and state officials to obtain their perspectives on plans, exercises, and the COVID-19 response.

What GAO Recommends

GAO is making four recommendations each to DHS, DOD, HHS, and USDA, including that the secretaries work through the Biodefense Steering Committee to communicate exercise priorities and conduct monitoring. The departments generally concurred but in response to comments GAO modified the recommendations to reflect that the secretaries work through the Committee identified above.

For more information, view [GAO-21-513](#) or contact Chris Currie at (404) 679-1875 or CurrieC@gao.gov.

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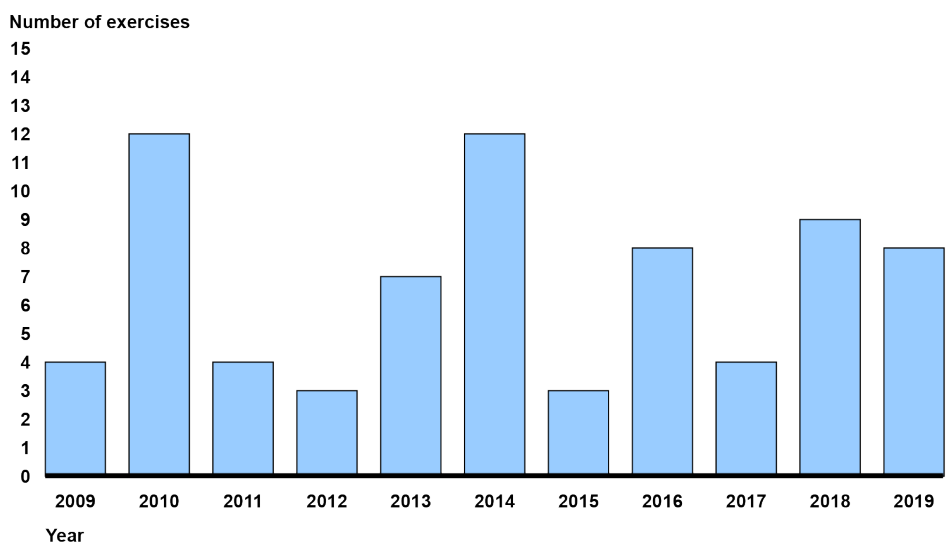
After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness

What GAO Found

Key federal agencies, including the Departments of Homeland Security (DHS), Defense (DOD), Health and Human Services (HHS), and Agriculture (USDA), developed a range of interagency response plans to prepare for nationally significant biological incidents. These strategic, operational, and tactical level plans address responding to a broad spectrum of biological threats, including those that are intentional, accidental, or naturally occurring.

DHS, DOD, HHS, and USDA conducted numerous interagency exercises to help prepare for and respond to a wide variety of biological incidents, such as anthrax attacks, influenza pandemics, and diseases affecting plants and animals. Specifically, GAO identified 74 interagency biological incident exercises conducted from calendar years 2009 through 2019.

Number of Interagency Biological Incident Exercises Conducted, Calendar Years 2009 through 2019



Source: GAO analysis of documentation from the Departments of Homeland Security, Defense, Health and Human Services, and Agriculture. | [GAO-21-513](#)

GAO's analysis of after-action reports for selected interagency biological incident exercises and real-world incidents, as well as the COVID-19 response, identified long-standing biodefense challenges. GAO found that the nation lacked elements necessary for preparing for nationally significant biological incidents, including a process at the interagency level to assess and communicate priorities for exercising capabilities. Further, it determined that agencies do not routinely work together in monitoring results from exercises and real-world incidents to identify patterns and root causes for systemic challenges. Assessing and communicating exercise priorities and routinely monitoring the results of the exercises and incidents will help ensure the nation is better prepared to respond to the next biological threat.

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Abbreviations

CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
DHS	Department of Homeland Security
DOD	Department of Defense
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
NDAA	National Defense Authorization Act
NSPM-14	National Security Presidential Memorandum-14
PanCAP	Pandemic Crisis Action Plan
SARS	Severe Acute Respiratory Syndrome
USDA	U.S. Department of Agriculture

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August 4, 2021

Congressional Committees

The outbreak of the Coronavirus Disease 2019 (COVID-19) pandemic demonstrates how catastrophic biological incidents have the potential to cause substantial loss of life and sustained damage to the economy, societal stability, and global security.¹ The National Biodefense Strategy, issued in 2018, outlines specific goals and objectives designed to help the nation prepare for and respond to nationally significant biological incidents like the COVID-19 pandemic, as well as future incidents that could be even more consequential. Throughout this report we use the term “nationally significant biological incident” to distinguish more routine public or animal health responses—such as localized or regional disease outbreaks or foodborne illness—from incidents that have an unusual impact on the nation.² Examples of nationally significant biological incidents contemplated in this report include attacks on the homeland using biological agents, emerging infectious outbreaks with pandemic potential, and declared pandemics.

The Strategy brings together, for the first time under one strategic umbrella, all the critical functions needed to prevent, detect, prepare for,

¹As defined by the National Biodefense Strategy, biological incidents are: (1) any act of biological warfare or terrorism; (2) a crime involving a biohazard; or (3) any natural or accidental occurrence in which a biohazard harms humans, animals, plants, or the environment.

²Individual federal agencies or established structures designed specifically for routine incidents generally can respond using existing authorities and responsibilities. Conversely, nationally significant biological incidents require extensive and sometimes unique applications of federal authorities and resources, across multiple federal departments and agencies, because of their scale or potential consequences (both economic and health). An overlapping concept in the context of disease outbreaks and biological attacks is the public health emergency. A public health emergency is a formal legal authority that the Secretary of Health and Human Services can invoke to direct response resources toward health-related emergencies. Apart from COVID-19 and the opioid crisis, nearly all declared public health emergencies in the past decade have been for secondary health effects resulting from climate or seismic disasters. Our definition of a nationally significant biological incident does not generally include such secondary health effects, because they tend to be more localized and can usually be addressed using existing authorities and responsibilities.

respond to, and recover from such incidents regardless of their cause.³ The nature of biological threats can be intentional, naturally occurring, or accidental and can affect human, animal, and plant health. Several federal agencies have responsibilities related to nationally significant biological incidents and for implementing the Strategy. The National Defense Authorization Act for Fiscal Year 2017 (NDAA) specifically charged four federal departments with developing the Strategy: the Departments of Homeland Security (DHS), Defense (DOD), Health and Human Services (HHS), and Agriculture (USDA).⁴

As we have previously reported, preparing for and responding to nationally significant biological incidents requires a whole-of-nation, multidisciplinary approach involving multiple federal agencies and coordination with nonfederal entities.⁵ The COVID-19 pandemic, for example, has required an unprecedented use of multiple systems and authorities established for both public health crises and natural disasters. The nation's biodefense capabilities consist of all efforts to counter biological threats, reduce risks, and prepare for, respond to, and recover from biological incidents that could have catastrophic consequences.⁶ Activities undertaken to prepare for such incidents, regardless of size or scale, include building and sustaining capabilities, developing interagency plans, conducting exercises with multiple federal and nonfederal entities, and developing after-action reports and lessons learned with corresponding corrective actions. We have previously reported on a wide range of biodefense-related efforts carried out by multiple federal

³See GAO, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, [GAO-20-273](#) (Washington, D.C.: Feb. 19, 2020).

⁴The National Defense Authorization Act for Fiscal Year 2017 (NDAA) called for the development of a national biodefense strategy. See Pub. L. No. 114-328, § 1086, 130 Stat. 2000, 2423 (2016) (codified at 6 U.S.C. § 104).

⁵[GAO-20-273](#). Nonfederal entities include state, local, tribal, and territorial entities, such as state and local public health departments, as well as private sector and nonprofit entities, such as hospitals and pharmaceutical companies.

⁶In the context of emergency management and related functions, a capability is the combination of leadership and organization, planning, personnel, training, equipment and systems, and assessment needed to successfully execute a particular mission.

departments and agencies and on long-standing challenges to building and maintaining the nation's biological defense capabilities.⁷

The CARES Act includes a provision for GAO to conduct monitoring and oversight of federal agencies' efforts to prepare for, respond to, and recover from the COVID-19 pandemic.⁸ GAO is to report on, among other things, the pandemic's effects on the health, economy, and public and private institutions of the United States, including the federal government's public health and homeland security efforts. This report addresses the following objectives:

1. What interagency plans have key federal agencies developed, and what exercises have they conducted, to help prepare for nationally significant biological incidents?
2. To what extent have past exercises and real-world incidents, including the COVID-19 response, revealed opportunities to better achieve the objectives of the National Biodefense Strategy?

To identify what interagency plans key agencies developed to help prepare for nationally significant biological incidents, we asked officials responsible for emergency preparedness planning from four key agencies—DHS, DOD, HHS, and USDA—to identify any biological incident plans their agencies contributed to from calendar years 2009 through March 2020.⁹ We reviewed strategic, operational, and tactical plans identified by the agencies to confirm whether they had both an interagency and biological incident nexus. We analyzed the interagency biological incident plans identified to obtain descriptive information on the different layers of federal planning efforts and to determine the types of biological threats covered. Specifically, we reviewed the 2018 National Biodefense Strategy, the 2017 Biological Incident Annex to the Federal

⁷GAO, *Biodefense: The Nation Faces Long-Standing Challenges Related to Defending Against Biological Threats*, [GAO-19-635T](#) (Washington, D.C.: June 26, 2019).

⁸Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020). We regularly issue government-wide reports on the federal response to COVID-19. For the latest report, see GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021). Our next government-wide report will be issued in October 2021 and will be available on GAO's website at <https://www.gao.gov/coronavirus>.

⁹We selected these agencies because of their roles in biodefense, and the NDAA requirement that they develop the National Biodefense Strategy. We selected this time period to cover a range of federal planning efforts from the H1N1 outbreak in 2009 through the beginning of the COVID-19 pandemic.

Interagency Operational Plans, the National Food and Agriculture Annex, and the 2018 Pandemic Crisis Action Plan, among others referenced in this report. We further interviewed DHS, DOD, HHS, and USDA officials to determine the process by which key agencies review and update interagency biological incident plans.¹⁰

To identify what interagency exercises these key federal agencies conducted to help prepare for nationally significant biological incidents, we obtained and reviewed documentation, such as after-action reports, on interagency biological incident exercises in which DHS, DOD, HHS, and USDA participated from calendar years 2009 through 2019.¹¹ We catalogued descriptive information, such as the exercise date, threat scenario exercised, types of exercise participants, and core capabilities exercised. We also interviewed or provided written questions to DHS, DOD, HHS, and USDA officials responsible for exercise efforts to obtain additional details on exercises within our scope.¹²

To address the extent to which past exercises and real-world incidents revealed opportunities to better achieve the objectives of the National Biodefense Strategy, we analyzed a non-generalizable, judgmental sample of 19 after-action reports developed from calendar years 2009 through 2019.¹³ The sample included 11 after-action reports produced for exercises and eight after-action reports produced for real-world incidents. To select the exercise after-action reports, we first categorized the threat scenario of each exercise based on four categories, then stratified the sample based on the proportion of exercises from each category to the total number of exercises we identified to ensure a range of different

¹⁰While biological incidents can have global implications and require outreach and coordination beyond our borders, this report focuses on domestic preparedness and response efforts.

¹¹We asked DHS, DOD, HHS, and USDA officials to identify interagency biological incident exercises in which they participated and compared the lists of exercises we received with exercise information obtained from DHS, DOD, and HHS for current and prior GAO work.

¹²Because of agencies' heavy involvement in COVID-19 response activities, we accepted written responses in lieu of meeting early in the review.

¹³We selected this time period to cover a range of exercises and events from the H1N1 outbreak in 2009 through the time period immediately before the start of the COVID-19 pandemic. Beginning in 2020, agency efforts across the whole-of-government were focused on responding to the pandemic.

scenarios.¹⁴ We then selected after-action reports in each category based on the number of federal agencies participating and the type of plan exercised.¹⁵ For real-world incidents, we selected and reviewed all of the after-action reports agencies identified for the H1N1, Ebola, and Zika incidents (a total of eight), because they were among the five incidents declared a Public Health Emergency of International Concern from 2009 through 2019.¹⁶ In addition, the H1N1 and Ebola incidents resulted the highest numbers of fatalities.¹⁷

In reviewing the 11 exercise and eight real-world incident after-action reports, we identified over 500 findings with which to conduct further analysis. We analyzed each finding from the 19 selected after-action reports and determined whether the finding had interagency implications, meaning that it involved activities undertaken by multiple federal departments. We categorized findings with interagency implications into one of the objectives from the preparedness or response goals of the National Biodefense Strategy.¹⁸ We then analyzed the results to identify any patterns or common areas of findings across the exercises. The results of our analysis are not generalizable to all biological incident after-action reports; however they provide insight into common areas of findings.

¹⁴The four categories included: (1) naturally occurring influenza incidents primarily affecting human health (“Natural influenza”); (2) naturally occurring non-influenza incidents primarily affecting human health (“Natural non-influenza”); (3) intentional incidents primarily affecting human health (“Intentional”); and (4) incidents primarily affecting animal/plant health (“Animal/plant”). We included four Natural influenza, two Natural non-influenza, three Intentional, and two Animal/plant exercise after-action reports in our sample.

¹⁵We selected exercises with the highest number of federal agencies participating as a proxy for the exercises that are more likely to have findings with interagency implications. We further considered whether the after-action reports provided sufficient detail for us to capture and categorize findings.

¹⁶The two remaining incidents declared to be Public Health Emergencies of International Concern from 2009 through 2019 were poliomyelitis (polio) (2014 to present) and the Ebola outbreak in Democratic Republic of Congo (2018–2020). The COVID-19 pandemic (2020 to present) was also declared a Public Health Emergency of International Concern.

¹⁷While fatalities from Zika infection were rare, the incident posed significant concerns for birth defects (e.g., microcephaly) in children born to mothers infected with the virus.

¹⁸We summarized the objectives for readability and ease of reporting. For a list of these objectives, see appendix I.

Because the COVID-19 response is ongoing, agencies had not yet produced after-action reports at the time of our review. We therefore reviewed documentation on initial federal response challenges, such as the Federal Emergency Management Agency's (FEMA) initial assessment report. We also asked selected agency officials and nonfederal entities—including health care and emergency management associations, health care experts, and state officials—about any challenges that emerged during the COVID-19 response and gaps in preparedness for biological incidents. Specifically, we interviewed officials from DHS, DOD, HHS, and USDA who were responsible for aspects of the COVID-19 response as well as officials from six FEMA regions, and officials from the departments of health and emergency preparedness from 10 states.¹⁹ We selected eight of these states to include a range of COVID-19 case counts per capita and number of recent disaster declarations.²⁰ We further selected these states to ensure regional diversity and include both participants and non-participants in Crimson Contagion—a 2019 large-scale influenza exercise—as well as a range in level of public health and state preparedness.²¹ In addition, we conducted an interview with the National Emergency Management Association, which offered perspectives of the association plus the individual perspectives of two additional states.²² While the results of these interviews are not generalizable to all states, they provide a range of perspectives on the topics in our review.

Once we identified and categorized findings from exercises and real-world incidents, including the COVID-19 response, we then assessed DHS, DOD, HHS, and USDA activities and documents against the National Biodefense Strategy's preparedness and response goals and objectives. Additionally, we reviewed after-action reports to determine whether past exercises focused on capabilities identified as challenges in the COVID-19 response. We also assessed agency efforts against Homeland Security Exercises and Evaluation Program guidance related to exercising capabilities and after-action reports. Several components of

¹⁹HHS regional officials participated in two of our FEMA region interviews.

²⁰The eight states are California, Colorado, Idaho, Massachusetts, Nebraska, New Jersey, New Mexico, and South Carolina.

²¹The FEMA regions we interviewed represent six of these eight states and were selected based on similar factors.

²²The two additional states were Kansas and Iowa.

standards for internal control were also significant to this objective.²³ Specifically: (1) the control environment component and the related principle that management should assign responsibility and delegate authority; (2) the information and communication component and related principle that management should communicate with external parties; and (3) the monitoring component and related principle that management should conduct ongoing monitoring and evaluations. We assessed DHS, DOD, HHS, and USDA activities and documents related to National Biodefense Strategy implementation against these components. We further interviewed DHS, DOD, HHS, and USDA officials responsible for implementing the National Biodefense Strategy to obtain their perspectives on interagency efforts to achieve the Strategy's objectives.

We conducted this performance audit from April 2020 to August 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Biological Threat Landscape

Understanding the vast and evolving biological threat landscape is a necessary step in effectively preparing for and responding to nationally significant biological incidents. Our prior work assessing biodefense activities has discussed a wide variety of biological threats facing the nation, including infectious disease threats to humans and animals, crop failure, threats of biological warfare and bioterrorism, and safety and security lapses at facilities that house biological threat agents, among others.²⁴

Biological threats can be unpredictable, as humans, animals, and plants are vulnerable to a variety of naturally occurring infectious disease and pest threats with potentially serious health, economic, and national security implications. Urbanization, habitat encroachment, and increased

²³GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sep. 10, 2014).

²⁴Recent reports from which these examples were drawn include [GAO-20-273](#) and [GAO, *Biodefense: Federal Efforts to Develop Biological Threat Awareness*, GAO-18-155](#) (Washington, D.C.: Oct. 11, 2017).

and faster travel, coupled with weaknesses in global health systems, increase the risk of infectious diseases spreading rapidly across the globe. This is evidenced by the rapid spread of COVID-19, which was first reported in Wuhan, China on December 31, 2019, declared a public health emergency in the United States by HHS on January 31, 2020, and characterized as a pandemic by the World Health Organization on March 11, 2020.

