PUBLIC HEALTH PREPAREDNESS

HHS Needs a Coordinated National Approach for Diagnostic Testing for Pandemic Threats

Report to Congressional Committees

June 2025

GAO-25-106980

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Accessible Version

GAO Highlights

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Highlights of GAO-25-106980, a report to congressional committees

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HHS Needs a Coordinated National Approach for Diagnostic Testing for Pandemic Threats

Why GAO Did This Study

Widespread diagnostic testing for diseases with pandemic potential can help reduce potential death rates. Diseases with pandemic potential are highly transmissible and virulent. During the COVID-19 public health emergency, HHS faced several challenges developing accurate tests quickly, deploying tests, developing clear guidance for test use, and collecting complete testing data. GAO placed HHS's leadership and coordination of public health emergencies on its High-Risk List in January 2022, in part, due to HHS's handling of COVID-19 testing.

The CARES Act includes a provision for GAO to monitor and report on the federal pandemic response. This report identifies actions suggested by experts for HHS to improve diagnostic testing for infectious diseases with pandemic potential, and steps HHS has taken related to these actions.

GAO convened a roundtable of 19 experts to discuss actions HHS should take to improve diagnostic testing. GAO contracted with the National Academies of Sciences, Engineering, and Medicine to help identify experts representing a range of perspectives. GAO also reviewed HHS documents and interviewed HHS officials.

What GAO Recommends

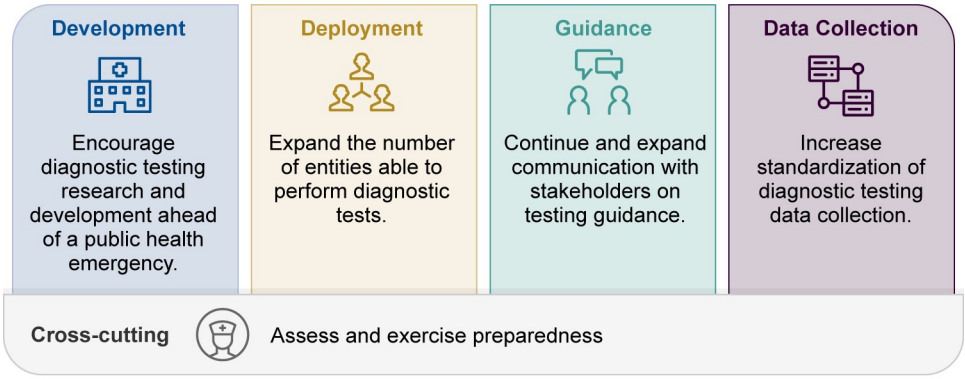
GAO is making four recommendations to HHS related to developing a national diagnostic testing strategy and establishing a national testing forum. HHS noted it is committed to carefully reviewing the recommendations and providing a future update.

What GAO Found

Infectious diseases with pandemic potential—such as avian influenza—pose a threat to American lives, national security, and economic interests. The Department of Health and Human Services (HHS) leads federal diagnostic testing efforts related to such diseases. It must work with public and private stakeholders who, among other things, administer tests and collect data.

An expert roundtable GAO convened suggested nearly 100 actions HHS should take to improve diagnostic testing development, deployment, guidance, and data collection for the future. Several actions also cut across these areas. HHS officials said they are taking some steps to improve diagnostic testing related to the actions suggested by experts. For example, to help expand the number of entities able to test during an emergency, HHS has developed guidance for non-traditional laboratories seeking approval to perform testing.

Examples of Actions Experts Suggested to Improve Diagnostic Testing



Source: GAO analysis of statements made by a roundtable of 19 experts; RaulAlmu/stock.adobe.com (illustrations). | GAO-25-106980

Accessible Data for Examples of Actions Experts Suggested to Improve Diagnostic Testing

- Development: Encourage diagnostic testing research and development ahead of a public health emergency.
- Deployment: Expand the number of entities able to perform diagnostic tests.
- Guidance: Continue and expand communication with stakeholders on testing guidance.
- Data Collection: Increase standardization of diagnostic testing data collection.

Cross-cutting: Assess and exercise preparedness

Source: GAO analysis of statements made by a roundtable of 19 experts; RaulAlmu/stock.adobe.com (illustrations). | GAO-25-106980

Note: The actions in this report are not listed in any specific rank or order, and their inclusion should not be interpreted as GAO endorsing any of them. Implementing any one action or a combination of actions listed in this report might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Experts coalesced around two of the suggested actions. These actions could guide a coordinated approach to testing, according to GAO's prior work, and help alleviate challenges. Specifically:

- A national diagnostic testing strategy would establish clear roles and responsibilities to improve collaboration during future public health threats. It would also help manage risks, such as conflicts arising from variation in jurisdictional resources and cooperation.
- A diagnostic testing coordinating group (forum) that includes all relevant partners would help coordinate diagnostic testing in preparation for, and in response to, public health threats. It would also help maintain and update a national testing strategy.

However, HHS has not established either a national testing strategy or forum. Establishing these before the next emergency would strengthen HHS's ability to implement testing for pandemic threats and other related public health threats.

Contents

Abbreviations

- ASPR Administration for Strategic Preparedness and Response
- CDC Centers for Disease Control and Prevention
- CLIA Clinical Laboratory Improvement Amendments of 1998
- CMS Centers for Medicare & Medicaid Services
- EUA emergency use authorization
- FDA Food and Drug Administration
- HHS Department of Health and Human Services
- NIH National Institutes of Health
- OIG Office of Inspector General
- PCR polymerase chain reaction
- PHEMCE Public Health Emergency Medical Countermeasures Enterprise
- RADx Rapid Acceleration of Diagnostics
- SNS Strategic National Stockpile

June 4, 2025

Congressional Committees

Infectious diseases with pandemic potential—such as COVID-19 and avian influenza—pose a threat to American lives, national security, and economic interests. These diseases are caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations. They are also highly virulent, making them likely to cause significant morbidity and mortality in humans. Pandemic threats are ever-present, with factors such as increasing animal-to-human disease transmission risk through farming practices, wildlife trade, and habitat loss in recent decades contributing to the threat.[1] In addition, other infectious disease public health threats, such as mpox, could develop pandemic potential through genetic mutations increasing transmissibility or virulence.

Diagnostic testing for infectious diseases is critical to informing treatment and tracking disease trends.[2] Accurate and widespread diagnostic testing can help reduce potential death rates by identifying those who should self-isolate to reduce the chances of disease transmission and by informing allocation of public health resources at the national, state, and local levels.

The Department of Health and Human Services (HHS) leads the federal public health and medical response to public health emergencies, including testing efforts.[3] During the COVID-19 and mpox public health emergencies, HHS faced numerous testing challenges resulting in delays in testing nationwide. For example, HHS agencies faced challenges developing accurate diagnostic tests quickly; deploying tests and testing supplies; developing clear guidance to facilitate consistent and appropriate use of tests; and collecting complete and consistent testing data. These challenges made it more difficult to track the spread of COVID-19, which in turn limited the information available to public health authorities about where lockdowns and other mitigation measures were most needed to control the spread of disease. Some research has suggested that earlier implementation of these mitigation measures by even a week or two during the initial phases of COVID-

[1]See GAO, *Pandemic Origins: Technologies and Challenges for Biological Investigations*, GAO-23-105406 (Washington, D.C.: Jan. 27, 2023); and *Zoonotic Diseases: Federal Actions Needed to Improve Surveillance and Better Assess Human Health Risks Posed by Wildlife*, GAO-23-105238 (Washington, D.C: May 31, 2023).

[2]For the purposes of this report, “diagnostic testing” and “testing” refers to diagnostic testing for infectious diseases with pandemic potential.
Diagnostic testing provides an individual with information on their health status. Health care providers can use test results to determine a course of treatment. In addition, testing is a component of infectious disease surveillance, which is the ongoing, systematic collection, analysis, and interpretation of health-related data essential for planning, implementation, and evaluation of public health practices related to infectious diseases. We have ongoing work related to infectious disease surveillance.

[3]The Secretary of Health and Human Services may declare a public health emergency upon a determination that (a) a disease or disorder presents a public health emergency; or (b) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. 42 U.S.C. § 247d(a).

19 could have prevented more cases and deaths.[4] In part due to these challenges, we added HHS's leadership and coordination of public health emergencies to our High-Risk List in January 2022.[5]

The CARES Act includes a provision for us to monitor and report on the federal pandemic response.[6] This report is part of our body of work in response to the CARES Act and related to the HHS leadership and coordination of public health emergencies high-risk area.[7] This report identifies actions that experts suggested for HHS to improve diagnostic testing for future infectious diseases with pandemic potential, and steps HHS has taken related to these actions.

To address this objective, we convened a roundtable of 19 experts in January 2024. Specifically, we contracted with the National Academies of Sciences, Engineering, and Medicine (National Academies) to help identify experts in this topic area.[8] The experts we selected to participate represented a broad spectrum of experience in this area, and a variety of professional and academic fields.[9] See appendix I for more information about these experts, their professional disciplines, and their institutional affiliations, as well as the methodology used to conduct the roundtable.

The actions suggested by experts are listed without any specific rank or order. See appendix II for more information about all the actions suggested. We generally did not analyze or evaluate the actions suggested by experts. Their inclusion should not be interpreted as our endorsement, unless we specifically recommended an action in this or a prior GAO report. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

After compiling the actions suggested by experts, we then compared these actions with prior recommendations to determine whether we or another entity had previously made a related recommendation. To do this, we reviewed relevant reports by GAO, the HHS Office of Inspector General (OIG), and the National Academies published between 2016 and 2024. We selected these entities due to their methodological rigor, and this time frame to cover multiple recent public health emergencies.[10] We identified recommendations from these reports

[4]See Sen Pei, Sasikiran Kandula, and Jeffrey Shaman, "Differential Effects of Intervention Timing on COVID-19 Spread in the United States," *Science Advances*, no.6 (2020) for one model that estimates the effects of variations in containment efforts on COVID-19 infection rates and mortality.

[5]See 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).

[6]Specifically, the act requires us to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the pandemic. Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020). The American Rescue Plan Act of 2021 also includes a provision for us to conduct oversight of the COVID-19 response. Pub. L. No. 117-2, § 4002, 135 Stat. 4, 78. All of our reports related to the COVID-19 pandemic are available on our website at https://www.gao.gov/coronavirus.

[7]See GAO, *High-Risk Series: Heightened Attention Could Save Billions More and Improve Government Efficiency and Effectiveness*, GAO-25-107743 (Washington, D.C.: Feb. 25, 2025).

[8]This roundtable was planned and convened with the assistance of the National Academies to help ensure a breadth of expertise in its preparation; however, all final decisions regarding meeting substance and expert participation were the responsibility of GAO.

[9]The roundtable included former, but not current, federal officials. The perspective of current federal officials is included in our description of the agency responses to the actions suggested. Additionally, comments provided by the experts reflected their own views and not those of the organizations with which they are affiliated. Further, the experts' views may not correspond with those of others with similar backgrounds and expertise.

