United States Government Accountability Office

Report to Congressional Committees

June 2025

PUBLIC HEALTH PREPAREDNESS

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

GAO-25-106980

GAO Highlights

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

June 2025

PUBLIC HEALTH PREPAREDNESS

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.

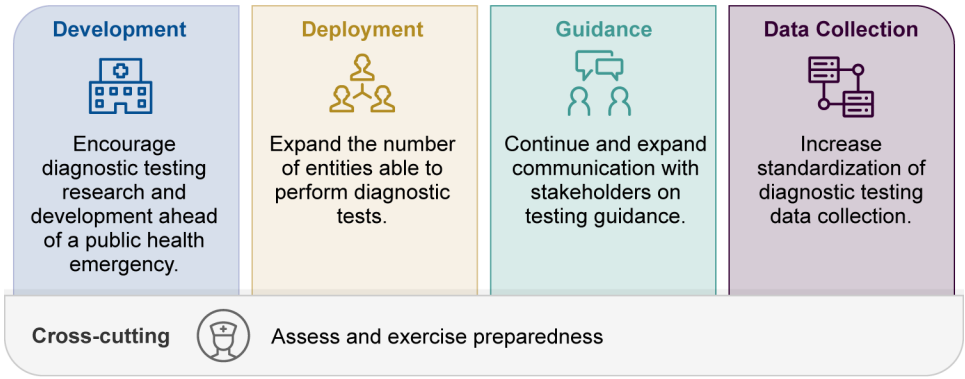
View GAO-25-106980. For more information, contact Mary Denigan-Macauley at deniganmacauleym@gao.gov.

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

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.

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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

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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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,

[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.

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-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

[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).

[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).

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 that were related to

[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.

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.

Background

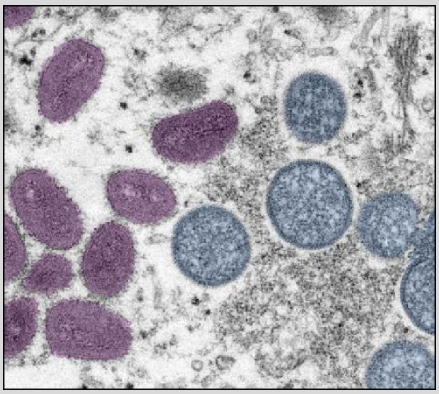
Key Federal Agency Responsibilities Related to Diagnostic Testing

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

[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).

[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.

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

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]

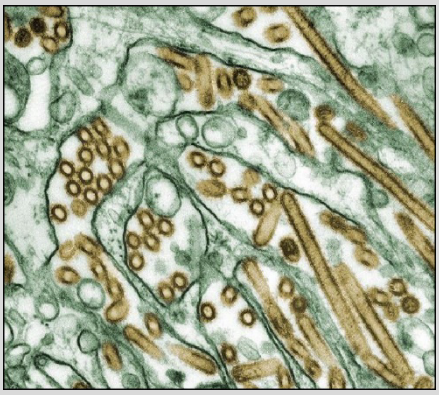
Key HHS agencies involved in diagnostic testing for infectious diseases with pandemic potential include ASPR, CDC, and FDA.

- 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.

[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.

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

- 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]

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

[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.

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.

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.

[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).

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

	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.

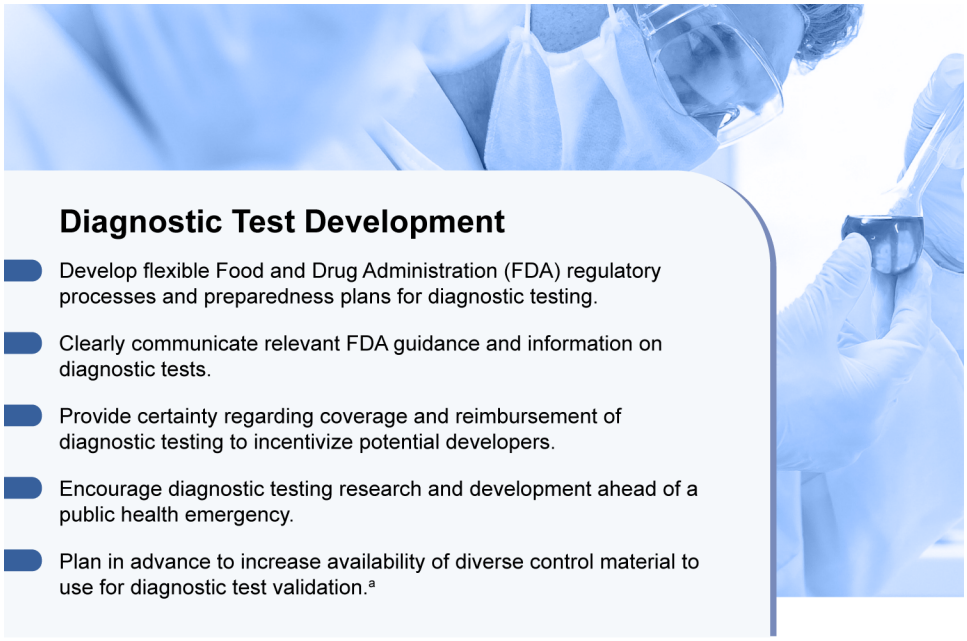
The following sections summarize the actions experts suggested by stage of testing and include examples of prior recommendations and steps HHS officials said they have already taken to improve diagnostic testing. For detailed information on each action experts suggested, see appendix II.

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.

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



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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.

[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.

[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

[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.

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.

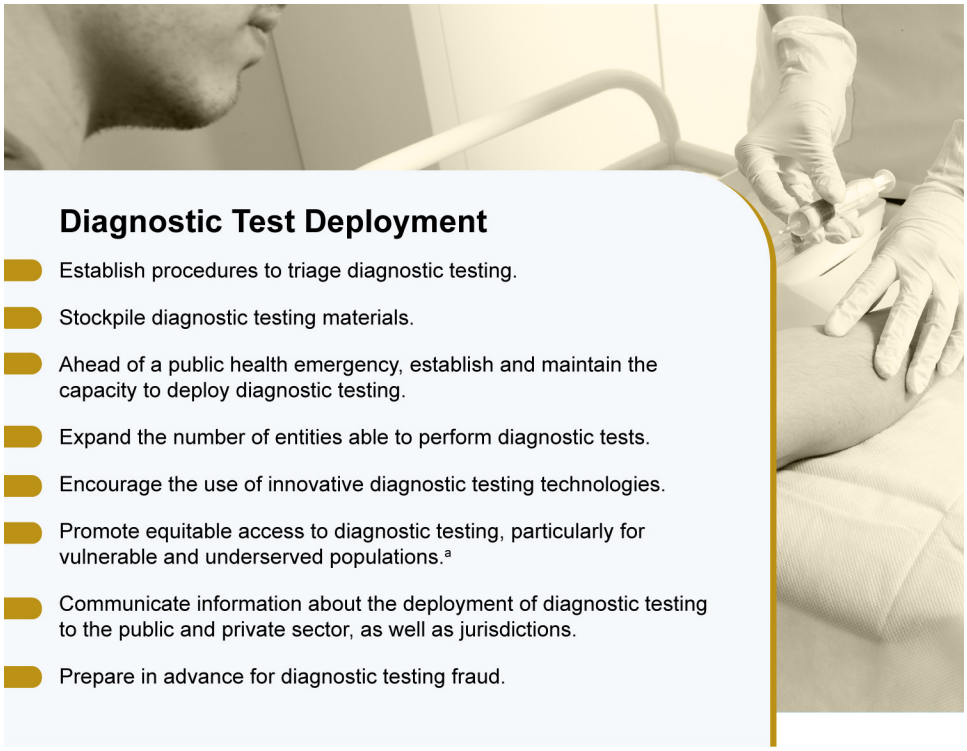
Deployment

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

[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.

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

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.

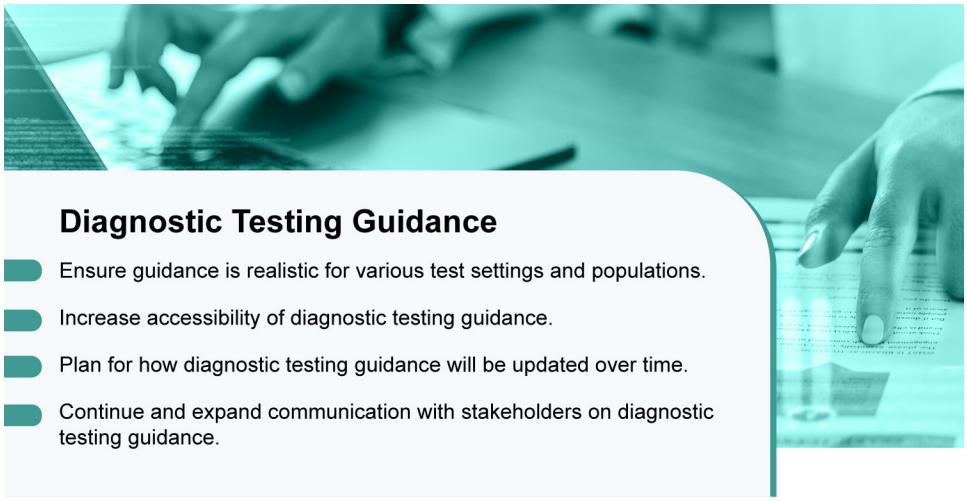
Guidance

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.

[25]See GAO-21-551.

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

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

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

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

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

[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).

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.

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

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.

[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).

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 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.

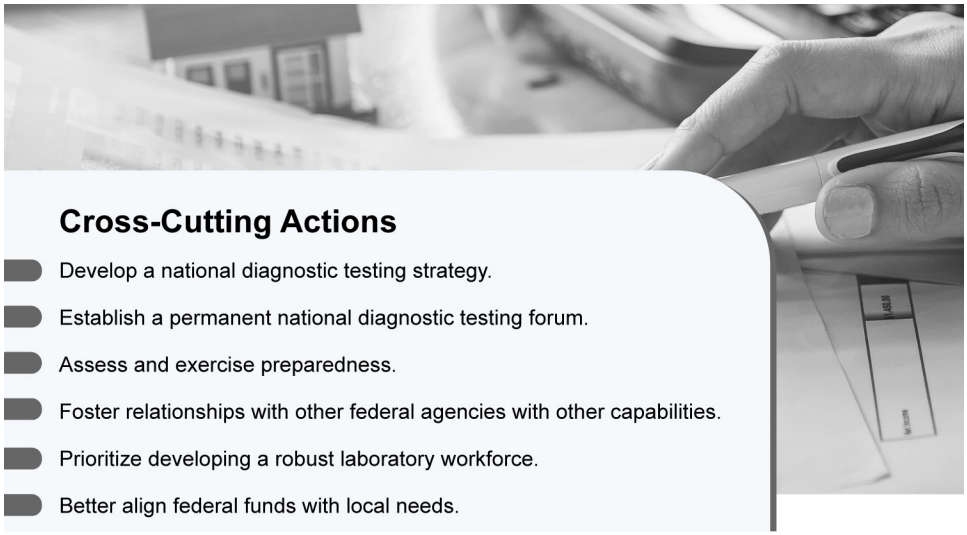
Cross-Cutting

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

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

[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).

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

[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.

various federal agencies.[37] The experts' suggestion is also consistent with the 2022 *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

[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.

[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.

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.

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.

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

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

Testing stage	Example deficiency	Potential for mitigation[a]
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,

[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.

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 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,

[47]See GAO-23-105460.

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 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

[48]See GAO-24-107175.

[49]See GAO-23-105520.

[50]See GAO-14-704G.

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

[51]See 5 U.S.C. §§ 1001–14.

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.

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
United States Senate

The Honorable Bill Cassidy, M.D.
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The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Rand Paul, M.D.
Chairman
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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The Honorable Mark E. Green, M.D.
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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.[1] 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.[2] 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.

[1]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.

[2]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.

Table 3 lists the 19 selected experts and their affiliations at the time of the roundtable.[3]

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
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

[3]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.

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.[4] 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.

[4]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.

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.

Appendix II

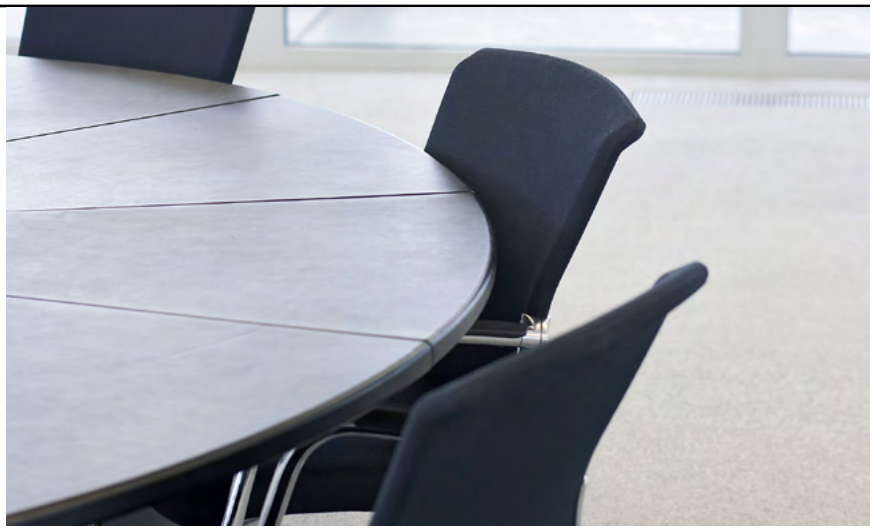
Actions Identified by Experts to Improve Diagnostic Testing for Infectious Diseases with Pandemic Potential

Photo: Gargonia/stock.adobe.com

In recent public health emergencies, the Department of Health and Human Services (HHS) faced challenges that resulted in delays in nationwide diagnostic testing for infectious diseases with pandemic potential, which are highly transmissible and highly virulent. To examine how HHS can improve diagnostic testing for future public health emergencies, we convened a roundtable of 19 experts representing a broad spectrum of views and expertise from a variety of professional and academic fields. The roundtable was organized around four stages of diagnostic testing: development, deployment, guidance, and data collection. Experts suggested actions related to each stage that HHS should take to improve diagnostic testing, as well as actions relevant to multiple stages, referred to as “cross-cutting” actions. Actions that experts suggested include both those that HHS has previously taken that experts believe should continue, as well as those HHS has not previously taken. See appendix I for more information on these experts and the methodology used to facilitate the roundtable.

Some actions suggested by experts are consistent with prior recommendations made to HHS by GAO, the HHS Office of Inspector General (OIG) or the National Academies of Sciences, Engineering, and Medicine (National Academies). We reviewed relevant reports from these entities published between 2016 and 2024, and identified related recommendations. The National Academies produces different types of publications; we limited our review to their consensus study reports due to their methodological rigor. Some recommendations may be related to multiple actions suggested by experts. Due to the volume of work produced by these entities, there may be other related recommendations that we did not identify.

Photo: Franz Pflueg/stock.adobe.com



Polls and votes at the roundtable

During the roundtable, we did not poll experts, take votes, or otherwise quantify support on actions discussed. Comments provided by the experts reflected their own views and not those of the organizations with which they were affiliated or those of others with similar backgrounds and expertise.

Actions are listed in this report without any specific rank or order, and their inclusion should not be interpreted as GAO endorsing any action. Implementing any one action or a combination of actions might require additional considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Navigation

Appendix II includes hyperlinks for easy navigation. Use the top-of-page menu to access each section. Each section also begins with an outline with hyperlinks for direct access.

To help ensure the accuracy of the statements presented, we provided relevant excerpts to HHS-OIG and the National Academies and incorporated their technical comments as appropriate.

Additionally, we provided HHS officials a description of all suggested actions for their review and written response. HHS component agency officials responded to actions related to their scope of responsibility and for which their component agency had taken or planned to take related steps. 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 assess whether or to what extent HHS has taken the actions suggested by experts.

The sections that follow provide details about the actions experts suggested for each stage, including additional information and considerations discussed by experts during the roundtable. We also note any similarities between the actions suggested by experts and prior recommendations made to HHS. Finally, we report the responses provided by HHS on each action, including any related steps planned or taken as described by the agency.

We have provided a **glossary of key terms** at the end of this appendix.

Stages

Photo: Pixel-Shot/stock.adobe.com

Development

The stage that includes developing, validating, and authorizing diagnostic tests.

Deployment

The stage that includes manufacturing, distributing, administering, and performing diagnostic tests.

Guidance

The stage that includes conveying information to providers and the public about the use of diagnostic tests.

Data collection

The stage that includes collecting and reporting diagnostic testing data, including test results and patient data such as race and ethnicity.

Cross-cutting

Certain elements of diagnostic testing cut across multiple stages.

Development

Develop flexible Food and Drug Administration (FDA) regulatory processes and preparedness plans for diagnostic testing

- Develop a process to review diagnostic test development, production, and validation documents from developers ahead of a public health emergency.
- Consider including “use case” as part of new diagnostic test evaluations.
- Re-evaluate the level of scrutiny needed for diagnostic test emergency use authorizations (EUA) as circumstances change during a public health emergency.
- Continue diagnostic test flexibilities established during the COVID-19 public health emergency for future public health emergencies.
- Develop guidance for an expedited review process for manufacturers making changes to existing diagnostic test products during public health emergencies.
- Develop infrastructure plans for expanding operations during public health emergencies.
- Develop a method to prioritize diagnostic test EUAs during a public health emergency.