Pandemic influenza also presents a constant threat to global public health and exemplifies the susceptibility of humans to diseases with animal origins. For example, a novel influenza A (H1N1) virus emerged in 2009 with a new combination of genes from swine, avian, and human influenza viruses and led to a global pandemic. Other examples of zoonotic disease threats—infectious diseases that are transmissible between animals and humans—include the Ebola and Zika viruses, and coronaviruses such as COVID-19.

Threats to agriculture can have serious economic consequences for the nation. For example, from December 2014 through June 2015, an outbreak of high pathogenicity avian influenza (known as HPAI) in the United States led to the deaths of approximately 7.4 million turkeys and 43 million egg-laying chickens, either from the disease itself or from depopulation efforts to contain the outbreak. HPAI was detected in commercial premises, backyard flocks, wild captive birds, and/or wild birds in 21 states. According to USDA, this outbreak was the most significant animal health event in U.S. history, costing federal taxpayers more \$700 million and devastating affected agricultural businesses.

Additionally, extreme climate conditions, such as sustained drought and heat waves can affect crops and livestock, and excess precipitation can also increase flooding events and erosion, and decrease soil quality. According to DHS, in addition to the direct impact of drought and heat waves on the crops and livestock, these conditions may also render the crops, the livestock, and even the population, more susceptible to disease of either natural or intentional origin. Losses of livestock and crops from the biological threats of disease, pests, or extreme climate conditions could have significant effects on trade and the national economy.

The use of biological weapons or their proliferation by state or non-state actors also presents a significant challenge to our national security, our population, our agriculture, the economy, and the environment. Additionally, in many countries around the world, pathogens are stored in laboratories that lack appropriate biosecurity measures which increases

the risk that pathogens could be diverted by actors with intent to do harm, such as terrorist organizations or lone wolves, or be accidentally released from the facility.

Key Federal Agencies' Planning and Exercising Responsibilities

Effectively preparing for and responding to nationally significant biological incidents transcends what any one agency can achieve on its own and requires a whole-of-community approach involving federal, state, local, tribal, territorial, and private sector involvement. As stated above, at the federal level, DHS, DOD, HHS and USDA were the agencies tasked in federal law with developing a national biodefense strategy.²⁵ Each has key biodefense responsibilities from a homeland security and national security perspective, including planning and exercising functions.

- **DHS.** Within DHS, FEMA is the lead federal agency responsible for disaster preparedness, response, and recovery. As such, FEMA facilitates planning efforts for all hazards, including biological incidents. FEMA also supports efforts to exercise capabilities nationwide through the National Exercise Program—a two-year cycle of exercises that examines and validates core capabilities. The Program includes selected exercises involving federal, state, local, territorial, tribal, and private sector partners that are aligned to a set of strategic priorities.²⁶ The Countering Weapons of Mass Destruction Office leads DHS efforts and coordinates with domestic and international partners to safeguard the United States against chemical, biological, radiation, nuclear, and health security threats. This includes serving as the DHS lead for developing biodefense strategy and policy, and coordinating the Department's efforts to

²⁵See Pub. L. No. 114-328, § 1086, 130 Stat. at 2423 (codified at 6 U.S.C. § 104). While our report focuses on the four departments originally tasked with developing the National Biodefense Strategy, a number of departments and agencies have responsibility for implementing the Strategy, which we describe in the next section.

²⁶These priorities are referred to as the Principals' Strategic Priorities and are determined by the Principals' Committee of the National Security Council. The priorities are determined by stakeholder input, data from reports such as the National Preparedness Report and the Threat and Hazard Identification and Risk Assessment, and exercise and real-world after-action reports, among other things.

defend U.S. food, agriculture, and veterinary systems against terrorism and other high-consequence events.²⁷

- **DOD.** DOD protects U.S. armed forces from biological threats worldwide. DOD is also responsible—subject to the availability of resources and the direction of the President or by approval of the Secretary of Defense—for providing support functions and supplementing civil authorities’ resources in response to public health and medical disasters. Within DOD, U.S. Northern Command provides strategic planning guidance for the department’s efforts to prepare for and respond to pandemic diseases, including influenza and other infectious diseases.
- **HHS.** The Assistant Secretary for Preparedness and Response leads the nation’s medical and public health preparedness effort for responding to and recovering from disasters and public health emergencies, such as biological incidents.²⁸ This office is responsible for coordinating the federal public health and medical response to emergent threats and all-hazards incidents, and develops and conducts exercises focused on HHS preparedness issues, among other things. It also leads the Biodefense Coordination Team, which coordinates implementation of the National Biodefense Strategy. The Centers for Disease Control and Prevention (CDC) supports public health preparedness efforts to prevent, detect, and respond to new and emerging health threats.²⁹ Within the National Institutes of Health, the National Institute of Allergy and Infectious Diseases conducts and supports research to control and prevent infectious disease. The Food

²⁷Additional DHS components also play a role in biodefense. For example, DHS’s Science and Technology Directorate leads key efforts related to enhancing threat awareness with a focus on bioterrorism; U.S. Customs and Border Protection plays a role in detecting biological threats at the border; and the U.S. Coast Guard conducts ports and waterways coastal security, search and rescue, and marine safety missions during a biological incident.

²⁸The Assistant Secretary for Preparedness and Response leads preparedness efforts through planning and response; building federal emergency medical operational capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. Among other things, the office also maintains the Strategic National Stockpile, a federal stockpile of vaccines, pharmaceuticals, and medical supplies and devices designed to be available for rapid deployment in a public health emergency.

²⁹CDC provides scientific expertise and collaborates with state, local, and international departments of health through the advancement of core public health functions such as surveillance, epidemiology and assessment sciences, and laboratory science.

and Drug Administration is also responsible for emergency and crisis response activities involving regulated products, such as intentional acts of food supply adulteration.³⁰

- **USDA.** USDA is the lead agency with responsibility to protect and improve the health, quality, and marketability of our nation's agricultural products. Within USDA, the Animal and Plant Health Inspection Service is responsible for working to prevent, control, or eliminate harmful pests, pathogens, and diseases of animals and plants. The Service consists of multiple component units with key roles in biodefense including Veterinary Services and the Plant Protection and Quarantine program. The Office of Homeland Security leads the department's security, preparedness and response efforts. The Food Safety and Inspection Service is USDA's public health agency and promotes food defense and preparedness to respond to acts of intentional food contamination.³¹

National Biodefense Strategy's Preparedness and Response Goals

The National Biodefense Strategy, issued in September 2018, outlines a whole-of-government approach intended to help the United States actively and effectively assess, prevent, prepare for, respond to, and recover from all types of biological threats, whether they are natural, accidental, or deliberate. The Strategy consists of five high-level goals with associated objectives and sub-objectives designed to strengthen the biodefense enterprise.³² Two goals specifically address preparedness and response actions needed to reduce or limit the effects of biological incidents. For example, they outline key objectives to strengthen public and veterinary health infrastructure as well as objectives designed to coordinate response actions, such as ensuring risk-informed, accurate, timely, and actionable public messaging during a response. Table 1 below summarizes the objectives under the Strategy's preparedness and

³⁰The Food and Drug Administration is also responsible for ensuring that medical countermeasures—such as drugs, vaccines, and diagnostic tests—are safe, effective, and secure. Additional HHS offices with a role in biodefense preparedness and response include the Office of Global Affairs and the Office of National Security, among others.

³¹Food defense is the protection of food products from intentional contamination or adulteration where there is an intent to cause public harm or economic disruption.

³²The five goals include: (1) Enable risk awareness to inform decision making across the biodefense enterprise; (2) Ensure capabilities to prevent bioincidents; (3) Ensure preparedness to reduce the impacts of bioincidents; (4) Rapidly respond to limit the impacts of bioincidents; and (5) Facilitate recovery to restore the community, the economy, and the environment after a bioincident.

response goals. For additional information on each of the objectives, see appendix I.

Table 1: National Biodefense Strategy Preparedness and Response Objectives

Preparedness

- Support U.S. biodefense research, development, and investment
- Ensure a strong public and veterinary health infrastructure
- Develop, exercise, and update plans and capabilities
- Develop, exercise, and update risk plans to support effective public messaging, enhance public trust, and promote consistent messaging
- Improve diagnostic capabilities and enhance medical countermeasures
- Enhance community mitigation measures development and capabilities
- Enhance decontamination preparedness
- Improve the ability for the federal government to collaborate with states and territories
- Work with international governments to improve global preparedness

Response

- Manage information
 - Coordinate response operations and resources
 - Conduct operations and investigations for intentional incidents
 - Provide effective public messaging
-

Source: GAO summary of National Biodefense Strategy information. | GAO-21-513

The Strategy is important because of the complexity and fragmentation inherent in an enterprise mission like biodefense. For example, our prior work identified the need for a strategy to help ensure efficiency and effectiveness across the entire biodefense enterprise (including federal agencies, nonfederal governments, and private/nonprofit entities) by connecting strategic approaches and investment decisions across disparate but interrelated functions within the biodefense enterprise.³³ These functions are (1) understanding and defining threats, (2) taking action to prevent and protect against attacks and significant national and international infectious disease outbreaks, (3) employing new and existing techniques and technologies to more quickly detect biological events, and (4) preparing to respond and recover.

National Security Presidential Memorandum-14 (NSPM-14)—issued at the same time as the Strategy—provides a governance structure to guide the Strategy’s implementation, coordinate federal biodefense activities,

³³See GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar 1, 2011).

and assess the effectiveness with which its goals and objectives are being met. NSPM-14 created the Biodefense Steering Committee, which is chaired by the Secretary of HHS and includes the heads of federal agencies with biodefense responsibilities or capabilities as members. It also required the formation of a Biodefense Coordination Team. The Team consists of staff from multiple agencies, and its purpose is to assist the Committee in monitoring and coordinating implementation of the Strategy.³⁴

NSPM-14 lays out, in broad strokes, a process to identify budget priorities across federal biodefense efforts and to assess (1) how current resources support the Strategy, (2) how existing programs and resources could better align with the Strategy, and (3) how additional resources, if available, could be applied to support the goals of the Strategy. This process begins through a data call with participating agencies documenting all biodefense programs, projects, and activities within their purview in a biodefense memorandum. This information is then assessed by the Biodefense Coordination Team and helps inform Joint Policy Guidance for the president's annual budget.

According to the Strategy, the Biodefense Steering Committee is expected to reach beyond the federal government and engage with nonfederal and nongovernmental entities, and to communicate recommendations and feedback stemming from this outreach to agencies in coordination with the annual budget cycle. NSPM-14 further states that agencies are to coordinate and manage biodefense activities in support of the broader biodefense enterprise, which includes federal, nonfederal, nongovernmental, and international partners. This is consistent with our past reporting that state and local resources are integral to supporting national biodefense capabilities, such as biosurveillance, and should be considered in federal planning efforts.³⁵

³⁴As identified in its charter, Biodefense Coordination Team members include representatives from: HHS, DOD, DHS, the Environmental Protection Agency, USDA, the Department of Justice (including the Federal Bureau of Investigation), the Department of Veterans Affairs, the Office of the Director of National Intelligence, the U.S. Agency for International Development, and the Departments of State, Commerce, Energy, Treasury, Interior, Transportation, and Labor.

³⁵GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, [GAO-12-55](#) (Washington, D.C.: Oct. 31, 2011).

The National Preparedness Goal and Public Health Capabilities

Following Hurricane Katrina in 2005, the Post-Katrina Emergency Management Reform Act of 2006 required FEMA to develop a national preparedness system and assess preparedness capabilities to determine the nation's disaster preparedness.³⁶ The White House released Presidential Policy Directive/PPD-8 on National Preparedness in March 2011. It directed the Secretary of Homeland Security to design a national preparedness system to address the threats posing the greatest risk to the security of the nation and issue various policy and planning documents designed to strengthen national preparedness. Additionally, it required the Secretary to develop a National Preparedness Goal that identifies the core capabilities necessary to achieve preparedness. In September 2011, DHS issued the National Preparedness Goal, which identifies and defines 32 core capabilities for national preparedness across five broad mission areas, which include but are not limited to disaster and emergency response.³⁷ These capabilities apply to all hazards and threats and are not incident specific. They form the foundation for measuring overall national preparedness and assisting the nation in allocating resources to fill identified preparedness gaps. Examples of these capabilities include information sharing, community resilience, logistics and supply chain management, mass care services, and housing, among others.³⁸

Additionally, in 2011, CDC developed 15 public health-specific capabilities as part of the Public Health Emergency Preparedness program to advance the emergency preparedness and response capacity of state and local public health systems.³⁹ CDC updated these capabilities in 2018 to address emerging technologies and threats.⁴⁰ According to CDC, these capabilities support the public health and medical components of the 32 core capabilities specified in the National Preparedness Goal. Examples of the public health capabilities include

³⁶U.S.C. §§ 744, 749.

³⁷The five mission areas are: prevention, protection, mitigation, response, and recovery.

³⁸The National Preparedness Goal identifies five functional areas or activities that contribute to building each core capability: planning, organizing, equipping, training, and exercising. This report focuses on two of these five areas: planning and exercising.

³⁹The Public Health Emergency Preparedness program provides funding to build and sustain public health preparedness and response capacity.

⁴⁰U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Health* (Atlanta, GA: October 2018).

medical countermeasure dispensing and administration, responder safety and health, and mass care, among others.⁴¹ For a complete list of National Preparedness Goal and public health capabilities, see appendix II.

Prior GAO Work on Biodefense and COVID-19

Since 2009, we have identified broad, cross-cutting issues in leadership, coordination, and collaboration that arise from fragmentation throughout the complex interagency, intergovernmental, and intersectoral biodefense enterprise. Our past work has identified a number of key challenges related to the nation's ability to detect and respond to biological incidents that transcend what any one agency can address on its own.⁴² Since March 2011, we have reported that the biodefense enterprise would benefit from institutionalized leadership with sufficient time, responsibility, authority, and resources needed to promote efficiency and accountability.⁴³ We further called for a national biodefense strategy and focused leadership because addressing these issues is a difficult and complex challenge that crosses mission areas, federal departments, and sectors.

In February 2020, we reported that the National Biodefense Strategy and its associated plans presented an opportunity to identify gaps and consider enterprise-wide risk and resources for investment trade-off decisions. We also reported on the early challenges agencies faced implementing the National Biodefense Strategy.⁴⁴ Among other things, we found that there was no documented methodology or guidance for how data are to be analyzed to help the enterprise identify gaps and opportunities to leverage resources, including no guidance on how nonfederal capabilities are to be accounted for in the analysis. Additionally, we found there were no clear, detailed processes, roles, and responsibilities for joint decision-making, including how agencies will identify opportunities to leverage resources or who will make and enforce those decisions. We made recommendations on these and other

⁴¹Medical countermeasures include both pharmaceutical products, such as vaccines, and non-pharmaceutical products, such as ventilators, diagnostic tests, and personal protective equipment, that may be used to prevent, mitigate, or treat health effects from a biological incident.

⁴²[GAO-19-635T](#).

⁴³GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar 1, 2011).

⁴⁴[GAO-20-273](#).

challenges to the Biodefense Coordination Team, which under NSPM-14 currently has responsibility for coordinating Strategy implementation.⁴⁵

Beginning in June 2020, we have issued a series of products in response to CARES Act provisions requiring GAO to report on our ongoing monitoring and oversight efforts related to the COVID-19 pandemic.⁴⁶ Our reports examine key actions the federal government has taken to address the COVID-19 pandemic and evolving lessons learned relevant to the nation's response to pandemics. Among other things, we reported on medical supply chain shortages; the need for clarity on the federal government's plans for distributing and administering vaccines; and inconsistencies on guidance for reopening schools. Overall, we identified four evolving lessons learned: (1) establish clear goals and define roles and responsibilities; (2) provide clear communication; (3) collect and analyze adequate and reliable data to drive future decisions; and (4) establish transparency and accountability mechanisms. We made 72 recommendations to federal agencies between June 2020 and March 2021 on these and other issues. We are monitoring ongoing efforts to address these recommendations.

Agencies Developed Interagency Response Plans and Conducted Biological Incident Exercises

Key federal agencies developed a range of interagency response and crisis action plans for biological incidents to provide strategic vision, describe operational coordination and incident command, and guide tactical response decisions. Likewise, agencies conducted numerous interagency exercises since 2009 to help prepare for and respond to a

⁴⁵HHS, which chairs the Biodefense Steering Committee, concurred with each of our recommendations, and in April 2021 reported steps underway to address them. We continue to monitor their efforts.

⁴⁶See GAO, *Opportunities to Improve Federal Response and Recovery Efforts*, [GAO-20-625](#) (Washington, D.C.: June 25, 2020); GAO, *COVID-19: Federal Efforts Could be Strengthened by Timely and Concerted Actions*, [GAO-20-701](#) (Washington, D.C.: Sept. 21, 2020); GAO, *COVID-19: Federal Efforts Accelerate Vaccine and Therapeutics Development, But More Transparency Needed on Emergency Use Authorizations*, [GAO-21-207](#) (Washington, D.C.: Nov. 17, 2020); GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, [GAO-21-191](#) (Washington, D.C.: Nov. 30, 2020); 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); and GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, [GAO-21-387](#) (Washington, D.C.: Mar. 31, 2021).

wide variety of biological incidents.⁴⁷ These planning and exercising activities included participation from more than one federal agency and leveraged frameworks used in all-hazards response, like the National Response Framework. Interagency exercises also included nonfederal participation.