[10]The National Academies produces different types of publications. We limited our review to their consensus study reports in this area due to their methodological rigor.

that were related to diagnostic testing and then compared them to the actions suggested by experts. Some recommendations may be related to multiple actions suggested by experts.

Due to the volume of work produced by GAO, HHS-OIG, and the National Academies, there may be other related recommendations that we did not identify. To help ensure the accuracy of the statements presented from these entities, we provided relevant excerpts of the report to HHS-OIG and the National Academies. We incorporated their technical comments as appropriate.

We also provided HHS officials the opportunity to respond to the actions suggested by the experts. We sent a description of each action to HHS for its review and response. HHS component agency officials responded in writing to those actions related to their scope of responsibility and for which their component agency had taken or planned any related steps. These component agencies included the Administration for Strategic Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), the Health Resources and Services Administration, and the National Institutes of Health (NIH). We reviewed the responses for each action, including any related documentation, and sought clarification where needed. We did not otherwise corroborate HHS's responses or take steps to determine whether or to what extent HHS has taken the actions suggested by our experts, with two exceptions.

Specifically, in compiling the list of actions experts suggested, we identified two areas that experts coalesced around—meaning actions that were mentioned repeatedly across multiple days of the roundtable by several experts representing various aspects of diagnostic testing. In order to evaluate HHS efforts in these two areas, we reviewed agency requirements in the 2022 *National Biodefense Strategy and Implementation Plan* (*National Biodefense Strategy*), leading practices from our prior work, and federal internal control standards.[11] We determined that the information and communication component of federal internal control standards was significant, along with the underlying principle that management should communicate with external parties. To assess HHS efforts against these criteria, we reviewed agency documentation related to diagnostic testing coordination, and interviewed HHS officials about their related efforts.

We conducted this performance audit from July 2023 through June 2025 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.

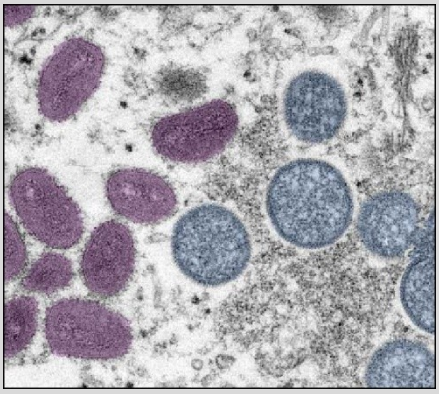
[11]See White House, *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Washington, D.C.: October 2022). See also GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004); *COVID-19: Lessons Can Help Agencies Better Prepare for Future Emergencies*, GAO-24-107175 (Washington, D.C.: Aug. 1, 2024); *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*, GAO-23-105520 (Washington, D.C.: May 24, 2023); *Federal Advisory Committees: Actions Needed to Enhance Decision-Making Transparency and Cost Data Accuracy*, GAO-20-575 (Washington, D.C.: Sept. 10, 2020); *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, GAO-23-105460 (Washington, D.C.: July 12, 2023); and *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014).

Background

Key Federal Agency Responsibilities Related to Diagnostic Testing

HHS and its component agencies lead federal efforts to provide diagnostic testing for infectious diseases, including those with pandemic potential.[12] Diagnostic testing efforts are fragmented across numerous HHS component agencies that each play a key role. Fragmentation refers to circumstances in which more than one federal agency or component agency is involved in the same activity or broad area.[13] Some degree of program fragmentation may be warranted because of the nature and magnitude of federal efforts in diagnostic testing. According to our prior work, coordination can help manage fragmentation.[14]

Mpox



The mpox virus, first identified in humans on the continent of Africa in 1970, is transmitted through close personal contact, contaminated materials, and animals. Symptoms of mpox include fever, malaise, headache, and rash. There are two main types of the virus that causes mpox: clade I and clade II, with clade I associated with higher mortality. Previously, mpox was typically transmitted from animals to humans with limited human-to-human spread. However, in 2022, an outbreak of mpox caused by a clade II virus occurred with significant person-to-person spread. This outbreak spread to the United States, leading to a public health emergency declaration. As of December 2024, 63 people had died in the United States of mpox, according to CDC officials. For more information on the federal response to this outbreak, see GAO, *Public Health Preparedness: Mpox Response Highlights Need for HHS to Address Recurring Challenges*, GAO-24-106276 (Washington, D.C., Apr: 18, 2024).

In addition, in 2024, there was an increase in clade I mpox cases in Central and Eastern Africa. This increase contributed to the World Health Organization declaring a Public Health Emergency of International Concern. This is the World Health Organization's highest level of global alert, recognizing the potential threat the virus poses to countries around the world.

Source: GAO and Centers for Disease Control and Prevention (CDC); CDC (photo). | GAO-25-106980

[12]HHS's Strategic Plan Fiscal Year 2022-2026 includes an objective to improve capabilities to prepare for, respond to, and recover from public health emergencies.

[13]See GAO, *2024 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Billions of Dollars in Financial Benefits*, GAO-24-106915 (Washington, D.C.: May 15, 2024).

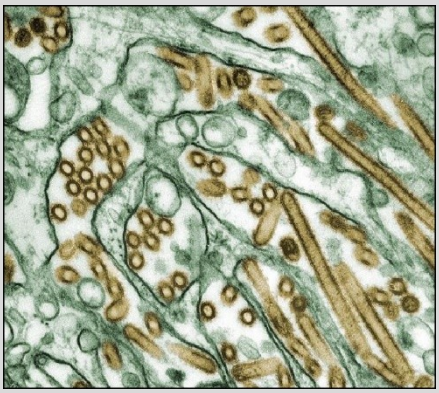
[14]See GAO-23-105520.

Key HHS agencies involved in diagnostic testing for infectious diseases with pandemic potential include ASPR, CDC, and FDA.

- ASPR is the agency responsible for preparing for, responding to, and recovering from public health emergencies. This includes responsibilities related to diagnostic testing, such as supporting the research, development, and acquisition of tests, and assisting with testing deployment. According to officials, ASPR receives annual funding for pandemic influenza research, and research for all other potential pandemic public health emergencies requires supplemental funding. ASPR also maintains the Strategic National Stockpile, the federal inventory of medical supplies that can be provided to state, local, territorial, and tribal governments (collectively referred to as jurisdictions) in response to a broad range of public health emergencies. Supplies from the Strategic National Stockpile can be deployed when local supplies run out or when the necessary supplies are not commercially available.
- CDC is the nation's lead public health agency, responsible for protecting the nation from dangerous health threats. This includes responsibilities related to diagnostic testing, such as test development and performing laboratory testing. Historically, CDC has led the development of diagnostic tests for new diseases, and the distribution of these tests to public health laboratories. CDC also provides diagnostic testing guidance to the public and to health care professionals; assists public and private laboratories in coordination of testing and testing readiness; provides relevant training for jurisdictions; and collects diagnostic testing data, among other things.
- FDA is the agency responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. This includes responsibilities related to diagnostic tests, such as authorizing tests for emergency use in public health emergencies; monitoring the performance of authorized tests; providing updates on which tests are authorized for use; and addressing the sale of fraudulent tests.[15]

[15]FDA can authorize unapproved diagnostic tests that it reasonably believes may be effective to be made available for emergency use. Authorizations for emergency use can be made if the known and potential benefits of the product outweigh the known and potential risks and other statutory criteria are met. See 21 U.S.C. § 360bbb-3.

Avian Influenza



The avian influenza A (H5N1) virus is a highly pathogenic avian virus first identified in South China in 1996. Highly pathogenic avian influenza viruses cause severe disease and high mortality in infected birds. It is now widespread in wild birds worldwide and is causing outbreaks in poultry and American dairy herds, with several human cases in U.S. dairy and poultry workers in 2024. Illnesses in people from H5N1 have ranged from mild illness (e.g., upper respiratory symptoms) to severe illness (e.g., pneumonia, multi-organ failure), which can result in death. For our previous work on the Department of Agriculture's efforts to reduce avian influenza risks, see GAO, *Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts*, GAO-17-360 (Washington, D.C.: Apr. 13, 2017).

Source: GAO and Centers for Disease Control and Prevention (CDC); CDC (photo). | GAO-25-106980

In addition, other HHS agencies contribute to federal diagnostic testing efforts. For instance, NIH has initiatives to speed the development, commercialization, and implementation of technologies for diagnostic testing. CMS provides oversight of nursing homes and clinical laboratories that perform diagnostic tests.

Other federal agencies outside of HHS have a role in diagnostic testing as well. For example, the Department of Defense may deploy personnel and mobile laboratories to support administering and processing tests, and the Department of Homeland Security (through the Federal Emergency Management Agency) works to source and procure testing supplies for jurisdictions.

Key Non-Federal Diagnostic Testing Stakeholders

Public, private, and nonprofit stakeholders are also key to diagnostic testing. Public stakeholders include jurisdictions, including state, local, territorial, and tribal public health departments; as well as public health laboratories; public health care facilities; and public academia.[16] Jurisdictions are responsible for the public health response in their area. This includes coordinating diagnostic testing efforts, including administering tests, communicating testing prioritization criteria to the public, and collecting and transmitting diagnostic testing data. Public academia conducts research on testing issues, such as new diagnostic testing technologies and lessons learned from previous public health emergencies.

[16]We have ongoing and past work regarding the federal government's coordination with jurisdictions during public health emergencies. For example, see GAO, *Public Health Preparedness: Mpox Response Highlights Need for HHS to Address Recurring Challenges*, GAO-24-106276 (Washington, D.C.: Apr. 18, 2024); and *Public Health Preparedness: HHS Should Assess Jurisdictional Planning for Isolation and Quarantine*, GAO-24-106705 (Washington, D.C.: July 25, 2024).

Private and nonprofit stakeholders include test developers, manufacturers, and distributors; private laboratories; private health care facilities and clinicians, such as doctors, nurses, and pharmacists; academia; and patient advocacy groups. Test developers, manufacturers, and distributors are involved in developing, producing, and distributing tests, while private laboratories may also develop and perform tests. Health care facilities and clinicians administer diagnostic tests and send the tests to laboratories. Academia conducts research on testing issues. Finally, patient advocacy groups represent patients' interests.

Diagnostic Testing Stages and Related Challenges

For the purposes of this report, we have identified four stages of diagnostic testing based on our prior work. The four stages are development, deployment, guidance, and data collection. See figure 1 for details about each stage.

