



**Testimony** 

Before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

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## **BIODEFENSE**

# Opportunities to Address National Strategy and Programmatic Challenges

Statement of Chris P. Currie, Director, Homeland Security and Justice

## **GAO Highlights**

Highlights of GAO-22-105733, a testimony before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

### Why GAO Did This Study

Biological threats, such as the COVID-19 pandemic, can cause catastrophic loss of life and damage to the economy. The 2018 National Biodefense Strategy outlines goals and objectives to help prepare for and respond to such threats. However, DHS has long faced challenges implementing its biodefense responsibilities, including acquiring biodetection capabilities.

This statement discusses GAO reports issued from December 2009 through August 2021 on efforts to implement the National Biodefense Strategy and strengthen biodefense preparedness, as well as ongoing challenges to DHS's biosurveillance and biodetection efforts. The statement also includes recommendation follow-up work conducted through January 2022.

For the prior work, GAO reviewed relevant presidential directives, statutes, regulations, policies, strategic plans, and after-action reports; and interviewed federal and state officials, among others. For recommendation updates, GAO reviewed agency documentation and met with agency officials.

### What GAO Recommends

GAO made 29 recommendations in its prior reports to address the challenges discussed in this statement. As of January 2022, agencies have taken steps to address the recommendations, but 25 of the 29 remain open. GAO continues to monitor agency progress in implementing them.

View GAO-22-105733. For more information, contact Chris Currie at (404) 679-1875 or curriec@gao.gov.

#### February 17, 2022

## **BIODEFENSE**

## Opportunities to Address National Strategy and Programmatic Challenges

### What GAO Found

For over a decade, GAO has conducted work evaluating federal biodefense efforts and has identified challenges and opportunities for improvement in several key areas:

- Implementing the National Biodefense Strategy. In February 2020, GAO found that challenges with data collection and assessment and decision-making across the biodefense enterprise could limit successful Strategy implementation. GAO recommended four actions, including that the Department of Health and Human Services, which coordinates interagency Strategy efforts, work with agencies to better define roles and responsibilities. The agency agreed and is taking steps to address these recommendations.
- Strengthening Biodefense Preparedness. In August 2021, GAO reported that key federal agencies, including the Department of Homeland Security (DHS), had developed interagency response plans and conducted exercises to prepare for biological incidents in the years prior to the COVID-19 pandemic. However, GAO found that the nation lacked certain elements necessary in preparing for biological incidents, including an interagency process to communicate priorities for conducting biodefense exercises. Further, GAO found that agencies did not routinely work together to monitor results from exercises and real-world incidents to identify patterns and root causes for systemic challenges. GAO recommended 16 actions, including that DHS and other agencies better identify root causes and the agencies responsible for addressing them. The agencies generally agreed with these recommendations and are taking steps to implement them.
- Strengthening DHS's National Biosurveillance Integration Center (NBIC). GAO has reported that NBIC—created to integrate data across the federal government to enhance detection and situational awareness of biological events—has experienced longstanding challenges related to its lack of a clear purpose and limited collaboration with other agencies. DHS implemented GAO's past recommendations to strengthen NBIC, However, in 2015 GAO found NBIC continued to face challenges, such as limited partner participation in the center's activities. GAO identified options that could address these challenges, ranging from strengthening the center's ability to implement its current roles to repealing NBIC's statute. GAO plans to initiate work to assess NBIC's more recent efforts.
- Acquiring Biodetection Technologies. GAO has reported on challenges with DHS efforts to implement its BioWatch program to detect an aerosolized biological attack. Most recently, GAO reported in May 2021 on DHS's current effort to replace BioWatch, known as BD21. For example, GAO found that BD21 faces challenges due to technology limitations and uncertainties with combining technologies for use in biodetection, including possible false alarms. GAO recommended three actions, including that the BD21 program office conduct technology readiness assessments that follow GAO's best practices prior to the program's future acquisition decision. DHS agreed with these recommendations and is taking steps to address them.

February 17, 2022

Chairman Peters, Ranking Member Portman, and Members of the Committee:

I am pleased to be here today to discuss our work assessing federal biodefense efforts.