Key federal agencies developed interagency response and crisis action plans

To prepare for nationally significant biological incidents, key federal agencies developed interagency response and crisis action plans informed by national level strategies. These strategies and plans reflect a continuum along long-range strategic vision at the highest level, to intermediate operational guidance (that describes how incident command is to be coordinated and structured to ensure clear roles and responsibilities for critical response functions), and finally, to tactical, incident-specific guidance at the most immediate and concrete level. DHS, DOD, HHS, and USDA officials identified national level strategy and planning frameworks that create an architecture that informed the specific biological incident response and crisis action plans the agencies developed.

According to agency officials, high-level national security strategies—specifically, the National Security Strategy and the Global Health Security Strategy, provide some of the highest-level strategic visions that inform their planning. Similarly, specific to nationally significant biological incidents, the 2018 National Biodefense Strategy provides an overarching strategic vision for how to achieve preparedness. Officials from two agencies also noted that they relied on the National Strategy for Pandemic Influenza to provide strategic and operational direction in the initial COVID-19 response.⁴⁸

The National Security Strategy sets priorities to address a broad array of threats to American interests, including biological threats. The Global Health Security Strategy describes how the United States will enhance the ability to prevent, detect, and respond to infectious disease threats globally and domestically by working with other nations, international

⁴⁷The scope of our work covers the ten year period from 2009 to March 2020 to reflect the time between the last declared global pandemics.

⁴⁸While the scope of our work covers 2009 to March 2020, two agencies identified the 2005 National Strategy for Pandemic Influenza as a key strategy document, maintaining that despite its age, it has not been superseded and remains an important planning document. Agencies also develop agency-specific response plans for biological incidents that pertain to internal operations, such as ensuring the continuity of operations during a biological incident. These plans are not reflected here, as our focus is interagency plans.

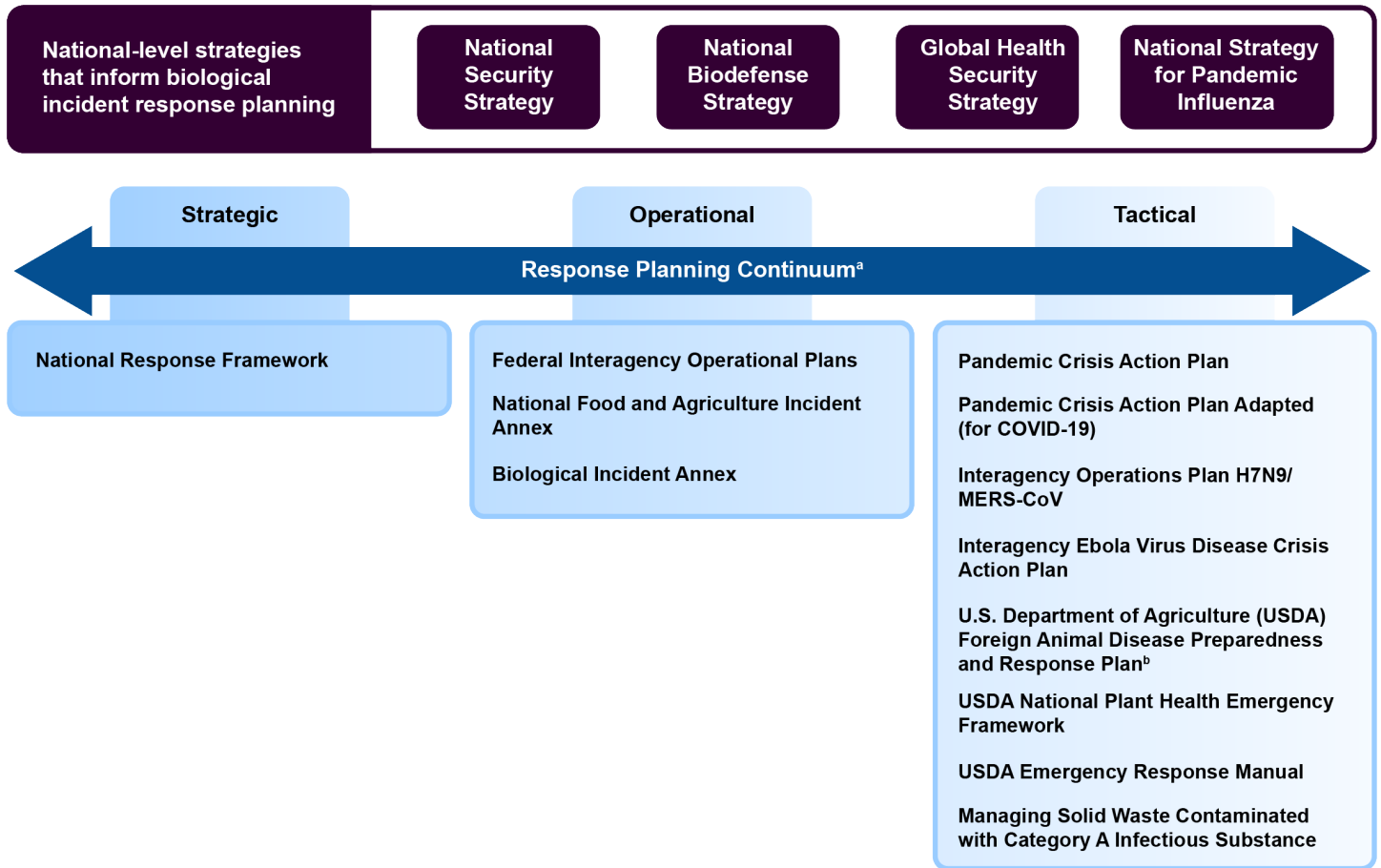
organizations, and nongovernmental stakeholders. The National Biodefense Strategy is specific to preparing for and responding to nationally significant biological threats regardless of their source; whereas the National Strategy for Pandemic Influenza addresses national coordination to prepare, detect, and respond to a pandemic.

Agencies engage in deliberate and incident-specific planning activities to advance national preparedness, that are guided by a long range vision and goals articulated in national level strategies. DHS developed a layered planning architecture with its National Planning System, which supports the National Preparedness Goal. This planning architecture creates the strategic, operational, and tactical levels of planning and planning integration. As described in DHS planning guidance, use of the National Planning System promotes a unified approach to planning through vertical and horizontal integration of plans across the whole community, including federal and nonfederal entities. Because the response to catastrophic incidents requires the capabilities of a wide range of stakeholders, DHS planning guidance supports planning that engages the whole community to developing response plans that appropriately anticipate the necessary resources and authorities, and identify the roles and responsibilities among partners for specific incidents.

The biological incident response plans DHS, DOD, HHS and USDA identified developing are nested within this planning architecture, as described below. However, while agencies work together to develop these plans, they may also interpret or use response plans in various ways, meaning that along the continuum of strategy and plans, some documents, such as the 2018 Pandemic Crisis Action Plan (PanCAP) may provide both operational and tactical guidance, depending on the context and the issues at hand.⁴⁹ We present the plans agencies identified along a continuum below, recognizing that plans may straddle more than one category (see figure 1).

⁴⁹The PanCAP focuses on incidents generated by viral pathogens that have pandemic potential.

Figure 1: Federal Interagency Biological Incident Planning Framework and Selected Response Plans, As Identified By Agencies



Source: GAO analysis of documentation from the departments of Homeland Security, Health and Human Services, Defense, and Agriculture. | GAO-21-513

^aPlans may straddle more than one category.

^bThe suite of documents within the USDA Foreign Animal Disease Preparedness and Response Plan includes disease-specific response plans, strategies, and concept of operations.

Strategic level. Strategic level planning allows stakeholders to identify a long-term vision and serves as a mechanism for unifying the efforts of multiple entities to support a comprehensive approach for addressing a particular issue or mission through agreed-upon governance, priorities, doctrine, and desired end-state.⁵⁰ At the strategic level, the National Response Framework—coordinated by DHS—is the nation’s highest level

⁵⁰DHS, *National Planning System*, February 2016.

guidance for how to prepare for a response to any type of disaster, regardless of the source of the hazard. The National Response Framework provides foundational emergency management doctrine for how the nation responds to all types of incidents.⁵¹ This all-hazards approach is designed to manage any type of disaster or emergency response, regardless of scale, scope, and complexity, including biological incidents. The National Response Framework sets the highest-level planning framework and doctrine for how entities build, sustain, and deliver response capabilities identified in the National Preparedness Goal. The biological incident plans key agencies identified make specific mention of their nexus to the National Response Framework.

Operational level. Planning efforts at the operational level may be guided by the objectives or priorities in national-level strategies, like the National Biodefense Strategy, and leverage guiding principles from strategic level plans, but operational plans further articulate the roles, responsibilities, and critical tasks among agencies that are needed for response.⁵² Biological incidents can affect the health of humans, animals, plants, and the environment; occur internationally or domestically; and may be intentional, accidental, or occur naturally, as in cases of infectious disease spread. Given the variety of scenarios these events can prompt, conducting deliberate planning at the operational level allows federal agencies and their nonfederal stakeholders to familiarize themselves—for example, through exercises for biological incidents—with which roles and responsibilities and what authorities might be used in different scenarios.

Within the National Response Framework are the Federal Interagency Operational Plans, which provide a federal concept of operations to integrate and synchronize national-level capabilities, and cover prevention, protection, mitigation, response, and recovery activities to support all levels of government.⁵³ Specifically, the Response Federal Interagency Operational Plan describes how the federal government coordinates its efforts to save lives, protect property and the environment,

⁵¹National level strategies that inform further strategic planning also have goals and objectives that cover international response efforts. However, we have focused attention on the National Response Framework because this report focuses on domestic, whole-of-nation response activities for biological incidents.

⁵²DHS, *National Planning System*, February 2016.

⁵³These plans also help federal departments and agencies develop and maintain department-level operational plans.

stabilize communities, and meet basic human needs following an emergency or disaster.

The response to certain types of threats or hazards may require unique roles, responsibilities, resources, and concepts of operations that are not addressed by the Response Federal Interagency Operational Plan.⁵⁴ Although the all-hazards approach of the National Response Framework offers a foundation for the response and recovery function for biodefense, the context in which federal agencies support response or recovery functions is different for nationally significant biological events, and some needs are wholly unique. Two specific incident annexes under the National Response Framework identified by key agencies are designed to address a variety of biological threats. They are the Biological Incident Annex and National Food and Agriculture Incident Annex to the Response and Recovery Federal Interagency Operational Plans.⁵⁵ These annexes identify, among other things, the lead federal agency for various types of incidents as well as funding and authorities to be leveraged for a response.

Officials from DOD and DHS identified the Biological Incident Annex as the primary interagency plan they use in response to biological events. As part of the National Response Framework, these plans are designed to be scalable, flexible, and adaptable to biological incidents, but are fundamentally federal level planning documents, which focus on the federal government's ability to support nonfederal response efforts during a biological incident.

The Biological Incident Annex and National Food and Agriculture Incident Annex identify the lead federal agency for the response, depending on the type of incident. For example, USDA is the lead federal agency for incidents involving animal and plant agriculture, while HHS is the lead federal agency for naturally occurring or intentional domestic incidents affecting human health. According to the incident annexes, during

⁵⁴DHS, *National Response Framework*, Fourth Edition, October 28, 2019.

⁵⁵Other individualized incident annexes address the threats of power outage, cyber incidents, oil/chemical incidents, nuclear/radiological incidents, terrorism, mass evacuation, and impending space weather incidents.

complex incidents, FEMA may be called upon to provide supplemental operational coordination support to the lead federal agency.⁵⁶

Finally, both incident annexes describe how the response to biological incidents will remain dynamic throughout, as full information about the incident may not be immediately available. For example, decisions during a response will be based on incomplete information as the cause, origin, transmission, and impact of the biological incident may take time to uncover and may evolve as events progress. Both documents also recognize that events could also have cascading effects, such as economic consequences, or may generate public fear.

Tactical level. In a supporting role to the incident annexes and further along the response planning continuum, DHS, DOD, HHS and USDA identified an additional layer of interagency response planning that is targeted to specific biological incidents. Tactical level planning may include both pre-incident plans and real-time plans. Key agencies identified the following as incident-specific response plans that represent pre-incident tactical planning efforts: the 2018 PanCAP, the USDA Foreign Animal Disease Preparedness and Response Plan, and the USDA National Plant Health Emergency Management Framework.⁵⁷ The 2018 PanCAP operationalized the Biological Incident Annex to focus on incidents generated by viral pathogens that have pandemic potential. The USDA Foreign Animal Disease Preparedness and Response Plan further operationalizes the National Food and Agriculture Incident Annex and consists of a suite of response planning materials.⁵⁸ The USDA National Plant Health Emergency Management Framework encompasses

⁵⁶During the early COVID-19 response, FEMA provided more than supplemental support. The FEMA Administrator was part of the Unified Coordination Group, the entity which provided incident management of the entire response effort. FEMA, specifically, provided logistics management support to address key supply chain shortages. FEMA, as of January 21, 2021, has also been assisting vaccine distribution efforts in alignment with the new administration's response strategy.

⁵⁷USDA also identified an interagency plan issued in 2019 on the proper handling and disposal of potentially highly infectious waste. Agencies developed this plan in response to challenges United States health care and waste management facilities experienced in 2014-2015 as a result of treating patients with Ebola virus disease. Ebola after-action reports developed by both the CDC and the National Security Council identified problems with unclear guidelines, processes, and communication plans with regard to hazardous waste management.

⁵⁸These materials include manuals on information management, standard operating procedures, roles and coordination among federal and nonfederal agencies and private industry, as well as disease-specific response plans and strategies that address activities related to diagnosing, treating, controlling, and eradicating the specific disease.

guidance on preventing, preparing, responding, and recovering from invasive pest introductions.

Officials from DHS, DOD, and HHS familiar with the planning processes of their agencies, as well as those with expertise in preparing for biological incidents, said that this type of pre-incident tactical planning that addresses specific types of biological incidents is beneficial, in part, because those plans immediately identify the key response partners needed to address the crisis. According to the National Planning System, tactical plans often outline the detailed actions necessary to accomplish goals identified in an operational plan, such as the types of personnel or equipment needed. In the biological incident context, this could mean identifying needs for alternative care facilities or knowing how and when to engage subject matter experts. For example, USDA personnel may be needed during a response to determine which animal products or live animals have the potential to introduce or spread a pandemic virus.

DHS and DOD officials said it is still important to recognize that each biological incident will have unique characteristics, so even these pre-incident tactical level plans may need to be further adapted to real-time tactical plans during an event. However, these officials also said that having pre-incident plans at this level allows also for opportunities to exercise these plans in order to bring together all the key parties on a more regular basis to discuss plan implementation and identify gaps.

Plans Have Evolved to Reflect Lessons Learned and New Threats

Federal agencies with responsibility for the range of plans in the National Planning System architecture have revised and adapted them over the years to reflect lessons learned from exercises and real-world events. For example, the 2017 revision of the Biological Incident Annex incorporated lessons learned from the H1N1 2009 pandemic, Ebola Virus Disease of 2013-2014, and Zika Virus Disease in 2015-2017. DHS officials stated that the revision also drew from lessons learned from exercises focused on aerosolized Anthrax attacks on large cities and the Severe Acute Respiratory Syndrome (SARS) outbreak. According to DHS officials, the Biological Incident Annex is currently undergoing another review and revision. Officials stated this revision will incorporate lessons learned from the ongoing COVID-19 pandemic, as well as lessons learned from the 2019 Crimson Contagion exercise, which exercised the planning

assumptions in both the Biological Incident Annex and the 2018 PanCAP.⁵⁹

According to FEMA officials and other federal agency officials we interviewed, FEMA determines when to review and revise the plans that fall under the National Response Framework, such as the Biological Incident Annex. DHS officials noted that when planning any revision to planning documents, they consider the following elements: (1) changes in guidance from DHS leadership, (2) any new information that informs the facts or assumptions underpinning planning efforts, and (3) past lessons learned. Officials we spoke with from all four agencies described how FEMA engages other federal agencies in its planning cycle, and officials from the DHS Countering Weapons of Mass Destruction Office and HHS said they are involved in the current revision of the Biological Incident Annex. USDA officials also said that FEMA finalized updates to the National Food and Agriculture Incident Annex—to which USDA contributed—in 2020, and they provide input on other planning documents when requested.

FEMA officials said they typically review the planning annexes on a two or three year schedule, but not all are reviewed on that schedule. They said that if an annex or plan has not been revised, that does not indicate a lack of planning. For example, officials noted that in between the 2008 and 2017 versions of the Biological Incident Annex, agencies worked together to develop other biological incident planning documents. Examples of these plans include the 2013 PanCAP and interagency plans to address the threat from Ebola, H7N9 avian influenza, and Middle-East Respiratory Syndrome Coronavirus.⁶⁰

⁵⁹The Crimson Contagion 2019 Functional Exercise, conducted August 13–16, 2019, exercised the nation’s ability to respond to a large-scale outbreak of a novel avian influenza virus (H7N9) strain, which quickly spreads via human-to-human transmission around the world and across the continental United States with high rates of morbidity and mortality. The after-action report for the exercise identified a number of areas for improvement related to planning and other response functions, including that the organization of the federal government response when HHS is the lead federal agency was not sufficiently outlined in the Biological Incident Annex or the 2018 PanCAP. As we reported in June 2020, HHS officials told us they had not been able to address the Crimson Contagion findings because they were busy responding to the COVID-19 pandemic. FEMA officials similarly told us that they were not able to implement solutions before the pandemic response began. See [GAO-20-625](#).

⁶⁰According to FEMA officials, the 2013 PanCAP was revised in 2018.