Figure 1: Diagnostic Testing Stages for an Infectious Disease with Pandemic Potential

Stages	Development	Deployment	Guidance	Data Collection
	The development stage of diagnostic testing includes developing, validating, and authorizing diagnostic tests.	The deployment stage of diagnostic testing includes manufacturing, distributing, administering and performing diagnostic tests.	The guidance stage of diagnostic testing includes conveying information about the use of diagnostic tests to the public.	The data stage of diagnostic testing includes collecting and reporting diagnostic testing data, including test results and patient data, such as race and ethnicity.
Examples of federal actions	*During this stage, the Food and Drug Administration may provide emergency use authorization to diagnostic tests if there is evidence that the products may be effective and if known and potential benefits outweigh known and potential risks.*	*During this stage, the Administration for Strategic Preparedness and Response (ASPR) coordinates with testing manufacturers and jurisdictions to deploy testing supplies into communities.*	*During this stage, the Centers for Disease Control and Prevention (CDC) develops and disseminates diagnostic testing guidance for schools, businesses, workplaces, and the general public about implementing and prioritizing testing.*	*During this stage, public health departments report testing data to CDC, which uses the data to inform policymakers and the public about the current state of a public health emergency to guide decision making.*

Source: GAO analysis of GAO reports and Department of Health and Human Services (HHS) websites; yurolaitsalbert, Gorodenkoff, yanik88, and Kzenon/stock.adobe.com (photos). | GAO-25-106980

Accessible Data for Figure 1: Diagnostic Testing Stages for an Infectious Disease with Pandemic Potential

	Development	Deployment	Guidance	Data Collection
Stages	The development stage of diagnostic testing includes developing, validating, and authorizing diagnostic tests.	The deployment stage of diagnostic testing includes manufacturing, distributing, administering and performing diagnostic tests.	The guidance stage of diagnostic testing includes conveying information about the use of diagnostic tests to the public.	The data stage of diagnostic testing includes collecting and reporting diagnostic testing data, including test results and patient data, such as race and ethnicity.
Examples of federal actions	During this stage, the Food and Drug Administration may provide emergency use authorization to diagnostic tests if there is evidence that the products may be effective and if known and potential benefits outweigh known and potential risks.	During this stage, the Administration for Strategic Preparedness and Response (ASPR) coordinates with testing manufacturers and jurisdictions to deploy testing supplies into communities.	During this stage, the Centers for Disease Control and Prevention (CDC) develops and disseminates diagnostic testing guidance for schools, businesses, workplaces, and the general public about implementing and prioritizing testing.	During this stage, public health departments report testing data to CDC, which uses the data to inform policymakers and the public about the current state of a public health emergency to guide decision making.

Source: GAO analysis of GAO reports and Department of Health and Human Services (HHS) websites; yurolaitsalbert, Gorodenkoff, yanik88, and Kzenon/stock.adobe.com (photos). | GAO-25-106980

Note: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

There may be overlap across these stages. For example, we define the guidance stage as the conveyance of information to the public about the use of diagnostic tests. However, there are other types of guidance that could affect other stages, such as guidance for test developers in the development stage or guidance for public health departments in the data collection stage.

We previously identified challenges related to diagnostic testing during recent public health emergencies in each of these stages.[17] In addition, some challenges we identified cut across multiple stages of diagnostic testing. See figure 2 for examples of challenges faced by HHS during recent public health emergencies by stage of diagnostic testing.

[17]We have ongoing and past work regarding the federal government's coordination with jurisdictions during public health emergencies. For example, 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); *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C.: June 27, 2011); *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, GAO-17-445 (Washington, D.C.: May 23, 2017); *Public Health Preparedness: HHS and Jurisdictions Have Taken Some Steps to Address Challenging Workforce Gaps*, GAO-25-107002 (Washington, D.C.: Jan. 29, 2025); and GAO-24-106276.

Figure 2: Challenges Faced by the Department of Health and Human Services (HHS) Related to Diagnostic Testing for an Infectious Disease with Pandemic Potential by Stage

Challenges faced	Development	Deployment	Guidance	Data Collection	Cross-cutting
	Failures in initial test development Insufficient supply of clinical samples to validate diagnostic test performance Difficulties managing a large influx of diagnostic test authorization requests	Shortages of key materials Barriers to patient access to diagnostic tests Insufficient laboratory capacity Insufficient financial mechanisms and manufacturing capacity for rapidly producing diagnostic tests at scale	Unclear guidance on the use and interpretation of diagnostic tests Confusion when communicating frequent changes as circumstances evolve Guidance that is inaccessible to certain populations	Difficulties collecting and transmitting data Inconsistent data on diagnostic test results and patient demographics A lack of interoperability across data collection systems	Coordination with nonfederal partners Overall readiness Public health workforce gaps Consistent funding
Examples	*The Centers for Disease Control and Prevention's (CDC) initial diagnostic test for COVID-19 failed. Due to this failure, diagnostic testing capacity was limited in the critical early weeks of the pandemic. See GAO-21-551 for more information.*	*During the mpox public health emergency, officials from HHS said that there was adequate national testing capacity. However, these tests were not always available in all areas they were needed. See GAO-24-106276 for more information.*	*During the H1N1 pandemic, CDC faced challenges reaching non-English speaking populations. State and local officials said they needed CDC materials in more languages to reach these populations with accurate public health guidance. See GAO-11-632 for more information.*	*During the Zika public health emergency, criteria for defining a Zika virus case for public health reporting changed as new information was learned about the virus. This change meant that public health departments had to reclassify case data to reflect these changes, which took time and resources. See GAO-17-445 for more information.*	*There are multiple and widespread gaps in the existing public health workforce needed to respond to public health emergencies. This could include the workforce necessary to establish and maintain diagnostic testing. See GAO-25-107002 for more information.*

Source: GAO analysis of GAO reports; yurolaitsalbert, Gorodenkoff, yanik88, Kzenon, and itchaznong/stock.adobe.com (photos). | GAO-25-106980

Accessible Data for Figure 2: Challenges Faced by the Department of Health and Human Services (HHS) Related to Diagnostic Testing for an Infectious Disease with Pandemic Potential by Stage

	Development	Deployment	Guidance	Data Collection	Cross-cutting
Challenges faced	• Failures in initial test development • Insufficient supply of clinical samples to validate diagnostic test performance • Difficulties managing a large influx of diagnostic test authorization requests	• Shortages of key materials • Barriers to patient access to diagnostic tests • Insufficient laboratory capacity • Insufficient financial mechanisms and manufacturing capacity for rapidly producing diagnostic tests at scale	• Unclear guidance on the use and interpretation of diagnostic tests • Confusion when communicating frequent changes as circumstances evolve • Guidance that is inaccessible to certain populations	• Difficulties collecting and transmitting data • Inconsistent data on diagnostic test results and patient demographics • A lack of interoperability across data collection systems	• Coordination with nonfederal partners • Overall readiness • Public health workforce gaps • Consistent funding
Examples	The Centers for Disease Control and Prevention's (CDC) initial diagnostic test for COVID-19 failed. Due to this failure, diagnostic testing capacity was limited in the critical early weeks of the pandemic. See GAO-21-551 for more information.	During the mpox public health emergency, officials from HHS said that there was adequate national testing capacity. However, these tests were not always available in all areas they were needed. See GAO-24-106276 for more information.	During the H1N1 pandemic, CDC faced challenges reaching non-English speaking populations. State and local officials said they needed CDC materials in more languages to reach these populations with accurate public health guidance. See GAO-11-632 for more information.	During the Zika public health emergency, criteria for defining a Zika virus case for public health reporting changed as new information was learned about the virus. This change meant that public health departments had to reclassify case data to reflect these changes, which took time and resources. See GAO-17-445 for more information.	There are multiple and widespread gaps in the existing public health workforce needed to respond to public health emergencies. This could include the workforce necessary to establish and maintain diagnostic testing. See GAO-25-107002 for more information.

Source: GAO analysis of GAO reports; yurolaitsalbert, Gorodenkoff, yanik88, Kzenon, and itchaznong/stock.adobe.com (photos). | GAO-25-106980

Note: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans. For more information on the GAO reports cited, 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); *Public Health Preparedness: Mpox Response Highlights Need for HHS to Address Recurring Challenges*, GAO-24-106476 (Washington, D.C.: Apr. 18, 2024); *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C.: June 27, 2011); *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, GAO-17-445 (Washington, D.C.: May 23, 2017); and *Public Health Preparedness: HHS and Jurisdictions Have Taken Some Steps to Address Challenging Workforce Gaps*, GAO-25-107002 (Washington, D.C.: Jan. 29, 2025).

Experts Suggested Actions to Improve Diagnostic Testing; HHS Has Taken Steps, but Lacks Key Coordination Mechanisms

Experts Suggested Actions HHS Should Take to Improve in Each Stage of Diagnostic Testing; HHS Has Taken Some Related Steps

Experts on the roundtable we convened suggested a range of actions that HHS should take to improve diagnostic testing. These suggestions included actions related to each stage of testing—development, deployment, guidance, and data collection—as well as actions that would cut across multiple stages. We found that many of these suggested actions aligned with prior recommendations to HHS made by GAO, HHS-OIG, and the National Academies. HHS officials said they are taking some steps to improve diagnostic testing related to the actions suggested by experts.

The following sections summarize the actions experts suggested by stage of testing and include examples of prior recommendations and steps HHS officials said they have already taken to improve diagnostic testing. For detailed information on each action experts suggested, see appendix II.

Development

We identified five high-level actions based on what experts suggested HHS should do to improve diagnostic test development (see fig. 3). Each of these high-level actions includes several specific actions. For example, experts suggested several specific actions that HHS—specifically FDA—should take to develop flexible regulatory processes and preparedness plans for diagnostic testing. One such specific action is for FDA to develop a process for prioritizing the review of diagnostic test emergency use authorization (EUA) requests during an emergency. Under its EUA authority, FDA can authorize unapproved diagnostic tests that it reasonably believes may be effective to be made available for emergency use, which can increase access to tests.[18] However, large influxes of EUA requests can overwhelm FDA reviewers during a public health emergency. This action could help FDA manage high volumes of diagnostic test EUA requests and ensure access to testing during a public health emergency, according to experts.

[18]Typically, before a medical device such as a diagnostic test can be marketed in the U.S., it must be approved or cleared by FDA. However, during a public health emergency like the COVID-19 pandemic, the Secretary of Health and Human Services may declare that circumstances justify the emergency use of certain medical products. Once such a declaration has been made, FDA may temporarily allow use of unapproved medical products through an EUA, provided certain statutory criteria are met. For example, there must be evidence that the product may be effective and that the known and potential benefits of the product outweigh its known and potential risks. See 21 U.S.C. § 360bbb-3.

Figure 3: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Test Development for Infectious Diseases with Pandemic Potential

Source: GAO analysis of statements made by a roundtable of 19 experts; yurolaitsalbert/stock.adobe.com (photo). | GAO-25-106980

Accessible Data for Figure 3: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Test Development for Infectious Diseases with Pandemic Potential

Diagnostic Test Development

- Develop flexible Food and Drug Administration (FDA) regulatory processes and preparedness plans for diagnostic testing.
- Clearly communicate relevant FDA guidance and information on diagnostic tests.
- Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers.
- Encourage diagnostic testing research and development ahead of a public health emergency.
- Plan in advance to increase availability of diverse control material to use for diagnostic test validation.[a]

Source: GAO analysis of statements made by a roundtable of 19 experts; yurolaitsalbert/stock.adobe.com (photo). | GAO-25-106980

Notes: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

These actions are not listed in any specific rank or order, and their inclusion should not be interpreted as a GAO endorsement. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

[a]Control material is material used to validate tests—that is, assess a test's sensitivity and specificity, among other things. Control material can include clinical samples from patients, or contrived samples, which are made from viral material that may come from a range of sources.