Biological threats—whether intentional, accidental, or naturally-occurring—have the potential to cause catastrophic loss of life and sustained damage to the economy, societal stability, and global security. In the 2001 anthrax attack, 22 people contracted anthrax resulting in five deaths from exposure to spores sent through the mail. This attack brought new awareness of the threat posed by bioterrorism. More recently, the COVID-19 pandemic—another biological threat—continues to have devastating effects on public health. By early February 2022, the U.S. had more than 76 million reported cases of COVID-19 and more than 900,000 total deaths, according to the Centers for Disease Control and Prevention (CDC).¹ The pandemic has also had far-reaching effects on the U.S. economy. The U.S. has continued to experience lower levels of employment relative to the prepandemic period and, more recently, rising U.S. consumer prices and widespread supply chain disruptions in multiple sectors.

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. The biodefense enterprise is a fragmented collection of federal, state, local, tribal, territorial, and private resources, programs, and initiatives designed for different purposes. Given this complexity, in 2011, we called for a strategic approach to help the federal government better leverage biodefense resources and

<sup>&</sup>lt;sup>1</sup>Data on COVID-19 cases in the U.S. are based on aggregate case reporting to CDC and include probable and confirmed cases as reported by states and jurisdictions. CDC COVID-19 counts are subject to change due to delays or updates in reported data from states and jurisdictions. According to CDC, the actual number of COVID-19 cases is unknown for a variety of reasons, including that people who have been infected may have not been tested or may have not sought medical care. See CDC, "COVID Data Tracker: Trends in Number of COVID-19 Cases and Deaths in the US reported to CDC, by State/Territory," accessed February 9, 2022, https://covid.cdc.gov/covid-data-tracker/#trends\_dailycases.

manage risk.<sup>2</sup> In 2016, federal law required the Departments of Homeland Security (DHS), Defense (DOD), Health and Human Services (HHS), and Agriculture (USDA) to develop a national biodefense strategy.<sup>3</sup> In 2018, the White House issued the National Biodefense Strategy outlining specific goals and objectives designed to help the nation prepare for and respond to nationally significant biological incidents.

However, even with this strategy in place, the COVID-19 pandemic has brought into sharp focus the shortcomings of our current preparations to respond to a nationally significant biological incident. Many of these shortcomings arise from longstanding challenges. For more than a decade, we have found persistent deficiencies in HHS's leadership role preparing for and responding to public health emergencies, including COVID-19, the H1N1 influenza pandemic, Zika, and Ebola. As a result, in January 2022, we added HHS's leadership and coordination of public health emergencies to our High Risk List to help ensure sustained executive branch and Congressional attention and to better prepare our nation for future threats.<sup>4</sup>

Additionally, we have reported on organizational challenges with DHS's Countering Weapons of Mass Destruction office, which serves as the DHS lead for developing biodefense strategy and policy, including implementing the National Biodefense Strategy. Specifically, in April 2016, after evaluating DHS's plans to consolidate chemical, biological, radiological, and nuclear security programs into this single office, we recommended DHS use, where appropriate, the key mergers and organizational transformation practices identified in our prior work, such

<sup>&</sup>lt;sup>2</sup>GAO, Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue, GAO-11-318SP (Washington, D.C.: Mar. 1, 2011).

<sup>&</sup>lt;sup>3</sup>The 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).

<sup>&</sup>lt;sup>4</sup>GAO, COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies, GAO-22-105291 (Washington, D.C. Jan. 27, 2022). We designate federal programs and operations as "high risk" due to their vulnerabilities to fraud, waste, abuse, and mismanagement, or because they need transformation. We consider qualitative factors, such as whether the risk involves public health or safety. For information on how we determine which federal government programs and functions should be designated high risk, see GAO, Determining Performance and Accountability Challenges and High Risks, GAO-01-159SP (Washington, D.C.: November 2000). For more information on programs and operations on our High-Risk List, see https://www.gao.gov/high-risk-list.

as conducting adequate stakeholder outreach.<sup>5</sup> DHS agreed with and addressed the recommendation. Taking the recommended steps provided opportunities for employee feedback and communication, but at the time we closed the recommendation in 2020, we observed that the Countering Weapons of Mass Destruction office faced other significant challenges, including low employee morale and questions about program efficacy. We have ongoing work evaluating these issues and plan to issue a report in 2022.