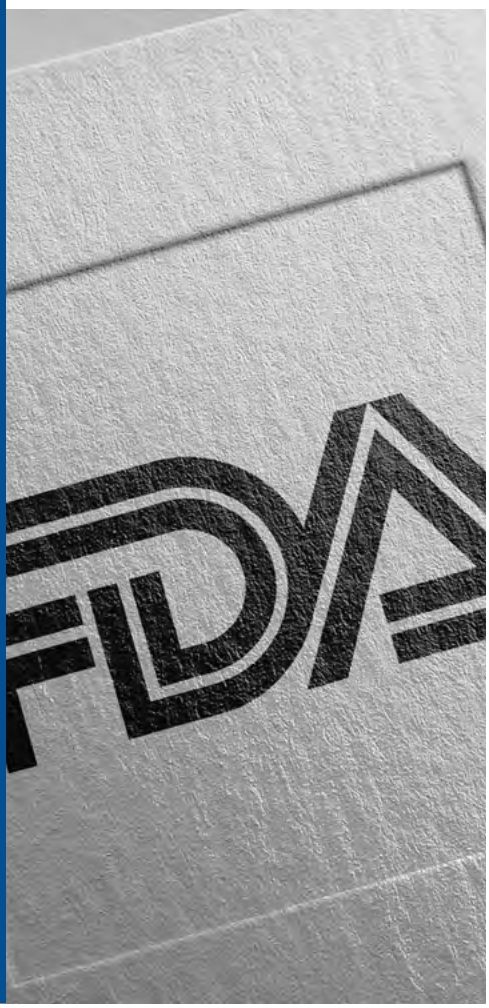
Clearly communicate relevant FDA guidance and information on diagnostic tests

- Develop and communicate clear, detailed guidance on the diagnostic test EUA request and review processes.
- Continue to hold weekly town halls with diagnostic test developers.
- Develop and communicate clear guidance on post-market evidence requirements for diagnostic tests before or early in a public health emergency.
- Provide specific staff contacts who can definitively respond to and make decisions regarding questions from diagnostic test developers.
- Develop a publicly available and user-friendly dashboard with accurate information on the current market status of diagnostic tests with EUAs.

Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers	• Provide more upfront information on coding, coverage, and payment of diagnostic testing to industry. • Establish a standing policy to automatically trigger nationwide Medicare coverage and reimbursement determinations for diagnostic tests at the start of an emergency. • Seek legislation to automatically trigger nationwide private payor coverage of diagnostic testing when an EUA declaration is made.
Encourage diagnostic testing research and development ahead of a public health emergency	• Develop and communicate a prioritized list of known infectious diseases with pandemic potential. • Continue the National Institutes of Health's Rapid Acceleration of Diagnostics initiative. • Support the development of open, simple-to-use diagnostic test platforms. • Invest in research to determine the types of diagnostic testing required for different types of infectious disease pathogens. • Identify ways to inactivate—that is, make non-infectious—control material used for diagnostic test validation.
Plan in advance to increase availability of diverse control material to use for diagnostic test validation	• Establish agreements ahead of a public health emergency for producing and distributing control material to use for diagnostic test validation. • Establish agreements to help ensure diversity of control material used to validate diagnostic tests. • Invest financial support and subject matter expertise in biobanking control material used to validate diagnostic tests.

Photo: Araki Illustrations/stock.adobe.com

Develop flexible Food and Drug Administration (FDA) regulatory processes and preparedness plans for diagnostic testing



- Develop a process to review diagnostic test development, production, and validation documents from developers ahead of a public health emergency.
- Consider including “use case” as part of new diagnostic test evaluations.
- Re-evaluate the level of scrutiny needed for diagnostic test emergency use authorizations (EUA) as circumstances change during a public health emergency.
- Continue diagnostic test flexibilities established during the COVID-19 public health emergency for future public health emergencies.
- Develop guidance for an expedited review process for manufacturers making changes to existing diagnostic test products during public health emergencies.
- Develop infrastructure plans for expanding operations during public health emergencies.
- Develop a method to prioritize diagnostic test EUAs during a public health emergency.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Develop a process to review diagnostic test development, production, and validation documents from developers ahead of a public health emergency.

Delays in developing tests for infectious diseases with pandemic potential could hinder the federal government's ability to respond in a crisis. Experts suggested HHS—specifically, FDA—should develop a process to review diagnostic test development, production, and validation documents from developers during inter-pandemic periods. Such a process could establish trust between FDA and test developers, which could in turn expedite emergency use authorization (EUA) requests and reviews once the Secretary of Health and Human Services declares circumstances exist justifying EUAs, according to experts. For example, one expert noted developers could submit information on their technical protocols in advance, such as their methods for designing elements of their polymerase chain reaction (PCR) tests, reagents they would use, or the number of samples they would use to validate tests. In the event a new infectious disease with pandemic potential emerges, FDA officials would already have reviewed a developer's general procedures, which experts said could shorten review times and thus the time it takes for a diagnostic test to become available for use. Establishing such a process may require legislative or regulatory changes, experts noted.

Related recommendations

In September 2022, HHS-OIG recommended FDA work with federal partners to determine the feasibility of pre-certifying laboratories for emergency test development and use for emerging infectious diseases.[i] According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

FDA and NIH officials responded to this action. FDA officials said they do not currently have statutory authority to authorize a developer's general procedures for test development, as the experts suggested; instead, FDA has the authority to authorize individual tests. Alternatively, officials noted FDA has developed draft guidance proposing that past developer performance and developer level of experience should be considered when making decisions regarding the agency's exercise of enforcement discretion (that is, not objecting to the use of certain tests under certain circumstances).[ii] FDA officials also mentioned the agency's voluntary pre-EUA submission process for tests that have already been developed, through which a developer submits data and information about the safety, quality, and effectiveness of a developed diagnostic test; its intended use under a future or current EUA; and information about the emergency or potential emergency situation. This pre-EUA submission process allows FDA experts to begin reviewing the information and assisting in the development of documentation needed for an EUA in advance of a public health emergency. NIH officials also responded to this action, agreeing it is a critical strategy during a public health emergency.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Consider including "use case" as part of new diagnostic test evaluations.

Developing and producing enough tests to meet demand during a public health emergency can be challenging, and there may be instances where FDA could ensure greater availability by adjusting its review processes, according to experts. Experts suggested that HHS—specifically, FDA—should consider including the use to which a test can be put, known as its "use case," as part of the evaluation of new diagnostic tests and potentially establish different standards for tests with different use cases. There may be value in authorizing diagnostic tests that meet different standards in order to ensure greater access to testing. For example, antigen tests for COVID-19 are less sensitive than PCR tests. However, antigen tests are more accessible for individuals because they can be used at home and do not require visiting a health care provider or using laboratory infrastructure to obtain results, as PCR tests often do. As one expert noted, if enough members of a population use home-based antigen tests and subsequently follow public health guidance based on the results, home-based antigen tests could reduce disease transmission, despite not being as sensitive as laboratory-based PCR tests.

HHS response

FDA officials said the agency considers the intended use of a new diagnostic test proposed by the manufacturer as part of its review. Specifically, in FDA's templates for EUA applications, the agency provides recommendations for test performance based on the test's intended use, including for different patient populations (e.g., symptomatic versus asymptomatic) and settings (e.g., laboratory versus home).

COVID-19 Testing

There are two common types of diagnostic tests that can be used to determine if a person is infected with COVID-19: polymerase chain reaction (PCR) tests and antigen tests. These tests use different processes to detect whether the person being tested has an active COVID-19 infection.

- **PCR tests.** PCR tests are a type of molecular diagnostic test that can detect the presence of genetic material from the virus that causes COVID-19. These tests are highly sensitive and considered "the gold standard" for diagnosing COVID-19.
- **Antigen tests.** Antigen tests detect the presence of a protein from the virus that causes COVID-19. These tests provide accurate positive results, but are more likely to miss the presence of an active COVID-19 infection than PCR tests. However, antigen tests can produce results quickly—generally within 30 minutes, which is why they are sometimes known as "rapid tests." Additionally, some types of

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Photo: Tomas Ragina/stock.adobe.com

antigen tests are available without a prescription, making them more readily accessible than diagnostic tests that require a prescription.

Both PCR and antigen tests can be performed in various locations, which has implications for how quickly results from these tests are available.

- **Laboratories.** Samples collected for either PCR or antigen testing can be tested in laboratories. Typically, PCR tests are conducted in laboratories. It can take several days to receive results from these tests because the sample must be collected, transported to the laboratory, and tested before results are available.
- **Point-of-care settings.** Samples can be collected and tested at point-of-care settings, such as clinics, pharmacies, and nursing homes, as well as schools and workplaces. Typically, these settings use antigen tests and can deliver results within 30 minutes. However, some point-of-care settings may also conduct PCR testing. Because the sample is tested on site—and does not have to be transported to a laboratory—results from a PCR test conducted at the point-of-care can be available within an hour.
- **Home.** Both PCR and antigen tests can be performed at home; however, antigen tests are more commonly available as at-home tests. These tests allow an individual to collect and test their own sample and receive results within an hour. Some PCR tests may use home collection of the sample, but the sample is tested in a laboratory.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Photo: Tada Images/stock.adobe.com

Re-evaluate the level of scrutiny needed for diagnostic test EUAs as circumstances change during a public health emergency.

Large influxes of EUA requests for newly developed diagnostic tests can overwhelm FDA reviewers during a public health emergency. Experts suggested HHS—specifically, FDA—should re-evaluate the level of scrutiny needed for diagnostic test EUAs as circumstances change during a public health emergency. Specifically, experts suggested HHS consider to what extent additional studies—often required as a condition of an EUA—are needed if there has been no significant adverse event reported and the public health emergency is waning. Taking this action could help to reduce agency workload and therefore decrease bottlenecks in the review process. In contrast, some experts cautioned that such an action must be balanced with the need to ensure the quality of diagnostic tests. For example, one expert expressed concern with relaxing requirements for additional studies due to the potential for poorly performing tests to persist on the market. Poorly performing tests can lead to individual- and population-level effects from false negatives (e.g., further disease transmission) and false positives (e.g., unnecessary treatment).

HHS response

FDA officials said the agency has and will continue to consider the appropriate level of evidence needed before and after authorization, based on the changing circumstances during a public health emergency.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Continue diagnostic test flexibilities established during the COVID-19 public health emergency for future public emergencies.

Developing and producing enough tests to meet demand during a public health emergency can be challenging, and there may be instances where FDA could ensure greater availability by adjusting its review processes, according to experts. Experts suggested HHS—specifically, FDA—should continue using flexibilities established during the COVID-19 public health emergency for future public health emergencies, when appropriate. Experts specifically mentioned flexibilities in terms of establishing new diagnostic test manufacturing sites and swapping vendors for diagnostic testing materials used in test kits to address supply shortages. One expert suggested HHS continue to consider the best use of its enforcement discretion for future public health emergencies. For example, during the COVID-19 public health emergency, FDA used its enforcement discretion at times to not object to the use of certain kinds of COVID-19 tests before they received an EUA.

Related recommendations

GAO and HHS-OIG have both made related recommendations regarding enforcement discretion. In May 2022, GAO recommended FDA develop a policy for the use of enforcement discretion regarding unauthorized tests during future public health emergencies.[iii] 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.[ii] Additionally, in September 2022, HHS-OIG recommended FDA assess and revise its guidance for test EUA requests, including its use of policies allowing certain test developers to use validated tests before requesting an EUA.[i] According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

FDA officials responded to this action, referencing the draft guidance issued in May 2024 for public comment that describes the agency's enforcement policies, including the use of enforcement discretion.[ii] For example, the guidance describes the factors FDA will consider in determining whether to exercise enforcement discretion, including the need for accelerated availability of tests and the known or potential risks of such tests, among other things.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Photo: Gorodenkoff/stock.adobe.com

Develop guidance for an expedited review process for manufacturers making changes to existing diagnostic test products during public health emergencies.

Developing and producing enough tests to meet demand during a public health emergency can be challenging, and there may be instances where FDA could ensure greater availability by adjusting its review processes, according to experts. Experts suggested HHS—specifically, FDA—should develop guidance for an expedited review process to be used when manufacturers need to make changes to existing diagnostic tests during public health emergencies. One expert noted this action could help, for example, when there are supply shortages and a test manufacturer needs to swap test components or component manufacturers—changes that often require FDA review. Without an expedited review process, such changes can slow down the ability to produce diagnostic tests.

HHS response

FDA officials said the agency used various strategies for test modifications during the COVID-19 public health emergency, such as exercising enforcement discretion. Officials explained that these policies were adjusted throughout the emergency as public health needs changed. FDA intends to consider the need for similar policies in future emergencies, per draft guidance issued for public comment.[ii] In addition, FDA officials said change control plans could be applied to EUAs when deemed appropriate. Change control plans describe certain planned modifications to a device and how the modifications will be assessed. Using these plans allows for certain diagnostic test changes without additional premarket review, according to FDA officials.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Photo: Wesley JvR/peopleimages.com/stock.adobe.com

Develop infrastructure plans for expanding operations during public health emergencies.

During a public health emergency, FDA staff may be overwhelmed by a large influx of diagnostic test EUA requests for review. Experts suggested HHS—specifically, FDA—should develop infrastructure plans for expanding its operations during emergencies. For example, such plans could include increasing staff available to review diagnostic test EUAs and engage with diagnostic test developers, while still maintaining FDA's other operations. This action could help FDA manage an influx of EUA requests without needing to freeze its reviews of other devices.

HHS response

FDA officials said the agency has considered and continues to consider the appropriate staffing levels for ongoing workload and surge capacity in the case of public health emergencies. Additional capacity would require additional funding, officials said.

Develop flexible FDA regulatory processes and preparedness plans for diagnostic testing

Photo: TuMeggy/stock.adobe.com

Develop a method to prioritize diagnostic test EUAs during a public health emergency.

Large influxes of EUA requests for newly developed diagnostic tests can overwhelm FDA reviewers during a public health emergency. Experts suggested HHS—specifically, FDA—should develop a method for FDA to prioritize diagnostic test EUAs for review during a public health emergency. For example, FDA could prioritize reviewing EUAs from test developers and laboratories that can produce or perform high volumes of tests over those with less capacity. This action could help FDA manage high volumes of diagnostic test EUA requests, such as those the agency received during the COVID-19 public health emergency, and ensure access to testing during a public health emergency.

Related recommendations

In September 2022, HHS-OIG recommended FDA assess and, as appropriate, revise FDA guidance for test EUA requests, including determining how to prioritize requests, how to communicate prioritization criteria to developers, and how best to leverage the criteria to address FDA's workload.[i] According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

FDA and NIH officials responded to this action. FDA has provided information on prioritization in its general EUA guidance, as well as emergency-specific guidance during the COVID-19 and mpox public health emergencies. Specifically, according to its general EUA guidance, FDA may consider factors such as manufacturing capacity for a test when establishing EUA review priorities. In its COVID-19 test EUA policy, as of January 2023, FDA's priorities for EUA review included requests from experienced developers for diagnostic tests that were likely to have a significant public health benefit or fulfill an unmet need, as well as requests supported by a U.S. government stakeholder, such as tests funded by NIH's Rapid Acceleration of Diagnostics (RADx) initiative. In its mpox test EUA policy, as of September 2022, FDA's priorities for EUA review included requests from experienced developers with high manufacturing capacity. In addition, NIH officials agreed the action experts suggested is an effective strategy.

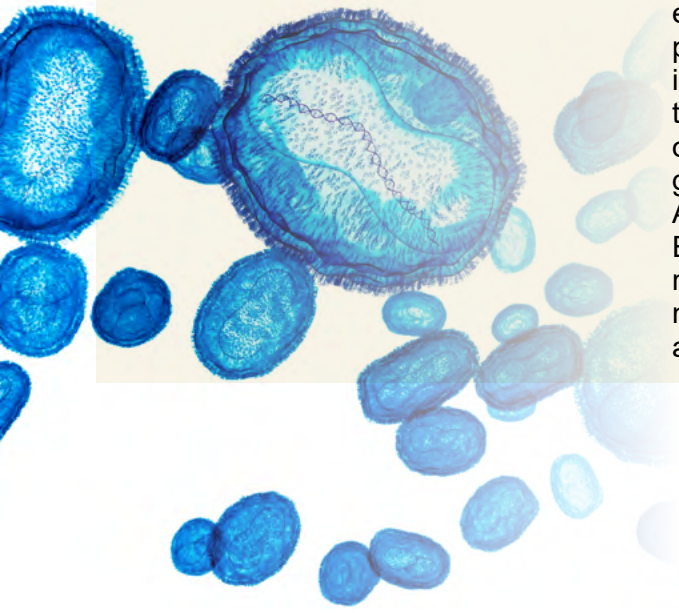
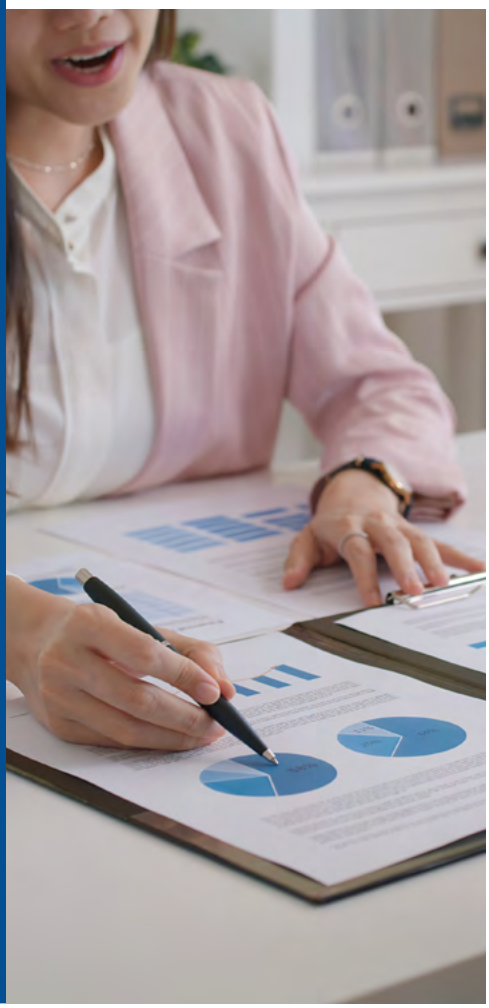


Photo: ChayTee/stock.adobe.com

Clearly communicate relevant FDA guidance and information on diagnostic tests



- Develop and communicate clear, detailed guidance on the diagnostic test EUA request and review processes.
- Continue to hold weekly town halls with diagnostic test developers.
- Develop and communicate clear guidance on post-market evidence requirements for diagnostic tests before or early in a public health emergency.
- Provide specific staff contacts who can definitively respond to and make decisions regarding questions from diagnostic test developers.
- Develop a publicly available and user-friendly dashboard with accurate information on the current market status of diagnostic tests with EUAs.