Several of the specific actions that experts suggested to improve diagnostic test development are consistent with prior recommendations made by GAO and others. For instance, similar to experts' suggestion to prioritize EUA requests, HHS-OIG recommended in September 2022 that FDA assess and, as appropriate, revise its

guidance for test EUA requests, including to determine how to prioritize requests for review.[19] According to HHS-OIG, as of February 2025, FDA has not implemented this recommendation. GAO also recommended FDA develop additional policies in this area. In May 2022, GAO reported that FDA exercised its enforcement discretion—that is, the agency allowed certain tests to be used before receiving EUAs—to increase the availability of COVID-19 tests. However, unauthorized tests pose risks such as uncertain accuracy, which could lead to false negative test results that allow further disease spread. To mitigate these risks, GAO recommended that FDA develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies.[20] HHS agreed and partially addressed this recommendation in May 2024 when FDA issued draft guidance for public comment that provides information on potential enforcement policies. [21]

In addition to issuing draft guidance on potential enforcement policies, HHS has taken other steps related to each of the five high-level actions suggested by experts to improve diagnostic test development, according to agency officials.[22] For example, regarding the expert suggestion to develop flexible regulatory processes, FDA has included information in its general EUA guidance on factors it will consider when prioritizing EUA requests.[23] FDA put this guidance into practice in its mpox diagnostic test EUA policy, which prioritized requests from experienced developers with high manufacturing capacity. Officials said that this helped increase the availability of mpox testing in a variety of settings and increased testing capacity. In addition, officials said that FDA has a voluntary pre-EUA submission process through which a developer submits information about an existing diagnostic test. According to officials, this allows the agency to begin reviewing the submission and assisting in the development of documentation needed for an EUA in advance of a public health emergency.

Deployment

We identified eight high-level actions based on what experts suggested HHS should do to improve diagnostic test deployment (see fig. 4). Each of these high-level actions generally includes several specific actions. For example, experts suggested several specific actions HHS should take to expand the number of entities able to perform diagnostic tests. One such specific action is developing procedures to allow non-traditional laboratories to conduct certain tests during a public health emergency.[24] Significant demand for testing during a public health emergency can overwhelm clinical laboratories. Allowing non-traditional laboratories to perform diagnostic testing would increase testing capacity, according to experts. This could help to meet increased

[19]See Department of Health and Human Services, Office of Inspector General, *FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing*, OEI-01-20-00380 (September 2022).

[20]See GAO, *COVID-19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed*, GAO-22-104266 (Washington, D.C.: May 12, 2022).

[21]See Food and Drug Administration, *Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency: Draft Guidance for Industry and Food and Drug Administration Staff* (May 6, 2024); and *Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564: Draft Guidance for Laboratory Manufacturers and Food and Drug Administration Staff* (Rockville, Md.: May 6, 2024).

[22]We generally did not assess the extent to which HHS has taken the actions suggested by experts.

[23]See Food and Drug Administration, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* (January 2017).

[24]Non-traditional laboratories are laboratories that are not typically certified by the Clinical Laboratory Improvement Amendments of 1988 program, which certifies and conducts oversight of clinical laboratories that perform laboratory testing on human samples. Examples of non-traditional laboratories include academic centers and veterinary laboratories.

demand during a crisis, though HHS officials cautioned against implementing such an expansion before having disease-specific information regarding the particular testing needed.

Figure 4: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Test Deployment for Infectious Diseases with Pandemic Potential

Source: GAO analysis of statements made by a roundtable of 19 experts; Gorodenkoff/stock.adobe.com (photo). | GAO-25-106980

Accessible Data for Figure 4: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Test Deployment for Infectious Diseases with Pandemic Potential

Diagnostic Test Deployment

- Establish procedures to triage diagnostic testing.
- Stockpile diagnostic testing materials.
- Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing.
- Expand the number of entities able to perform diagnostic tests.
- Encourage the use of innovative diagnostic testing technologies.
- Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations.[a]
- Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions.
- Prepare in advance for diagnostic testing fraud.

Source: GAO analysis of statements made by a roundtable of 19 experts; Gorodenkoff/stock.adobe.com (photo). | GAO-25-106980

Notes: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

These actions are not listed in any specific rank or order, and their inclusion should not be interpreted as a GAO endorsement. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

[a]The Department of Health and Human Services defines vulnerable and underserved populations as those that face health, financial, educational, or housing disparities. Some examples of these populations include older adults, rural populations, racial and ethnic minorities, people with physical or intellectual disabilities, and low income or homeless individuals.

Several of the specific actions that experts suggested to improve diagnostic test deployment are consistent with prior recommendations made by GAO and others. For instance, similar to the experts' suggestion to expand the role of non-traditional laboratories in diagnostic testing, GAO recommended in July 2021 that CDC work with appropriate stakeholders to develop a plan to enhance laboratory surge testing capacity.[25] Such a plan could help reduce the spread of infectious disease by establishing the collaboration necessary to supplement public health diagnostic testing capabilities with private laboratories during an emergency. HHS agreed with this recommendation, and in May 2022, HHS implemented this recommendation by developing a plan for surge capacity that includes select laboratories beyond CDC and public health laboratories.

HHS has taken other steps related to each of the eight high-level actions suggested by experts to improve diagnostic test deployment, according to agency officials.[26] For instance, regarding the expert suggestion to expand the number of entities performing diagnostic tests, CMS officials said their agency—which regulates clinical laboratories—has developed specialized toolkits that provide guidance to non-traditional laboratories seeking approval to perform diagnostic testing. These toolkits can be updated and used during future public health emergencies should there be a need for additional testing capacity from non-traditional laboratories, according to CMS officials.

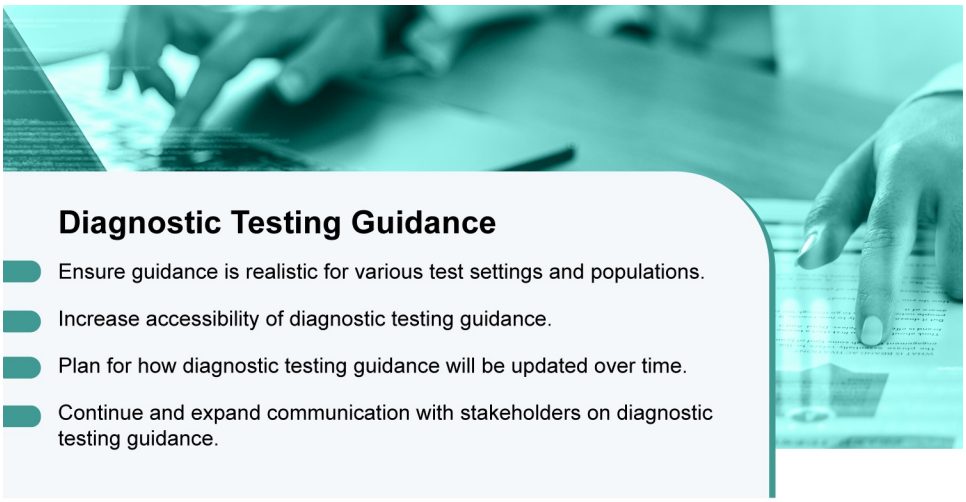
[25]See GAO-21-551.

[26]We generally did not assess the extent to which HHS has taken the actions suggested by experts.

Guidance

We identified four high-level actions based on what experts suggested HHS should do to improve diagnostic testing guidance (see fig. 5). Each of these high-level actions includes several specific actions. For example, experts suggested several specific actions HHS should take to plan for how diagnostic testing guidance will be updated over time. One such specific action is to help manage public expectations by establishing, in advance, and communicating a process for determining when diagnostic testing guidance will be updated based on new information. Frequent changes in guidance can lead to confusion about the reason for these changes. Sharing a plan with the public about when and under what circumstances guidance will be updated would help manage public expectations, according to one expert.

Figure 5: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing Guidance for Infectious Diseases with Pandemic Potential



Source: GAO analysis of statements made by a roundtable of 19 experts; yanik88/stock.adobe.com (photo). | GAO-25-106980

Accessible Data for Figure 5: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing Guidance for Infectious Diseases with Pandemic Potential

Diagnostic Testing Guidance

- Ensure guidance is realistic for various test settings and populations.
- Increase accessibility of diagnostic testing guidance.
- Plan for how diagnostic testing guidance will be updated over time.
- Continue and expand communication with stakeholders on diagnostic testing guidance.

Source: GAO analysis of statements made by a roundtable of 19 experts; yanik88/stock.adobe.com (photo). | GAO-25-106980

Notes: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

These actions are not listed in any specific rank or order, and their inclusion should not be interpreted as a GAO endorsement. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Several of the specific actions experts suggested to improve diagnostic testing guidance are consistent with prior recommendations made by GAO and others. For instance, similar to the experts' suggestion to establish a process for updating guidance based on new information, GAO recommended in November 2020 that CDC clearly disclose the scientific rationale for changes in diagnostic testing guidance.[27] HHS agreed with this recommendation, and CDC implemented the recommendation with a framework for developing guidance that describes the importance of providing scientific evidence to support public health guidance, such as diagnostic testing guidance updates. Additionally, in November 2021, the National Academies recommended that HHS establish mechanisms for transparent communication with external partners and the public.[28]

In addition to describing the importance of scientific evidence in its framework for developing guidance, HHS has taken other steps related to each of the four high-level actions suggested by experts to improve diagnostic testing guidance, according to agency officials.[29] For example, regarding the expert suggestion to ensure guidance is realistic for various settings, CDC officials said that while diagnostic testing guidance is intended to be broadly applicable and adaptable, they may work with other federal agencies to provide additional information for specific settings. During the COVID-19 public health emergency, CDC and CMS worked together to provide additional information to long-term care facilities. Additionally, agencies took steps to increase the accessibility of diagnostic testing guidance. CDC created videos that provided information about diagnostic testing in American Sign Language during the COVID-19 public health emergency. Further, NIH convened a listening session about testing challenges for people with disabilities and published a document on best practices for designing accessible COVID-19 tests.[30] For future public health emergencies, CDC officials said the agency will strive to provide guidance that is responsive to the needs of specific populations, such as rural and tribal populations, individuals experiencing homelessness, and individuals working and living in correctional facilities.

Data Collection

We identified four high-level actions based on what experts suggested HHS should do to improve diagnostic testing data collection (see fig. 6). Each of these high-level actions includes several specific actions. For example, experts suggested several specific actions HHS should take to increase efficiency in diagnostic testing data collection. One such specific action is establishing preapproved data use agreement templates for testing data. Delays in diagnostic testing data collection can hinder the government's ability to make informed decisions about public health threats. Data use agreement templates can establish required data elements and processes for how collected data will be used. Having these templates in place ahead of a public health emergency would increase efficiency and improve the timeliness of diagnostic testing data collection and reporting, according to experts.