Since 2009, we have also reported on long-standing challenges with biodetection and building a national biosurveillance capability—that is, the ability to detect biological events to provide early warning and information to guide public health and emergency response.<sup>6</sup> Clandestine attacks using aerosolized biological agents could be carried out in urban areas, at sporting events, at transportation hubs, or at indoor facilities like office buildings.<sup>7</sup> DHS, the federal agency tasked with developing a national biosurveillance capability to detect such an attack, has struggled to respond to the ever-changing nature and broad array of biological threats, develop new technologies and approaches, and make decisions about how to best prioritize resources.

This testimony discusses key findings from our past work on (1) efforts to implement the National Biodefense Strategy and strengthen preparedness for biological incidents, and (2) ongoing challenges to DHS's biosurveillance and biodetection efforts.

This statement is based on products we issued from December 2009 to August 2021 on biodefense issues, as well as follow-up work conducted through January 2022 related to agency efforts to address our recommendations. To conduct our prior work, we reviewed relevant documents, including presidential directives, statutes, regulations, policies, strategic plans, and other reports, such as after-action reports. We also interviewed federal and state officials, and a range of relevant stakeholders. More information on our scope and methodology can be

<sup>&</sup>lt;sup>5</sup>GAO, Homeland Security: DHS's Chemical, Biological, Radiological, Nuclear and Explosives Program Consolidation Proposal Could Better Consider Benefits and Limitations. GAO-16-603. (Washington, D.C.: Aug.11, 2016).

<sup>&</sup>lt;sup>6</sup>GAO, Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center, GAO-15-793 (Washington, D.C.: Sept. 24, 2015) and Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

<sup>&</sup>lt;sup>7</sup>Aerosolized refers to the ability to disperse tiny particles or droplets suspended in air.

found in each of the reports cited throughout this statement. In addition, after the issuance of our reports and through January 2022, we contacted DHS, DOD, HHS, and USDA to obtain updated information and documentation, as appropriate, on the status of the recommendations we made in our prior work.

We conducted the work on which this statement is based 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Efforts to Implement the National Biodefense Strategy and Strengthen Preparedness

Challenges to Implementing the National Biodefense Strategy In February 2020, we found that the 2018 National Biodefense Strategy and its associated plans brought together all the key elements of federal biodefense capabilities to address naturally-occurring, accidental, and intentional threats. This presented an opportunity to identify capability gaps and consider enterprise-wide risk and resources for investment trade-off decisions. The Strategy and associated plans provide processes for collecting and analyzing comprehensive information across the biodefense enterprise, an important step toward the kind of enterprise-wide strategic decision-making we have called for.

<sup>8</sup>GAO, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, GAO-20-273 (Washington, D.C.: Feb. 19, 2020). The National Biodefense Strategy and its associated plans bring together the efforts of federal agencies with significant biodefense roles, responsibilities, and resources. Issued at the same time as the Strategy, Presidential Memorandum on the Support for National Biodefense/National Security Presidential Memorandum-14 (NSPM-14) details a governance structure and implementation process to achieve the Strategy's goals. For example, it established two governing bodies: the Biodefense Steering Committee—chaired by the Secretary of HHS—and the Biodefense Coordination Team, to support the efforts of the Steering Committee.

However, we also found in February 2020 that early challenges could limit successful implementation of the Strategy. For example, we determined that parts of the data collection and assessment process were underdeveloped, raising questions about (1) the plans to support change management practices and ensure that early-implementation limitations did not become institutionalized; (2) the guidance and methods for meaningfully analyzing the data collected; and (3) the clarity of decision-making processes, roles, and responsibilities.

We recommended that HHS, as the agency responsible for coordinating interagency Strategy efforts, establish a plan that includes change management practices—such as strategies for feedback, communication, and education—to reinforce collaborative behaviors and enterprise-wide approaches. We also recommended that HHS work with other agencies to document methods for analysis and the processes, roles, and responsibilities for enterprise-wide decision making. HHS concurred with the recommendations but has not yet fully implemented them.<sup>9</sup>

Challenges in Conducting Biodefense Exercises and Responding to Real-World Incidents

In August 2021, we found that key federal agencies, including DHS, DOD, HHS, and USDA, had developed a range of interagency response plans and conducted numerous interagency exercises—well before the COVID-19 pandemic—to help prepare for and respond to a wide variety of biological incidents. These included incidents such as anthrax attacks, influenza pandemics, and diseases affecting plants and animals.