Clearly communicate relevant FDA guidance and information on diagnostic tests

Develop and communicate clear, detailed guidance on the diagnostic test EUA request and review processes.

Diagnostic test developers and laboratories previously described difficulties navigating the EUA process during the COVID-19 pandemic. Experts suggested that HHS—specifically, FDA—should develop and communicate clear, detailed guidance on its diagnostic test EUA request and review processes. According to the experts, this information would improve understanding of expectations among public and private diagnostic test developers and manufacturers. It would also guide developers in navigating the process successfully, regardless of size or previous EUA experience. Some experts said that EUA templates FDA created during the COVID-19 public health emergency were a helpful example of clear, detailed guidance they would like to see continued or expanded. For example, FDA could create generic templates that are adaptable for various infectious diseases with pandemic potential.

Related recommendations

GAO and HHS-OIG have both made related recommendations regarding clear FDA guidance on the EUA process. In May 2022, GAO recommended FDA develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies.[iii] Developing such a policy could provide clarity for developers regarding FDA's plans for EUA reviews. HHS agreed with the recommendation, and partially addressed it in May 2024 when FDA issued draft guidance for public comment that provides information on potential enforcement policies.[ii] In addition, in September 2022, HHS-OIG made three relevant recommendations that FDA (1) assess and, as appropriate, revise guidance for test EUA requests; (2) develop a suite of EUA templates for future emergencies involving novel pathogens; and (3) expand and improve resources for test developers on the EUA process, including technical guidance and educational material, and potentially including guidance to address gaps in developers' knowledge and experience.[i] According to HHS-OIG, as of February 2025, these three recommendations had not been implemented.

HHS response

FDA and NIH officials responded to this action. FDA is continuing its work on these topics, agency officials said, building on the progress made during the COVID-19 and mpox public health emergencies. In addition, NIH officials agreed this action experts suggested is an effective strategy. NIH officials described related efforts during the COVID-19 public health emergency when NIH's RADx initiative worked directly with FDA to create recommendations and milestones for developers to follow that would accelerate the FDA review process.

Clearly communicate relevant FDA guidance and information on diagnostic tests

Photo: Chinnapong/stock.adobe.com

Continue to hold weekly town halls with diagnostic test developers.

Diagnostic test developers and laboratories previously described difficulties navigating the EUA process during the COVID-19 pandemic. Experts suggested HHS—specifically, FDA—should continue holding weekly town halls with FDA and diagnostic test developers, and potentially expand these town halls to include CDC. Experts with experience with the town halls found these meetings helpful.

Related recommendations

In September 2022, HHS-OIG recommended FDA expand and improve resources for test developers on the EUA process, including continuing communication strategies like town halls.[i] According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

FDA officials said that the weekly town halls were particularly useful during the COVID-19 public health emergency, and that FDA and CDC would evaluate communication and education needs for future scenarios

Clearly communicate relevant FDA guidance and information on diagnostic tests

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Develop and communicate clear guidance on post-market evidence requirements for diagnostic tests before or early in a public health emergency.

Diagnostic test developers and laboratories previously described difficulties navigating the EUA process during the COVID-19 pandemic. Experts suggested HHS—specifically, FDA—should develop and communicate clear guidance on post-market evidence requirements for diagnostic tests before or early in a public health emergency. One expert stated that such an action could remove poorly performing tests from the market.

Related recommendations

In March 2021, GAO made a related recommendation to FDA regarding ensuring clarity in post-market requirements. GAO reported manufacturers were not sure if they would need to immediately stop making and remove devices with EUAs from the market after the termination of the COVID-19-related EUA declaration, or if there were any circumstances in which FDA might permit use of authorized devices after the end of the EUA declaration.[iv] GAO recommended FDA specify a process for transitioning authorized devices to clearance, approval, or appropriate disposition. HHS agreed with the recommendation, and FDA implemented it, in part, by issuing guidance on this process in March 2023.[v]

HHS response

FDA officials said the agency generally intends to provide evidence recommendations for diagnostic tests in EUA templates, which could include post-market evidence requirements. In addition, the conditions of authorization for an EUA may address post-market evidence requirements, according to officials.

Clearly communicate relevant FDA guidance and information on diagnostic tests

Photo: Михаил Решетников/stock.adobe.com

Provide specific staff contacts who can definitively respond to and make decisions regarding questions from diagnostic test developers.

Diagnostic test developers and laboratories previously described difficulties navigating the EUA process during the COVID-19 pandemic. Experts suggested HHS—specifically, FDA—should provide diagnostic test developers with specific FDA staff contacts who can definitively respond to and make decisions regarding questions from developers. One expert noted this action could reduce challenges developers faced in receiving definitive answers to questions during the COVID-19 public health emergency.

HHS response

FDA has established an EUA mailbox to which developers can direct questions for responses from knowledgeable staff, according to officials. Additionally, officials said FDA will include specific contacts in emergency-specific guidance and templates in the future as needed.

Clearly communicate relevant FDA guidance and information on diagnostic tests

Develop a publicly available and user-friendly dashboard with accurate information on the current market status of diagnostic tests with EUAs.

Keeping up with changing information in an evolving public health emergency can be challenging. Experts suggested HHS—specifically, FDA—should develop a publicly available and user-friendly dashboard with accurate information on the current market status of diagnostic tests with EUAs to help users determine if there have been notable changes, such as a diagnostic test being removed from the market. For example, FDA maintains websites with information on EUAs for COVID-19 diagnostic tests. One expert acknowledged FDA's efforts, but described them as a little too slow. This expert noted that providing more up-to-date information in a similar format during a future public health emergency could help individuals make decisions when purchasing tests.

HHS response

FDA maintains information on current market status on its website. Creating a new, more user-friendly dashboard would require additional resources, according to officials. The officials also noted that ongoing updates on market status require continual input from developers, some of whom do not want to share specific status information that they consider to be proprietary.

Photo: zorandim75/stock.adobe.com

Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers

- Provide more upfront information on coding, coverage, and payment of diagnostic testing to industry.
- Establish a standing policy to automatically trigger nationwide Medicare coverage and reimbursement determinations for diagnostic tests at the start of an emergency.
- Seek legislation to automatically trigger nationwide private payor coverage of diagnostic testing when an EUA declaration is made.

Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers

Photo: alexskopje/stock.adobe.com

Provide more upfront information on coding, coverage, and payment of diagnostic testing to industry.

Uncertainty regarding the potential for reimbursement of diagnostic tests can discourage test developers from participating in the early days of a public health emergency, hindering efforts to increase testing capacity. Experts suggested HHS should provide more upfront information on coding, coverage, and payment to industry to remove uncertainty concerning reimbursement during development. One expert noted that providing this information could provide greater predictability to industry and therefore incentivize development of diagnostic tests. As another expert observed, some test developers and laboratories involved in diagnostic testing are for-profit and thus may require incentives to be engaged in pandemic preparedness.

HHS response

CMS officials responded that during the COVID-19 public health emergency, the agency engaged with laboratory stakeholders to identify and address barriers related to the availability and timeliness of laboratory diagnostic tests. For example, CMS maintained a website with various resources for laboratories and held multiple stakeholder calls and meetings, according to officials. Through this engagement, CMS officials said that they learned of resource challenges laboratories faced using high-throughput COVID-19 tests. CMS established a separate payment rate specific to high-throughput testing. In addition, to incentivize quicker turnaround times, CMS established a differential payment for high-throughput testing based on how long a laboratory took to perform a test, according to officials.

Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers

Establish a standing policy to automatically trigger nationwide Medicare coverage and reimbursement determinations for diagnostic tests at the start of an emergency.

Uncertainty regarding the potential for reimbursement of diagnostic tests can discourage test developers from participating in the early days of a public health emergency, hindering efforts to increase testing capacity. Experts suggested HHS—specifically, CMS—should establish a standing policy to automatically trigger nationwide Medicare coverage and reimbursement determinations for diagnostic tests whenever a public health emergency or EUA declaration is made. Experts acknowledged that the agency may need to seek legislative authority to accomplish this action. One expert said that CMS establishing a nationwide rate for COVID-19 testing during the public health emergency was important for increasing laboratory-based testing capacity. This expert noted that, in contrast, when CMS did not establish a nationwide reimbursement rate during the mpox public health emergency, there was variation in reimbursement rates for mpox diagnostic tests, with payment below the cost of care in some regions and meeting the cost of care in others. Implementing a standing policy or seeking legislative authority to establish nationwide Medicare coverage and reimbursement of diagnostic tests for future emergencies would ensure consistency nationwide and improve testing capacity, according to experts.

Related recommendations

In April 2024, HHS-OIG found existing CMS policies and procedures do not always specifically address payment rates for diagnostic laboratory tests in emergency situations in a timely manner, and CMS had to take additional action beyond its standard procedures to set and adjust rates.[vi] HHS-OIG recommended CMS improve its procedures for setting and adjusting rates for new laboratory tests during a public health emergency, which may require seeking legislative authority. According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

CMS officials noted that any procedures or changes to authority regarding coverage and reimbursement determinations during future public health emergencies should ensure there is flexibility to meet the needs of and be responsive to a given situation. In CMS officials' view, Medicare coverage, coding, and reimbursement was established in a timely manner during the COVID-19 public health emergency using existing policies and procedures.

Provide certainty regarding coverage and reimbursement of diagnostic testing to incentivize potential developers

Photo: lazyllama/stock.adobe.com

Seek legislation to automatically trigger nationwide private payor coverage of diagnostic testing when an EUA declaration is made.

Uncertainty regarding the potential for reimbursement of newly developed diagnostic tests can discourage test developers from participating in the early days of a public health emergency, hindering efforts to increase testing capacity. Experts suggested that HHS should seek legislation to automatically trigger private payor coverage of diagnostic testing when an EUA declaration is made. As one expert noted, for-profit commercial laboratories and private hospitals rely on reimbursement from health insurance to operate. Another expert noted that immediate private payor coverage of diagnostic testing could therefore be helpful for ensuring diagnostic testing capacity to respond to public health emergencies.

HHS response

CMS officials noted that this action would require a change in legislation.

Photo: kwanchaift/stock.adobe.com

Encourage diagnostic testing research and development ahead of a public health emergency

- Develop and communicate a prioritized list of known infectious diseases with pandemic potential.
- Continue the National Institutes of Health's Rapid Acceleration of Diagnostics initiative.
- Support the development of open, simple-to-use diagnostic test platforms.
- Invest in research to determine the types of diagnostic testing required for different types of infectious disease pathogens.
- Identify ways to inactivate—that is, make non-infectious—control material used for diagnostic test validation.

Encourage diagnostic testing research and development ahead of a public health emergency

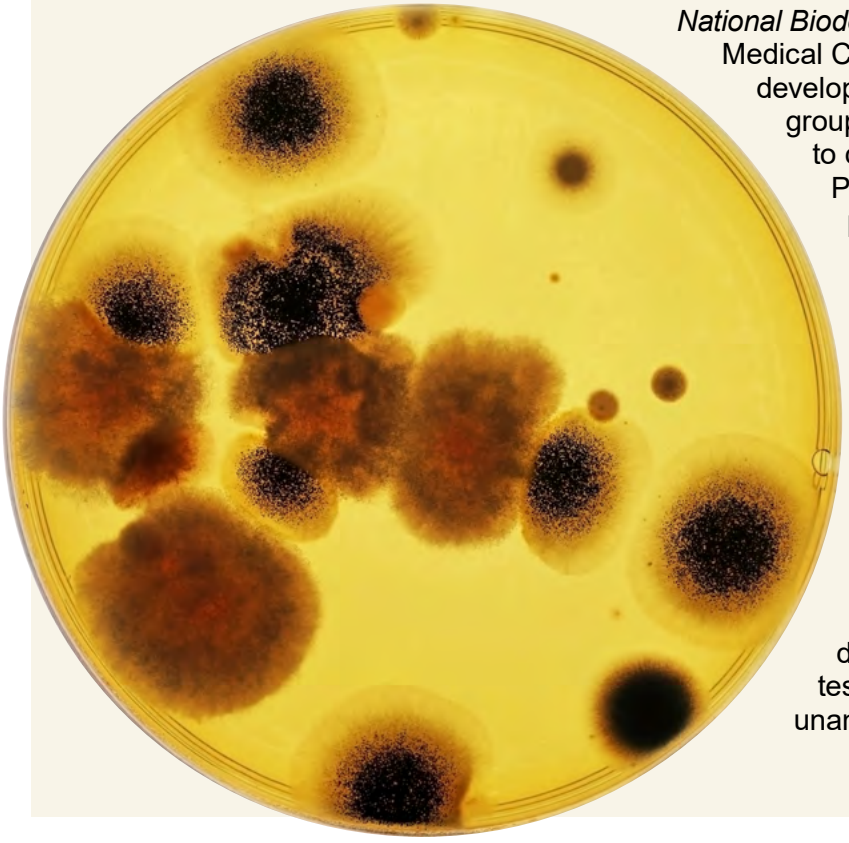
Photo: TopMicrobialStock/stock.adobe.com

Develop and communicate a prioritized list of known infectious diseases with pandemic potential.

Delays in developing diagnostic testing in a public health emergency can hinder the federal government's response. Experts suggested HHS should develop and communicate a prioritized list of known infectious diseases with pandemic potential to government, industry, and other partners to use to develop diagnostic tests ahead of a pandemic. As one expert noted, there are many infectious diseases with pandemic potential for which diagnostic tests have not been developed. Creating and communicating such a list could ensure the relevant diagnostic testing partners are all working toward the same goals, according to this expert.

HHS response

ASPR, CDC, NIH, and FDA officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the 2022 *National Biodefense Strategy*.[vii] Officials said the joint capabilities plan would include direction for the development of such a prioritized list of known infectious diseases with pandemic potential. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. Additionally, ASPR officials said that, in alignment with the goals of the *National Biodefense Strategy*, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) developed a publicly available list of pathogen groups—mostly viral families—with the potential to cause domestic public health emergencies. PHEMCE identifies capabilities needed to protect the U.S. population and strategies to address gaps.



CDC officials added that CDC is developing a list of priority pathogens to focus internal efforts and external collaboration regarding diagnostic tests. CDC is also exploring disease-agnostic technologies that could potentially be adapted for emerging or re-emerging pathogens for which a diagnostic test has not yet been developed, according to officials. CDC officials noted that while prioritizing is helpful, it is also important to develop flexible and adaptable systems for test development because of the possibility of unanticipated pandemic threats.

Encourage diagnostic testing research and development ahead of a public health emergency

Develop and communicate a prioritized list of known infectious diseases with pandemic potential. (continued)

HHS response (continued)

In addition, NIH officials noted its 2021 Pandemic Preparedness Plan established a framework for pandemic research, such as identifying prototype pathogens of concern.[viii] Prototype pathogens of concern are representative of a particular virus family and have the potential to cause a human epidemic or pandemic. Studying these prototype pathogens and developing diagnostic tests to detect them may be a pathway to gain knowledge that may be applicable to part or all of a particular virus family. NIH also held a workshop in 2021 to select prototype pathogens for future study and to identify knowledge gaps within the selected families.[ix]

Further, FDA officials noted in developing priorities, it would be helpful to prioritize the development of tests that can still accurately detect a pathogen even if the pathogen changes. Officials also noted the lack of financial incentive inherent in developing tests when there is no current market.

Encourage diagnostic testing research and development ahead of a public health emergency

Photo: Grandbrothers/stock.adobe.com

Continue NIH's RADx initiative.

Delays in developing diagnostic testing in a public health emergency can hinder the federal government's response. Experts suggested HHS should continue NIH's RADx initiative to speed innovation in diagnostic test development. Experts described RADx as a successful partnership between industry and the federal government.

HHS response

NIH and FDA officials responded to this action. NIH officials agreed that continuing the RADx initiative is an effective strategy. NIH has begun to use the RADx infrastructure to support the development of non-COVID-19-related technologies for a range of health problems, including influenza, officials said. The RADx initiative's benefits include the flexibility to allow projects to be implemented on demand in response to questions that arise, and close collaboration with partner agencies (e.g., FDA) to quickly respond to results, according to NIH officials. The officials said maintaining the RADx infrastructure via ongoing projects—up to five per year—will allow the program to maintain a state of readiness to respond to emerging public health threats. According to NIH officials, there is no base appropriation for RADx, so these projects would have to be supported through a combination of sources, such as grants and partnership agreements. The officials acknowledged that sustainable funding for the RADx initiative is a key challenge.