[27]See GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191 (Washington, D.C.: Nov. 30, 2020).

[28]See the National Academies of Sciences, Engineering, and Medicine, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise* (Washington, D.C.: Nov. 3, 2021).

[29]We generally did not assess the extent to which HHS has taken the actions suggested by experts.

[30]See U.S. Access Board, *Best Practices for the Design of Accessible COVID-19 Home Tests* (Washington, D.C.: July 27, 2023).

Figure 6: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing Data Collection for Infectious Diseases with Pandemic Potential

Source: GAO analysis of statements made by a roundtable of 19 experts; Kzenon/stock.adobe.com (photo). | GAO-25-106980

Accessible Data for Figure 6: High-Level Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing Data Collection for Infectious Diseases with Pandemic Potential

Diagnostic Testing Data Collection

- Seek and exercise new authorities related to diagnostic testing data collection.
- Increase standardization of diagnostic testing data collection.
- Increase efficiency in the collection of diagnostic testing data.
- Build and expand partnerships with nonfederal entities around diagnostic testing data collection.

Source: GAO analysis of statements made by a roundtable of 19 experts; Kzenon/stock.adobe.com (photo). | GAO-25-106980

Notes: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

These actions are not listed in any specific rank or order, and their inclusion should not be interpreted as a GAO endorsement. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Several of the specific actions experts suggested to improve diagnostic testing data collection are consistent with prior recommendations made by GAO and others. For instance, similar to the experts' suggestion to use preapproved data use agreement templates, in November 2021, the National Academies recommended that national public health agencies, such as CDC, increase the ability of local authorities to rapidly report data about pathogens.[31] Establishing preapproved agreements could be one part of enabling more rapid testing data collection and reporting. Additionally, regarding an expert suggestion to align data elements with best practices for demographic data collection, GAO recommended in January 2021 that HHS consult with an expert committee of both public and private stakeholders to review and inform the alignment of its data

[31]See the National Academies of Sciences, Engineering, and Medicine, *Public Health Lessons for Non-Vaccine Influenza Interventions: Looking Past COVID-19* (Washington, D.C.: Nov. 17, 2021).

standards for key health indicators.[32] HHS would benefit from consistent and complete data to inform its decisions regarding the public health response, including the allocation of resources needed to prevent disease transmission. HHS partially agreed with this recommendation, and as of April 2023, HHS implemented this recommendation by taking steps to involve external stakeholders in its efforts to prepare for data collection and reporting standards in future pandemics.

HHS has taken some other steps related to each of the four high-level actions suggested by experts to improve diagnostic testing data collection, according to agency officials.[33] For example, regarding the expert suggestion to increase the efficiency of data collection, CDC has established an agency-wide data use agreement that includes an addendum for diagnostic testing data, according to CDC officials. In addition, NIH has a program to promote the reporting of at-home test results. This program created the Make My Test Count website, which allows individuals to self-report results from at-home diagnostic tests. As a result, self-reported data can complement lab-based information, according to officials, providing a more comprehensive picture.

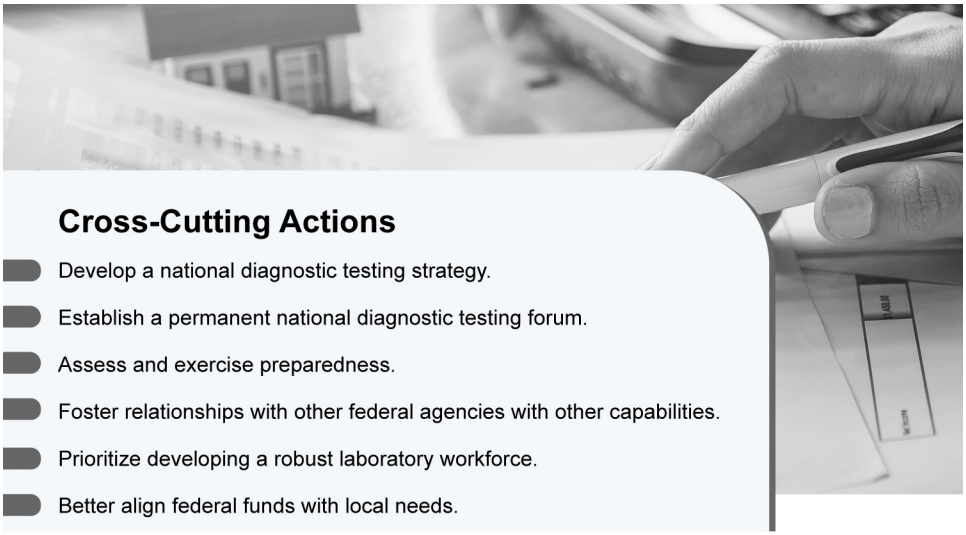
Cross-Cutting

We identified six high-level, cross-cutting actions based on what experts suggested HHS should do to improve diagnostic testing across the four stages of diagnostic testing: development, deployment, guidance, and data collection (see fig. 7). Most of these high-level actions include several specific actions. For example, experts suggested several specific actions HHS should take to assess and exercise preparedness. Conducting exercises of plans is a key component of response preparedness because exercises help identify what works and what does not. One specific action suggested by experts is conducting preparedness exercises to practice and identify problems with quickly developing and deploying diagnostic tests.

[32]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).

[33]We generally did not assess the extent to which HHS has taken the actions suggested by experts.

Figure 7: High-Level Cross-Cutting Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing for Infectious Diseases with Pandemic Potential



Source: GAO analysis of statements made by a roundtable of 19 experts; itchaznong/stock.adobe.com (photo). | GAO-25-106980

Accessible Data for Figure 7: High-Level Cross-Cutting Actions Experts Suggested the Department of Health and Human Services Should Take Related to Diagnostic Testing for Infectious Diseases with Pandemic Potential

Cross-Cutting Actions

- Develop a national diagnostic testing strategy.
- Establish a permanent national diagnostic testing forum.
- Assess and exercise preparedness.
- Foster relationships with other federal agencies with other capabilities.
- Prioritize developing a robust laboratory workforce.
- Better align federal funds with local needs.

Source: GAO analysis of statements made by a roundtable of 19 experts; itchaznong/stock.adobe.com (photo). | GAO-25-106980

Notes: An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

These actions are not listed in any specific rank or order, and their inclusion should not be interpreted as a GAO endorsement. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Several of the specific cross-cutting actions experts suggested are consistent with prior recommendations made by GAO and others. For instance, similar to the experts' suggestion to conduct preparedness exercises, GAO has a long-standing history of recommending that plans be exercised to test their effectiveness and identify ways to improve, including an April 2021 recommendation that HHS plan and conduct regular

exercises with relevant stakeholders to test and update certain plans related to pandemic response.[34] HHS agreed with this recommendation, but ASPR officials noted a lack of funding for these efforts. However, as of May 2022, HHS conducted a related exercise. Conducting exercises related to diagnostic testing as part of pandemic response would align with this recommendation. Additionally, in July 2020, the National Academies recommended HHS conduct regular scenario-based simulations to identify capacity gaps and promote process improvement.[35]

HHS has taken some steps related to each of the six high-level actions suggested by experts to alleviate these cross-cutting challenges, according to agency officials.[36] For example, in May 2023, regarding the expert suggestion to assess and exercise preparedness, ASPR held a preparedness exercise with test manufacturers and HHS agencies to see how government and industry could coordinate to accelerate diagnostic test development and production early in a public health emergency, ASPR officials said. In addition, FDA officials said the agency has been working on plans to incentivize the development of pathogen-agnostic tests, which are tests that can detect any pathogen and could be used in various infectious disease scenarios. These plans could consider whether there are existing tests for known pathogens and be updated on a periodic basis, according to officials.

HHS Has Not Taken Certain Cross-Cutting Steps to Guide a Coordinated National Approach to Diagnostic Testing

HHS has not taken two cross-cutting, foundational steps suggested by the experts to help guide a coordinated national approach to testing: establishing a national diagnostic testing strategy and a diagnostic testing forum that involves all relevant stakeholders. Experts coalesced around these two steps, which are consistent with agency requirements and our past work on enhancing coordination and emergency preparedness. Experts described these actions as foundational infrastructure that could guide the implementation of many of the other actions experts suggested.

National Diagnostic Testing Strategy

Experts suggested HHS should establish a national diagnostic testing strategy, which is consistent with our prior work and agency requirements. Our prior work has demonstrated that a national strategy can be a valuable tool for leading a coordinated approach to managing cross-cutting issues, like diagnostic testing, that are fragmented across various federal agencies.[37] The experts' suggestion is also consistent with the 2022

[34]See GAO, *Disaster Response: Criteria for Developing and Validating Effective Response Plans*, GAO-10-969T (Washington, D.C.: Sept. 22, 2010); *National Preparedness: FEMA Has Made Progress, but Needs to Complete and Integrate Planning, Exercise, and Assessment Efforts*, GAO-09-369 (Washington, D.C.: Apr. 30, 2009); and *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).

[35]See the National Academies of Sciences, Engineering, and Medicine, *Genomic Epidemiology Data Infrastructure Needs for SARS-CoV-2: Modernizing Pandemic Response Strategies* (Washington, D.C.: July 31, 2020).

[36]We generally did not assess the extent to which HHS has taken the actions suggested by experts.

[37]For example, see GAO-23-105520 and GAO, *Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts*, GAO-21-593 (Washington, D.C.: Aug. 17, 2021). Fragmentation refers to circumstances in which more than one federal agency (or organization within an agency) is involved in the same broad area of national need. See GAO-24-106915.

National Biodefense Strategy, which calls for the development of a national diagnostic testing strategy to ensure high-quality tests are widely and quickly available in the case of a public health emergency.[38]

National strategies can provide a vision for how the federal government will respond to public health emergencies, and are critical to the nation's preparedness and ability to implement a timely response.[39] Our prior work has identified six desirable characteristics of an effective national strategy.[40] These six characteristics are

- clear purpose, scope, and methodology;
- problem definition and risk assessment;
- goals, subordinate objectives, activities, and performance measures;
- resources, investments, and risk management;
- organizational roles, responsibilities, and coordination; and
- integration and implementation.

A national testing strategy incorporating these six desirable characteristics could, for example, establish plans for managing risks and conflicts associated with variation in jurisdictional resources, capacity, and cooperation.[41]

In addition, once a national testing strategy is in place, periodically updating it to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises is an important step. Our prior work demonstrates that such updates to agency response plans, such as a national testing strategy, are necessary to enhance preparedness.[42]

A national testing strategy that is periodically updated with such lessons learned could help HHS avoid in the future some of the challenges it encountered in previous public health emergencies. We and HHS-OIG identified several deficiencies in HHS's coordination of diagnostic testing efforts during previous public health emergencies.[43] The deficiencies in coordination exacerbated the failure of the initial COVID-19 test developed by CDC and included other issues like the lack of access to mpox tests early in that outbreak, and issues with COVID-19 testing guidance and data, as described in table 1. The table also identifies ways the development of a national testing strategy could have helped mitigate such deficiencies, such as by establishing clear plans and responsibilities for key agencies early in a public health emergency response.