In the early stages of the COVID-19 pandemic, agencies adapted the 2018 PanCAP, thereby creating a real-time tactical plan to address the needs of the whole-of-nation response. The *PanCAP Adapted U.S. Government COVID-19 Response Plan* (PanCAP Adapted), issued March 13, 2020, was created to outline in real time the key federal decisions, federal actions, and interagency coordination structures that may be used during the COVID-19 pandemic. It was designed to coordinate activities to limit the spread of COVID-19; to mitigate the effect of illness, suffering, and death; and to sustain critical infrastructure and key resources in the United States. Modifications made to adapt the 2018 PanCAP to the PanCAP Adapted for the COVID-19 response included: (1) creating a White House Coronavirus Task Force to coordinate the whole-of-government approach, (2) updating facts, assumptions, and critical considerations unique to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, the virus that causes COVID-19), as it was understood at the time, (3) expanding coordination structures for each phase of the response, including options for HHS lead and FEMA lead with the Unified Coordination Group, and (4) creating an Operations Annex with detailed implementation guidance using a task force construct.⁶¹ According to DOD officials, response actions during the COVID-19 pandemic continue to evolve to adapt to changing needs, but the PanCAP Adapted has not been modified to reflect every evolution of this dynamic event.⁶²

Officials said that they plan to revise the 2018 PanCAP in 2021 to highlight existing COVID-19 response structures that have been

⁶¹The FEMA Administrator, the Assistant Secretary for Preparedness and Response at HHS, and a CDC representative jointly lead the Unified Coordination Group for COVID-19, which coordinates federal response and recovery operations. As we reported in June 2020, to address the multiple dimensions of the early pandemic response, eight operational task forces brought together federal departments and agencies with the relevant expertise, authorities, and capabilities necessary to address unmet needs. Through these task forces, the National Response Coordination Center which is operated out of FEMA and is the hub for coordinating actions and resources across federal agencies, can use existing authorities, processes, resources, and funding for each of the agencies that comprise each Emergency Support Function under the National Response Framework to meet the needs of the response as they arise. See [GAO-20-625](#). The Unified Coordination Group is a key coordination structure identified in the Incident Annexes mentioned above.

⁶²DOD officials further stated that even the 2020 PanCAP Adapted, when it was released in March 2020, reflected a single moment and understanding of the conditions at the time and that agencies have continued to learn and adapt to the pandemic conditions to execute response actions.

successful and shift the focus from short-term response to planning for emerging infectious diseases with pandemic potential. Officials from all four agencies described ongoing efforts to collect lessons learned from the COVID-19 response which will be used when updating plans, such as the PanCAP.

In addition to interagency planning efforts, as the pandemic continues to unfold and changes in leadership have occurred, additional changes to manage the COVID-19 response continue to be made. For example, in January 2021, the new administration released a new National Strategy for the COVID-19 Response and Pandemic Preparedness. This strategy includes goals for addressing the pandemic and is intended to improve the effectiveness of the response and improve public trust and accountability. On January 20, 2021, the President issued an Executive Order to reorganize the structure of the COVID-19 response.⁶³ DHS officials said they take these types of policy changes into consideration when updating response planning documents. However, because updates to the BIA and PanCAP are not yet complete, it is not clear whether or how these changes will be reflected.

Agencies Conducted Numerous Interagency Biological Incident Exercises

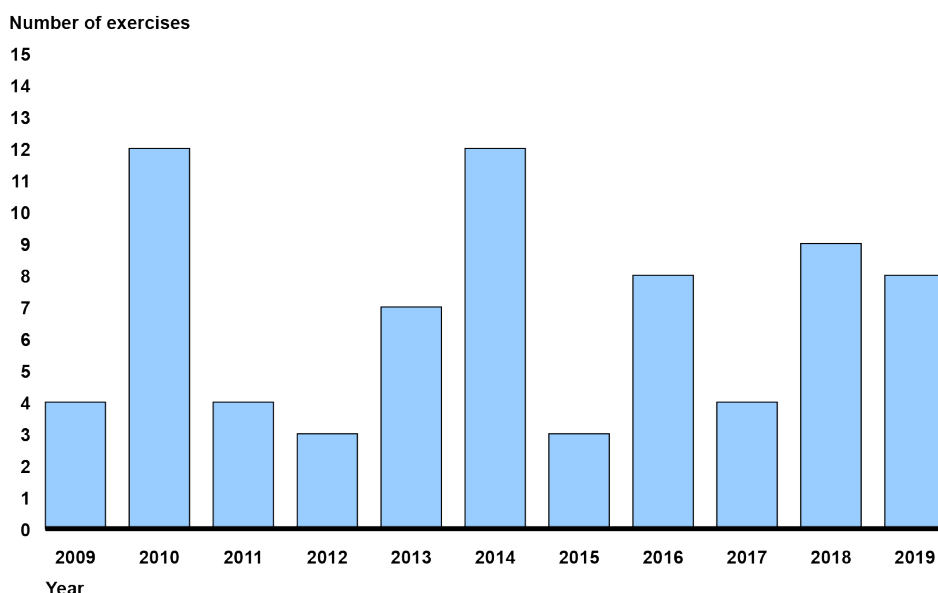
Key federal agencies have conducted numerous interagency exercises to prepare for biological incidents. Specifically, we identified 74 interagency biological incident exercises conducted from calendar years 2009 through 2019.⁶⁴ We defined “interagency” to mean participation from one of the federal departments in our scope (DHS, DOD, HHS, or USDA) and at least one other federal department or agency. The exercises we identified ranged from smaller tabletop exercises with a limited number of participants exercising a biological incident scenario in one geographic area, to full-scale functional exercises involving multiple federal and

⁶³The Executive Order “established within the Executive Office of the President the position of Coordinator of the COVID-19 Response and Counselor to the President (COVID-19 Response Coordinator) and the position of Deputy Coordinator of the COVID-19 Response. The COVID-19 Response Coordinator shall report directly to the President; advise and assist the President and executive departments and agencies (agencies) in responding to the COVID-19 pandemic; coordinate all elements of the COVID-19 response; and perform such duties as the President may otherwise direct.” Exec. Order No. 13,987, 86 Fed. Reg. 7019 (Jan. 25, 2021).

⁶⁴We identified these exercises through interviews with DHS, DOD, HHS, and USDA officials and documentation provided by each agency, as well as by reviewing documentation from current and prior GAO work.

nonfederal partners exercising widespread scenarios.⁶⁵ As shown in figure 2, at least three exercises were conducted each calendar year during this time period, and 2010 and 2014 saw the highest number, at 12 exercises each.

Figure 2: Number of Interagency Biological Incident Exercises Conducted, Calendar Years 2009 through 2019



Source: GAO analysis of documentation from the Departments of Homeland Security, Defense, Health and Human Services, and Agriculture. | GAO-21-513

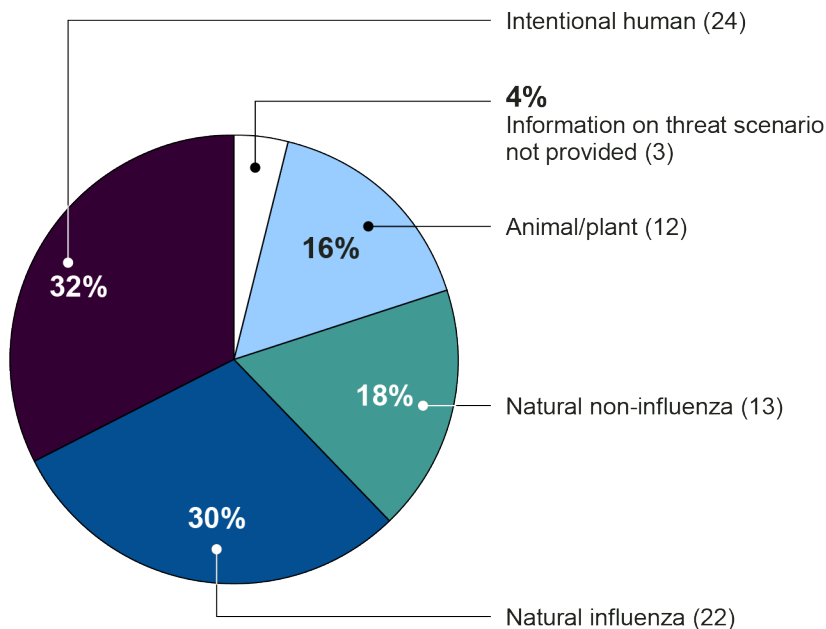
Note: We identified 74 biological incident exercises in which the Department of Homeland Security, Defense, Health and Human Services, or Agriculture and at least one other federal department or agency participated. The total includes 21 individual exercises that were conducted across five separate exercise series. Exercises conducted as part of the same exercise series typically use the same threat scenario. Specifically, the total includes three exercises conducted during the 2019 Crimson Contagion series, four conducted during the 2013–2014 Pandemic Accord series, 10 conducted during the 2009–2010 Anthrax Response Exercise Series, two conducted during Lightning Rescue 2012, and two conducted during the 2015–2016 Palo Duro II series).

Of the 74 exercises our analysis identified, agencies provided information on the specific threat scenario exercised for 71. From calendar years 2009 through 2019, agencies exercised a range of naturally occurring and intentional threat scenarios, including threats primarily affecting human

⁶⁵For example, a 2013 tabletop exercise we reviewed involved participants from two federal agencies and one state; while a 2019 exercise included participants from 18 federal agencies and 12 states. We did not evaluate the design of the exercises we identified.

health, such as pandemic influenza and anthrax attacks, as well as threats primarily affecting animal health, such as foot-and-mouth disease.⁶⁶ As shown in figure 3, 22 of the 71 exercises included a naturally occurring influenza threat scenario; 24 included an intentional scenario; 13 included a naturally occurring non-influenza scenario; and 12 included threat scenarios affecting animal or plant health.

Figure 3: Number of Interagency Biological Incident Exercises Conducted from Calendar Years 2009 through 2019, by Threat Scenario Category



Source: GAO analysis of documentation from the Departments of Homeland Security, Defense, Health and Human Services, and Agriculture. | GAO-21-513

Note: We identified 74 interagency biological incident exercises and agencies provided information on the specific threat scenario exercised for 71 of the 74 exercises.

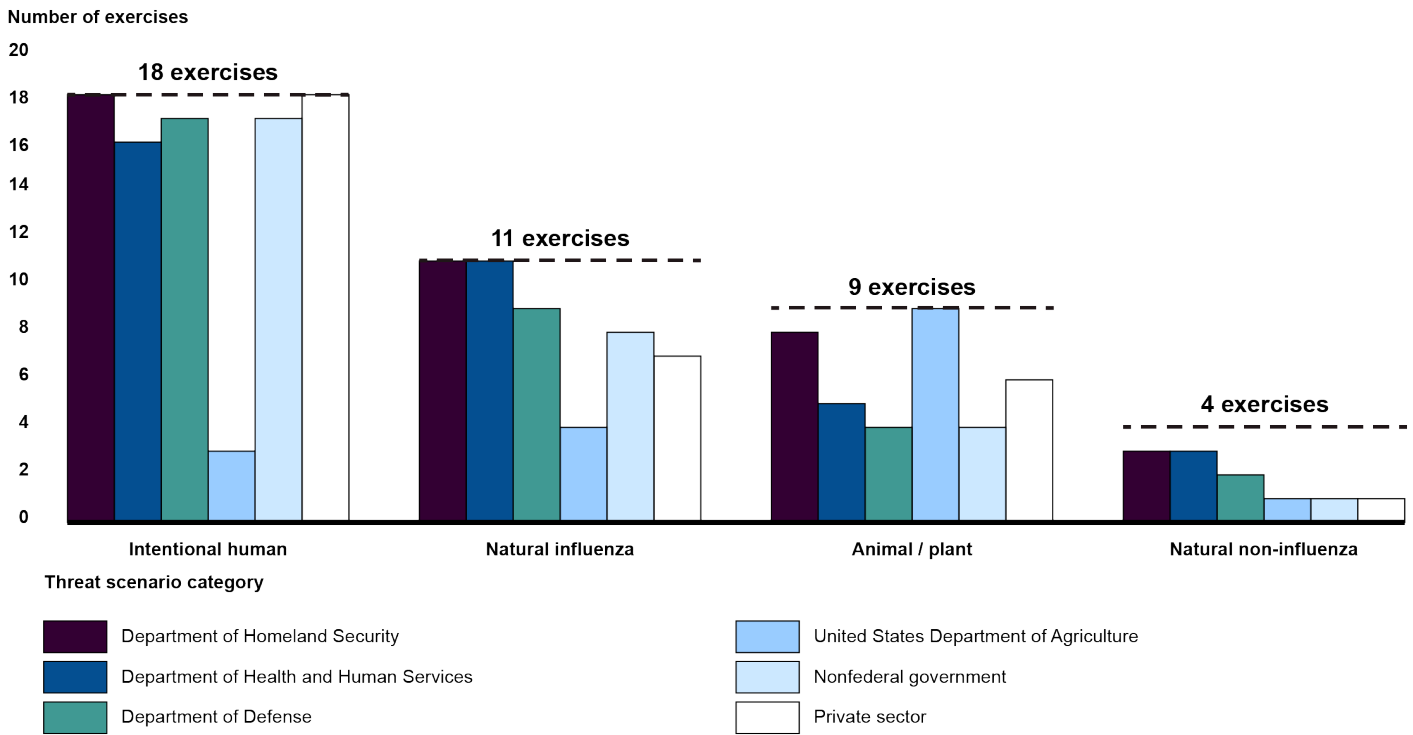
⁶⁶Foot-and-mouth disease is a highly contagious viral disease that causes painful lesions on the hooves and mouths of some livestock, making it difficult for them to stand or eat. The disease generally does not infect humans and is not considered a public health or food safety threat. However, it poses a significant economic threat to U.S. interests.

For 42 of the 74 exercises, we were able to determine additional descriptive information, such as participant information.⁶⁷ As shown in figure 4, more than half of these 42 exercises included nonfederal government participants, such as state, local, and tribal governments. Nonfederal government participation in exercises is important because the capabilities and resources needed to respond to a nationally significant biological incident exist at all levels and should be taken into account when assessing capability and preparedness gaps.⁶⁸ Similarly, more than half of the 42 exercises also included nongovernmental participants, such as hospitals, universities, and professional associations. According to FEMA officials, the ongoing COVID-19 response has demonstrated the necessity of effectively integrating the private sector into planning and response operations.

⁶⁷We obtained detailed descriptive information on 42 of the 74 exercises our analysis identified. Specifically, we obtained after-action reports or other documentation on 11 of 22 natural influenza, four of 13 natural non-influenza, 18 of 24 intentional human, and nine of 12 animal/plant exercises. Agencies provided several reasons for the lack of an exercise after-action report, including: (1) the agency did not develop a report; (2) no after-action report records were found; and (3) the agency was not the release authority for the after-action report and was unable to identify such authority.

⁶⁸We have previously reported on the challenges in assessing state and local preparedness for emergencies and natural disasters. See: GAO, *Federal Emergency Management Agency: Progress and Continuing Challenges in National Preparedness Efforts*, [GAO-16-560T](#) (Washington, D.C.: Apr. 12, 2016); GAO, *National Preparedness: FEMA Has Taken Steps to Strengthen Grant Management, But Challenges Remain in Assessing Capabilities*; [GAO-18-512T](#) (Washington, D.C.: Apr. 23, 2018); GAO, *FEMA: Strengthening Regional Coordination Could Enhance Preparedness Efforts*, [GAO-16-38](#) (Washington, D.C.: Feb. 4, 2016).

Figure 4: Participants in Interagency Biological Incident Exercises Conducted from Calendar Years 2009 through 2019, by Threat Scenario Category



Source: GAO analysis of documentation from the Departments of Homeland Security, Defense, Health and Human Services, and Agriculture. | GAO-21-513

Note: This graph represents participation across the interagency biological incident exercises we identified from 2009 through 2019 for which we obtained information on both the specific threat scenario and participants (42 of 74 total exercises identified). The dashed line and number above each threat scenario category represents the total number of exercises in that category for which we obtained detailed participant information. The bars represent the number of exercises each stakeholder group participated in out of the total for that category.

Interagency Exercises and Real-World Incidents Show Opportunities to Better Implement the National Biodefense Strategy

Our analysis of after-action reports for selected interagency biological incident exercises and real-world incidents, as well as findings from the COVID-19 response, demonstrates that the biodefense enterprise has gaps in its capabilities-based approach to response planning. We identified common long-standing biodefense challenges in coordinating response capabilities, managing information, and in overall planning and exercise efforts. Existing gaps in preparing for nationally significant biological events limit the ability to implement the preparedness and response goals of the National Biodefense Strategy. Specifically, we found the biodefense enterprise lacked elements necessary for preparing for nationally significant biological incidents, including:

-
- a set of defined capabilities that account for the unique elements specific to responding to nationally significant biological incidents;
 - a process at the interagency level for agencies to assess and communicate priorities for exercising capabilities and consistently reporting on those capabilities in after-action reviews; and
 - routine monitoring at the interagency level of exercises and real-world incidents in order to evaluate lessons learned across the government, identify patterns and possible root causes for systemic challenges, and make recommendations to address these challenges.