FDA officials also discussed the RADx initiative, noting some of its successes. For example, the RADx initiative contributed to the manufacture of over 7.8 billion diagnostic tests during the

Encourage diagnostic testing research and development ahead of a public health emergency

Continue NIH's RADx initiative. (continued)

HHS response (continued)

COVID-19 public health emergency from September 2020 to March 2023, according to NIH data. FDA officials particularly noted the value of the RADx Independent Test Assessment Program that provides third-party, independent test evaluation. As a part of this program, FDA provided data templates, allowing for standardized data submission formats, which resulted in more timely review of data, according to officials. However, FDA officials noted that some of the other RADx initiative work—which largely focused on supporting inexperienced test developers—took significant FDA resources to guide the developers through the relevant EUA processes during the COVID-19 public health emergency. Though the RADx initiative employed personnel intended to serve as regulatory support to facilitate successful EUA requests, officials said significant FDA resources were required to train those individuals. Moreover, in some instances, FDA officials said they later learned the tests from some of these developers were never distributed or were distributed in limited numbers, thus having little public health impact.

Encourage diagnostic testing research and development ahead of a public health emergency

Support the development of open, simple-to-use diagnostic test platforms.

Delays in developing diagnostic testing in a public health emergency can hinder the federal government's response. Experts suggested HHS should support the development of open, simple-to-use diagnostic testing platforms that can be used with any manufacturer's reagent. Diagnostic test developers could then readily adapt these platforms to detect newly emerging pathogens. Experts suggested HHS could support such efforts through NIH's RADx initiative.

HHS response

NIH and FDA officials responded to this action. NIH officials agreed that this action is an effective strategy. NIH officials noted some RADx initiative work involves the development of new technologies that are disease agnostic, meaning they could be adapted for potential new and emerging viruses, as well as other future pathogens.

FDA officials added that in their opinion, laboratories would be unlikely to invest in new platforms during an emergency and would rather have tests that work on existing platforms. Therefore, it would be more useful to take steps to understand the platforms used in laboratories currently, according to FDA officials. This information could be taken into account during future test development. In addition, regarding the role of the RADx initiative, officials said they believe RADx efforts would be more beneficial if they focused on testing environments outside of laboratories.

Encourage diagnostic testing research and development ahead of a public health emergency

Photo: Steffen Kögler/stock.adobe.com

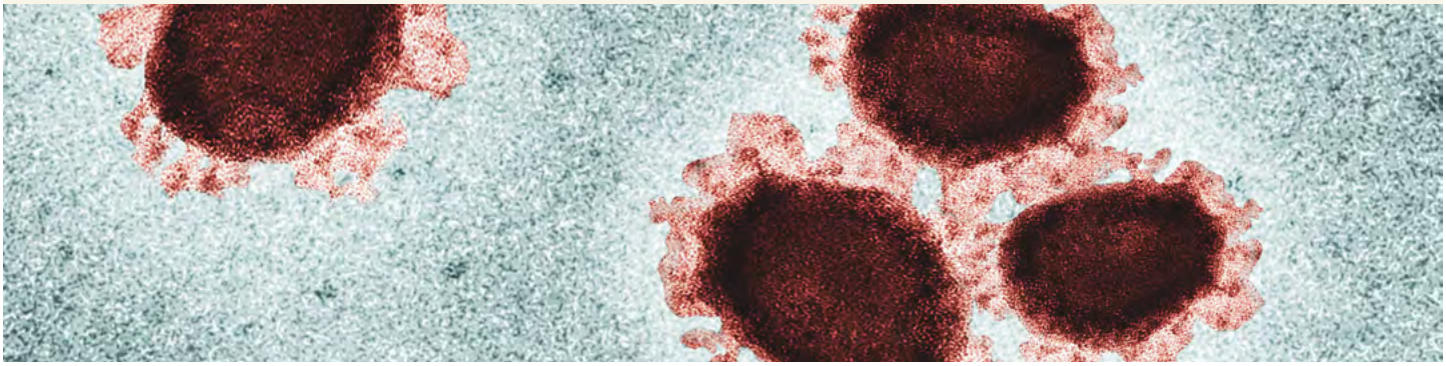
Invest in research to determine the types of diagnostic testing that would be required for different types of infectious disease pathogens.

Delays in developing diagnostic testing in a public health emergency can hinder the federal government's response. Experts suggested HHS should invest in research to determine the types of diagnostic testing that would be required for different types of infectious disease pathogens (e.g., influenza viruses). This advanced research would produce a clearer picture of what is needed for diagnostic testing in different potential pandemic scenarios. For example, one expert noted this research could help establish the types of specimens needed for a particular pathogen, such as nasal swabs or blood specimens. Identifying these needs before the next public health emergency could expedite diagnostic test development.

HHS response

ASPR, CDC, and NIH officials responded to this action. ASPR has been investing in developing diagnostic tests for influenza, according to ASPR officials, but investment in diagnostic test development for other pathogens requires supplemental funding. CDC officials added that within their agency, each laboratory and program working with such diseases would determine the type of diagnostic testing required for their specific pathogen, as needed. Additional tests could be developed as new needs arise, CDC officials said.

In addition, NIH officials said NIH funds programs to detect emerging pathogens with pandemic or epidemic potential. Officials also noted that during past infectious disease outbreaks, HHS has funded diagnostic test research and development programs. Further, NIH's 2021 Pandemic Preparedness Plan established the concept of prototype pathogens of concern. Studying these prototype pathogens and developing diagnostic tests to detect them may be a pathway to gain knowledge applicable to part or all of a particular virus family. NIH also held a workshop in 2021 to select prototype pathogens for future study.[ix]



Encourage diagnostic testing research and development ahead of a public health emergency

Identify ways to inactivate—that is, make non-infectious—control material used for diagnostic test validation.

Photo: Joseph/stock.adobe.com

There were concerns about the safety of laboratory staff handling control material used for diagnostic test validation in the initial days of the COVID-19 and mpox public health emergencies, one expert recalled. Experts suggested HHS should identify ways to inactivate control material for diagnostic test validation. Doing so would help ensure the safety of laboratory staff conducting diagnostic tests for infectious diseases with pandemic potential, according to experts.

Related recommendations

GAO has made several related recommendations. For example, in August 2016, GAO recommended HHS direct CDC and NIH to create comprehensive and consistent guidance for the development, validation, and implementation of inactivation protocols of certain dangerous pathogens.[x] HHS agreed and implemented the recommendation with the release of the sixth edition of the *Biosafety in Microbiological and Biomedical Laboratories* manual, revised in June 2020, which included an appendix on inactivation that is consistent with previously released guidance. The appendix included comprehensive information on the development, validation, and implementation of inactivation protocols.

HHS response

CDC laboratories working with infectious disease pathogens must have their inactivation procedures reviewed by a Laboratory Safety Review board prior to use, according to CDC officials. As a part of this review process, laboratories must submit data demonstrating the effectiveness of the inactivation procedures, officials said. CDC officials stated that the board process—in conjunction with annual reviews—is sufficient for ensuring control materials used by CDC laboratories are inactive. CDC officials also noted that prior to the mpox outbreak, CDC had inactivation data for the virus, due to previous years

Encourage diagnostic testing research and development ahead of a public health emergency

Identify ways to inactivate—that is, make non-infectious—control material used for diagnostic test validation. (continued)

HHS response (continued)

of working with the virus and the relatively newly established CDC safety board that reviews and approves inactivation data. CDC officials said the agency shared the inactivation data with public health laboratories and commercial laboratories to increase safety when working with mpox samples. Additionally, officials said CDC shared and continues to share inactivated virus material with other agencies (e.g., NIH's RADx program), academic laboratories, public health laboratories, and commercial laboratories for test validation.

Freedomz/stock.adobe.com

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

- Establish agreements ahead of a public health emergency for producing and distributing control material to use for diagnostic test validation.
- Establish agreements to help ensure diversity of control material used to validate diagnostic tests.
- Invest financial support and subject matter expertise in biobanking control material used to validate diagnostic tests.

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Photo: industrieblick/stock.adobe.com

Establish agreements ahead of a public health emergency for producing and distributing control material to use for diagnostic test validation.

Test validation requires the use of control material, which may include clinical samples from patients or contrived samples made from viral material that may come from a range of sources. Control material may be difficult to obtain in the beginning of an emergency when there have been few confirmed cases of a disease.

Experts suggested HHS take actions to produce and distribute control material for test validation. Specifically, experts suggested HHS should establish agreements ahead of an emergency to

- produce control material before a public health emergency. Producing control material for certain prioritized infectious diseases during inter-pandemic periods would mean the control material would then be ready for use in test validation in the event of a public health emergency involving one of those diseases;
- produce control material during a public health emergency. Having agreements in place for manufacturing control material during an emergency could reduce the time needed to obtain the material and subsequently reduce the time it takes to develop a working diagnostic test; and
- distribute control material to laboratories and other test developers during a public health emergency. Experts also suggested HHS initially prioritize distribution to those laboratories and developers with higher capacity for producing and performing tests, which would help ensure widespread availability of any tests validated by those control materials. One expert noted that coordinating these aspects of test development upfront would speed up these steps during an emergency.

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Establish agreements ahead of a public health emergency for producing and distributing control material to use for diagnostic test validation. (continued)

Related recommendations

In July 2021, GAO recommended CDC assess the agency's needs for goods and services for the manufacturing and deployment of diagnostic test kits in public health emergencies, including an evaluation of how establishing contracts in advance of an emergency could help CDC quickly and cost-effectively acquire those capabilities in future public health emergencies.[xi] This could include control material. CDC agreed with the recommendation and implemented it in March 2022 by completing an assessment and instituting additional flexibilities and contract options for existing, new, and future contract mechanisms.

HHS response

ASPR, CDC, NIH, and FDA officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. ASPR officials expected the completion of this plan to fulfill the intent of the action experts suggested, but as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. In addition, ASPR officials noted the agency could develop an allocation strategy for prioritizing control material distribution based on criteria. ASPR did this in distributing early orders of COVID-19 materials among jurisdictions, as well as to vulnerable populations and long-term care populations, officials said.

In addition, CDC officials noted that the agency is collaborating with the Department of Commerce's National Institute of Standards and Technology to develop a plan for the manufacture and distribution of synthetic controls when needed during a public health emergency. Through existing infrastructure, such as the International Reagent Resource, CDC has the capacity to rapidly scale up the distribution of control materials to registered public health laboratories using a CDC-developed diagnostic test, officials said. The International Reagent Resource infrastructure—established by CDC to acquire, authenticate, and produce reagents and other supplies that it provides to laboratories to carry out basic research and develop diagnostic tests—has been used similarly before. For example, during the COVID-19 pandemic, the list of items provided to laboratories through this resource expanded to include additional diagnostic supplies beyond reagents. In addition, CDC is awarding indefinite delivery, indefinite quantity contracts to support testing, according to officials. In September 2024, CDC awarded five contracts regarding building testing capacity for new and

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Establish agreements ahead of a public health emergency for producing and distributing control material to use for diagnostic test validation. (continued)

HHS response (continued)

emerging pathogens and enhancing access to critical clinical laboratory data to support situational awareness. In addition, CDC officials said they expected to award a contract in early 2025 related to diagnostic test development and production for emergency response.

NIH provides support for materials in the absence of clinical specimens through the Biodefense and Emerging Infections Research Resources Repository, according to NIH officials. NIH established the Biodefense and Emerging Infections Research Resources Repository to provide biological and chemical research organisms and materials related to NIH's research portfolio to the scientific community. For example, NIH is collecting isolates of H5N1 avian influenza virus for diagnostic test validation, officials said. Control materials are made on an as-needed basis for emerging threats of infectious diseases with pandemic potential, officials said.

In FDA's response, officials proposed supporting the production of contrived control material, which officials said could be manufactured quickly and distributed to developers even before a public health emergency or EUA declaration has been made. A benefit of such material is that it can be easily modified as a pathogen evolves, according to FDA officials.

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Photo: JoseManuel/stock.adobe.com

Establish agreements to help ensure diversity of control material used to validate diagnostic tests.

Ensuring that clinical samples used as control material for test validation are diverse and not only representative of one particular demographic can be a challenge, one expert noted. Experts suggested HHS should establish agreements with health care facilities to provide clinical samples to local public health departments from diverse patient populations, to be used for diagnostic test validation. One expert noted that federally qualified health centers in particular could be useful for providing diverse samples, due to their role providing health care to a diverse population. (Federally qualified health centers are safety net providers that provide services typically given in an outpatient clinic.) However, another expert cautioned against singling out federally qualified health centers because of the historical mistreatment of marginalized populations in medical research. This expert proposed other types of health care facilities could also contribute to providing diverse clinical samples.

Related recommendations

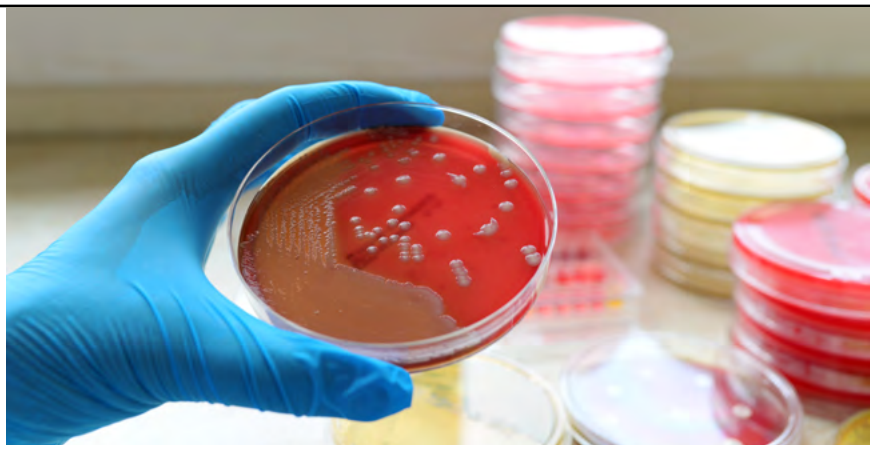
In July 2020, the National Academies recognized the importance of representative samples in infectious disease research by recommending HHS ensure the generation of representative, high-quality full genome sequences of emerging epidemic or pandemic pathogens.[xii] The National Academies further specified that pathogen samples must be obtained from individuals who represent a broad diversity of factors such as race and ethnicity, gender, age, geography, and other demographic types, such as housing type.

HHS response

HHS officials did not have any comments regarding this action.

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Photo: tony4urban/stock.adobe.com



Invest financial support and subject matter expertise in biobanking control material used to validate diagnostic tests.

Obtaining control material for diagnostic test validation is challenging early in a public health emergency when confirmed cases are few. Experts suggested HHS should invest subject matter expertise and financial support in biobanking for infectious diseases to use for diagnostic test validation. (Biobanks are infrastructures that collect and provide standardized, high-quality, and research-ready biological material and associated data.) Experts suggested biobanks could provide control material for test validation when clinical samples may be difficult to obtain. Experts noted HHS could provide financial support for biobanking as part of federal grants, for example.

A potential constraint related to biobanking is storage space, according to one expert. This expert proposed that organizations that specialize in biobanking would be more appropriate than laboratories, which have limited space to dedicate to such an effort. Another expert suggested that developing a prioritization of infectious diseases with pandemic potential could guide biobanking efforts to help address space limitations.

HHS response

NIH and FDA officials responded to this action. NIH officials agreed this action is an effective strategy. NIH supports some biobanking efforts already, such as the Biodefense and Emerging Infections Research Resources Repository and the World Reference Center for Emerging Viruses and Arboviruses, according to NIH officials. In addition, NIH has a contract to collect and biobank specimens for generating evidence, officials said, but these funds are limited to COVID-19. NIH officials noted that it is important to consider the objective of biobanking; for example, samples may be biobanked for studies to characterize

Plan in advance to increase availability of diverse control material to use for diagnostic test validation

Invest financial support and subject matter expertise in biobanking control material used to validate diagnostic tests. (continued)

HHS response (continued)

an infectious disease or to generate evidence for regulatory approval of new diagnostic tests.

FDA officials also discussed this action, stating that biobanking would be useful after a pandemic has started. However, officials also noted that the challenge early in a pandemic is a lack of widely available clinical samples. To address this challenge, FDA officials proposed supporting the production of surrogate material that could be used to create contrived samples for initial test development and validation of diagnostic tests, until sufficient positive clinical samples become available for full test validation. FDA officials said surrogate material could be manufactured quickly and distributed to developers even before a public health emergency or EUA declaration has been made, and could be modified as a pathogen evolves. However, validation using contrived samples should generally be considered a temporary measure, and validation should be confirmed with clinical samples once they are available, officials said.

CDC officials added that the agency has initiated the development of a preparedness repository to support internal methods development and validation. Officials also noted that, in addition to positive clinical and culture specimens, they thought the acquisition of negative specimens for methods validation and research purposes should be considered. They also suggested HHS consider the utility of synthetic biology to general controls and validation panels for priority pathogens.