[38]See White House, *National Biodefense Strategy*.

[39]See GAO-24-107175.

[40]We identified these characteristics by consulting numerous sources, such as the Government Performance and Results Act of 1993 and general literature on strategic planning and performance. Each characteristic has several subcomponents. See GAO-04-408T.

[41]Jurisdictions include state, local, territorial, and tribal entities.

[42]See GAO-24-107175 and GAO-10-969T.

[43]For example, see GAO-21-551.

Table 1: Examples of Diagnostic Testing Deficiencies During Previous Public Health Emergencies and How a National Testing Strategy Could Have Helped Mitigate Them, by Testing Stage

Testing stage	Example deficiency	Potential for mitigation[a]
Development	**Initial COVID-19 test failure.** Our prior work and HHS-OIG found that the Centers for Disease Control and Prevention's (CDC) initial COVID-19 test failed.[b] This failure was exacerbated by the fact that CDC did not coordinate with other test developers to manage risks associated with initial test development. As a result, CDC's test was the only COVID-19 test available in the United States until the end of February 2020, limiting testing capacity during the critical early weeks of the pandemic, when the nation needed to understand the spread of the novel virus.	**A national diagnostic testing strategy could help systematically manage risks** to help ensure a sufficient number of tests. For example, experts from our roundtable suggested that a testing strategy could include plans for coordinating with developers beyond CDC to build in redundancy in initial test development and reduce the risk that the failure of any one test in the future would leave the nation without the ability to track disease spread. Such plans for coordination could include, for example, establishing contracts with test developers to develop initial tests concurrently with CDC.
Deployment	**Inadequate mpox testing access.** Our prior work on the mpox response found that, despite having sufficient numbers of diagnostic tests to meet nationwide demand, HHS initially failed to coordinate access to testing in certain areas. Coordination with commercial laboratories was required to resolve these access issues.[c]	**A national diagnostic testing strategy could describe roles and responsibilities** and include milestones related to nationwide access to testing. As one expert from our roundtable explained, a national diagnostic testing strategy could clearly delineate "who does what when." This could improve coordination and ensure the right actors are in place to respond in a timely manner.
Guidance	**Lack of transparency regarding changes to COVID-19 testing guidance.** Our prior work on the COVID-19 response found CDC changed testing guidance several times in the first year of the pandemic, with little scientific explanation of the rationale behind the changes. In addition, CDC did not always coordinate with jurisdictions and public health organizations to prepare them for testing guidance changes.[d] Failing to coordinate updates that included scientific rationale with external stakeholders sparked confusion and disagreement from the public health community and others.[e]	**A national diagnostic testing strategy could establish specific processes for coordination and collaboration** related to issuing and revising testing guidance. This could include laying out the conditions under which guidance might change and the information that should be included with that change. A strategy could also establish processes for coordination regarding the release of updates to testing guidance to ensure jurisdictions and frontline providers are prepared to implement the guidance upon its release.
Data collection	**Lack of public health information technology infrastructure.** Our prior work found HHS faced challenges coordinating the transmission of COVID-19 data. During the early stages of COVID-19, some jurisdictions had to manually collect, process, and transfer data from one place to another. For example, a state official described having to fax documents, make copies, and physically transport relevant documents. The timeliness and completeness of information during public health emergencies can be impeded by the absence of a coordinated public health information technology infrastructure.[f]	**A national diagnostic testing strategy could establish systematic plans for resources and investments** like those related to establishing a robust public health information technology infrastructure, which would help HHS and jurisdictions coordinate information-sharing in response to a public health emergency.

Source: GAO analysis of GAO and Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports and statements made by a roundtable of 19 experts. | GAO-25-106980

[a]The way a national diagnostic testing strategy could potentially mitigate deficiencies is based on our past work identifying desirable characteristics of an effective national strategy. The desirable characteristics are (1) clear purpose, scope, and methodology; (2) problem definition and risk assessment; (3) goals, subordinate objectives, activities, and performance measures; (4) resources, investments, and risk management; (5) organizational roles, responsibilities, and coordination; and (6) integration and implementation. See GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

[b]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); and Department of Health and Human Services, Office of Inspector General, CDC's Internal Control

Weaknesses Led to Its Initial COVID-19 Test Kit Failure, but CDC Ultimately Created a Working Test Kit, A-04-20-02027 (Washington, D.C.: October 2023).

[c]See GAO, *Public Health Preparedness: Mpox Response Highlights Need for HHS to Address Recurring Challenges*, GAO-24-106276 (Washington, D.C.: Apr. 18, 2024).

[d]Jurisdictions refer to states, localities, U.S. territories, and Tribes.

[e]See GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191 (Washington, D.C.: Nov. 30, 2020).

[f]See GAO, *Public Health Emergencies: Data Management Challenges Impact National Response*, GAO-22-106175 (Washington, D.C.: Sept. 22, 2022).

In addition, in our prior work on the COVID-19 response, we recommended HHS develop a comprehensive national COVID-19 testing strategy.[44] We closed this recommendation as no longer valid in April 2024 because, with COVID-19 becoming endemic and the circulation of other infectious diseases, such as mpox and avian influenza, we believe a strategy exclusive to COVID-19 is no longer sufficient.

HHS officials said the agency is developing a diagnostics joint capabilities plan under the leadership of the Executive Office of the President in response to the *National Biodefense Strategy*.[45] However, as of May 2025, HHS officials were unable to provide documentation of the plan, nor could they provide details regarding its content or completion date. Written responses from officials from the White House Office of Pandemic Preparedness and Response Policy did not include details, such as content or completion date, either.[46] In addition, CDC officials said the agency is developing a national response testing framework that would include plans for how multiple government agencies, laboratory organizations, and private sector partners would coordinate during a response. CDC officials said this framework would align with the national diagnostic testing strategy being developed under the leadership of the Executive Office of the President as of December 2024.

As we have reported in our High-Risk series, HHS must improve its leadership and coordination of public health emergencies—including its diagnostic testing efforts—to save lives and mitigate severe economic impacts. Having a national diagnostic testing strategy in place that incorporates desirable characteristics of a national strategy would strengthen HHS's ability to provide testing in a timely manner, and potentially help avoid some of the testing problems that arose during previous public health emergencies. In addition, updating it as appropriate to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises would help keep the strategy current and leverage opportunities for continuous improvement.

National Diagnostic Testing Forum

Experts we convened, our prior work, and actions by HHS point to the value of a forum: a coordinating group that includes all relevant partners to coordinate diagnostic testing in preparation for and in response to a public health threat. Experts described several ways a forum that meets regularly, and includes all relevant federal

[44]See GAO-21-265.

[45]Congress has considered draft legislation that would require the development of a national diagnostic testing strategy. H.R. 4421, 118th Cong. § 107 (2023); S. 2333, 118th Cong. § 203 (2023).

[46]The Consolidated Appropriations Act, 2023, included a provision establishing the Office of Pandemic Preparedness and Response Policy within the Executive Office of the President. PREVENT Pandemics Act, Pub. L. 117-328, § 2104, div. FF, tit. II, 136 Stat. 5706, 5715 (2022). In July 2023, the White House stood up the new office, which is charged with leading, coordinating, and implementing actions related to preparedness for, and response to, known and unknown biological threats or pathogens that could lead to a pandemic or to significant public health-related disruptions in the United States.

agencies and external stakeholders, could be an effective coordinating mechanism for diagnostic testing. Specifically, they suggested a forum could improve diagnostic testing efforts by

- establishing relationships before a public health threat that can be quickly called upon during a public health emergency or the threat of one,
- encouraging flow of information between agencies and external stakeholders,
- allowing for real-time communication during a public health emergency,
- facilitating long-term planning to address systemic issues,
- providing input on resource allocation plans,
- providing a venue to discuss lessons learned from previous public health emergencies, and
- assisting with maintaining and updating a national diagnostic testing strategy.

Establishing such a forum would be consistent with federal internal control standards and our prior work. Federal internal control standards and our prior work demonstrate the importance of interagency coordination and of agencies regularly engaging with relevant external stakeholders to address issues like diagnostic testing that cut across agencies and the federal and private sectors. Coordination with other agencies and external stakeholders can help an agency determine its priorities, target its resources, and align its goals and strategies with that of others involved in achieving the same or similar outcomes.

Additionally, our prior work recommended that stakeholder engagement should be regular, not a one-time event.[47] To facilitate this engagement, federal agencies should identify other agencies and external stakeholders key to implementing the response and regularly coordinate with them, such as through regular meetings.[48] This includes meeting before and—as resources permit—during a response to an infectious disease with pandemic potential or other public health threat as deemed relevant, or any related preparedness exercises.

Further, our prior work suggests this forum should include key decision makers and facilitate two-way discussion. Federal stakeholders should be able to commit staff to coordination groups that have authority to make decisions on behalf of the agency.[49] Coordination with external stakeholders should also be two-way, so agencies can communicate and obtain quality information from these stakeholders to achieve their objectives and address related risks.[50]

Our prior work suggests the forum should include a broad representation of knowledgeable testing stakeholders from HHS and its component agencies, along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits. In the context of diagnostic testing, interagency coordination could involve the various HHS component agencies identified in this report—ASPR, CDC, CMS, FDA, and NIH—and agencies outside of HHS with which the department has previously coordinated testing efforts, such as the Department of Agriculture, the Department of Veterans Affairs, the Office of the Director of

[47]See GAO-23-105460.
[48]See GAO-24-107175.
[49]See GAO-23-105520.
[50]See GAO-14-704G.

National Intelligence, the Department of Defense, and the Department of Homeland Security's Federal Emergency Management Agency. These departments have played key roles in testing during recent public health emergencies. For example, the Department of Defense may deploy personnel and mobile laboratories to support administering and processing tests, and the Federal Emergency Management Agency works to source and procure testing supplies for jurisdictions.

Based on our prior work and statements from the experts, external stakeholders could include jurisdictions; public and private laboratories; test developers, manufacturers, and distributors; academia; health care facilities; clinicians, such as doctors, nurses, and pharmacists; and nonprofits, such as patient advocacy groups. These stakeholders are at the front lines of a response, distributing and performing testing and providing data to the federal government.

HHS's testing efforts in recent public heath emergencies have experienced a variety of issues due to a lack of coordination. For example, based on a review of our and HHS-OIG's prior work, we identified several deficiencies in HHS's coordination of diagnostic testing efforts during previous public health emergencies, as described in table 2. We also identified ways a forum could help mitigate these deficiencies based on experts' comments about ways a forum could address testing coordination issues, such as by encouraging two-way information sharing.