Exercises and Real-World Incidents, Including COVID-19, Reveal Common, Long-standing Biodefense Challenges

Federal after-action reports from exercises and real-world biological incidents, as well as challenges identified in the COVID-19 response, highlight a number of common, long-standing challenges related to interagency biological incident preparedness and response efforts needed to achieve National Biodefense Strategy goals and objectives.⁶⁹ In analyzing our judgmental sample of 19 after-action reports developed from calendar years 2009 through 2019,⁷⁰ we determined that the most common interagency challenges, or areas for improvement, identified in these reports correspond to three specific response and preparedness objectives in the National Biodefense Strategy: (1) Coordinate response operations and resources; (2) Manage information; and (3) Develop, exercise, and update plans and capabilities (see table 2 below). These areas for improvement spanned after-action reports across the 10-year period we reviewed.

⁶⁹We determined that a finding had interagency implications if the gap or challenge, or strength, identified applied to activities undertaken by two or more federal agencies.

⁷⁰Specifically, we selected a non-generalizable sample of exercise after-action reports and stratified the sample by the common threat scenario categories shown in figure 3.

Table 2: Number of After-Action Report Areas for Improvement with Interagency Implications, by Most Common National Biodefense Strategy Objectives

National Biodefense Strategy objective	Number of areas for improvement
Coordinate response operations and resources: Conduct federal response operations in coordination with nonfederal actors to contain, control, and rapidly mitigate the impacts of biothreats or bioincidents.	54
Manage information: Compile and share biothreat and bioincident information to enable decision-making and response operations across all levels of government and with nongovernmental, private sector, and international entities.	52
Develop, exercise, and update plans and capabilities: Develop, exercise, and update prevention, response, and recovery plans and capabilities.	22
Other^a	27
Total	155

Source: GAO analysis of documentation from the Departments of Homeland Security (DHS), Defense (DOD), Health and Human Services (HHS), and Agriculture (USDA). | GAO-21-513

Note: This table includes findings from a stratified, non-generalizable, judgmental sample of 19 exercise and real-world event after-action reports developed by DHS, DOD, HHS, and USDA from calendar years 2009 through 2019. We determined that a finding had interagency implications if the gap or challenge, or strength, identified applied to activities undertaken by two or more federal agencies.

^aOther areas for improvement include providing effective public messaging and working with international governments to improve global preparedness, among others.

After-action reports we reviewed often identified strengths as well as areas for improvement. Specifically, we identified a total of 70 strengths with interagency implications in our sample. According to FEMA’s continuous improvement guidance, in addition to sharing areas for improvement, observations of strengths should also be shared on a regular basis to promote successes and innovations across the community.

In addition to areas for improvement in the after-action reports we reviewed, we also identified challenges in the initial COVID-19 response. Specifically, agency officials, health care associations, health care experts, and selected state officials we interviewed identified a number of similar challenges in the initial COVID-19 response and general gaps in preparedness for biological incidents. In our prior 2020 and 2021 CARES Act reports, we noted that federal agencies have demonstrated extraordinary dedication and commitment in responding to the unprecedented COVID-19 pandemic. We reported on extensive and evolving efforts to respond to the pandemic, including through managing the medical supply chain, increasing testing capacity; developing, manufacturing, and distributing COVID-19 vaccines and therapeutics; and collecting data on racial and ethnic disparities as they relate to COVID-19. However, we also identified response challenges in these and other

areas. These COVID-19-specific challenges and gaps primarily correspond to the same three response and preparedness objectives in the National Biodefense Strategy that our after-action report analysis identified as the most frequently cited areas for improvement.⁷¹ The following are examples of challenges identified in the after-action reports we reviewed and in the COVID-19 response.

Coordinate response operations and resources. Areas for improvement and challenges identified in this category included providing overall coordination among response partners, defining roles and responsibilities, and pursuing efforts to secure and distribute supplies, specifically medical countermeasures such as personal protective equipment and testing supplies. For example, CDC's after-action report on the 2014 Ebola response found that CDC and the State Department experienced challenges coordinating responder health and safety procedures. The 2019 HHS Crimson Contagion after-action report found that federal partners lacked clarity on interagency roles and responsibilities during a pandemic, which led to confusion about who was leading various exercise response activities.

Health care associations as well as officials from five of six FEMA regions and eight of 10 states we interviewed cited initial COVID-19 response challenges related to coordination between emergency management and public health functions at both the federal and nonfederal level, particularly with regard to supplies.⁷² In June and September 2020, we reported on challenges with the overall distribution, acquisition, and adequacy of supplies during the initial COVID-19 response, and we have continued to report on ongoing

⁷¹We did not review the status of any corrective actions associated with each of the individual interagency findings or challenges identified. As such, agencies may have taken action to address findings in the individual examples we provide below. Rather, we asked agencies about overall actions taken to address the broad categories of challenges identified.

⁷²HHS regional officials also participated in two of the six interviews we conducted with FEMA regions, including those that identified challenges with emergency management and public health coordination. HHS and FEMA each operate 10 regional offices nationwide.

challenges as well as improvements in this area as the response evolves.⁷³

Manage information. After-action reports identified both federal-to-nonfederal and nonfederal-to-federal information flow as challenges in this category. For example, a DHS report on a 2010 anthrax-attack exercise noted that state and local jurisdictions needed to be better aware of information requirements from each federal agency. Similarly, the 2019 HHS Crimson Contagion after-action report found that HHS' regional staff lacked clear guidance on the distribution of information to state and local partners, and that states lacked clarity on which channels they should use to request information from and report information to federal partners throughout the response.

Health care associations and experts and officials from five of six FEMA regions and all 10 states in our sample also identified information management challenges in the COVID-19 response. These challenges included inconsistent guidance from the federal government, lack of transparency regarding supplies available in the Strategic National Stockpile,⁷⁴ and data collection challenges. Additionally, in January 2021, we reported that the federal government did not have a process to help systematically define and ensure the collection of standardized data across the relevant federal agencies and related stakeholders to help respond to COVID-19. As a result, we reported that information collected and reported by states

⁷³GAO-20-625 and GAO-20-701. Challenges related to supplies have been due in part to a supply chain that was overwhelmed by the demands of the global pandemic. We reported on numerous efforts by federal agencies to mitigate supply chain shortages and also made recommendations related to remaining challenges, including that HHS and FEMA clearly document roles and responsibilities for supply chain management functions and develop and communicate plans to stakeholders for addressing remaining supply chain shortages. HHS disagreed with these recommendations, noting, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but continue to maintain that our recommendations are warranted. In March 2021, we reported that, to address more immediate supply needs, the President has called for action that is consistent with our September 2020 recommendation that HHS—in coordination with FEMA—develop and communicate plans to stakeholders outlining specific federal government actions that will be taken to help mitigate supply gaps. See GAO-21-387.

⁷⁴The Strategic National Stockpile is a federal stockpile of vaccines, pharmaceuticals, and medical supplies and devices designed to be deployed to support the response to a public health emergency.

and other entities to the federal government is often incomplete and inconsistent.⁷⁵

Develop, exercise, and update plans and capabilities.

Preparedness related findings from after-action reports and the COVID-19 response include the need to improve capabilities, conduct exercises with a range of relevant participants, and improve overall planning. For example, a DOD report on a 2015 anthrax-attack exercise found a lack of surge capacity government-wide to respond to a biological attack. The report also identified the need for exercises to be conducted with a full range of federal, state, local, and regional partners to create a better understanding of response capabilities.

Health care associations and experts, and officials from one FEMA region and three states we interviewed noted that there was a lack of a national plan or strategy for key COVID-19 response elements, such as a testing strategy or a plan for acquiring personal protective equipment, which exacerbated response problems. Additionally, as we reported in September 2020, representatives of state, local, and territorial health officials and health care providers we interviewed emphasized the need for the federal government to develop and share plans for the distribution and administration of COVID-19 vaccines.⁷⁶ DHS officials stated that the pandemic exposed the need for more active engagement with the private sector in the face of the unique and complex challenges posed, particularly with regard to medical supplies.

In addition, our analysis of the COVID-19 response identified challenges in two other National Biodefense Strategy categories that appeared less

⁷⁵[GAO-21-265](#). We recommended that HHS immediately establish an expert committee or use an existing one to systematically review and inform the alignment of ongoing data collection and reporting standards for key health indicators. HHS partially agreed with our recommendation, noting that it would not be able to take action immediately because of resource constraints and the ongoing response to the pandemic.

⁷⁶[GAO-20-701](#). We recommended that HHS, with the support of DOD, establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccine, and among other things, outline an approach for how efforts would be coordinated across federal agencies and nonfederal entities. DOD partially concurred, while HHS neither agreed nor disagreed with our recommendation. In November 2020, we reported that HHS and DOD had released initial planning documents. We are continuing to monitor federal efforts related to vaccine implementation. In January 2021, we also recommended that HHS develop a comprehensive COVID-19 national testing strategy. See [GAO-21-265](#). HHS partially agreed with our recommendation, but expressed concern that developing a strategy would be overly burdensome during the pandemic. We maintain that a comprehensive and public national strategy is an important and worthwhile investment and can be done efficiently and flexibly, without imposing unnecessary burden.

frequently in the after-action report findings we reviewed: (1) Provide effective public messaging, and (2) Ensure a strong public and veterinary health infrastructure.

Provide effective public messaging. We identified providing clear, consistent communication as an evolving lesson learned in our June and September 2020 reports.⁷⁷ Specifically, we reported that clear and consistent communication among all levels of government, with health care providers, and to the public is key during a nationwide emergency. Uncoordinated communication between the federal government and state and local jurisdictions, and with providers and the general public can contribute to confusion and frustration. We further reported on examples of inconsistent and conflicting information from the White House and federal public health officials; and noted that two public health experts we interviewed for the September 2020 report stated that confusing and conflicting communication from the federal government hindered response and recovery efforts. Officials from one state noted that public messaging from the federal government on supplies sent to states did not match what they actually received and caused confusion and frustration with regard to expectations and planning. Additionally, in November 2020, we reported that frequent changes in CDC COVID-19 testing guidelines, without transparent scientific rationale, raised the risk of creating confusion and eroding trust in federal partners.⁷⁸

Ensure a strong public and veterinary health infrastructure.⁷⁹ DHS officials and health care associations we interviewed noted that the lack of investments in public health infrastructure exacerbated challenges in the COVID-19 response. For example, DHS officials stated that public health investments have atrophied and that declines in resources and grants combined with hospitals and emergency

⁷⁷[GAO-20-625](#), [GAO-20-701](#).

⁷⁸[GAO-21-191](#).

⁷⁹The National Biodefense Strategy refers to both public and veterinary health in this category. While interviews related to the COVID-19 response did not discuss veterinary health, we have previously reported on challenges in this area. For example, in March 2019, we reported on challenges USDA might face in detecting and responding to an outbreak of foot-and-mouth disease and made recommendations aimed at strengthening preparedness activities, including prioritizing corrective actions from exercises. USDA agreed with our recommendations. See *GAO, Foot-and-Mouth Disease: USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened*, [GAO-19-103](#) (Washington, D.C.: Mar. 12, 2019).

rooms closing in the years leading up to COVID-19 had negative national impacts on preparedness and response. As a result, officials noted that limited capabilities at the nonfederal level necessitated a more prominent federal response. In May 2018, we reported that, according to HHS officials, grant awards funded by annual appropriations are intended to establish and strengthen emergency preparedness and capacity building, but may not fully support the need for surge capacity that states and other jurisdictions require in order to respond to an infectious disease threat.⁸⁰ We further reported that HHS officials and nonfederal stakeholders noted that a funding mechanism to fund rapid response activities when additional support is needed would be beneficial and could help address timing challenges.⁸¹

When asked what steps agencies had taken to address the long-standing challenges identified in after-action reports, officials from DHS and USDA pointed to the development of a number of strategic and operational plans—such as the 2017 Biological Incident Annex, 2018 National Biodefense Strategy, and 2018 PanCAP—that were designed to improve interagency efforts. DHS officials cited FEMA and HHS co-locating staff at the National Response Coordination Center during the COVID-19 response as an example of improved coordination. In that regard, officials said there has been steady improvement in preparedness since the 2009 H1N1 outbreak because of the results of lessons learned from exercises and real-world incidents.

Nevertheless, challenges identified in prior exercises and incidents persisted during the COVID-19 response, and selected federal and nonfederal partners we interviewed felt underprepared to respond to the COVID-19 pandemic. As we discuss below, the challenges revealed during the COVID-19 response and our analysis of after-action report findings with interagency implications highlight opportunities to better achieve the National Biodefense Strategy’s objectives across federal agencies and with nonfederal entities they depend on for successful response.

⁸⁰GAO, *Infectious Disease Threats: Funding and Performance of Key Preparedness and Capacity-Building Programs*, [GAO-18-362](#) (Washington, D.C.: May 24, 2018).

⁸¹We did not make recommendations as part of this work, but for certain HHS grant programs, this type of mechanism has been developed and was used to award funding for the COVID-19 pandemic.

Federal Agencies Have Not Defined the Set of Capabilities Needed to Drive Preparedness Efforts under the Strategy

Agencies responsible for implementing the National Biodefense Strategy have not defined the set of capabilities that account for the unique elements specific to responding to nationally significant biological incidents. The COVID-19 response illustrated that nationally significant biological incidents require unique capabilities and application of existing capabilities in novel and complex contexts. For example, FEMA officials said that the COVID-19 response presented unique challenges, because the pandemic affected the entire country simultaneously and posed challenges for acquiring life-saving supplies in the face of global supply chain shortages. Officials from DHS's Countering Weapons of Mass Destruction Office further stated that the pandemic revealed limitations of a traditional emergency management response when an event is not limited by time and geography—such as a wildfire or hurricane. Figure 5 below shows a supply shipment coordinated by the federal response during the COVID-19 pandemic.

Figure 5: Supply Shipment during the COVID-19 Pandemic



Source: David Yost/Federal Emergency Management Agency. | GAO-21-513

Federal agencies have defined capabilities intended to address a wide range of hazards, but these capabilities are not defined in a way that provides sufficient context for nationally significant biological incidents. As discussed in the background of this report, the federal government has

defined 32 all-hazards preparedness capabilities and 15 compatible capabilities specific to public health preparedness.⁸² However, the current sets of capabilities, as defined and implemented, do not provide federal and nonfederal entities with sufficient context and detail on how to apply them for the unique circumstances associated with nationally significant biological incidents. For example, standard capability components, such as mutual aid agreements, that may help nonfederal entities address supply shortages during a response to a routine event, are likely not practical to employ during a catastrophic incident affecting the entire nation. Throughout the COVID-19 pandemic, nonfederal entities simultaneously faced the same resource shortages in terms of supplies and, in many cases, care facility capacity.

FEMA's initial review of the COVID-19 response demonstrated that capabilities needed for nationally significant biological incidents were underdeveloped. In its January 2021 assessment of its response activities during the initial phase of the pandemic, FEMA recognized that its ability to anticipate nonfederal requirements during the pandemic was affected by an insufficient understanding of projected consequences and capabilities of nonfederal partners.⁸³ The report further states that existing federal preparedness efforts did not adequately anticipate the magnitude of the national response to the COVID-19 pandemic. FEMA's assessment report provided an example of one of their efforts to assess nonfederal preparedness efforts at a very high level—the Stakeholder Preparedness Report, which relies on input from nonfederal stakeholders' Threat and

⁸²As discussed above, the 32 core capabilities apply across five broad mission areas: prevention, protection, mitigation, response, and recovery. Some core capabilities fall within a single mission area, while others apply to multiple or all mission areas. For example, 11 of the 32 capabilities apply only to the response mission area, while an additional four capabilities apply to both response and one or more other mission area. See appendix II for a list of all 32 core capabilities and their corresponding mission area(s). These capabilities are a critical and well-established framework to drive overall national preparedness efforts that support the National Preparedness Goal and CDC's efforts to build public health capabilities at the nonfederal level. For example, FEMA and CDC have used the sets of core capabilities as a key performance management tool in measuring emergency preparedness and public health emergency preparedness and response.

⁸³U.S. Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, (Washington, D.C.: January 2021).

Hazard Identification and Risk Assessment.⁸⁴ According to the report, in 2019, only 25 states' risk assessments included a pandemic among the threats to which their communities are the most vulnerable. Additionally, states and urban areas indicated that in a worst-case scenario, medical care and life-sustaining goods delivery were two of the capabilities that were furthest from the desired goal. In its assessment, FEMA also recognized the important role of CDC's preparedness efforts to help build and strengthen nonfederal public health capabilities, but they also described the need to better integrate preparedness efforts going forward, based on the whole-of-nation response to COVID-19.

Additionally, in April 2021, we reported on challenges related to communication and coordination capabilities that HHS faced in the context of repatriation activities during the COVID-19 response.⁸⁵ Specifically we reported that HHS was not prepared for a repatriation event in response to a pandemic, because the department and component agencies had not exercised that scenario, including during the 2019 Crimson Contagion exercise, which was a multi-state, whole-of-government exercise based on the spread of a novel influenza virus starting in China.⁸⁶ For example, among other things, we found a lack of clarity as to which agency was in charge when the first repatriation flight from Wuhan, China, arrived at the quarantine facility, which caused confusion among the HHS component agencies. The challenges HHS experienced repatriating U.S. citizens from abroad have the potential to cut across multiple National Preparedness Goal and CDC capabilities, such as operational coordination, communication, or provision of public health services.

The purpose of the National Biodefense Strategy is to help guide the United States in assessing, preventing, detecting, preparing for,

⁸⁴According to the FEMA report, states, territories, major urban areas, and tribes conduct a Threat and Hazard Identification and Risk Assessment to model the consequences of their most likely threats and hazards to better understand their risks and set targets for preparedness capabilities, which are then assessed through the Stakeholder Preparedness Report.