Deployment

Establish procedures to triage diagnostic testing	• Establish criteria for triaging who to test. • Establish a hotline or automated assistance that triages individuals for diagnostic testing if they meet certain criteria.
Stockpile diagnostic testing materials	• Add diagnostic test specimen collection supplies to the Strategic National Stockpile. • Utilize vendor-managed inventory as part of the Strategic National Stockpile. • Provide guidance and recommendations for jurisdictions to create their own stockpiles, including of diagnostic testing materials.
Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing	• Establish sustained warm base manufacturing agreements ahead of an emergency. • Establish sustained warm base agreements with commercial, large hospital reference, and academic laboratories for capacity in development, specimen collection and transport, and performing tests. • Identify critical components and raw materials of diagnostic testing, and establish financial incentives and monetary fines ahead of an emergency for domestic manufacturing suppliers to meet commitments for producing these items. • Establish a network that public health laboratories could access to transport specimens for diagnostic testing. • Ensure funding for public health laboratories to maintain a warm base for diagnostic testing infrastructure and specimen collection capacity.
Expand the number of entities able to perform diagnostic tests	• Develop procedures to allow non-traditional laboratories to perform moderate and high-complexity diagnostic tests during a public health emergency. • Establish logistical infrastructure for non-traditional laboratories to perform diagnostic tests.

	• Seek legislative authority to permanently remove licensing barriers for certified pharmacists to perform diagnostic testing in cases of pandemics.
Encourage the use of innovative diagnostic testing technologies	• Continue to support and augment the Centers for Disease Control and Prevention's efforts to explore and evaluate the use of new generations of diagnostic testing equipment. • Develop processes for overseeing implementation of alternative diagnostic testing methods to ensure consumer safety. • Encourage innovation of diagnostic test reagents with longer shelf life.
Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations	• Ensure that diagnostic testing is free (and for home tests, broadly distributed) to the public during a public health emergency. • Develop, incentivize, and disseminate best practices to provide diagnostic testing in ways that can overcome patient barriers faced by vulnerable and underserved populations. • Provide guidance on including vulnerable and underserved populations as part of pandemic preparedness planning, including diagnostic testing. • Increase training opportunities on diagnostic testing for rural areas, the Indian Health Service, and federally qualified health centers. • Partner with existing and trusted community infrastructure to help perform diagnostic testing. • Ensure residential facilities and federally qualified health centers have funding and adequate payment mechanisms for bulk purchase of rapid tests.
Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions	• Communicate to affected communities the purpose and intention behind diagnostic testing. • Increase coordinated communication of transparent information on diagnostic testing through reliable and trusted sources. • Partner with news and social media outlets to advertise important diagnostic testing information.

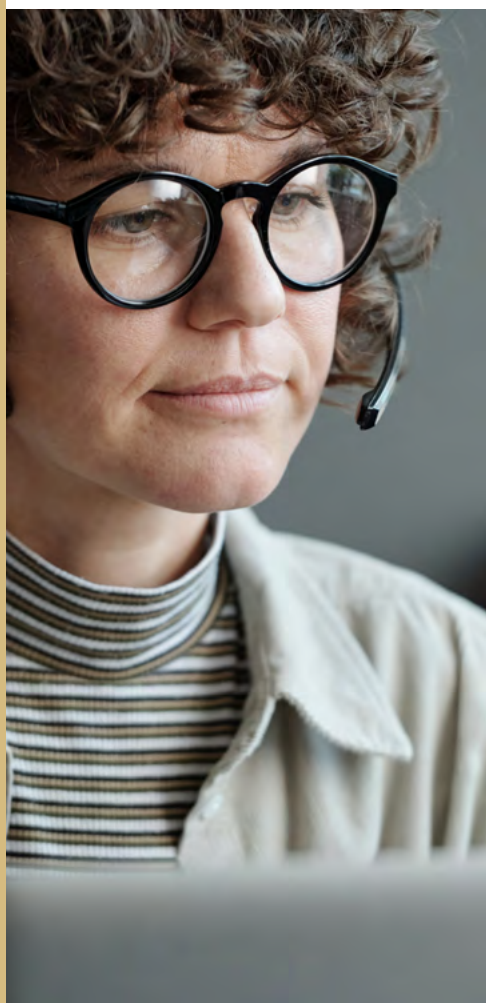
- Provide better communication about diagnostic testing materials provided by the federal government to gain community trust.
- Provide transparency about where diagnostic test kits are going to be deployed.
- Communicate diagnostic testing supply chain issues to the private sector.
- Develop a mechanism to notify skilled nursing facility staff and other clinicians and pharmacists of point-of-care diagnostic testing for new emerging infectious diseases, and provide information on the correct way to perform testing.

Prepare in advance for diagnostic testing fraud

- Make diagnostic testing fraud prevention part of pandemic preparedness planning.

Photo: pressmaster/stock.adobe.com

Establish procedures to triage diagnostic testing



- Establish criteria for triaging who to test.
- Establish a hotline or automated assistance that triages individuals for diagnostic testing if they meet certain criteria.

Establish procedures to triage diagnostic testing

Photo: Milos/stock.adobe.com

Establish criteria for triaging who to test.

The demand for diagnostic tests early in a pandemic can quickly exceed a nation's testing capacity. Experts suggested that HHS should establish criteria for who to triage for diagnostic testing and identify where to deploy tests to manage demand in the early weeks and months of a public health emergency when supplies are scarce. Ensuring the right individuals are being tested in the early stages of a pandemic could reduce demand on laboratory capacity. One expert said that it would also be important to clearly communicate why certain populations are included or excluded using these criteria to avoid the perception of limiting test access.

HHS response

Criteria for triaging or managing testing demand will vary based on the nature of the public health emergency or response, CDC officials said. As a result, CDC believes that such criteria cannot be developed prior to an event. However, CDC officials added that careful attention should be paid to communicating clearly to partners and the public early in a public health emergency.

Establish procedures to triage diagnostic testing

Photo: Eakrin/stock.adobe.com

Establish a hotline or automated assistance that triages individuals for diagnostic testing if they meet certain criteria.

During public health emergencies, the amount of phone calls from the public requesting tests can overwhelm public health staff, particularly during the initial weeks of the emergency, according to experts. Experts suggested HHS should establish a hotline or automated assistance that triages individuals for diagnostic testing if they meet certain criteria. Such a resource would alleviate demands on public health staff and support more consistent triaging and access to testing nationally, according to experts. Experts said that triaging should be based on recommendations for testing and automated to reduce time spent by public health staff answering phone calls regarding testing criteria.

HHS response

CDC officials said that ASPR established a hotline to triage individuals for diagnostic testing and that it was a useful strategy during the COVID-19 public health emergency. However, officials noted that hotline capacity is no longer a funded activity and would need to be reestablished for a future response. Fulfilling this action should include other partners to establish triage support lines and ensure this service is available to all U.S. populations across jurisdictions, CDC officials said.

Photo: .shock/stock.adobe.com

Stockpile diagnostic testing materials

- Add diagnostic test specimen collection supplies to the Strategic National Stockpile.
- Utilize vendor-managed inventory as part of the Strategic National Stockpile.
- Provide guidance and recommendations for jurisdictions to create their own stockpiles, including of diagnostic testing materials.

Stockpile diagnostic testing materials

Add diagnostic test specimen collection supplies to the Strategic National Stockpile (SNS).	Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested HHS should add diagnostic specimen collection supplies into the SNS. Prior to the COVID-19 pandemic, the SNS did not hold testing supplies. Specimen collection supplies available from the SNS could be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient, according to ASPR's website.
HHS response	ASPR officials noted that the SNS has not historically maintained diagnostic tests, nor has the Secretary of Health and Human Services established a requirement to stockpile diagnostic tests and testing supplies for any specific threat. ASPR does not support such an acquisition due to limited resources for the SNS, officials said.

Stockpile diagnostic testing materials

Photo: J Bettencourt/peopleimages.com/stock.adobe.com

Utilize vendor-managed inventory as part of the SNS.

Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested HHS should utilize vendor-managed inventory as part of the SNS, rather than current just-in-time inventory, to ease diagnostic test supply chain issues. Just-in-time inventory is the practice of keeping inventory as minimal as practical in order to reduce capital and storage costs. With vendor-managed inventory, vendors would maintain laboratory supplies onsite at various public health laboratories, commercial laboratories, and hospital laboratories for use in the event of an emergency. The vendor would then manage rotation of supplies to avoid expiration. However, experts acknowledged that the finite budget for the SNS means HHS may need additional funding to implement this change.

HHS response

ASPR officials noted that because of a limited annual budget, the SNS does not plan to purchase diagnostic test supplies or invest in a vendor-managed inventory contract for such supplies. ASPR sometimes utilizes vendor-managed inventory contracts as one of many tools, officials said. However, ASPR officials noted that the cost of utilizing vendor-managed inventory contracts can be prohibitive, especially with a limited budget.

Stockpile diagnostic testing materials

Photo: GAO file photo

Provide guidance and recommendations for jurisdictions to create their own stockpiles, including of diagnostic testing materials.

Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested HHS should provide guidance and recommendations for jurisdictions to create their own stockpiles, including of diagnostic testing materials.

Related recommendations

In January 2021, GAO recommended ASPR establish a process for regularly engaging with nonfederal stakeholders, including jurisdictional governments and private industry, as HHS refines and implements a supply chain strategy for pandemic preparedness to include the role of the SNS.[xiii] HHS generally agreed with this recommendation, and ASPR implemented it by formalizing its stakeholder engagement efforts in its strategy for the SNS.

HHS response

ASPR officials noted that there is no designated lead within HHS to provide guidance and recommendations for jurisdictions to create their own stockpiles. Individual states, which face different public health challenges, can procure and stockpile material they deem necessary to enhance their state's preparedness. The SNS develops general stockpiling best practices, and SNS officials can serve as subject matter experts for jurisdictions as needed.

Photo: Halfpoint/stock.adobe.com

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

- Establish sustained warm base manufacturing agreements ahead of an emergency.
- Establish sustained warm base agreements with commercial, large hospital reference, and academic laboratories for capacity in development, specimen collection and transport, and performing tests.
- Identify critical components and raw materials of diagnostic testing, and establish financial incentives and monetary fines ahead of an emergency for domestic manufacturing suppliers to meet commitments for producing these items.
- Establish a network that public health laboratories could access to transport specimens for diagnostic testing.
- Ensure funding for public health laboratories to maintain a warm base for diagnostic testing infrastructure and specimen collection capacity.

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Establish sustained warm base manufacturing agreements ahead of an emergency.

Experts said that during previous public health emergencies, HHS established time-limited contracts for large volumes of tests at the advent of a surge, rather than contracting long-term through both surges and lulls. This led to companies having to rapidly rebuild capacity every time there was a new surge. Experts suggested HHS should establish sustained warm base manufacturing agreements ahead of an emergency so diagnostic testing manufacturers are prepared to rapidly respond to surges in demand for tests. Warm base manufacturing refers to the capacity to be operationally ready to quickly manufacture diagnostic tests during a public health emergency response. Having a formal agreement could provide manufacturers the financial security needed to maintain readiness to produce tests, experts said. Experts noted maintaining a warm base may require sustained funding.

Related recommendations

GAO and the National Academies have made related recommendations. In July 2021, GAO recommended that CDC assess the agency's needs for goods and services for the manufacturing and deployment of diagnostic test kits in public health emergencies, including an evaluation of how establishing contracts in advance of an emergency could help CDC quickly and cost-effectively acquire these capabilities when responding to future public health emergencies.[xi] CDC agreed with this recommendation and implemented it in March 2022 by completing an assessment and instituting additional flexibilities and contract options for existing, new, and future contract mechanisms. These changes could support emergency production of goods and services. Additionally, in November 2021, the National Academies recommended national governments secure sources that can reliably supply all items needed during an influenza pandemic.[xiv] The National Academies further recommended that appropriate authorities assess and establish local production capabilities for all such items.

HHS response

CDC officials noted that the agency has published indefinite delivery, indefinite quantity contracts for test manufacturers to act as a warm base for rapid test manufacturing response. Officials said they expected to award contracts to up to five diagnostic test manufacturers in early 2025.

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Photo: FotoArtist/stock.adobe.com

Establish sustained warm base agreements with commercial, large hospital reference, and academic laboratories for capacity in development, specimen collection and transport, and performing tests.

Significant demand for testing during a public health emergency can overwhelm laboratories. Experts suggested HHS should establish sustained warm base agreements with commercial, large hospital reference, and academic laboratories to increase capacity in development, specimen collection and transport, and for performing of tests. Maintaining testing capacity could include maintaining instrumentation and physical space, having the ability to perform a certain number of tests per week, and maintaining a large enough workforce to perform tests. One expert said that having pre-arranged agreements with these partners can help sustain diagnostic testing-related capacity during pandemics, even when demand temporarily diminishes. Experts suggested laboratories with warm base agreements should be those deemed key to the national laboratory infrastructure and able to rapidly respond to surges as an extension of the Laboratory Response Network. Additionally, experts said that pre-arranged agreements with partners would help establish geographic diversity and nationwide availability of testing. Experts noted maintaining a warm base would require sustained funding.

HHS response

ASPR and CDC officials responded to this action. ASPR's Center of Industrial Base Management and Supply Chain executed 13 warm-based contracts during the COVID-19 response to support the testing distribution program with domestic manufacturers of diagnostic tests, according to ASPR officials. ASPR officials noted that without sustained funding, those contracts are set to expire in June 2025. As of January 2025, officials said that there are no

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Establish sustained warm base agreements with commercial, large hospital reference, and academic laboratories for capacity in development, specimen collection and transport, and performing tests (continued)

HHS response (continued)

plans to extend or recompete them. In addition, ASPR officials said HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, which is a requirement of the *National Biodefense Strategy*. Officials anticipated the document would contain plans to implement agreements with laboratories, test manufacturers, and component manufacturers. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. The extent to which these objectives are achieved is dependent on availability of funds, ASPR officials said.

Additionally, CDC officials said they are focused on engaging commercial laboratories with nationwide capacity, noting that the reach of hospital or academic partners is often limited to specific geographic regions or patient populations. In fall 2023, CDC released two requests for information, one for diagnostic surge testing and another for diagnostic test development and production. CDC used the responses to develop a request for proposal that was posted in the summer of 2024. The contract was awarded in September 2024. Additional funding support may be needed to expand capacity, officials said.

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Identify critical components and raw materials of diagnostic testing and establish financial incentives and monetary fines ahead of an emergency for domestic manufacturing suppliers to meet commitments for producing these items.

Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested HHS should, ahead of an emergency, identify key components (e.g., swabs) and raw materials for diagnostic testing to ensure, where possible, that there is domestic capacity to produce those components. Experts said taking this step would reduce reliance on foreign sourcing of raw materials, components, and manufacturing, which is particularly important during times of scarcity, such as during a pandemic. For example, one expert noted that during the beginning of the COVID-19 public health emergency, there was insufficient domestic manufacturing capacity for swab components. Once domestic capabilities are in place, experts suggested HHS should establish oversight to ensure domestic manufacturers meet any commitments they have made regarding component manufacturing. One expert noted that one method to do this would be to financially incentivize selected domestic supplies and establish monetary fines for when commitments are not kept.

Related recommendations

GAO, HHS-OIG, and the National Academies have made related recommendations regarding the importance of domestic manufacturing of supplies. In November 2020, GAO recommended that ASPR identify how the Defense Production Act and similar actions will be used to increase domestic production of medical supplies.[xv] HHS agreed with this recommendation and implemented it. Steps HHS took to address this recommendation included

- issuing priority ratings for contracts for health resources and industrial expansion to ensure private sector partners can acquire prerequisite raw materials, components, and products; and
- establishing a program for investments to sustain production of critical medical supplies and scale emergency technologies to enhance or expand domestic public health industrial base capabilities.

In October 2023, HHS-OIG recommended that ASPR mitigate the risk presented by relying on foreign supply chains when determining annual stockpile purchases.[xvi] According to HHS-OIG, in July 2024, ASPR implemented this recommendation. Additionally, in November 2021, the National Academies recommended that national governments secure sources that can reliably supply all items needed during an influenza

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

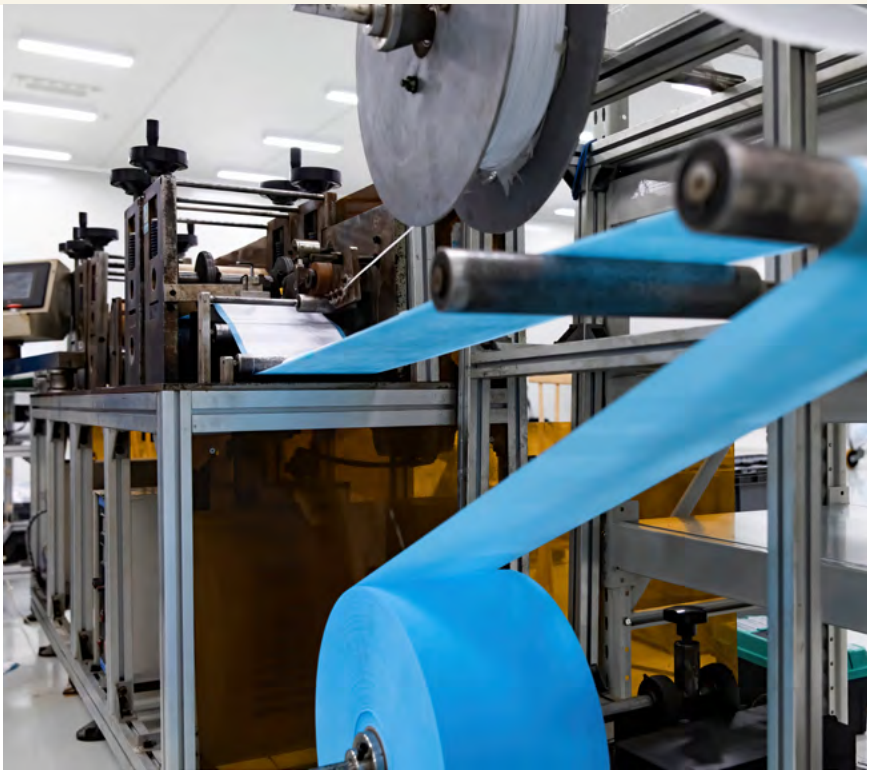
Photo: InkheartX/stock.adobe.com

Related recommendations (cont.)

pandemic.[xiv] The National Academies further recommended that appropriate authorities assess and establish local production capabilities for all such items.