Table 2: Examples of Diagnostic Testing Deficiencies During Previous Public Health Emergencies and How a National Testing Forum Could Help Mitigate Them in the Future, by Testing Stage

Testing stage	Example deficiency	Potential for mitigation
Development	**Lack of pre-existing relationships between the Food and Drug Administration (FDA) and laboratories.** HHS-OIG found that during the COVID-19 response, FDA was slow to realize that testing by public health laboratories was far more limited than it initially expected, due in part to its limited prior engagement and coordination with these laboratories.[a] In addition, our prior work found many laboratories developing COVID-19 tests had difficulty navigating the process for receiving emergency use authorization to use these tests because of the lack of pre-existing relationships between FDA and laboratories.[b] These difficulties limited the ability of some laboratories to scale up testing quickly.	**A national diagnostic testing forum could establish relationships during inter-pandemic periods**, including between FDA and laboratories, to ease coordination during a public health emergency. Experts noted that these relationships could then be quickly called upon during a public health emergency, resulting in a better understanding of laboratories' testing capacity and easier navigation of the emergency use authorization process to scale up testing quickly.
Deployment	**Difficulties tracking the status and delivery of testing supplies from the federal government.** Our prior work found that jurisdictions and other external stakeholders had difficulties tracking the status and delivery of medical supplies, such as testing supplies, during the COVID-19 response. Challenges tracking supplies limited the ability of jurisdictions to determine if their supply requests had been met, which orders were pending, and what additional requests they needed to make. These tracking challenges, combined with uncertainty about the eventual cost sharing responsibility states and other external stakeholders would have, limited the information they could use to understand their overall supply picture and to budget for ongoing and future supply needs.[c]	**A national diagnostic testing forum could encourage two-way information sharing to improve understanding of testing supplies deliveries.** This information sharing could help increase jurisdictional awareness about processes for tracking and receiving testing supplies. It could also provide a venue for jurisdictions to raise concerns about and help devise solutions to issues such as confusion regarding the testing supply request process.

Testing stage	Example deficiency	Potential for mitigation
Guidance	**Poorly communicated testing guidance.** Our prior work and HHS-OIG found HHS failed to effectively coordinate its frequent updates to COVID-19 testing guidance.[d] For example, HHS-OIG found that hospitals surveyed during the COVID-19 response reported it was sometimes difficult to remain current with Centers for Disease Control and Prevention (CDC) guidance, and that they received conflicting guidance from different governmental and medical authorities, including criteria for testing.[e] Our prior work also found challenges regarding the communication of testing guidance from CDC during the Zika virus public health emergency. For example, representatives from a public health organization told us that they were sometimes not informed of changes in Zika-related testing information before learning about a change from a CDC media release.[f]	**A national diagnostic testing forum could facilitate real-time coordination and communication of guidance.** Experts noted that real-time coordination and communication could ensure that critical information and clarity about government priorities are disseminated promptly and uniformly across all stakeholders, therefore improving consistency in applying testing guidance. A forum could help ensure that information about updated guidance is passed along to individual jurisdictions and hospitals through their professional associations. Real-time coordination and communication about testing guidance could also help resolve and synchronize conflicting guidance from different jurisdictions.
Data collection	**Inconsistencies in COVID-19 testing demographic data.** Our prior work and HHS-OIG identified inconsistencies in demographic data collected in relation to COVID-19 testing data, due to variation in the categories jurisdictions used to collect racial and ethnic data. For example, some jurisdictions combine categories for race, while others do not. As a result, two people of the same race and ethnicity residing in different jurisdictions could appear in the reported data to belong to different demographic groups. This impedes HHS's ability to compare disparities across jurisdictions or to identify national or regional trends.[g]	**A national diagnostic testing forum could facilitate long-term planning to address systemic issues like lack of data standardization.** Experts noted that a forum could be a venue to discuss solutions for addressing systemic issues, such as inconsistencies in collection of demographic data. Members could discuss how to incorporate lessons learned about issues from previous public health emergencies to establish consistent racial and ethnic categories across jurisdictions. This could improve demographic data collection for the next pandemic.

Source: GAO analysis of GAO and Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports and statements made by a roundtable of 19 experts. | GAO-25-106980

[a]See Department of Health and Human Services, Office of Inspector General, *FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing*, OEI-01-20-00380 (Washington, D.C.: Sept. 16, 2022).

[b]See GAO, *COVID-19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed*, GAO-22-104266 (Washington, D.C.: May 22, 2022).

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

[d]See GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191 (Washington, D.C.: Nov. 30, 2020).

[e]See Department of Health and Human Services, Office of Inspector General, *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23-27, 2020*, OEI-06-20-00300 (Washington, D.C.: April 2020).

[f]See GAO, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, GAO-17-445 (Washington, D.C.: May 23, 2017).

[g]See Department of Health and Human Services, Office of Inspector General, *CDC Found Ways To Use Data To Understand and Address COVID-19 Health Disparities, Despite Challenges With Existing Data*, OEI-05-20-00540 (Washington, D.C.: July 13, 2022).

HHS and other agencies have established several diagnostic testing groups to coordinate testing efforts, but none of these groups provide all of the benefits of a testing forum.

- **Tri-Agency Task Force for Emergency Diagnostics.** This task force was created to coordinate among FDA, CDC, and CMS to advance rapid development and deployment of diagnostic tests in clinical and public health laboratories during public health emergencies.
- **Testing Coordination Group.** According to HHS officials, this group was created to facilitate information exchange between HHS executives regarding test development portfolios, manufacturing and regulatory issues, and proposed solutions for improving response capabilities. Participating agencies include ASPR,

CDC, CMS, FDA, and NIH, with officials from the Department of Defense attending on an ad hoc basis, according to HHS officials.

- **Public Health Emergency Medical Countermeasures Enterprise.** This group is an interagency partnership of federal medical countermeasure experts created to make recommendations to the Secretary of Health and Human Services about medical countermeasure research, advanced research, development, procurement, stockpiling, deployment, distribution, and stockpile needs for response to public health emergencies. This includes medical devices such as diagnostic tests, as well as other needed medical products that may be used to detect or assess, prevent, mitigate, or treat the adverse health effects of a public health emergency. This group is co-chaired by ASPR and the White House Office of Pandemic Preparedness and Response Policy, and also includes CDC, NIH, FDA, Department of Homeland Security, the Department of Defense, Department of Agriculture, Department of Veterans Affairs, and Office of the Director of National Intelligence.
- **CDC Diagnostic Surge Testing Capacity for Public Health Emergencies Memorandum of Understanding.** This memorandum of understanding was created for the sharing of information between testing stakeholders to address surge testing capacity issues before and during an emergency. Agencies involved include ASPR, CDC, and FDA. Some external stakeholders participate as well, such as industry associations.

HHS officials indicated they believe these groups and their processes for engaging with other agencies and external stakeholders are sufficient for coordinating testing. ASPR and CDC officials noted that Testing Coordination Group agencies bring to bear their previous experience in engaging with external stakeholders when they attend coordinating group meetings. In addition, CDC officials told us they believe the memorandum of understanding has provided sufficient opportunities for coordination with external stakeholders on diagnostic testing. Additional members can be added to the memorandum of understanding during annual updates.

However, experts we convened and our own review of these coordinating groups indicated they are not achieving all the benefits a forum could achieve. For example, we found that none of the coordinating groups include representatives from all relevant federal agencies. In addition, only some of the coordinating groups engaged with any external stakeholders. Including all relevant federal agencies and external stakeholders could ensure that all relevant authorities, resources, and skills are involved. This is important to address cross-cutting areas, such as diagnostic testing, in which no single stakeholder has all the necessary capabilities. Experts noted additional concerns regarding the exclusion of certain relevant external stakeholders and the lack of two-way discussion. For example, experts involved in the Memorandum of Understanding for Diagnostic Surge Testing said the group is missing health care facilities and clinicians. One expert also noted that the meetings typically consist of federal agencies reporting information to the external stakeholders rather than facilitating a dialogue. Experts emphasized that the inclusion of a broader group of external stakeholders and holding two-way discussions could ensure that there is a more holistic approach to diagnostic testing coordination and a better understanding of the roles, responsibilities, and capabilities of all the stakeholders involved.

A national diagnostic testing forum could be accomplished through the expansion of membership and scope of a current coordinating group, or through the establishment of a new forum. Such a forum would

- include key decision makers from all relevant federal agencies and external stakeholders;
- facilitate two-way discussion; and

- meet regularly, including both before and during infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises.

HHS officials also told us any coordinating group involving external stakeholders needs to comply with the Federal Advisory Committee Act.[51] Officials noted HHS must be unbiased when engaging with private sector stakeholders who could potentially receive competitive funding from the department.

Establishing a national diagnostic testing forum—or expanding an existing group—that meets regularly could improve real-time communication during an emergency. Including a broad representation of knowledgeable testing stakeholders from HHS and its component agencies along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits could support long-term institutional relationship-building. Doing so could strengthen HHS's ability to provide testing and help ensure the department avoids testing problems that arose during previous public health emergencies.

Conclusions

Infectious diseases with pandemic potential pose a threat to American lives, national security, and economic interests. Experts we convened identified numerous actions they believe HHS should take to improve diagnostic testing for these diseases. Many of these actions align with recommendations we and others have previously made. Many require close coordination with stakeholders on the front lines of diagnostic testing, such as jurisdictions, which have varying levels of available resources for responding to infectious disease public health emergencies. HHS has taken steps to implement some of our prior recommendations, as well as steps to improve diagnostic testing related to the actions suggested by experts.

The COVID-19 public health emergency drew attention to the impact that delays in establishing nationwide diagnostic testing can have on timely test availability and on the implementation of response measures, potentially leading to greater loss of life. Our prior work has shown that national strategies can improve the government's response to a public health emergency. Having a national diagnostic testing strategy in place that incorporates desirable characteristics of a national strategy would strengthen HHS's ability to provide testing in a timely manner, and potentially help avoid some of the testing problems that arose during previous public health emergencies. In addition, updating it as appropriate to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises would help keep the strategy current and leverage opportunities for continuous improvement.

Our past work has also demonstrated the value of a forum to enhance coordination and collaboration on cross-cutting issues. Establishing a national diagnostic testing forum—or expanding an existing group—that meets regularly could improve real-time communication during an emergency. Including a broad representation of knowledgeable testing stakeholders from HHS and its component agencies along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits could support long-term institutional relationship-building. Doing so could strengthen HHS's ability to provide testing and help ensure the department avoids testing problems that arose during previous public health emergencies.

[51]See 5 U.S.C. §§ 1001–14.