⁸⁵GAO, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, [GAO-21-334](#) (Washington, D.C., Apr 19, 2021). HHS agreed to the two recommendations we made, and we continue to monitor HHS's progress in implementing them.

⁸⁶The National Preparedness Goal highlights the important role exercises play in preparedness as a means to evaluate capabilities.

responding to, and recovering from a biological incident. The Strategy recognizes the importance of developing, implementing, and exercising biodefense and health security capabilities and acknowledges that the federal biodefense mission is contingent upon coordination with and the success of the community response. Specifically, Goal 3 of the Strategy urges responsible agencies to develop, exercise, and update prevention, response, and recovery plans and capabilities. Further, the Strategy's implementation guidance says that officials responsible for implementing the Strategy have a responsibility for helping to identify and address gaps in capabilities and preparedness through an annual assessment of biodefense activities against the Strategy's goals.⁸⁷ This guidance, along with the NDAA, also anticipated that the Strategy and its implementation would need to be reassessed and revised on a regular basis, recognizing that biological threats and the actions needed to best prepare and respond to them are ever changing.⁸⁸

DHS, DOD, USDA, and HHS officials stated that initial efforts within the Biodefense Coordination Team to implement the Strategy focused on identifying overarching interagency priorities, and did not focus on defining a set of key biodefense capabilities. Additionally, cases of COVID-19 began to appear in the U.S. in late January 2020; therefore, Biodefense Coordination Team member agencies lacked sufficient time to fully implement the Strategy by the time COVID-19 was declared a pandemic and necessitated an interagency response. The process described by the agencies to identify biodefense priorities is meant to identify critical needs across the federal biodefense enterprise and

⁸⁷Over the past decade, our work has found that many of the resources that contribute to the nation's biodefense are largely owned by nonfederal entities and that effective response to significant national biological incidents relies heavily on nonfederal resources and capabilities. In February 2020, we recommended that the Secretary of HHS direct the Biodefense Coordination Team to, among other things, document methods and guidance that ensure nonfederal resources and capabilities are accounted for in the annual analysis of the resources needed to support the nation's biodefense. HHS concurred with the recommendation, and we continue to monitor their efforts to address this. See, [GAO-20-273](#).

⁸⁸See *Presidential Memorandum on the Support for National Biodefense/National Security Presidential Memorandum-14*, White House (September 18, 2018). The NDAA requires that the Strategy be reviewed and, as appropriate, revised biennially. Pub. L. No. 114-328, § 1086, 130 Stat. at 2423 (codified at 6 U.S.C. § 104).

subsequently drive federal agencies' budget submissions.⁸⁹ As such, it is an important part of effective and efficient implementation of the Strategy. However, this process does not provide the kind of foundation for advancing preparedness across federal and nonfederal response partners through planning, exercising, and investing over time that a clear and consistent articulation of the set of capabilities needed to fully implement the Strategy could provide.

Defining the set of capabilities needed to prepare for and respond to nationally significant biological incidents could not only help entities at all levels identify and help address gaps in capabilities and preparedness, but also serve as a means to measure preparedness for such events across the nation. A clearer understanding of how to build, maintain, and apply capabilities in the context of nationally significant biological incidents should be consistent with the preparedness and response goals for the National Biodefense Strategy. Defining the set of capabilities needed to implement the goals of the Strategy is a key step in creating plans that are threat-agnostic, adaptable to changing pathogen characteristics, and scalable to address a whole-of-nation response. Without defining the set of capabilities needed for nationally significant biological incidents (which could include capabilities already identified in the National Preparedness Goal and by CDC), the federal and nonfederal agencies who play vital roles in responding to these incidents are without a key source of information to drive effective and efficient preparedness.

The Biodefense Enterprise Lacks a Process and Guidance to Assess and Communicate Exercise Priorities and Consistently Track Findings

There is no process at the interagency level for agencies to assess and communicate priorities for exercising capabilities that are specific to nationally significant biological incidents. Additionally, our analysis found that agencies do not consistently identify the capabilities exercised across after-action reports. Officials from DHS, DOD, and HHS acknowledge that there is no formal process for assessing and communicating exercise priorities at the interagency level. However, they said the Biodefense Coordination Team has held initial preliminary discussions about priorities and scenarios for exercising biological incidents. DHS, DOD, HHS, and USDA officials also acknowledged that there was an opportunity for the Biodefense Coordination Team, in its role as the working-level federal interagency group implementing the National Biodefense Strategy, to help

⁸⁹As part of this process, agency officials said the Biodefense Coordination Team identified budget priorities for fiscal year 2021, including biosurveillance, medical countermeasure development, and strengthening global health. These priority budget areas were consistent with some of the areas identified in our analysis of after-action reporting and COVID-19 challenges.

assess and set priorities for exercising capabilities specific to the unique needs of nationally significant biological incidents. For example, an HHS official noted that as the Biodefense Coordination Team further develops and evolves, HHS expects its members will begin to discuss capabilities that should be exercised for biological incidents and will communicate those to interagency partners.

The response to the COVID-19 pandemic highlighted a disconnect between preparedness activities and exercises conducted prior to the pandemic and what was needed for an effective response. For example, officials we interviewed from five of 10 states and one of six FEMA regions said they felt underprepared to respond to the current pandemic, in part due to its unprecedented complexity and scale. Officials from these five states further commented that exercises were infrequently designed to exercise large-scale logistics capabilities and other challenges that arose during the COVID-19 response. For example, officials from two states noted that past biological incident exercises did not include scenarios that emphasized the significant role FEMA would come to play in response to the COVID-19 pandemic.⁹⁰ Officials from one state noted that no one had practiced responding to a long-duration event with high unemployment rates and long-term economic consequences. Officials from another state noted that it would be helpful to conduct an exercise scenario in which there were severe supply shortages and a vaccine was not available. Officials from two states further commented that the COVID-19 response did not play out how they had exercised public health emergencies in the past, particularly with regard to

⁹⁰In March 2020, leadership for the overall response shifted from HHS to FEMA. HHS officials noted that past exercises, such as the 2019 Crimson Contagion exercise, assumed that because an influenza pandemic is not explicitly defined as a major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, FEMA would not be the lead agency in a pandemic response. The 2019 Crimson Contagion after-action report found that existing statutory authorities and policies tasking HHS to lead the federal government's response to an influenza pandemic were insufficient and policies were often in conflict with one another, resulting in confusion among exercise participants. However, as discussed above, agency officials did not have time to take corrective actions prior to the COVID-19 outbreak.

requesting and receiving supplies through the Strategic National Stockpile.⁹¹

Additionally, our analysis of selected after-action reports shows that past interagency biological incident exercises have not always focused on capabilities identified as challenges in the COVID-19 response.⁹² In particular, evidence from the ongoing COVID-19 response indicates that capabilities such as Supply Chain Integrity and Security and Logistics and Supply Chain Management are especially necessary for responding to large-scale biological incidents. For example, in 2020, we reported on widespread challenges with the distribution, acquisition, and adequacy of supplies during the initial COVID-19 response—including personal protective equipment and testing supplies.⁹³ However, of the 28 interagency biological exercises we reviewed that included capabilities information in their after-action reports, none identified Supply Chain Integrity and Security as capabilities that were being exercised. Additionally, only four individual exercises, and the exercises from one exercise series, listed Logistics and Supply Chain Management as a focus of the exercise.⁹⁴

After-action reports from these exercises identified a number of areas for improvement related to the Logistics and Supply Chain Management capability. For example, HHS identified supply chain-related challenges in

⁹¹The March 2020 PanCAP Adapted anticipated that states, tribes, and territories would request federal assistance when requirements exceeded their capabilities to respond to COVID-19. For the distribution of supplies, it focused on use of the Strategic National Stockpile, which, at the outset of the COVID-19 pandemic was a critical resource to states for needed and scarce medical supplies. However, as we reported in June 2020, nationwide need for critical supplies to respond to COVID-19 quickly exceeded the quantity of supplies contained in the national stockpile. When this condition became clear, the federal government and its nonfederal partners had to employ numerous additional avenues to meet supply needs. For additional information about the national stockpile's role in the response and efforts to modernize it, see [GAO-21-387](#).

⁹²We used examples from the COVID-19 response as a proxy for capabilities for nationally significant biological events, as they have not yet been defined. As discussed above, exercising is one of five functional areas FEMA has identified as key to building core capabilities. FEMA officials noted the importance of training, another of the five functional areas, and stated that exercises are most successful if training is provided in advance and a common baseline knowledge is developed.

⁹³[GAO-20-625](#) and [GAO-20-701](#).

⁹⁴From December 2009 through October 2010, FEMA and DHS' Office of Health Affairs sponsored a series of anthrax response exercises in the FEMA regions. This series exercised the Logistics and Supply Management capability, among others. We analyzed after-action information for a total 42 exercises.

the after-action report for the 2019 Crimson Contagion exercise. The report found that the supply chain for medical countermeasures (such as personal protective equipment and ventilators) may not meet the demand of a global pandemic. It also found that states participating in the exercise experienced multiple challenges requesting resources from the federal government due to a lack of standardized, well-understood, and properly executed resource request processes. The after-action report contained a number of recommendations to address these challenges; however, HHS officials told us that they have not yet had time to address the recommendations due to the COVID-19 pandemic response that began in 2020. Figure 6 below shows participants gathering for a biological incident exercise—an important practice to enhance preparedness.

Figure 6: Participants in a Biological Incident Exercise



Source: Centers for Disease Control and Prevention. | GAO-21-513

Our analysis further found that agencies did not consistently identify the capabilities exercised across the after-action reports we reviewed. Specifically, 28 of the 42 interagency biological incident exercises for which we analyzed after-action reports clearly discussed assessing one or more of the National Preparedness Goal core capabilities.⁹⁵ However, the remaining 14 after-action reports did not identify the capabilities exercised.

⁹⁵The most frequently exercised core capabilities included the three that span all five mission areas—"Operational Coordination" (27), "Public Information and Warning" (14), and "Planning" (12)—as well as the "Public Health, Healthcare, and Emergency Medical Services" (12) core capability from the Response mission area. Some exercise more than one capability.

Homeland Security Exercise and Evaluation Program guidance provides a set of fundamental principles for exercise programs across the whole community and all mission areas, including that exercises should be “capability-based and objective-driven.” The guidance notes that exercise design and objectives, including the capabilities to be exercised, should consider senior leader intent and guidance, as well as past findings from exercises and real-world events, among other things. Applying Homeland Security Exercise and Evaluation Program guidance at the interagency level would involve the Biodefense Coordination Team assessing and communicating updated priority capabilities for federal and nonfederal response partners to exercise. This guidance also states that the after-action reporting process can validate current capabilities already in place and describe areas for improvement. Additionally, Standards for Internal Control in the Federal Government states that management should communicate quality information externally through reporting lines so that external parties can help the entity achieve its objectives and address related risks.⁹⁶

DHS, HHS, and DOD officials told us that, prior to the COVID-19 pandemic, it was challenging to build interest in and support for large-scale biological incident exercises. Federal, state, and health care association officials we spoke with also noted that it is important for exercises to include a broad range of participants across multiple levels of government, but that at the same time, it can be difficult to get response partners to recognize the need to exercise high consequence, low probability biological events such as the COVID-19 pandemic. For example, officials from one state commented that, prior to the COVID-19 pandemic, some localities were reluctant to participate in biodefense exercises because they thought it was a waste of time to exercise a scenario that would never happen.

Additionally, as noted earlier in this report, agencies that make up the Biodefense Coordination Team have been focused on responding to the COVID-19 pandemic and have not had the opportunity to conduct activities that would fully advance the preparedness goal of the National Biodefense Strategy. Specifically, they have not yet had time to take additional actions to assess and communicate exercise priorities, which will be predicated on them first defining those capabilities to prioritize in

⁹⁶[GAO-14-704G](#).

exercises. Additionally, they have not had the opportunity to develop exercise reporting guidance for interagency partners.

Without a process to assess and communicate exercise priorities and guidance on reporting the key capabilities needed to respond to nationally significant biological incidents, the Biodefense Coordination Team cannot track progress over time and across the biodefense enterprise to help ensure efficient and effective preparedness efforts. As a result, federal and nonfederal response partners may remain underprepared in key biodefense capability areas. Moreover, establishing a process for assessing and communicating exercise priorities that are based on a defined set of capabilities, would help stakeholders coalesce around the biodefense mission that transcends, but is supported by, individual agency missions. Additionally, guidance about how to report on the unique aspects of capabilities needed for nationally significant biological events could help partners across the enterprise—federal and nonfederal—capture critical information in a consistent manner so that the Biodefense Coordination Team can track findings across time and across the enterprise.

Lack of Cross-Government Review of Exercises and Incidents Limits Ability to Identify and Address Systemic Challenges

Our interviews with agency officials and our analysis of real-world after-action reports revealed that agencies do not routinely work together to monitor and review results from exercises and real-world events and evaluate lessons learned across the government to identify patterns and possible root causes for systemic challenges.⁹⁷ According to FEMA officials, through the National Exercise Program, FEMA facilitates solicitation of interagency feedback and reviews after-action reports to develop priorities for the next National Exercise Program 2-year cycle. However, these officials further noted that analysis of after-action reports submitted to the program do not reflect the comprehensive view of all exercises conducted across the nation. The National Exercise Program is only one line of effort to conduct exercises, meaning analysis done through this effort does not encapsulate all exercise or real-world incident findings in order to identify patterns of challenges related to the unique aspects of nationally significant biological incidents. Officials at HHS,

⁹⁷In February 2009, we recommended that the Secretaries of HHS, USDA, and the Department of Interior coordinate with federal, state, and local agencies to periodically review assessments following zoonotic disease outbreaks to identify common challenges and strategies to address them. These recommendations were closed as not implemented. See GAO, *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, [GAO-09-178](#) (Washington D.C.: Feb. 4, 2009).

which also organizes interagency biological incident exercises, further noted that they do not have a process that would collect and analyze exercise outcomes at multiple levels to drive future interagency biological incident efforts.

As discussed above, our analysis of after-action reports for interagency biological exercises and real-world events identified patterns of challenges that existed before the COVID-19 pandemic.⁹⁸ Additionally, our analysis of these after-action reports showed that approximately 44 percent (225 of 507) of the findings had interagency implications, meaning that the gap or strength applied to activities undertaken by two or more federal agencies. The response to COVID-19 continues to demonstrate that a whole-of-nation response relies on multiple agencies at all levels of government, as well as nongovernment sectors, to coordinate in order to reduce morbidity and mortality, and to ensure economic stability and national security.

Officials at DHS, DOD, HHS, and USDA also stated that ensuring accountability for addressing these findings is a challenge and that in addition to not having a mechanism to conduct cross government analysis of findings, there is also no interagency mechanism to ensure agencies implement corrective actions. For example, much like agencies' responsibility for implementing the National Biodefense Strategy, heads of agencies are responsible for holding their agencies accountable for implementation of corrective actions. Officials from two associations representing public health interests expressed concern that lessons learned following exercises are not addressed and are not transferred from one administration to another. Officials from DHS' Countering Weapons of Mass Destruction Office also recognized the challenge in losing continuity of effort from one administration to the next, as each administration sets its own priorities and must address emerging challenges. They said those with institutional history—who work on these issues across administrations—and those familiar with exercising nationally significant biological incidents can use their knowledge to help ensure that the best preparedness results in the best response.

Internal control standards state that management should establish and operate monitoring activities to monitor the internal control system and

⁹⁸We found that these same categories of challenges—such as coordinating response operations and managing information—manifested during the COVID-19 response.

evaluate the results.⁹⁹ This can be achieved through ongoing monitoring, separate evaluations, or a combination of the two to obtain reasonable assurance of the operating effectiveness of the organization's internal controls over the assigned process. In the context of implementing the National Biodefense Strategy, the Biodefense Steering Committee needs information that allows it to identify gaps and areas for improvement to ensure efficient and effective preparedness for nationally significant biological incidents. Federal internal control standards also state that in order to achieve the entity's objectives, management should assign responsibility and delegate authority to key roles. In this context, once patterns and root causes are identified, the Biodefense Coordination Team could also identify responsibility for addressing these causes among interagency partners and ensure implementation actions are taken or endorsed by the Biodefense Steering Committee. Federal internal control standards further state that, in deciding what information is required to achieve objectives, management should consider the needs of both internal and external users and that management should externally communicate necessary quality information in order to meet objectives. Communicating the results of monitoring activities to key decision makers—such as cabinet-level secretaries and administrators—allows them to be informed of critical issues that may require their attention and action.

While agency officials we interviewed described the development and updating of biodefense-related response plans as an interagency activity, as discussed above, this type of interagency engagement does not extend to implementing corrective actions. Additionally, interagency efforts to implement the National Biodefense Strategy have focused on identifying budget priorities. Attention among Biodefense Coordination Team agencies has been divided between these efforts as well as responding to the daunting and specific challenges of the COVID-19 response. Further, officials from DHS's Countering Weapons of Mass Destruction Office described an organic process through exercise development, rather than a consistent, formal process to look at the results of exercises and identify gaps and lessons learned across the government. These officials said that most health, medical, and biological exercises cascade off each other, meaning when one exercise identifies a problem, the next exercise will use that as a gap and try to address it. In that regard, officials said there has been steady improvement in preparedness because of the results of exercises. However, officials from

⁹⁹[GAO-14-704G](#).

DHS, DOD, HHS, and USDA recognized the value cross-agency analysis of after-action findings could provide and said the Biodefense Coordination Team, as the working-level group with responsibility for the National Biodefense Strategy, is well-positioned to be the entity that conducts analysis to identify patterns and root causes of longstanding problems.