HHS response

ASPR officials noted that ASPR monitors critical supplies, but is selective regarding which supplies due to funding. ASPR officials also said the agency can produce Industrial Based Assessments ahead of an emergency to understand what steps can be taken to mitigate potential future testing supply chain issues. These assessments include information regarding the sourcing of critical components, including the strengths and weaknesses and any foreign dependencies within the supply chain for a particular component. For example, an assessment of needles and syringes—used for diagnostic tests requiring a blood draw—might highlight a dependence on stainless steel imports for producing needles. However, ASPR officials said they lack the funding or authority to levy or enforce fines of any kind.



Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Establish a network that public health laboratories could access to transport specimens for diagnostic testing.

One expert described challenges getting patient samples to public laboratories for testing at the beginning of a public health emergency. Experts suggested HHS should establish a network that public health laboratories could access to transport specimens for diagnostic testing. Although some smaller states have couriers to transport specimens to public health laboratories, many other states—especially larger geographic ones—do not, according to one expert.

HHS response

CDC officials noted that intrastate transport of specimens is a state-specific issue that is outside the purview of CDC. State public health laboratories can transport specimens directly to CDC for diagnostic testing. CDC officials also mentioned the agency's Increasing Community Access to Testing, Treatment, and Response program, which allows contracted pharmacies, such as CVS and Walgreens, to send samples to state public health, federal public health, and commercial laboratories to support surveillance, research, and test development. The contracts for the program are funded through May 2025, and officials said additional funding will be needed to maintain these capabilities further.

Ahead of a public health emergency, establish and maintain the capacity to deploy diagnostic testing

Ensure funding for public health laboratories to maintain a warm base for diagnostic testing infrastructure and specimen collection capacity.

Maintaining the ability to respond to surges in demand for testing during a public health threat or emergency requires reserved resources. Experts suggested HHS should ensure funding for public health laboratories so that they can maintain a warm base for infrastructure and specimen collection capacity required for infectious disease diagnostic testing through the Laboratory Response Network. However, experts noted additional funding may be required to implement this action due to associated additional costs.

HHS response

CDC officials noted that agency resources support Laboratory Response Network activities at CDC, and the Public Health Emergency Preparedness cooperative agreement provides support to state and local Laboratory Response Network member laboratories. CDC continues to maintain the Laboratory Response Network, which has grown since its inception and continues to evolve to meet changing needs, according to officials.

Photo: rh2010/stock.adobe.com

Expand the number of entities able to perform diagnostic tests

- Develop procedures to allow non-traditional laboratories to perform moderate and high-complexity diagnostic tests during a public health emergency.
- Establish logistical infrastructure for non-traditional laboratories to perform diagnostic tests.
- Seek legislative authority to permanently remove licensing barriers for certified pharmacists to perform diagnostic testing in cases of pandemics.

Expand the number of entities able to perform diagnostic tests

Photo: Atthapon/stock.adobe.com

Develop procedures to allow non-traditional laboratories to perform moderate and high-complexity diagnostic tests during a public health emergency.

Significant demand for testing during a public health emergency can overwhelm clinical laboratories. Experts suggested HHS—specifically, CMS—should develop procedures to allow non-traditional laboratories that are typically not certified by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, such as academic and veterinary laboratories, to perform moderate and high-complexity diagnostic tests.[xvii] Experts said leveraging instruments and staff in non-traditional laboratories, such as academic centers, to do testing could improve testing capacity during a public health emergency. One expert noted that during the COVID-19 public health emergency, there was confusion regarding what amount of professional training and education was needed for deployment of tests outside of the clinical laboratory setting. According to another expert, HHS should develop processes allowing non-traditional laboratories to obtain any type of laboratory licensure necessary for emergency situations.

Related recommendations

In July 2021, GAO recommended CDC work with appropriate stakeholders—including public health and private laboratories—to develop a plan to enhance laboratory surge testing capacity.[xi] HHS agreed with this recommendation and in May 2022, HHS implemented it by developing a plan to enhance laboratory surge capacity to include laboratories other than CDC and public health laboratories.

Expand the number of entities able to perform diagnostic tests

Develop procedures to allow non-traditional laboratories to perform moderate and high-complexity diagnostic tests during a public health emergency. (continued)

HHS response

According to CMS's website, the objective of the CLIA program is to ensure quality laboratory testing. While CMS has broad authority to establish regulations that authorize different groups to perform testing in the event of a public health emergency, agency officials have concerns regarding developing regulations specific to non-traditional laboratories that are typically not CLIA-certified. CMS officials explained they believe such determinations are best made upon the emergence or re-emergence of a particular infectious disease rather than in advance, due to the uncertain nature of the specific testing that may be necessary. However, CMS has developed specialized toolkits that will be updated and released in a future public health emergency that provide guidance specific to non-traditional testing laboratories to facilitate expedited approval to test, should the need arise, according to officials. Additionally, HHS's fiscal year 2025 budget proposal contained a proposal that would provide CMS with the ability to temporarily modify or waive specific CLIA program requirements that impede laboratory testing access and availability. Absent this statutory authority, the agency relies on enforcement discretion to promote prompt testing access, according to CMS officials.

CDC officials added that one considerable barrier to entry in diagnostic testing during the COVID-19 pandemic was the discrepancy between educational requirements for veterinary diagnostic laboratory directors compared to CLIA director requirements. CDC officials suggested reevaluating CLIA director requirements could be a useful step.

Expand the number of entities able to perform diagnostic tests

Establish logistical infrastructure for non-traditional laboratories to perform diagnostic tests.

Significant demand for testing during a public health emergency can overwhelm clinical laboratories. Experts suggested that HHS should establish logistical infrastructure for non-traditional laboratories—such as infrastructure to receive testing requests from providers and report test results—so they can be used to increase diagnostic testing capacity. Non-traditional laboratories have expert researchers that frequently perform testing, one expert noted, and HHS could use these researchers as additional surge capacity. However, experts noted this may require additional infrastructure to ensure laboratory workers in non-traditional laboratories can order tests, receive tests, and communicate back test results.

Related recommendations

In July 2021, GAO recommended that CDC should work with appropriate stakeholders—including public health and private laboratories—to develop a plan to enhance laboratory surge testing capacity during the COVID-19 public health emergency.[xi] HHS agreed with this recommendation and implemented it in May 2022 by developing a plan to enhance laboratory surge testing capacity at laboratories other than CDC and public health laboratories.

HHS response

NIH officials agreed that establishing logistical infrastructure for non-traditional laboratories is an effective strategy for addressing diagnostic testing capacity. NIH's RADx initiative demonstrated the impact non-traditional laboratory infrastructure can have on diagnostic testing for vulnerable and underserved populations, such as older adults, rural populations, racial and ethnic minorities, people with disabilities, and low income or homeless individuals. Agency officials said that these laboratories can provide access outside of traditional care settings at convenient locations commonly frequented by vulnerable and underserved populations. For example, agency officials said one RADx-funded research project offered on-site COVID-19 rapid antigen testing to patients via a mobile unit, which resulted in a significant increase in testing uptake.

Expand the number of entities able to perform diagnostic tests

Photo: Orhan Çam/stock.adobe.com

Seek legislative authority to permanently remove licensing barriers for certified pharmacists to perform diagnostic testing in cases of pandemics.

Increasing access to testing can help track a disease, inform treatment, and suppress transmission during a public health emergency. One expert noted that expanding the types of providers able to offer diagnostic testing can improve patient access. Experts suggested HHS should seek legislative authority to permanently remove licensing barriers for certified pharmacists to perform CLIA-waived infectious disease diagnostic testing in cases of pandemics. One expert said that during the COVID-19 public health emergency, public health authorities directed communities and individuals to get tested at pharmacies, but many pharmacists were unable to provide testing due to state licensing barriers. The Public Readiness and Emergency Preparedness Act allowed for the preemption of state laws that prevented pharmacists from ordering and administering authorized COVID-19 tests.[xviii] One expert noted that once this authority and preemption expires, pharmacists will once again face state licensing barriers to providing tests in the case of another pandemic.

HHS response

CMS officials noted that pharmacies with the appropriate Medicare enrollment and CLIA certification can continue to perform laboratory tests. While a pharmacist is not a Medicare provider, a pharmacy enrolled as a laboratory can collect the specimen and be reimbursed by Medicare, according to CMS officials.

Photo: littlewolf989/stock.adobe.com

Encourage the use of innovative diagnostic testing technologies

- Continue to support and augment the Centers for Disease Control and Prevention's efforts to explore and evaluate the use of new generations of diagnostic testing equipment.
- Develop processes for overseeing implementation of alternative diagnostic testing methods to ensure consumer safety.
- Encourage innovation of diagnostic test reagents with longer shelf life.

Encourage the use of innovative diagnostic testing technologies

Photo: Tada Images/stock.adobe.com

Continue to support and augment CDC's efforts to explore and evaluate the use of new generations of diagnostic testing equipment.

Advancements in testing technology could potentially result in improved diagnostic test performance. Experts suggested HHS should continue to support and augment CDC's efforts to explore and evaluate the use of new generations of diagnostic testing equipment. Experts said multiple CDC programs are currently working to explore and evaluate new generations of testing equipment, including extractors—used to extract genetic material from a sample—and PCR analyzers. Experts suggested HHS allocate additional resources to these CDC programs to accelerate their progress and the deployment of the new generation of equipment into laboratories. Taking this action could better position public health laboratories and HHS's clinical, academic, and commercial partners to address testing challenges.

HHS response

CDC and FDA officials responded to this action. CDC officials said updating diagnostic testing equipment to newer platforms will ensure availability of testing capacity in the Laboratory Response Network in the future, but that such efforts are dependent upon the sufficiency of available resources. Agency officials said CDC has modified the majority of diagnostic tests used by the Laboratory Response Network to allow for use with updated and newer testing platforms. In addition, CDC is transitioning away from manual extraction methods to automated methods to improve turnaround time and laboratory efficiency, according to agency officials. FDA officials said FDA should be consulted on work related to this action.

Encourage the use of innovative diagnostic testing technologies

Develop processes for overseeing implementation of alternative diagnostic testing methods to ensure consumer safety.

Incorrect test results can contribute to the spread of an outbreak during a public health emergency. Experts suggested that HHS should develop processes for overseeing implementation of alternative diagnostic testing methods, such as at-home tests and point-of-care tests, to ensure consumer safety. HHS should put quality regulatory infrastructure in place to oversee these alternative testing methods, experts said. This may include special accreditation through the CLIA program for laboratories that distribute at-home collection kits and perform tests on returned specimens, experts noted. Establishing oversight of these alternative testing methods could help ensure that their use is appropriate and provide a clearer path for those seeking to implement them, according to an expert.

HHS response

CDC, CMS, and FDA officials responded to this action. FDA officials said that FDA reviews the safety and effectiveness of a test per its intended use. FDA also considers usability and user comprehension when it reviews a test for home use prior to authorization.

CMS officials said that diagnostic tests should include instructions for use appropriate for the intended user, such as a lay person, for home collection. Laboratories that perform testing on specimens collected using at-home collection kits must have a CLIA certificate for the complexity of the testing they are performing, according to CMS officials. Officials said laboratories performing CLIA-regulated testing must follow regulations that require written instructions be provided to each client. The instructions should contain information on specimen handling (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances).

CDC officials said that testing with at-home tests or self-tests is not regulated by CMS under CLIA, but the laboratories that process specimens collected at home or by a health care provider are regulated by CMS under CLIA. CDC is not involved in CLIA oversight of external manufacturers or laboratories, officials said.

Encourage the use of innovative diagnostic testing technologies

Photo: Evgeniy Kalinovskiy/stock.adobe.com

Encourage innovation of diagnostic test reagents with longer shelf life.

Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested HHS should encourage the innovation of diagnostic test reagents with longer shelf life. For instance, one expert said HHS could encourage innovation in the storage of freeze-dried reagents that have much longer shelf lives than liquid reagents. This expert suggested that encouraging this type of innovation would increase the longevity of potential stockpiles.

HHS response

NIH and FDA officials responded to this action. NIH officials noted that they play a role in encouraging such innovation through research and development contracts that support methods to stabilize reagents for longer periods at elevated temperatures. NIH officials said the agency will continue to stipulate in its contracts that developers must develop reagents with longer shelf life for extended stability and product utility. FDA officials noted that FDA could recommend this to developers, but could not require it without additional statutory authorities. Manufacturers would likely need to be incentivized to do this, according to officials.

Photo: ipopba/stock.adobe.com

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

- Ensure that diagnostic testing is free (and for home tests, broadly distributed) to the public during a public health emergency.
- Develop, incentivize, and disseminate best practices to provide diagnostic testing in ways that can overcome patient barriers faced by vulnerable and underserved populations.
- Provide guidance on including vulnerable and underserved populations as part of pandemic preparedness planning, including diagnostic testing.
- Increase training opportunities on diagnostic testing for rural areas, the Indian Health Service, and federally qualified health centers.
- Partner with existing and trusted community infrastructure to help perform diagnostic testing.
- Ensure residential facilities and federally qualified health centers have funding and adequate payment mechanisms for bulk purchase of rapid tests.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Photo: MKPhoto/stock.adobe.com

Ensure that diagnostic testing is free (and for home tests, broadly distributed) to the public during a public health emergency.

Vulnerable and underserved populations have been disproportionately affected by previous public health emergencies. Experts suggested HHS should ensure that diagnostic testing is free (and for home tests, broadly distributed) during a public health emergency, especially for federally qualified health centers, Tribal Nations, and vulnerable and underserved populations. Experts stressed the importance of making sure the public is aware of this free testing. Experts suggested HHS should also ensure a reimbursement mechanism exists for providers offering free diagnostic testing, as well as all other services that accompany testing. One expert added that another consideration when providing free diagnostic testing is ensuring these tests are reliable to avoid creating distrust of testing materials and equipment among communities.

HHS response

Officials from ASPR noted that ensuring free diagnostic testing to the public was a successful approach during the COVID-19 public health emergency. During that emergency, nearly 900 million test kits were ordered by the public, with more than a third reaching communities of high social vulnerability. HHS has also previously collaborated with the U.S. Postal Service for an at-home test kit program to provide free testing. In the future, HHS could build on existing methods for bulk distribution to include long-term care facilities and other health care facilities.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Develop, incentivize, and disseminate best practices to provide diagnostic testing in ways that can overcome patient barriers faced by vulnerable and underserved populations.

Vulnerable and underserved populations have been disproportionately affected by previous public health emergencies. Experts suggested HHS should develop, incentivize, and disseminate best practices for overcoming patient barriers to diagnostic testing faced by vulnerable and underserved populations, such as a lack of transportation for drive-through testing. HHS should foster shared understanding about potential solutions for patient barriers, especially across different communities, one expert said. For example, one expert noted state and county public health departments and regional authorities could prioritize non-traditional approaches to testing sites, including at drive-throughs, pop-up sites, community gathering places, barber shops, and churches.

Related recommendations

In November 2021, the National Academies recommended that government leaders should take the racial and socioeconomic disadvantages that affect the health of affected populations into consideration when developing and implementing public health interventions.[xiv]

HHS response

NIH and CDC officials responded to this action. NIH officials agreed that developing, incentivizing, and disseminating best practices to provide diagnostic testing to underserved populations is an effective strategy. NIH officials noted that bringing resources to where individuals gather can have a positive impact on the health of vulnerable and underserved populations. They described a project under the RADx initiative that provided toolkits and other resources for implementing testing in community gathering spaces like churches, which were then shared with other RADx projects. Other RADx projects included strategies for overcoming patient barriers, such as providing translated and culturally appropriate COVID-19 testing communications.

Additionally, CDC officials said CDC maintains websites that provide testing best practices, testing site locator tools, and links to test scheduling services. The agency is also partnering with national and independent pharmacies to provide testing services and developing communications to overcome testing information barriers. CDC will consult with jurisdictional partners to develop these materials and then disseminate any best practices back to these partners, officials said. During the COVID-19 public health emergency, CDC developed multiple strategies with testing vendors to improve testing access for vulnerable populations, including, for example, fully automated testing kiosks, officials added.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Photo: Kawee/stock.adobe.com

Provide guidance on including vulnerable and underserved populations as part of pandemic preparedness planning, including diagnostic testing.

Vulnerable and underserved populations have been disproportionately affected by previous public health emergencies. Experts suggested that HHS should provide guidance on including the consideration of vulnerable and underserved populations as part of pandemic preparedness planning, including diagnostic testing.

Related recommendations

In November 2021, the National Academies recommended that government leaders should take the racial and socioeconomic disadvantages that affect the health of affected populations into consideration when developing and implementing public health interventions.[xiv]

HHS response

ASPR officials noted guidance can take several forms, including planning guidance, operational guidance as diagnostic tests are made available, and guidance through office hours. In addition, officials said ASPR has historically conducted regular analysis of the ordering and distribution of test kits and has records of historic demand that can be leveraged to identify at-risk populations.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Photo: ruslanita/stock.adobe.com

Increase training opportunities for diagnostic testing for rural areas, the Indian Health Service, and federally qualified health centers.