However, our analysis of after-action reports for exercises and real-world incidents, as well as the subsequent COVID-19 response, identified common interagency challenges in coordinating response capabilities, managing information, and in overall planning and exercise efforts. For example, a DHS after-action report on a 2010 anthrax-attack exercise noted that state and local jurisdictions needed to be better aware of federal agencies' information requirements. Similarly, a 2019 HHS after-action report for an influenza pandemic exercise found that states lacked clarity on which communication channels they should use throughout the response for requesting information from, and reporting information to,

<sup>&</sup>lt;sup>9</sup>As of January 2022, HHS had not demonstrated that it had taken steps to fully address these recommendations. In April 2021, HHS described some actions it has taken to implement these recommendations, such as developing standard operating procedures for annual data assessments, but these actions alone do not meet the intent of the recommendations.

<sup>&</sup>lt;sup>10</sup>GAO, Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness, GAO-21-513 (Washington, D.C. Aug. 4, 2021).

federal partners. Figure 1 shows participants gathering for a biological incident exercise.



Figure 1: Participants in a Biological Incident Exercise

Source: Centers for Disease Control and Prevention. | GAO-22-105733

With regard to the subsequent COVID-19 response, health care associations and experts we interviewed, along with federal and state officials, also identified information management challenges. These challenges included inconsistent guidance from the federal government, lack of transparency regarding supplies available in the Strategic National Stockpile, and data collection challenges.<sup>11</sup>

We further found that existing gaps in preparing for nationally significant biological events limit agencies' abilities to achieve the preparedness and response goals outlined in the National Biodefense Strategy. Specifically, we found that the nation lacked elements necessary for preparing for nationally significant biological incidents, including:

<sup>&</sup>lt;sup>11</sup>The 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. In January 2021, we found 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 found that information collected and reported by states and other entities to the federal government is often incomplete and inconsistent. See 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).

- a set of defined capabilities for responding to nationally significant biological incidents;
- an interagency process for assessing and communicating exercise priorities;
- an interagency process for agencies to consistently report on the capabilities exercised 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.

In August 2021, we recommended steps that DHS, DOD, HHS, and USDA should take to address these gaps. For example, we recommended that these agencies work through the Biodefense Steering Committee—the governing body tasked with overseeing implementation of the Strategy—to define a set of capabilities needed to prepare for and respond to nationally significant biological incidents; communicate interagency exercise priorities; and conduct monitoring and assign accountability. 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. Assigning accountability for addressing root causes could help ensure a more effective response to future incidents.

The agencies generally concurred with our recommendations and articulated planned steps to address them. However, none of the recommendations have been fully implemented. For example, DHS and HHS identified ways in which the interagency partners could communicate about challenges and their root causes through National Biodefense Strategy implementation committees and working groups. In January 2022, DHS also described its efforts to advocate for conducting exercises, through National Security Council-led biodefense efforts, that would involve priority biological response capabilities. DHS further noted plans to work with federal partners to ensure routine, principal-level exercises are included in updated biological incident preparedness documents to provide a high-level means to identify root cause issues and evaluate potential solutions.

## Ongoing Challenges of DHS's Biosurveillance and Biodetection Efforts

Since 2009, we have reported on progress and challenges with several DHS biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the pursuit of replacements for the BioWatch program, which was designed to detect aerosolized biological attacks. <sup>12</sup> In short, we have found that DHS's biosurveillance and biodetection programs have struggled to define and carry out their missions.

## National Biosurveillance Integration Center Collaboration Challenges

Established by the Implementing Recommendations of the 9/11 Commission Act of 2007, NBIC is tasked with (1) integrating and analyzing information from human health, animal, plant, food, and environmental monitoring systems across the federal government to improve the likelihood of identifying a biological event at an earlier stage, and (2) supporting the interagency biosurveillance community.<sup>13</sup>

In December 2009, we reported that NBIC faced a variety of collaboration challenges with its partners—HHS, DOD, USDA, and others. <sup>14</sup> For example, interviews with agency officials demonstrated confusion on roles and responsibilities and incomplete policies and strategies for operating across agency boundaries. To help NBIC enhance and sustain collaboration, including the provision of data, personnel, and other resources, in 2009, we recommended that NBIC develop a strategic plan for addressing collaboration challenges and develop accountability mechanisms to monitor these efforts. NBIC concurred with these recommendations and, in August 2012, implemented our recommendations by issuing the NBIC Strategic Plan. The plan was intended to provide NBIC's strategic vision and clarify the center's mission and purpose; articulate the value that NBIC seeks to provide to its partners; and lay the groundwork for establishing interagency roles, responsibilities, and procedures.