Institutionalized mechanisms to identify root causes of pervasive and recurrent issues and to provide structure and accountability to help ensure actions to address those causes would promote more effective and efficient preparedness over time and across organizational boundaries. Our analysis of findings regarding lessons learned during interagency biological incident exercises and real-world events identified longstanding challenges that existed before COVID-19. Taking steps to monitor and identify persistent issues at the interagency level—that would not otherwise be captured during individual agency reviews—could help further enhance the preparedness activities of the many different partners responsible for responding to nationally significant biological incidents. Further, assigning accountability for addressing root causes to these challenges at the interagency level could help ensure a more effective response to future incidents.

Conclusions

The unprecedented scope and scale of the COVID-19 pandemic placed into sharp focus the critical capabilities needed to execute a whole-of-nation response to a nationally significant biological incident. Capabilities such as global supply chain logistics, mass testing and vaccination, data integration and analysis, and communication among various levels of government and directly with the public reach beyond the mission space of a single agency and require federal and nonfederal agencies to work united during a response. Federal agencies have taken steps to identify both all-hazard and public health capabilities that could be used to support or execute a response to biological incidents, but do not fully address the unique characteristics and response needs for nationally significant biological incidents.

The nature of biological incidents presents inherent and unique challenges, not only because of the fragmented nature of preparedness and response activities, but also because nationally significant biological incidents tend to be low-probability, yet high-consequence events. While executing large scale or complex scenarios that reflect the conditions and challenges the nation faced during the COVID-19 pandemic may come at a cost, so too will the repercussions of not effectively preparing for such events in the future. Preparation for nationally significant biological

incidents like COVID-19 cannot afford to suffer from a lack of imagination. We found that several key themes continued to emerge as areas for improvement over the past ten years during exercises and real-world events, and that those same issues manifested as challenges during the COVID-19 response.

The ability to monitor and assess the outcomes of interagency biological incident exercises and real-world events could be instrumental in identifying persistent challenges and their root causes before they become systemic, intractable problems. Identifying these issues could also help agencies prioritize which capabilities need further development or exercising. The Biodefense Steering Committee includes the heads of federal agencies with biodefense responsibilities. The Biodefense Coordination Team, which plays a key role in implementing the National Biodefense Strategy in coordination with the Biodefense Steering Committee, is uniquely positioned to carry out these types of analysis activities, as it combines the expertise from federal agencies with biodefense responsibilities. Once the Team defines the set of capabilities required, establishing interagency exercise priorities around those capabilities, ensuring consistent reporting of capabilities exercised, and routinely monitoring and communicating the results of the exercises and incidents will help ensure the nation is better positioned to respond to the next biological threat.

Recommendation for Executive Action

We are making 16 recommendations to the Secretaries of Homeland Security, Defense, Health and Human Services, and Agriculture.

The Secretary of Homeland Security, should, with input from key nonfederal partners, work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team defines the set of capabilities needed to prepare for and respond to nationally significant biological incidents. (Recommendation 1)

The Secretary of Defense, should, with input from key nonfederal partners, work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team defines the set of capabilities needed to prepare for and respond to nationally significant biological incidents. (Recommendation 2)

The Secretary of Health and Human Services, should, with input from key nonfederal partners, work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team defines the set of

capabilities needed to prepare for and respond to nationally significant biological incidents. (Recommendation 3)

The Secretary of Agriculture, should, with input from key nonfederal partners, work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team defines the set of capabilities needed to prepare for and respond to nationally significant biological incidents. (Recommendation 4)

The Secretary of Homeland Security should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team establishes a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. (Recommendation 5)

The Secretary of Defense should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team establishes a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. (Recommendation 6)

The Secretary of Health and Human Services should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team establishes a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. (Recommendation 7)

The Secretary of Agriculture should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team establishes a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. (Recommendation 8)

The Secretary of Homeland Security should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team provides guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. (Recommendation 9)

The Secretary of Defense should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team provides guidance for federal and nonfederal partners for how to report on

capabilities in after-action reports for exercises and real-world incidents in a consistent manner. (Recommendation 10)

The Secretary of Health and Human Services should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team provides guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. (Recommendation 11)

The Secretary of Agriculture should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team provides guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. (Recommendation 12)

The Secretary of Homeland Security should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team routinely monitors the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges, and reports these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. (Recommendation 13)

The Secretary of Defense should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team routinely monitors the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges, and reports these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. (Recommendation 14)

The Secretary of Health and Human Services should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team routinely monitors the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges, and reports these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. (Recommendation 15)

The Secretary of Agriculture should work through the Biodefense Steering Committee to ensure that the Biodefense Coordination Team routinely monitors the results of interagency biological exercises and real-world

incidents to identify patterns of challenges and potential root causes of identified challenges, and reports these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. (Recommendation 16)

Agency Comments and Our Evaluation

We provided a draft of this report to DHS, DOD, HHS, and USDA for review and comment. In the draft report, we made a set of recommendations to the secretaries to work through the Biodefense Coordination Team, which is the working level group established to help with National Biodefense Strategy implementation. DHS, DOD, and USDA suggested that the recommendations be directed instead through the Biodefense Steering Committee. This Committee is the group of secretary-level officials with responsibility for the Strategy and for directing the work of the Biodefense Coordination Team. We agree with the departments' suggestion. Accordingly, we have made this change to the recommendations.

In addition to the above comments, DHS, HHS, and USDA otherwise stated they concurred with all four recommendations made to each agency and provided technical comments, which we incorporated as appropriate. DOD partially concurred with all four recommendations. The written comments of DHS, DOD, and HHS are reproduced in appendices III, IV, and V. USDA's audit liaison provided comments via email.

In response to recommendations 1 through 4 to define a set of capabilities needed to prepare for and respond to nationally significant biological incidents, with key input from nonfederal partners, DHS, HHS, and USDA concurred. In its partial concurrence, in addition to suggesting that the recommendations be made through the Biodefense Steering Committee, DOD expressed concerns about the appropriateness of the Secretary of Defense's role in gathering and assessing nonfederal input and providing it to the Biodefense Coordination Team. In response, we note that the intent of the sixteen recommendations we make in this report—four each to the four agencies given responsibility for the National Biodefense Strategy in statute—is to ensure that all four agencies work as full partners leading this effort in the ways that are most appropriate to their particular responsibilities, authorities, and resources.

The agencies also described actions they have taken or plan to take to address recommendations 1 through 4. Specifically, DOD, HHS, and USDA described Biodefense Coordination Team efforts to identify capabilities necessary for advancing the goals and objectives of the National Biodefense Strategy. Although none of these agencies specified

that the set of capabilities they described was to be the final set of capabilities intended to form the foundation to prepare the nation for future biologically significant incidents, they did indicate that work is already underway. To fully address this recommendation, the agencies, working through the Biodefense Coordination Team, will need to provide a finalized set of capability descriptions and evidence of input from key nonfederal partners.

In response to recommendations 5 through 8 to establish a process to periodically assess and communicate exercise priorities, DHS, HHS, and USDA concurred. DOD partially concurred. As with the other recommendations, DHS, DOD, and USDA suggested that the recommendation be made through the Biodefense Steering Committee. DHS, HHS, and USDA also described avenues that the Biodefense Coordination Team could use to help identify and communicate exercise priorities. To fully address this recommendation, the agencies, working through the Biodefense Coordination Team, will need to finalize a process that includes a means for periodic assessment to prioritize among the capabilities for exercises.

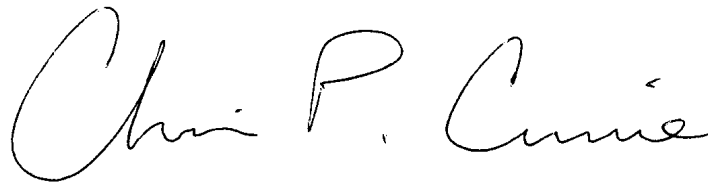
In response to recommendations 9 through 12 to provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner, DHS, HHS, and USDA concurred. DOD partially concurred. In its partial concurrence, DOD noted concerns about the appropriateness of the Secretary of Defense's role in leading efforts to standardize after-action reporting for federal and nonfederal partners. As noted above, the intent of the recommendation was for DOD to work with its interagency partners in this effort. DHS and HHS also described mechanisms that could be used for reporting capabilities in after-action reports. To fully respond to this recommendation, the agencies, working through the Biodefense Coordination Team, will need to provide guidance for reporting on capabilities in after-action reports.

In response to recommendations 13 through 16 to routinely monitor the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify responsible agencies, DHS, HHS, and USDA concurred. DOD partially concurred. DHS and HHS also described ways in which the interagency partners could communicate about challenges and their root causes. To fully respond to this recommendation, the agencies, working through the

Biodefense Coordination Team, will need to put in place the means to routinely monitor incidents, to identify patterns of challenges and their root causes, and to make recommendations to the Biodefense Steering Committee for addressing those root causes.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Homeland Security, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Agriculture, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff members have any questions about this report, please contact Chris Currie at (404) 679-1875 or CurrieC@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributors to this report are listed in appendix VI.

A handwritten signature in black ink that reads "Chris P. Currie". The signature is written in a cursive style with a large initial "C" and a distinct "P" and "Currie".

Chris P. Currie
Director, Homeland Security and Justice

List of Committees

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
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Committee on Health, Education, Labor, and Pensions
United States Senate

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Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
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House of Representatives

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House of Representatives

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

Appendix I: National Biodefense Strategy Preparedness and Response Categories

The National Biodefense Strategy consists of five high-level goals intended to help enable the efficient assessment, prevention, preparation, response, and recovery from natural, accidental, or deliberate biological threats. Each goal has associated objectives and sub-objectives designed to strengthen the biodefense enterprise. Table 3 below describes the objectives under the Strategy's preparedness and response goals.

Table 3: National Biodefense Strategy Preparedness and Response Objectives

National Biodefense Strategy objectives	Description
<i>Preparedness</i>	
Support U.S. biodefense research, development, and investment	Ensure an innovative national science and technology base to support biodefense by: <ul style="list-style-type: none"> • enabling U.S.-led innovation through scientific, technical, and industrial bases; and • integrating research and development into federal planning.
Ensure a strong public and veterinary health infrastructure	Ensure a strong public and veterinary health infrastructure by: <ul style="list-style-type: none"> • ensuring critical capacities and establishing capabilities to provide surge staffing, resources, and supplies; and • modernizing public and veterinary laboratories so they have access to updated diagnostic tests, methods, equipment, and technologies.
Develop, exercise, and update plans and capabilities	Develop, exercise, and update prevention, response, and recovery plans and capabilities. This includes: <ul style="list-style-type: none"> • developing and exercising policies, plans, guidelines, and recommendations to support prevention, response, and recovery activities; • ensuring that emergency funding mechanisms exist to support urgent responses to bioincidents; • supporting the effective deployment of medical counter-measure stockpiles; • supporting the provision of health care and the conduct of clinical research during bioincidents; • supporting the continuity of operations; and • supporting the provision of essential services, critical infrastructure, and long-term recovery.
Develop, exercise, and update risk plans to support effective public messaging, enhance public trust, and promote consistent messaging	Develop, exercise, and update risk communication plans and promote consistent messaging to inform key audiences, expedite response actions, and address public uncertainty and fear. This includes: <ul style="list-style-type: none"> • improving federal messaging coordination for biothreats and bioincidents; • developing and exercising communications plans; and • enhancing messaging partnerships with the private sector.
Improve diagnostic capabilities and enhance medical countermeasures	Enhance preparedness to save lives through medical countermeasures by: <ul style="list-style-type: none"> • improving diagnostic capabilities; and • enhancing the development, sustainment, and availability of medical counter-measures.

**Appendix I: National Biodefense Strategy
Preparedness and Response Categories**

National Biodefense Strategy objectives	Description
Enhance community mitigation measures development and capabilities	Enhance preparedness to limit the spread of disease through community mitigation measures. This includes: <ul style="list-style-type: none"> • developing and assessing the effectiveness of community mitigation measures to mitigate the impact of bioincidents; and • establishing and promoting best practices for implementing such measures.
Enhance decontamination preparedness	Enhance preparedness to support decontamination by: <ul style="list-style-type: none"> • conducting research and developing verified technologies; and • developing and exercising decontamination plans.
Improve the ability for the federal government to collaborate with states and territories	Strengthen preparedness to operate and collaborate across the United States, including U.S. territories by: <ul style="list-style-type: none"> • establishing collaborative and resource sharing policies and operational frameworks.
Work with international governments to improve global preparedness	Strengthen international preparedness to support international response and recovery capabilities. This includes: <ul style="list-style-type: none"> • strengthening foreign governments and international organizations' commitment to, preparedness for, and capacity to respond to bioincidents; • enhancing international preparedness through medical countermeasures; • enhancing international preparedness through community mitigation measures; and • further developing, exercising, and updating plans for responding to and recovering from international bioincidents.
<i>Response</i>	
Manage information	Compile and share biothreat and bioincident information to enable decision-making and response operations across all levels of government and with non-governmental, private sector, and international entities. This includes: <ul style="list-style-type: none"> • ensuring access to timely, accurate, and useful information; • coordinating federal decision making to support response operations; and • enhancing situational awareness through real-time information sharing.
Coordinate response operations and resources	Conduct federal response operations in coordination with non-federal actors to contain, control, and rapidly mitigate the impacts of biothreats or bioincidents. This includes: <ul style="list-style-type: none"> • ensuring appropriate oversight and coordination; • deploying medical countermeasures and implementing community mitigation measures; • conducting real-time research regarding threats and countermeasures; • implementing and supporting response operations; and • preserving the continuity of operations of the U.S. government and critical infrastructure.
Conduct operations and investigations for intentional incidents	Conduct operations and investigations, and use available tools to hold perpetrators accountable. This includes: <ul style="list-style-type: none"> • strengthening capacity and capabilities to conduct incident operations and investigations; • conducting forensic examinations to support attribution of a biothreat or a bioincident; and • providing technical and logistical support to international investigations.

**Appendix I: National Biodefense Strategy
Preparedness and Response Categories**

National Biodefense Strategy objectives	Description
Provide effective public messaging	Execute risk-informed, accurate, timely, and actionable public messaging. <ul style="list-style-type: none">• Deliver public messaging to facilitate public understanding and decision-making during a bioincident, including by providing timely, regular, accessible, and coordinated information and combating misinformation.

Source: GAO analysis of National Biodefense Strategy. | GAO-21-513

Appendix II: National Preparedness Goal and Public Health Capabilities

National Preparedness Goal Capabilities

The National Preparedness Goal identifies and defines 32 core capabilities across five broad mission areas.¹ These capabilities apply to all hazards and threats and are not incident specific. Further, they are intended to apply to the whole community, and are not specific to any one federal or nonfederal agency or organization. The core capabilities form the foundation for measuring overall national preparedness and assisting the nation in allocating resources to fill identified preparedness gaps.² As shown in figure 7 below, three of the 32 core capabilities affect all mission areas and are considered to be “crosscutting.”

¹The five mission areas are: prevention, protection, mitigation, response, and recovery.

²The White House released Presidential Policy Directive 8 on National Preparedness in March 2011. It directed the Secretary of Homeland Security to design a national preparedness system to address the threats posing the greatest risk to the security of the nation and issue various policy and planning documents designed to strengthen national preparedness. Additionally, it required the Secretary to develop a National Preparedness Goal that identifies the core capabilities necessary to achieve preparedness.

Appendix II: National Preparedness Goal and Public Health Capabilities

Figure 7: National Preparedness Goal's 32 Emergency Management Core Capabilities by Mission Area

Prevention ^a	Protection ^b	Mitigation ^c	Response ^d	Recovery ^e	Crosscutting
		Planning			
		Public information and warning			
		Operational coordination			
Intelligence and information sharing		Community resilience	Infrastructure systems		
Interdiction and disruption		Long-term vulnerability reduction	Critical transportation	Economic recovery	
Screening, search, and detection		Risk and disaster resilience assessment	Environmental response/health and safety	Natural and cultural resources	
Forensics and attribution	Access control and identity verification	Threats and hazards identification	Fatality management services	Housing	
	Cybersecurity		Logistics and supply chain management	Health and social services	
	Physical protective measures		Public health, healthcare, and emergency medical services		
	Risk management for protection programs and activities		Mass search and rescue operations		
	Supply chain integrity and security		On-scene security, protection, and law enforcement		
			Operational communications		
			Mass care services		
			Situational assessment		
			Fire management and suppression		

Source: GAO analysis of Department of Homeland Security and Federal Emergency Management Agency documents. | GAO-21-513

^aPrevention: Preventing an imminent threat, or actual act of terrorism.

^bProtection: Protecting citizens, residents, visitors, and assets in a manner that allows interests, aspirations, and way of life to thrive.

^cMitigation: Mitigating the loss of life and property by lessening the impact of future disasters.

^dResponse: Responding quickly to save lives, protect property and the environment, and meet basic human needs in the immediate aftermath of an incident.

^eRecovery: Recovering through a focus on the timely restoration, strengthening, and revitalization of infrastructure, housing, and a sustainable economy, as well as the health, social, cultural, historic, and environment fabric of communities affected by an incident.

Public Health Capabilities

In 2011, the Centers for Disease Control and Prevention (CDC) developed 15 public health-specific capabilities as part of the Public Health Emergency Preparedness program.³ CDC updated these capabilities in 2018 to address emerging technologies and threats.⁴ As shown in figure 8 below, CDC's capability standards are organized into six domains and two tiers. According to CDC, Tier 1 capability standards are intended to form the foundation for public health emergency preparedness and response, while Tier 2 capability standards are cross-cutting, and reliant on the establishment of Tier 1 capability standards in collaboration with external partners and stakeholders.