Vulnerable and underserved populations have been disproportionately affected by previous public health emergencies. Experts suggested that HHS should increase training opportunities for diagnostic testing in rural areas, Indian Health Service facilities, and federally qualified health centers. One expert suggested that when growing these opportunities, HHS should minimize budgetary impact by using systems that already exist across HHS in agencies like CMS and CDC. This could entail shifting or evolving current programming.

HHS response

CDC officials said that the agency maintains CDC's OneLab Reach, which is a centralized online platform for laboratory training that provides collaborative communities of practice for public health and clinical laboratory professionals and testing professionals in non-laboratory settings. Trainings, job aids, and other resources are free and available on demand.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Photo: Deen Jacobs/peopleimages.com/stock.adobe.com

Partner with existing and trusted community infrastructure to help perform diagnostic testing.

Misinformation and mistrust of government can hinder efforts to respond to a public health emergency. Experts suggested HHS should partner with existing and trusted community infrastructure to help perform diagnostic testing. Experts gave examples, including using mobile testing vans and buses and establishing Test-to-Treat programs, which allow any patients who test positive to also receive appropriate treatment, if eligible. Experts also said that partnering with federally qualified health centers could help perform diagnostic testing. One expert noted that using trusted, community-based infrastructure will help increase testing engagement in environments with misinformation. However, another expert said HHS may need sufficient resource investment for the existing infrastructure to perform this engagement in communities.

HHS response

NIH, ASPR, CDC, and Health Resources and Services Administration officials responded to this action. NIH officials agreed that partnering with existing and trusted community infrastructure to help perform diagnostic testing is an effective strategy. The officials said that during the COVID-19 public health emergency, some RADx projects built on pre-existing relationships with community partners to harness the trust, knowledge, and expertise of local community partners and tailor approaches to COVID-19 test distribution and treatment access. For instance, one project coordinated with approximately 20 local partners to distribute 40,000 COVID tests.

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Partner with existing and trusted community infrastructure to help perform diagnostic testing. (continued)

HHS response (continued)

Additionally, ASPR officials noted that the Test-to-Treat program and testing for vulnerable populations via federally qualified health centers and long-term care sites were especially effective in managing and rapidly mitigating COVID-19 infections. Officials from ASPR also said it is important to pair diagnostic test availability via existing and trusted community infrastructure with education for providers and locator tools to help community members locate available tests within this community infrastructure.

CDC officials said they partnered with national and independent pharmacies to provide drive-through testing and pop-up testing sites, though funding to continue such efforts will be needed after existing contracts end in May 2025.

Health Resources and Services Administration officials noted that from April 10, 2020, to August 31, 2024, health centers funded by the agency performed over 26 million COVID-19 tests in the communities they served. These efforts were undertaken in collaboration with state and local health departments to deliver a comprehensive public health response

Promote equitable access to diagnostic testing, particularly for vulnerable and underserved populations

Photo: J.A./stock.adobe.com

Ensure residential facilities and federally qualified health centers have funding and adequate payment mechanisms for bulk purchase of rapid tests.

People who live and work in residential facilities have been disproportionately affected by COVID-19. Experts suggested HHS should ensure residential facilities and federally qualified health centers have funding and adequate payment mechanisms for bulk purchase of rapid antigen tests. Residential facilities could include long-term care, behavioral health, and substance use facilities, and homeless shelters. Experts said massive shipments of rapid tests to facilities during the COVID-19 public health emergency were helpful for ensuring an efficient testing-to-treatment timeline. However, many facilities are now purchasing rapid tests using their operating budget because federal COVID-19 funds designated for the bulk purchase of rapid tests have run out, according to one expert.

HHS response

HHS officials did not have any comments regarding this action.

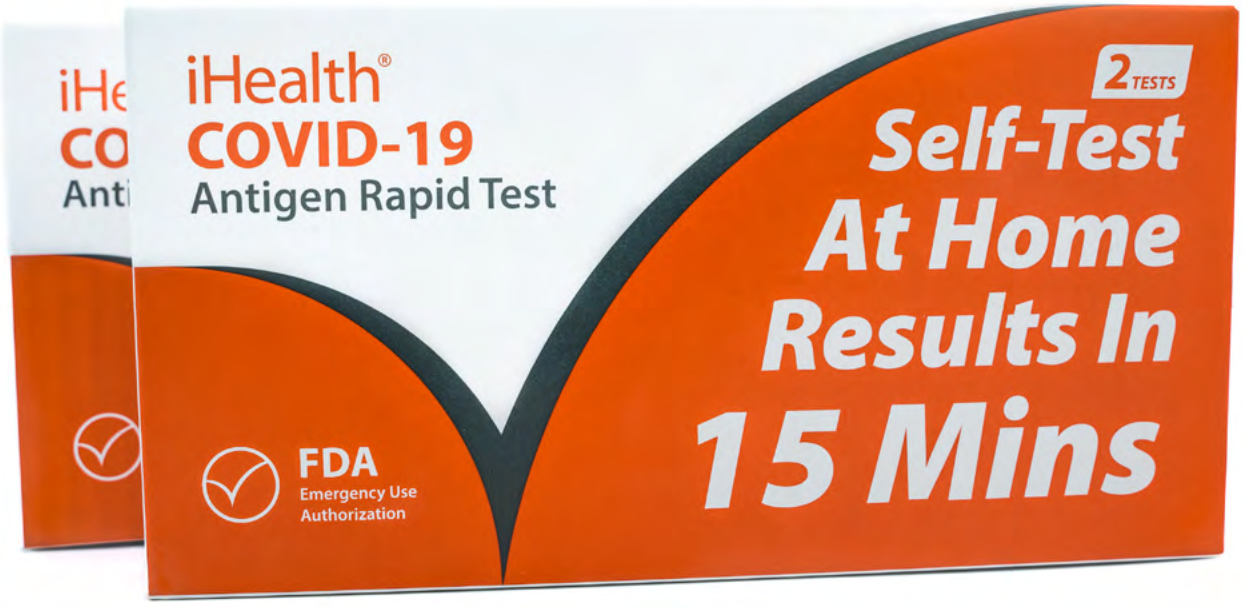
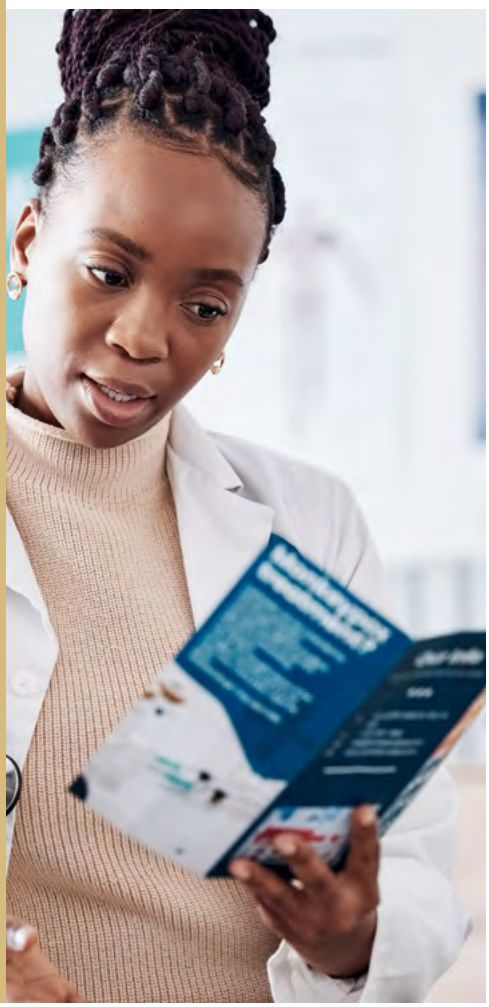


Photo: Talia Mdlungu/peopleimages.com/stock.adobe.com

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions



- Communicate to affected communities the purpose and intention behind diagnostic testing.
- Increase coordinated communication of transparent information on diagnostic testing through reliable and trusted sources.
- Partner with news and social media outlets to advertise important diagnostic testing information.
- Provide better communication about diagnostic testing materials provided by the federal government to gain community trust.
- Provide transparency about where diagnostic test kits are going to be deployed.
- Communicate diagnostic testing supply chain issues to the private sector.
- Develop a mechanism to notify skilled nursing facility staff and other clinicians and pharmacists of point-of-care diagnostic testing for new emerging infectious diseases, and provide information on the correct way to perform testing.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Communicate to affected communities the purpose and intention behind diagnostic testing.

Misinformation and mistrust of government can hinder efforts to respond to a public health emergency. Experts suggested HHS should communicate with affected communities the purpose and intention behind diagnostic testing to engage their participation. This could include partnerships with organizations like Citizen Science, experts said. Citizen Science is a government website that seeks to engage the general public in engaging in scientific research. One expert noted this communication should be translated into multiple languages.

Related recommendations

In November 2021, the National Academies recommended that governments engage the community—including grassroots organizations, spiritual leaders, teachers, and sports coaches—in making and communicating decisions about public health measures.[xiv]

HHS response

NIH officials agreed that communicating the purpose and intention behind diagnostic testing to affected communities is an effective strategy, and noted that the RADx initiative used a similar strategy to increase testing access and uptake during the COVID-19 public health emergency. NIH officials said numerous RADx projects tailored communication regarding the purpose and intention behind diagnostic testing to engage participation in local communities. For example, one project partnered with the government of American Samoa, universities, health centers, non-profit organizations, and multiple community-based organizations and churches to provide culturally specific materials and documents containing community engagement strategies to be distributed in the native languages of Pacific Islander communities.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

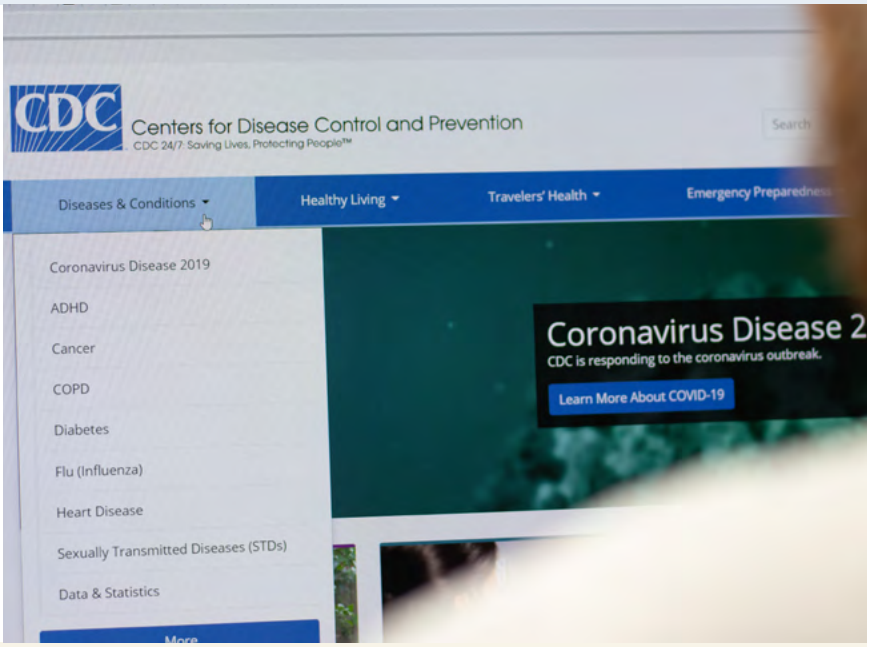
Photo: Postmodern Studio/stock.adobe.com

Increase coordinated communication of transparent information on diagnostic testing through reliable and trusted sources.

Misinformation and mistrust of government can hinder efforts to respond to a public health emergency. Experts suggested HHS should increase coordinated communication of transparent information on diagnostic testing through reliable and trusted sources. Such communication can help combat misinformation, according to one expert. For instance, one expert said the COVID-19 public health emergency demonstrated the importance of trusted messengers embedded within local communities. Another expert said it is also important that CDC communicate testing information with hospitals and professional organizations, such as the Infectious Disease Society of America, so that their websites display consistent testing information.

Related recommendations

In November 2021, the National Academies recommended governments engage the community in making and communicating decisions about public health measures.[xiv] This included engaging grassroots organizations, spiritual leaders, teachers, and sports coaches in the community.



HHS response

NIH and CDC officials responded to this action. NIH officials agreed that increasing coordinated communication through reliable and trusted sources is an effective strategy. During the COVID-19 public health emergency, RADx projects emphasized that trusted community members and organizations, including faith-based organizations, may serve as a highly accessible

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Increase coordinated communication of transparent information on diagnostic testing through reliable and trusted sources. (continued)

HHS response (continued)

setting in which to provide reliable information on testing. For example, in one project officials described, researchers and faith leaders created a comprehensive toolkit that included sermon guides, responsive readings, church bulletins, Bible bookmarks, and testimonials from people who received COVID-19 testing. This project resulted in more than 300 COVID-19 tests performed during or after Sunday church services and outreach ministry activities, according to officials.

CDC officials added that CDC generally provides diagnostic testing guidance to laboratories and health care facilities. However, CDC may also work with other federal agencies, professional organizations, jurisdictions, and other public health partners to tailor messaging for specific health care settings or providers, according to officials. During the COVID-19 public health emergency, CDC and CMS provided ongoing outreach to health care facilities, providers, laboratories, and the public, officials said. CDC is continuing to improve its communications processes as part of CDC Moving Forward, according to officials, including leveraging multiple communication streams to share scientific findings and data. CDC Moving Forward is an ongoing agency-wide initiative to transform and modernize how the agency operates through the implementation of more than 160 key actions identified by CDC staff and leadership.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Partner with news and social media outlets to advertise important diagnostic testing information.

Providing clear and timely testing information to the public is an important component of responding to a public health emergency. Experts suggested HHS should partner with news and social media outlets to advertise important diagnostic testing information, particularly what to expect from the test, where and how to access testing, and what to do with a test result. One expert noted that it may be difficult to advertise important diagnostic testing information for every vulnerable community. Additional difficulties experts mentioned include the overall pervasiveness of misinformation, lack of funding to address misinformation, and the consequences of misinformation (e.g., public officials receiving death threats). One possibility for HHS to consider would be a workforce tasked with communicating reliable, important diagnostic testing information, according to an expert.

HHS response

CDC officials noted some benefits and challenges to using the news and social media for communicating with the public. Benefits mentioned included reaching a wide audience quickly and enabling real-time communication with the public. These benefits provide an opportunity to address misinformation, combat rumors, and correct misconceptions, officials said. CDC regularly posts information on social media, suggests stories to media outlets, and responds to queries from reporters, according to officials. Among the challenges mentioned were the ability for misinformation to spread rapidly and the lack of accessibility for individuals without reliable internet connectivity or the digital literacy skills to navigate social media platforms effectively.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Provide better communication about diagnostic testing materials provided by the federal government to gain community trust.

Lack of transparency about testing science can create confusion and decrease confidence in the federal government, hindering response efforts. Experts suggested HHS should provide better communication about diagnostic testing materials provided by the federal government to gain community trust. During the COVID-19 public health emergency, HHS sent letters to jurisdictions authorizing the use of expired diagnostic tests provided by the federal government, but, according to one expert, the lack of scientific justification for this change led to decreased confidence among providers and laboratory staff. This expert said HHS should clearly communicate that there are times when using expired diagnostic test materials is appropriate during a pandemic and that such materials can still be reliable enough to be used for proper testing. Better communication from HHS in this regard could help instill the trust necessary for public health partners to utilize these materials.

Related recommendations

In November 2021, the National Academies recommended PHEMCE establish mechanisms for transparent communications across the government and with nonfederal and private sector partners and the public.[xix]

HHS response

ASPR officials said they previously explained to jurisdictions the reasoning for using expired diagnostic tests for the at-home program during the COVID-19 public health emergency, and justified their use of expired tests with FDA and manufacturers through web links and communications campaigns. However, ASPR officials said they have never provided expired diagnostic materials to end-users as part of their test distribution programs.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Photo: DisobeyArt/stock.adobe.com

Provide transparency about where diagnostic test kits are going to be deployed.

Lack of transparency regarding federal testing efforts can lead to confusion, hindering the response to the public health emergency. Experts suggested that HHS should provide transparency about where diagnostic test kits are going to be deployed. When supplies were limited during the COVID-19 public health emergency, many jurisdictions had difficulty tracking federal distribution of tests to their at-risk communities, according to one expert. Providing additional transparency would make it easier to identify locations where additional state and local distribution of tests is needed and reduce the risk of over-supplying a given location, according to this expert.

HHS response

ASPR officials noted that ASPR maintains a tracker for all diagnostic materials that were shipped. The tracker includes zip codes and county codes for all materials, according to officials. The amount and type of diagnostic supplies shipped to jurisdictions was provided to each jurisdiction upon request or at an interval requested by the jurisdiction, officials said. There is no formal process for communicating this information to the state and local governments, according to ASPR officials.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Photo: Artinun/stock.adobe.com

Communicate diagnostic testing supply chain issues to the private sector.

Shortages of key testing supplies can contribute to delays in widespread testing. Experts suggested that HHS should increase communication between the federal government and private sector to mitigate potential diagnostic test supply chain issues. Currently, private industry has difficulty gathering insight into how various conflicts, such as geopolitical disputes, might disrupt the supply of diagnostic testing materials, according to one expert. This expert suggested HHS could establish a program similar to the Health Care Information Sharing and Analysis Center, which is a non-profit organization that provides information about cybersecurity threats to its members, who are private sector health care entities. A similar model could be adopted from a supply chain perspective with a formalized mechanism for information sharing on supply chain issues.