Recommendations for Executive Action

We are making the following four recommendations to HHS:

The Secretary of Health and Human Services should develop a national diagnostic testing strategy for infectious diseases with pandemic potential that incorporates all six desirable characteristics of a national strategy. (Recommendation 1)

The Secretary of Health and Human Services should periodically update the national diagnostic testing strategy to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises. (Recommendation 2)

The Secretary of Health and Human Services should establish a national diagnostic testing forum for infectious diseases with pandemic potential, or expand an existing group. The forum should include a broad representation of knowledgeable testing stakeholders from HHS and its component agencies along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits. This forum should include key decision makers and facilitate two-way discussion. (Recommendation 3)

The Secretary of Health and Human Services should ensure the national diagnostic testing forum meets regularly, including both before and during infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises. (Recommendation 4)

Agency Comments and Our Evaluation

We provided a draft copy of this report to HHS for review and comment. In its written comments, reproduced in appendix III, HHS noted it is committed to carefully reviewing the recommendations and providing a future update. HHS also provided technical comments, which we incorporated as appropriate.

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

If you or your staff have any questions about this report, please contact me at DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

//SIGNED//

Mary Denigan-Macauley
Director, Health Care

List of Committees

The Honorable Susan Collins
Chair
The Honorable Patty Murray
Vice Chair
Committee on Appropriations
United States Senate

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

The Honorable Rand Paul, M.D.
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The Honorable Gary C. Peters
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Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Tom Cole
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House of Representatives

The Honorable Mark E. Green, M.D.
Chairman

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

The Honorable James Comer
Chairman
Ranking Member
Committee on Oversight and Government Reform
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Expert Roundtable on Diagnostic Testing for Infectious Diseases with Pandemic Potential

To address our objective, we convened a 3-day virtual roundtable of 19 experts to discuss actions the Department of Health and Human Services (HHS) should take to improve diagnostic testing for infectious diseases with pandemic potential.[52] We contracted with the National Academies of Sciences, Engineering, and Medicine (National Academies) to help identify potential experts representing a broad spectrum of views and expertise, and a variety of professional and academic fields related to diagnostic testing.[53] The National Academies identified potential experts for participation in the following sectors and occupations:

- Laboratories, both public and private.
- Non-laboratory public health, such as state, local, and tribal public health officials.
- Health care facilities, such as hospitals.
- Clinicians, such as physicians and nurses.
- Test manufacturers.
- Former HHS officials from both Republican and Democratic administrations.
- Academia, such as published infectious disease or public policy researchers.

We selected experts for participation based on several factors. Specifically, we considered (1) type and depth of experience; (2) recognition in the professional community, as demonstrated by relevant publications and professional affiliations, among other distinctions; and (3) recommendations from National Academies and public health associations. Some experts had experience or qualifications in multiple areas of interest. The team also considered other factors like geographic representation; and gender, racial, and ethnic diversity, where possible. Table 3 lists the 19 selected experts and their affiliations at the time of the roundtable.[54]

Table 3: Alphabetical List of Expert Participants in GAO Roundtable on Diagnostic Testing for Infectious Diseases with Pandemic Potential, Held January 22 and 25-26, 2024

Expert	Institutional affiliation at time of roundtable
Ilisa Bernstein, PharmD, JD	American Pharmacists Association

[52]An infectious disease with pandemic potential is a disease caused by bacteria, viruses, or other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations, as well as highly virulent, making them likely to cause significant morbidity and mortality in humans.

[53]This meeting of experts was planned and convened with the assistance of the National Academies to help ensure a breadth of expertise in its preparation; however, all final decisions regarding meeting substance and expert participation were the responsibility of GAO.

[54]The comments provided by the experts reflected their own views and not those of the organizations with which they are affiliated. Further, the experts' views may not correspond with those of others with similar backgrounds and expertise.

Expert	Institutional affiliation at time of roundtable
Gavin Cloherty, PhD[a]	Abbott Laboratories
Vicki Collie-Akers, PhD, MPH	University of Kansas Medical Center
Elizabeth (Beth) Daly, DrPH, MPH	Council of State and Territorial Epidemiologists
Abigail Echo-Hawk, MA	Seattle Indian Health Board; Urban Indian Health Institute
Gigi Gronvall, PhD	Johns Hopkins Bloomberg School of Public Health; Johns Hopkins Center for Health Security
Stephen (Steve) Hahn, MD, FASTRO	Flagship Pioneering; Harbinger Health
Kimberly (Kim) Hanson, MD, MHS	University of Utah
Steve Henn, MBA[a]	Abbott Laboratories
Susan Kansagra, MD, MBA	North Carolina Department of Health and Human Services
Syra Madad, DHSc, MS, MCP, CHEP	New York City Health + Hospitals
Elizabeth (Beth) Marlowe, PhD, D(ABMM), SM(ASCP)	Quest Diagnostics
Christian Ramers, MD, MPH, AAHIVS	Family Health Centers of San Diego
Zachary (Zach) Rothstein, JD	AdvaMed
Timothy (Tim) Southern, PhD, MS, D(ABMM)	South Dakota Public Health Laboratory
Jill Taylor, PhD, MS	Association of Public Health Laboratories
Susan Van Meter, MA	American Clinical Laboratory Association
Rochelle Walensky, MD, MPH	Harvard University
Elizabeth White, APRN, PhD	Brown University School of Public Health

Legend: AAHIVS = American Academy of HIV Medicine HIV Specialist; APRN = Advanced Practice Registered Nurse; CHEP = Certified Healthcare Emergency Professional; D(ABMM) = Diplomate, American Board of Medical Microbiology; DrPH = Doctor of Public Health; DHSc = Doctor of Health Science; FASTRO = Fellow of the American Society of Radiation Oncology; JD = Juris Doctor; MA = Master of Arts; MBA = Master of Business Administration; MCP = Master Continuity Practitioner; MD = Doctor of Medicine; MHS = Master of Health Science; MPH = Master of Public Health; MS = Master of Science; PharmD = Doctor of Pharmacy; PhD = Doctor of Philosophy.

Source: GAO. | GAO-25-106980

Notes: The comments provided by the experts reflected their own views and not those of the organizations with which they are affiliated. Further, the experts' views may not correspond with those of others with similar backgrounds and expertise. To help identify any potential biases or conflicts of interest, before finalizing the participation of experts, we asked each expert who participated in the roundtable to disclose whether they had investments, sources of earned income, organizational positions, relationships, or other circumstances that could affect, or could be viewed to affect, their statements during the roundtable. None of the experts reported potential conflicts that would affect their ability to participate, according to our determination.

[a]Due to availability, the roundtable included two different experts from Abbott who participated on different days of the panel.

To help identify any potential biases or conflicts of interest before we finalized the participation of experts, we asked each expert to disclose whether they had investments, sources of earned income, organizational positions, relationships, or other circumstances that could affect, or could be viewed to affect, their statements during the roundtable. We determined that none of the experts reported potential conflicts that would affect their ability to participate.

To facilitate discussion, we organized the roundtable sessions around four stages of diagnostic testing: development, deployment, guidance, and data collection.[55] For each of these stages, we compiled a list of challenges faced during recent public health emergencies, such as COVID-19 and mpox, from a review of relevant literature, agency documentation, and GAO reports, among others. During the roundtable, we began each session with a discussion of the challenges associated with each stage, including the challenges we identified and any additional challenges the experts mentioned. After this discussion, we identified the top challenges in each stage and facilitated a roundtable discussion about what actions experts suggested HHS should take to improve diagnostic testing in these areas for the future.

The expert roundtable discussions were recorded and transcribed to ensure that we accurately captured experts' statements. We then reviewed and analyzed the transcripts to compile the list of actions that experts suggested HHS should take to improve diagnostic testing. We grouped the specific actions suggested into higher-level actions. Following this analysis, we sent the compiled list of actions to the experts for review and comment. We incorporated those comments into our report as appropriate to accurately reflect the actions and considerations suggested by the experts.

We did not poll experts or take votes on actions discussed during the roundtable or attempt to reach consensus. Consequently, we do not provide counts or otherwise quantify the number of experts supporting an action. Throughout the report, we use the term "experts" to refer to more than one expert.

Additionally, the actions in this report are listed without any specific rank or order. We generally did not analyze or evaluate the actions suggested by experts. Their inclusion should not be interpreted as GAO endorsing any action, unless an action is specifically recommended by GAO. Implementing any one action or a combination of actions might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

[55]For the purposes of this report, we defined diagnostic test development as the stage of diagnostic testing that includes developing, validating, and authorizing diagnostic tests. We defined diagnostic test deployment as the stage of diagnostic testing that includes manufacturing, distributing, administering and processing diagnostic tests. We defined diagnostic testing guidance as the stage of diagnostic testing that includes conveying information to the public about the use of diagnostic tests. We defined diagnostic testing data collection as the stage of diagnostic testing that includes collecting and reporting diagnostic testing data, including test results and patient data such as race and ethnicity.

Appendix II: Actions Identified by Experts to Improve Diagnostic Testing for Infectious Diseases with Pandemic Potential

Appendix III: 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

April 23, 2025

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"PUBLIC HEALTH PREPAREDNESS: HHS Needs a Coordinated National Approach for Diagnostic Testing for Pandemic Threats"** (GAO-25-106980).

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

Sincerely,

Mitchell Hailstone

Mitchell Hailstone
Acting Assistant Secretary for Legislation
and
Principal Deputy Assistant Secretary

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT - PUBLIC HEALTH PREPAREDNESS: HHS NEEDS A COORDINATED NATIONAL APPROACH FOR DIAGNOSTIC TESTING FOR PANDEMIC THREATS (GAO-25-106980)

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.

GAO Recommendation 1:
The Secretary of Health and Human Services should develop a national diagnostic testing strategy for infectious diseases with pandemic potential that incorporates all six desirable characteristics of a national strategy.

HHS Response:
HHS is committed to ensuring that it carefully reviews GAO recommendations and will provide a future update to GAO in its Statement of Actions letter.

GAO Recommendation 2:
The Secretary of Health and Human Services should periodically update the national diagnostic testing strategy to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises.

HHS Response:
As with recommendation 1, HHS will provide a future update to GAO in its Statement of Actions letter.

GAO Recommendation 3:
The Secretary of Health and Human Services should establish a national diagnostic testing forum for infectious diseases with pandemic potential, or expand an existing group. The forum should include a broad representation of knowledgeable testing stakeholders from HHS and its component agencies along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits. This forum should include key decision makers and facilitate two-way discussion.

HHS Response:
HHS is committed to ensuring that it carefully reviews GAO recommendations and will provide a future update to GAO in its Statement of Actions letter.

GAO Recommendation 4:
The Secretary of Health and Human Services should ensure the national diagnostic testing forum meets regularly, including both before and during infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises.

HHS Response:
As with recommendation 3, HHS will provide a future update to GAO in its Statement of Actions letter.

Accessible Text for Appendix III: 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

April 23, 2025

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

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Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley at DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the contact named above, key contributors to this report were Tom Conahan (Assistant Director), Hannah Marston Minter (Analyst-in-Charge), Caitlyn Leiter-Mason, Camille McKenzie, and Chase Polak. Also contributing were Sonia Chakrabarty, Joycelyn Cudjoe, Hayden Huang, Drew Long, Eric Peterson, Ethiene Salgado-Rodriguez, Rebecca Sero, Amber Sinclair, Walter Vance, Sarah Veale, and Emily Wilson Schwark.

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