³The Public Health Emergency Preparedness program provides funds to build and sustain public health preparedness and response capacity.

⁴U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Health* (Atlanta, GA: October 2018).

Figure 8: Public Health Emergency Preparedness and Response Capabilities

Community resilience	Incident management	Information management	Countermeasures and mitigation	Surge management	Biosurveillance
<i>Tier 1</i>					
Community preparedness	Emergency operations coordination	Emergency public information and warning Information sharing	Medical countermeasure dispensing and administration Medical material management and distribution Responder health and safety		Public health laboratory testing Public health surveillance and epidemiological investigation
<i>Tier 2</i>					
Community recovery			Nonpharmaceutical interventions	Fatality management Mass care Medical surge Volunteer management	

Source: GAO analysis of Centers for Disease Control and Prevention documentation. | GAO-21-513

Note: According to the Centers for Disease Control and Prevention, Tier 1 capability standards are intended to form the foundation for public health emergency preparedness and response, while Tier 2 capability standards are cross-cutting, and reliant on the establishment of Tier 1 capability standards in collaboration with external partners and stakeholders.

Appendix III: Comments from the Department of Homeland Security

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



**Homeland
Security**

July 14, 2021

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

Re: Management Response to Draft Report GAO-21-513, "BIODEFENSE: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness"

Dear Mr. Currie:

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

The Department is pleased to note GAO's acknowledgement that the COVID-19 response illustrated the importance of the National Biodefense Strategy (NBS) to establish both: (1) national goals and objectives that strengthen the Nation's biodefense enterprise; and (2) a layered risk management approach to counter biological threats and incidents. DHS recognizes that robust prevention, preparedness, and response efforts require timely and accurate awareness of biological threats, risks, and incidents. Consequently, the Department maintains a layered approach, consistent with what the NBS outlines, to provide early warning of biological threats and incidents to operators at all levels of government, including through intelligence, surveillance, and environmental detection. The Department coordinates closely with federal, state, local, tribal, and territorial (FSLTT) partners and the private sector to prepare the Nation for biological incidents and to ensure that local communities, first responders, and DHS operators can quickly and safely respond to, and reduce the impact of, biological incidents. Overall, DHS programs and capabilities help ensure the Nation is prepared for biological incidents impacting our agriculture and food.

In coordination with FSLTT partners, for example, DHS develops response plans for biological incidents, and integrates these processes into the response structure of the individual jurisdictions. Further, DHS provides policy guidance documents that can be used to develop responses at the state and local level. The Department also leads a sophisticated exercise program that ranges from limited scope drills on specific aspects of a response to full scale national-level exercises that may encompass multiple jurisdictions across multiple states. This is integrated with the National Exercise Program, managed by the Federal Emergency Management Agency, which is a two-year cycle of exercises conducted across the nation that examine, and validate, capabilities in all preparedness mission areas.

DHS remains committed to safeguarding the Nation against biological threats and achieving the goals of the NBS. The Department will continue work with the Biodefense Steering Committee (BSC) and the Biodefense Coordination Team (BCT) via the National Security Council (NSC), as outlined in National Security Memorandum (NSM-2) "Renewing the National Security Council System," dated February 4, 2021, to enhance the national biodefense enterprise.

The draft report contained 16 recommendations, including four for DHS with which the Department concurs. Attached find our detailed response to each recommendation. DHS previously submitted technical comments addressing several accuracy, contextual, and other issues under a separate cover for GAO's consideration.

Again, thank you for the opportunity to review and comment on this draft report. Please feel free to contact me if you have any questions. We look forward to working with you again in the future.

Sincerely,

JIM H
CRUMPACKER

Digitally signed by JIM H
CRUMPACKER
Date: 2021.07.14 10:29:05 -04'00'

JIM H. CRUMPACKER, CIA, CFE
Director
Departmental GAO-OIG Liaison Office

Attachment

**Attachment: Management Response to Recommendations
Contained in GAO-21-513**

GAO recommended that the Secretary of Homeland Security, with input from key nonfederal partners:

Recommendation 1: Work through the Biodefense Coordination Team to define the set capabilities needed to prepare for and respond to nationally significant biological incidents.

Response: Concur. The Countering Weapons of Mass Destruction Office (CWMD) Strategy, Plans, and Policy (SPP) Directorate, which coordinates the Department's biodefense policy and implementation of the NBS, will work with the BCT to communicate inputs from DHS and state, local, tribal, and territorial partners to identify capability gaps and analyze solutions for closure. This input will contribute to the Nation's capabilities that define preparedness and response for significant biological incidents. Further coordination will occur through the NSC's interagency coordination mechanisms outlined in NSM-2, including the Interagency Policy Committee (IPC) structures established to address biodefense issues. DHS will further engage the Department of Health and Human Services (HHS) BCT to provide inputs to inform capability gap analysis. Estimated Completion Date (ECD): September 30, 2021.

GAO recommended that the Secretary of Homeland Security work through the BCT to:

Recommendation 5: Establish a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents.

Response: Concur. CWMD SPP will work with the BCT to establish a process to periodically assess and communicate exercise priorities among the identified capabilities. Specifically, CWMD will recommend establishing a dedicated working group on biological exercises (BEWG), in coordination with the BCT and the appropriate IPCs, so that exercise goals, objectives, and after-action reports can be shared, tracked, and coordinated. DHS will also engage the HHS BCT to establish the BEWG as a mechanism to assess and communicate exercise priorities and outcomes. ECD: September 30, 2021.

Recommendation 9: Provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner.

Response: Concur. CWMD SPP will coordinate with the BCT to develop after-action report guidance for federal and nonfederal partners so that capabilities are reported when either exercises are conducted or following real-world incidents. Specifically, CWMD will recommend that BEWG develop, manage, and disseminate this guidance. DHS will engage HHS BCT to recommend the BEWG, once established, develop after-action report guidance as an initial, priority action. ECD: September 30, 2021.

Recommendation 13: Routinely monitor the results of interagency biological exercises and real world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies.

Response: Concur. CWMD SPP will coordinate with the BCT to routinely monitor the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges. Specifically, CWMD will recommend that the BEWG review, manage, and develop solutions for the identified challenges and root causes. In partnership the BCT and BEWG, CWMD will report findings to the BSC and the appropriate IPCs and help develop recommendations for addressing the root causes of identified challenges, with responsible agencies identified. Additionally, the DHS Exercise and Evaluation Program will exercise biodefense plans as they are updated and revised, in coordination with DHS components, as appropriate. Results will also be shared with the National Exercise Program to ensure that lessons learned help inform updates to national and departmental policy and future planning revisions. DHS will further engage HHS BCT to recommend the BEWG initiate this reporting process that includes recommendations with responsible agencies. ECD: September 30, 2021.

Appendix IV: Comments from the Department of Defense



HOMELAND DEFENSE &
GLOBAL SECURITY

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
2600 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-2600

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

Dear Mr. Christopher P. Currie

This is the Department of Defense (DoD) response to the GAO Draft Report GAO-21-513SU, "Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness," dated June 10, 2021 (GAO Code 104292).

Thank you for the opportunity to comment on this draft report. Attached is DoD's response to the subject report. My point of contact is COL Paul Navas at (703)-693-2448 or via email at paul.navas2.mil@mail.mil.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather King".

Heather King
Deputy Assistant Secretary of Defense
Homeland Defense Integration and
Defense Support of Civil Authorities

Enclosure:
As stated



GAO DRAFT REPORT DATED JUNE 10, 2021
GAO-21-513SU (GAO CODE 104292)

**“BIODEFENSE: AFTER-ACTION FINDINGS AND COVID-19 RESPONSE
REVEALED OPPORTUNITIES TO STRENGTHEN PREPAREDNESS”**

**DEPARTMENT OF DEFENSE COMMENTS
TO THE GAO RECOMMENDATION**

DoD RECOMMENDATION 1: The GAO recommends that the Secretary of Defense, should, with input from key nonfederal partners, work through the Biodefense Coordination Team to define the set of capabilities needed to prepare for and respond to nationally significant biological incidents. (Recommendation 2)

DoD RESPONSE: DoD partially concurs with the recommendation. As written, the recommendation can be interpreted that the Secretary of Defense will gather, assess, and provision to the BCT the input from nonfederal partners. This would not be an appropriate action for the Secretary of Defense to initiate and lead. DoD feels that the most appropriate course of action would be for the Biodefense Coordination Team (BCT) to be tasked to define the set of capabilities needed to prepare for and respond to nationally significant biological incidents, including input from nonfederal partners. In accordance with NSPM-14, DoD suggests that the recommendation be for the Secretary of Defense to work through the Biodefense Steering Committee (BSC) to task the Biodefense Coordination Team (BCT) to define the set of capabilities needed to prepare for and respond to nationally significant biological incidents, with input from key nonfederal partners. DoD has worked with the BCT to identify eleven capabilities, (Threat Awareness, Surveillance and Detection, Prevention, Preparedness Addressing Planning, Preparedness Addressing Strengthening Global Capacity, Preparedness Addressing Scientific Research and Development, Response Addressing Public Information and Warning; Response Addressing Public Health, Healthcare and Emergency Medical Services, and Environmental Response, Recovery, Bioforensics and Attribution, and Mitigation) which have been linked to the NBS sub-objectives by the BCT.

DoD RECOMMENDATION 2: The GAO recommends that the Secretary of Defense should work through the Biodefense Coordination Team to establish a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. (Recommendation 6)

DoD RESPONSE: DoD partially concurs with the recommendation. DoD feels that the most appropriate course of action would be for the Biodefense Coordination Team (BCT) to be tasked to establish a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. In accordance with NSPM-14, DoD suggests that the recommendation be for the Secretary of Defense to work through the Biodefense Steering Committee (BSC) to task the Biodefense Coordination Team

(BCT) to establish a process to periodically assess and communicate exercise priorities among the capabilities they identify to support nationally significant biological incidents. The Department conducts a number of exercises to ensure execution capabilities of core DoD mission in biological threat environments. While the prioritization of objectives for DoD exercises will remain a process internal to the Department, opportunity exists to coordinate and communicate, where appropriate, exercise priorities with interagency partners in effort to support an integrated exercise approach against nationally significant biological incidents.

DoD RECOMMENDATION 3: The GAO recommends that the Secretary of Defense should work through the Biodefense Coordination Team to provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. (Recommendation 10)

DoD RESPONSE: DoD partially concurs with the recommendation. As written, the recommendation can be interpreted that the Secretary of Defense will lead the BCT's effort in standardization of capabilities reporting in after-action reports for federal and nonfederal partners. This would not be an appropriate action for the Secretary of Defense to initiate and lead the engagement, particularly with nonfederal partners. DoD is also not the lead D/A for exercises and after-action reporting, but may provide useful input as support. DoD feels that the most appropriate course of action would be for the Biodefense Coordination Team (BCT) to be tasked to define the appropriate guidance on how to report capabilities in after-action reports for exercises and real-world incidents, including input from nonfederal partners. In accordance with NSPM-14, DoD suggests that the recommendation be for the Secretary of Defense to work through the Biodefense Steering Committee (BSC) to task the Biodefense Coordination Team (BCT) to provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner.

DoD RECOMMENDATION 4: The GAO recommends that the Secretary of Defense should work through the Biodefense Coordination Team to routinely monitor the results of interagency biological exercises and real world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. (Recommendation 14)

DoD RESPONSE: DoD partially concurs with this recommendation. DoD feels that the most appropriate course of action would be for the Biodefense Coordination Team (BCT) to be tasked routinely monitor the results of interagency biological exercises and real world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. In accordance with NSPM-14, DoD suggests that the recommendation be for the Secretary of Defense to work through the Biodefense Steering Committee (BSC) to task the Biodefense Coordination Team (BCT) to routinely monitor the results of interagency biological exercises and real world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies.

Appendix V: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

July 8, 2021

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

Dear Mr. Currie:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*" (Job code 104292/GAO-21-513SU).

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

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Hild".

Jeff Hild
Acting Assistant Secretary for Legislation
Principal Deputy Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — BIODEFENSE: AFTER-ACTION FINDINGS AND COVID-19 RESPONSE REVEALED OPPORTUNITIES TO STRENGTHEN PREPAREDNESS (GAO-21-513SU)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report entitled, "Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness" (GAO-21-513SU).

The National Biodefense Strategy (Strategy) sets the long-term course for United States to enhance our capabilities and combat the real and serious 21st century biothreats our country faces, whether they arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the deliberate actions of terrorists or state actors. The Strategy encompasses five goals for strengthening the biodefense enterprise including: enabling risk awareness to inform decision-making across the biodefense enterprise; ensuring biodefense enterprise capabilities to prevent bioincidents; ensuring biodefense enterprise preparedness to reduce the impacts of bioincidents; rapidly responding to limit the impacts of bioincidents; and facilitating recovery to restore the community, the economy, and the environment after a bioincident.

Recommendation 3

The Secretary of Health and Human Services, should, with input from key nonfederal partners, work through the Biodefense Coordination Team to define the set of capabilities needed to prepare for and respond to nationally significant biological incidents. (**Recommendation 3**)

HHS Response

HHS concurs with GAO's recommendation.

The Biodefense Coordination Team highlighted federal Departments' and Agencies' capabilities essential to advancing the goals and objectives of the Strategy and implementing a comprehensive approach to counter biological threats, reduce risk, prepare for, respond to, and recover from biological incidents. Eleven capabilities of the federal biodefense enterprise were identified: Threat Awareness; Surveillance and Detection; Prevention; Preparedness Addressing Planning; Preparedness Addressing Strengthening Global Capacity; Preparedness Addressing Scientific Research and Development; Response Addressing Public Information and Warning; Response Addressing Public Health, Healthcare and Emergency Medical Services, and Environmental Response; Recovery; Bioforensics and Attribution; and Mitigation. The Biodefense Coordination Team aligned Strategy sub-objectives with these capabilities. Departments and Agencies reported on their biodefense programs, projects, and activities in the second year Biodefense Memoranda under these capabilities.

Recommendation 7

The Secretary of Health and Human Services should work through the Biodefense Coordination Team to establish a process to periodically assess and communicate exercise priorities among the

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — BIODEFENSE: AFTER-ACTION FINDINGS AND COVID-19 RESPONSE REVEALED OPPORTUNITIES TO STRENGTHEN PREPAREDNESS (GAO-21-513SU)

capabilities they identify to support nationally significant biological incidents.
(**Recommendation 7**)

HHS Response

HHS concurs with GAO's recommendation.

Opportunities exist to establish a process to periodically assess and communicate exercise priorities through the Biodefense Coordination Team.

To support implementation of the National Biodefense Strategy, the Biodefense Coordination Team developed a yearly priority setting process to inform a Biodefense Assessment. Department and Agency-identified priorities, as well as other information from the annual Biodefense Assessment, are considered by the National Security Council in the development of the Joint Policy Guidance (Guidance), highlighting priorities of this Administration in biodefense. Overarching biodefense priorities for the USG are codified in the annual Guidance. Following the assessment of findings from exercises, the priority setting process could be leveraged to identify and communicate priorities.

Recommendation 11

The Secretary of Health and Human Services should work through the Biodefense Coordination Team to provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner.
(**Recommendation 11**)

HHS Response

HHS concurs with GAO's recommendation.

Opportunities exist for the Biodefense Coordination Team to provide guidance for federal and nonfederal partners for how to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. This action would support implementation of the National Biodefense Strategy. The programs, projects, and activities underpinning the five goals of the Strategy fall into eleven capabilities.

Federal Departments and Agencies currently report on capabilities in reporting on biodefense programs, projects, and activities in their Biodefense Memoranda in response to the Biodefense Request for Information. Opportunities exist for federal and non-federal partners to report on capabilities in after-action reports for exercises and real-world incidents in a consistent manner. This could be accomplished through development and provision of a template to stakeholders.

The template used by HHS/ASPR is a potential model that could be leveraged for use by other federal and non-federal partners. The results of the Corrective Action Process (AAR/IP) allowed ASPR to inform modifications, updates and creations of plans, policies and procedures. Exercises are developed based on Leadership priorities and available funding.

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — BIODEFENSE: AFTER-ACTION FINDINGS AND COVID-19 RESPONSE REVEALED OPPORTUNITIES TO STRENGTHEN PREPAREDNESS (GAO-21-513SU)

Federal and non-federal stakeholders could incorporate exercise and real-world findings, lessons learned, and perspectives to inform best practices.

Recommendation 15

The Secretary of Health and Human Services should work through the Biodefense Coordination Team to routinely monitor the results of interagency biological exercises and real world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee along with recommendations for addressing the root causes that also identify the responsible agencies. **(Recommendation 15)**

HHS Response

HHS concurs with GAO's recommendation.

Opportunities exist for the Biodefense Coordination Team to routinely monitor the results of interagency biological exercises and real-world incidents to identify patterns of challenges and potential root causes of identified challenges, and report these to the Biodefense Steering Committee. Results of biological exercises could be routinely discussed during regularly scheduled Biodefense Coordination Team meeting and included as topics for discussion in Biodefense Steering Committee meetings.

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Chris P. Currie at (404) 679-1875 or CurrieC@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kathryn Godfrey (Assistant Director), Sarah Turpin (Analyst-in-Charge), Nasreen Badat, Benjamin Crossley, Danielle Curet, David Dornisch, Tracey King, Susanna Kuebler, and Andrew Stavisky made key contributions to this report.

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Washington, DC 20548

Strategic Planning and External Liaison

Stephen J. Sanford, Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548



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