<sup>&</sup>lt;sup>12</sup>GAO, Biodefense: DHS Exploring New Methods to Replace BioWatch and Could Benefit from Additional Guidance GAO-21-292 (Washington, D.C.: May 20, 2021); Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established, GAO-16-99 (Washington, D.C.: Oct. 23, 2015); GAO-15-793; Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition, GAO-12-810 (Washington, D.C.: Sep. 10, 2012); and GAO-10-171.

<sup>&</sup>lt;sup>13</sup>Pub. L. No. 110-53, title XI, § 1101, 121 Stat. 266, 375-79 (codified, as amended, at 6 U.S.C. § 195b).

<sup>&</sup>lt;sup>14</sup>GAO-10-171.

Following the adoption of the NBIC Strategic Plan, we began to monitor the effectiveness of NBIC's collaborative efforts and, in September of 2015, found that NBIC still experienced a variety of challenges. For example, some partner agencies expressed uncertainty about NBIC's value, and NBIC was unable to secure streams of raw data needed to conduct near real-time quantitative analysis to reveal unusual patterns and trends. Along with NBIC's interagency partners and other major stakeholders in the biosurveillance community, we acknowledged that no single problem limited NBIC's mission to integrate biosurveillance data. Instead, over the years, several long-standing problems—such as data sharing across disparate missions—had combined to inhibit the achievement of the mission. In our September 2015 report, we identified five options for policy or structural changes that could help better fulfill the biosurveillance integration mission. However, no significant change has occurred in NBIC's charge since that time.

The options we identified were to:

- Reinforce NBIC's Analyzer Role. NBIC would be provided with new authorities and resources designed to access additional public and private data sources and statistical and modeling tools to develop meaningful information.
- Strengthen NBIC's Coordinator Role. NBIC would be provided with greater authority for coordinating the federal biosurveillance enterprise.
- Expand NBIC's Innovator Role. NBIC would be provided with new authorities and resources to lead research and development investments of new tools and technology to address gaps.
- Maintain the Status Quo. NBIC would continue to implement the mission, goals, and objectives detailed in the August 2012 NBIC Strategic Plan or subsequent approved updates.
- Repeal the NBIC Statute. National biosurveillance integration would not be pursued through NBIC.

We plan to initiate new work evaluating NBIC, including its roles and responsibilities during the COVID 19 pandemic.

## Biodetection Technology Acquisition Challenges

In 2003, in response to the 2001 anthrax attack, DHS started BioWatch—designed as an air monitoring system to detect an aerosolized

<sup>&</sup>lt;sup>15</sup>GAO-15-793.

bioterrorism attack. However, DHS has faced challenges justifying the mission need for a detection capability narrowly limited to detecting aerosolized attacks. Further DHS has not always followed DHS acquisition guidance when acquiring upgrades to BioWatch. Since the program's inception, DHS has pursued enhancements and replacements to the existing system, known as BioWatch Generation 2 (Gen-2), to reduce the time needed to detect an aeorosolized biological attack, which should reduce morbidity and mortality rates from such an attack.

In September 2012, we found that DHS had previously approved the BioWatch Generation 3 (Gen-3) acquisition—an effort to acquire an autonomous detection capability—in 2009 without engaging in the early phases of its Acquisition Life-Cycle Framework, which would have included, for example, an analysis of alternatives. <sup>16</sup> We recommended that before continuing with the Gen-3 acquisition, DHS reevaluate the mission need and systematically analyze alternatives based on cost-benefit and risk information. DHS concurred with the recommendation and took steps to address it. <sup>17</sup> As a result of these actions, in April 2014, DHS canceled the acquisition of Gen-3 because the analysis did not confirm an overwhelming benefit to justify the cost of a full technology switch.

In October 2015, we reported that DHS lacked reliable information about the current Gen-2 system's technical capabilities to detect a biological attack. This was, in part, due to DHS not having developed technical performance requirements for the system after BioWatch's initial deployment in 2003. We recommended that DHS not update its current BioWatch system until it establishes technical performance requirements, assesses its current system against these requirements, and produces a full accounting of any uncertainties and limitations regarding the system's capability to meet its operational objectives. DHS concurred but, as of January 2022, these recommendations remain open while DHS considers a new acquisition effort to replace BioWatch, known as the Biological Detection for the 21st Century program (BD21).

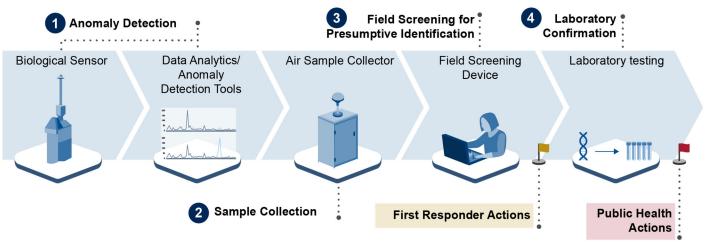
<sup>&</sup>lt;sup>16</sup>GAO-12-810.

<sup>&</sup>lt;sup>17</sup>Specifically, in 2013, DHS conducted an analysis of alternatives prepared by an independent entity.

<sup>&</sup>lt;sup>18</sup>GAO-16-99.

BD21 intends to combine various technologies, such as biological sensors, data analytics, anomaly detection tools, collectors, and field screening devices to enable more timely and efficient detection of an aerosolized attack involving a biological agent. (See fig. 2.) In May 2021, we found that while the BD21 program office was following the agency's acquisition policy and guidance, the program was still early in the acquisition phase. <sup>19</sup> DHS was still analyzing potential technologies to demonstrate that certain components of the overall concept were feasible, such as an anomaly detection algorithm. <sup>20</sup>

Figure 2: Department of Homeland Security's High-level Concept of Operations for the Ideal End State for Biological Detection for the 21st Century



Source: GAO analysis of Department of Homeland Security information. | GAO-22-105733

We also found that BD21 faced technical challenges due to uncertainties with combining multiple technologies for biodetection and inherent limitations in the technologies. For example, common environmental materials, like pollen, can emit a signal similar to that of a biological threat

<sup>&</sup>lt;sup>19</sup>GAO-21-292.

<sup>&</sup>lt;sup>20</sup>For BD21, an anomaly detection algorithm is intended to use data from biological sensors that continuously monitor the air, as well as other data sources, to determine if there is a departure or deviation from the baseline environmental data, known as an anomaly. Baseline environmental data is the characterization of background environments, which can vary by geography, climate, topography, and urban density, as well as by time of day, seasons, weather, animal population dynamics, farming patterns, construction, and manufacturing (emissions).

agent, increasing the false alarm rates in biological aerosol sensors. Program officials told us that the risk of false alarms attributed to biological sensor technologies could be minimized by using an anomaly detection algorithm in addition to the sensor. However, we reported that it is too early to determine whether integration of an anomaly detection algorithm will successfully mitigate the false alarm rate, as the algorithms have never been developed and used for the purpose of biodetection in an urban, civilian environment.

To help mitigate risk in the BD21 acquisition, the BD21 program office plans to conduct technology readiness assessments along the way as part of the acquisition lifecycle using DHS's technology readiness assessment guide. However, in May 2021 we found the guide lacked sufficient detail to help the program ensure objectivity and independence, among other important best practices. We recommended, among other things, that the BD21 program office conduct technology readiness assessments in line with our best practices before making the next key acquisition decision. DHS concurred and provided information on the steps the agency has taken or plans to take to address our recommendations. We will continue to monitor its progress.

Chairman Peters, Ranking Member Portman, and Members of the Committee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

## GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact Christopher P. Currie at (404) 679-1875 or curriec@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are Claudia Becker (Assistant Director), Sarah Turpin (Analyst-In-Charge), Benjamin Crossley, Dominick Dale, Michele Fejfar, Tracey King, Susanna Kuebler, and Tasha Straszewski. Key contributors for the previous work that this testimony is based on are listed in each product.

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