Related recommendations

GAO, HHS-OIG, and the National Academies have made related recommendations. In January 2021, GAO recommended that ASPR establish a process for regularly engaging nonfederal stakeholders as HHS refines and implements a supply chain strategy for pandemic preparedness.[xiii] ASPR generally agreed with this recommendation and implemented it by formalizing its stakeholder engagement efforts in its strategy for the SNS. In September 2022, HHS-OIG recommended that FDA establish formal communication channels between FDA and the laboratory community, to be used in emergencies that require testing.[i] According to HHS-OIG, in April 2024, FDA implemented this recommendation. In November 2021, the National Academies recommended that PHEMCE establish mechanisms for transparent communications across the government, nonfederal and private-sector partners, and stakeholders and the public.[xix]

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Communicate diagnostic testing supply chain issues to the private sector. (continued)

HHS response

FDA and ASPR officials responded to this action, noting efforts in this area. For example, FDA is required to maintain a list of certain medical devices that are currently in shortage.[xx] FDA developed a list of devices for which manufacturers are required to notify the FDA of a permanent discontinuance or interruption in manufacturing during or in advance of a public health emergency.[xxi] However, FDA does not currently have the authority to require notifications outside of a public health emergency. FDA also routinely communicates with private sector partners about supply chain disruptions and shortages, including potential systemic supply chain disruptions from extreme weather, geopolitical conflicts, and other events. In addition, FDA officials said that because of its regulatory role, FDA has unique visibility into the supply chain across medical devices, providing its medical device subject matter experts with the ability to identify potential alternatives and mitigations when a supply chain disruption occurs. Officials at FDA noted that this communication is effective in helping mitigate shortages that affect patients.

Officials from ASPR also described ASPR's Supply Chain Control Tower, which works directly with distributors to engage and obtain industry insights on supply chain disruptions for select medical products that are critical to support public health emergencies. ASPR officials said it is anticipated that during times of declared public health emergencies, most major distributors will voluntarily share detailed transactional data with the Supply Chain Control Tower to allow increased supply chain visibility. This will enable the monitoring of diagnostic tests and discussions on any potential supply chain vulnerabilities, according to ASPR officials. At the time of our review, diagnostic tests were not on this list. ASPR officials said despite this, they could still determine potential courses of action to assist with downstream availability and accessibility.

Communicate information about the deployment of diagnostic testing to the public and private sector, as well as jurisdictions

Develop a mechanism to notify skilled nursing facility staff and other clinicians and pharmacists of point-of-care diagnostic testing for new emerging infectious diseases, and provide information on the correct way to perform testing.

One expert noted that the scarcity of testing education can lead to faulty diagnostic test results, as happened early in the COVID-19 public health emergency. Experts suggested HHS should develop a mechanism to notify skilled nursing facility staff, other clinicians, and pharmacists of point-of-care diagnostic testing for new emerging infectious diseases. Experts also suggested HHS provide information on the correct way to perform the testing to these clinicians and pharmacists. While CDC has previously used email notifications through the Health Alert Network to reach individuals with licenses or billing numbers, this process took an extended period of time with limited outreach, experts said. According to the experts, HHS does not have a mechanism to educate all types of providers on the correct way for clinicians to administer diagnostic tests for new infectious diseases.

HHS response

CDC officials said that CDC generally provides diagnostic testing guidance to laboratories and health care facilities and may also work with other federal agencies, professional organizations, jurisdictions, and other public health partners to tailor messaging for specific health care settings or providers. During the COVID-19 public health emergency, CDC and CMS provided ongoing outreach to health care facilities, providers, laboratories, and the public, CDC officials said. CDC is continuing to improve its communications processes as part of CDC Moving Forward, according to officials, including leveraging multiple communication streams to share scientific findings and data.

Photo: Andrey Popov/stock.adobe.com

Prepare in advance for diagnostic testing fraud

- Make diagnostic testing fraud prevention part of pandemic preparedness planning.

Prepare in advance for diagnostic testing fraud

Make diagnostic testing fraud prevention part of pandemic preparedness planning.

Fraud related to diagnostic testing was a challenge during the COVID-19 pandemic. Experts suggested that HHS should make diagnostic testing fraud prevention part of pandemic preparedness planning. For example, HHS could prepare advance communications for the public on how to identify real testing sites and educate law enforcement about the signs of illegal or fraudulent tests, according to experts. HHS could also conduct advance planning to avoid double billing for tests.

HHS response

FDA and CMS officials responded to this action. FDA officials described steps the agency takes to protect against diagnostic testing fraud, including educating the public, taking necessary enforcement actions, and using regulatory tools, such as import alerts, to prevent entrance of fraudulent tests into the United States. For example, FDA published a statement on its website warning consumers about unauthorized, fraudulent COVID-19 test kits, and posted a series of safety communications about specific COVID-19 test kits to avoid.

CMS officials added that CMS continually assesses new risks of fraud, waste, and abuse, including those that would occur during a pandemic, through its Vulnerability Collaboration Council—the centralized component of CMS's vulnerability management process. This council is composed of CMS leadership and subject matter experts who work collaboratively to identify and mitigate vulnerabilities in payment and coverage policies. CMS officials also noted the importance of public education in combating fraud, waste, and abuse. CMS maintains a webpage with fraud reporting resources and, officials said, will continue to educate the general public and Medicare beneficiaries throughout future public health emergencies. During the COVID-19 public health emergency, officials said CMS also provided information about testing fraud through emails, phone calls, and via CMS public information campaigns.

Guidance

Ensure guidance is realistic for various test settings and populations.

- Seek external feedback, including from front-line providers, on implementation before finalizing diagnostic testing guidance.
- Tailor diagnostic testing guidance to specific settings.
- Consider implementation challenges for vulnerable and underserved populations.

Increase accessibility of diagnostic testing guidance

- Translate diagnostic testing guidance into multiple languages for dissemination.
- Develop versions of diagnostic testing guidance that are accessible to people with vision and hearing impairments.
- Ensure that diagnostic testing guidance is written at an appropriate reading level for general public comprehension.

Plan for how diagnostic testing guidance will be updated over time

- Establish and communicate a process for determining the amount of new information needed to trigger new public guidance.
- Develop a website that communicates real-time updates of diagnostic testing guidance to the public.
- Revise policies to allow diagnostic test developers, in collaboration with the Food and Drug Administration, to provide additional information on the different ways antigen test results can be used.

Continue and expand communication with stakeholders on diagnostic testing guidance

- Continue offering educational webinars and calls for health care professionals through existing Centers for Disease Control and Prevention programs.
- Increase communication with health care systems and hospitals when updating diagnostic testing guidance.
- Ensure coordination of diagnostic testing guidance with Tribal Nations and Tribal Epidemiology Centers.

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Ensure guidance is realistic for various test settings and populations

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- Tailor diagnostic testing guidance to specific settings.
- Consider implementation challenges for vulnerable and underserved populations.

Ensure guidance is realistic for various test settings and populations

Seek external feedback, including from front-line providers, on implementation before finalizing diagnostic testing guidance.

Stakeholders previously described difficulties implementing diagnostic testing guidance. Experts suggested HHS should seek feedback about its diagnostic testing guidance from external partners who can provide perspective on the feasibility of its implementation. Seeking this feedback before finalizing the guidance could prevent the need for future revisions by ensuring the guidance is practical and possible to implement, according to experts. Experts suggested that front-line providers, professional societies, and health care administrators could offer this kind of feedback. However, one expert noted a possible tradeoff between seeking and incorporating feedback and releasing guidance quickly.

Related recommendations

GAO and the National Academies have made recommendations related to the importance of engaging stakeholders in public health emergency response efforts, which could include diagnostic testing guidance. In September 2020 and January 2021, GAO recommended that HHS engage with stakeholders on a number of issues related to response efforts, including the implementation of its supply chain strategy and CDC's Health Equity Strategy.[xxii, xiii] Seeking feedback from stakeholders on diagnostic testing guidance would align with these recommendations. HHS generally concurred with these recommendations and has implemented them. Regarding HHS's supply chain strategy, ASPR formalized its stakeholder engagement efforts in its strategy for the SNS. Regarding stakeholder engagement on CDC's Health Equity Strategy, CDC reported collecting information from listening sessions with community health workers, among other actions. Additionally, in November 2021, the National Academies recommended that HHS use external stakeholders to inform its public health preparedness efforts.[xix]

HHS response

CDC developed and launched the Public Health Guidance Development Framework in 2023, which encourages engagement with external stakeholders during the development of public health guidance, according to CDC officials. Officials said that while the framework has been adapted for use in public health emergencies, there may not be enough time during such emergencies for robust engagement of external stakeholders before the release of guidance.

Ensure guidance is realistic for various test settings and populations

Tailor diagnostic testing guidance to specific settings.

General guidance may not be appropriate for specific settings. Experts suggested HHS should tailor diagnostic testing guidance to certain care settings, such as long-term care facilities. In tailoring the guidance, experts said HHS would be able to include practical considerations for these settings. Experts reiterated that when drafting this guidance, HHS should seek feedback from stakeholders with experience in these facilities, such as providers.

Related recommendations

HHS-OIG and the National Academies have made related recommendations. In February 2024, HHS-OIG recommended that CMS provide guidance to nursing homes related to various infection control requirements, including diagnostic testing.[xxiii] According to HHS-OIG, as of February 2025, CMS has not implemented this recommendation. Additionally, the National Academies recommended in November 2021 that national governments develop readily implementable plans for infectious disease response that take into consideration the needs of specific populations, like those in long-term care facilities.[xiv]

HHS response

CDC's diagnostic testing guidance is intended to be broadly applicable to various settings and facilities, according to CDC officials. However, the officials noted that when needed, they may work with other federal agencies and public health partners to provide additional information for specific settings. During the COVID-19 public health emergency, for example, CDC and CMS worked together to provide additional information to long-term care facilities.

Ensure guidance is realistic for various test settings and populations

Consider implementation challenges for vulnerable and underserved populations.

General guidance may not be applicable or accessible to all populations. Experts suggested HHS should consider challenges faced by vulnerable and underserved populations, such as homeless, rural, and tribal populations, when developing diagnostic testing guidance. For example, one expert said that early guidance instructed users to wash their hands before using an at-home diagnostic test. However, this expert explained that certain tribal populations, as well as homeless populations, do not always have ready access to running water for handwashing. Another expert noted that some rural populations lack internet access, which limits their ability to access web-based guidance.

Related recommendations

In November 2021, the National Academies recommended that governments should take into consideration factors such as these when developing public health interventions.[xiv]

HHS response

CDC and NIH officials responded to this action. CDC officials said that consistently addressing the unique needs of disproportionately affected populations is part of its strategy to address public health threats. In future public health emergencies, officials said CDC will strive to provide guidance that is responsive to the needs of specific populations, such as individuals experiencing homelessness, rural and tribal populations, and individuals working and living in correctional facilities.

Additionally, NIH officials said this action aligned with strategies used in the RADx initiative during the COVID-19 public health emergency. Across the RADx initiative, researchers collaborated with communities to target outreach to underserved and vulnerable communities, according to officials. NIH officials referenced two specific research projects they funded that examined barriers to testing in rural areas, including one Tribal Nation.

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Increase accessibility of diagnostic testing guidance

- Translate diagnostic testing guidance into multiple languages for dissemination.
- Develop versions of diagnostic testing guidance that are accessible to people with vision and hearing impairments.
- Ensure that diagnostic testing guidance is written at an appropriate reading level for general public comprehension.

Increase accessibility of diagnostic testing guidance

Photo: CDC

Translate diagnostic testing guidance into multiple languages for dissemination.

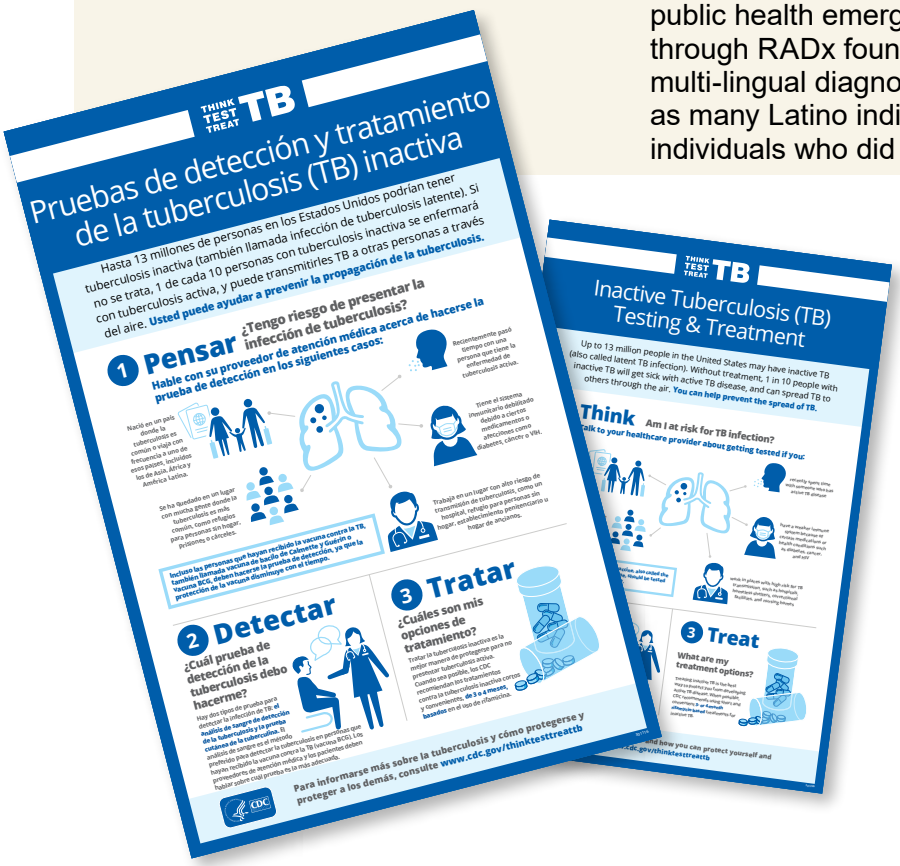
Guidance is not always accessible to non-English speaking populations. Experts suggested HHS should translate its diagnostic testing guidance into different languages. One expert said that this could improve efficiency, noting that during the COVID-19 public health emergency, health care systems would receive guidance and then need to arrange for its translation before being able to use it with non-English speaking populations.

Related recommendations

In November 2021, the National Academies recommended that national governments develop readily implementable plans for infectious disease response that take into consideration the needs of specific populations.[xiv]

HHS response

CDC and NIH officials responded to this action. CDC regularly translated materials into other languages during the COVID-19 public health emergency, such as translating web-based guidance and information for patients into Spanish, according to CDC officials. Additionally, NIH officials agreed with this action, noting that interventions funded by the RADx initiative supported its effectiveness. For example, during the COVID-19 public health emergency, a randomized controlled trial funded through RADx found that culturally informed outreach, including multi-lingual diagnostic testing guidance, led to nearly four-times as many Latino individuals being tested compared to Latino individuals who did not receive such outreach.



Increase accessibility of diagnostic testing guidance

Develop versions of diagnostic testing guidance that are accessible to people with vision and hearing impairments.

General guidance may not be accessible to people with disabilities. Experts suggested HHS should adapt diagnostic testing guidance to ensure its accessibility to people with vision and hearing impairments, such as low-vision and deafness.

Related recommendations

In November 2021, the National Academies recommended that national governments develop readily implementable plans for infectious disease response that take into consideration the needs of specific populations, especially marginalized populations such as those with disabilities.[xiv]

HHS response

CDC and NIH officials responded to this action. CDC officials agreed with the importance of making diagnostic testing guidance accessible and indicated that the agency has taken steps related to this action. For example, in 2021, CDC partnered with HHS's Administration for Community Living to launch the Disability Information and Access Line. This service helped people with disabilities access COVID-19 testing, including more accessible antigen tests. CDC also created videos in American Sign Language, including some that provided information related to COVID-19 diagnostic testing.

Additionally, NIH officials agreed that this action would be effective. They noted that during the COVID-19 public health emergency, NIH convened a listening session through the RADx initiative to better understand the challenges with antigen tests for people with disabilities. The findings from this panel and additional work were published in a document on best practices for the design of accessible COVID-19 tests.[xxiv] While complying with these best practices is voluntary, as of June 2024, NIH officials said there is one authorized COVID-19 test on the market utilizing these best practices and that others are in development. Officials noted that while these examples are specific to COVID-19, the substance of these best practices could be applied to diagnostic testing more broadly.

Increase accessibility of diagnostic testing guidance

Ensure that diagnostic testing guidance is written at an appropriate reading level for general public comprehension.

Guidance can be difficult for the public to understand. Experts suggested HHS should ensure that diagnostic testing guidance intended for use by the general public be written at an appropriate reading level. One expert observed that diagnostic testing guidance for diseases such as Ebola, Zika, and COVID-19 was not written in common language that could be understood by the general public.

Related recommendations

In November 2021, the National Academies recommended that national governments develop readily implementable plans for infectious disease response that take into consideration the needs of specific populations.[xiv]

HHS response

CDC officials noted that diagnostic testing guidance is generally targeted to public health laboratories and health care facilities, while other guidance is developed for the general public. This action as suggested by experts aligned with several agency efforts, including sharing scientific findings and data faster, ensuring guidance is clear and easily adaptable, and prioritizing public health communications, according to CDC officials.

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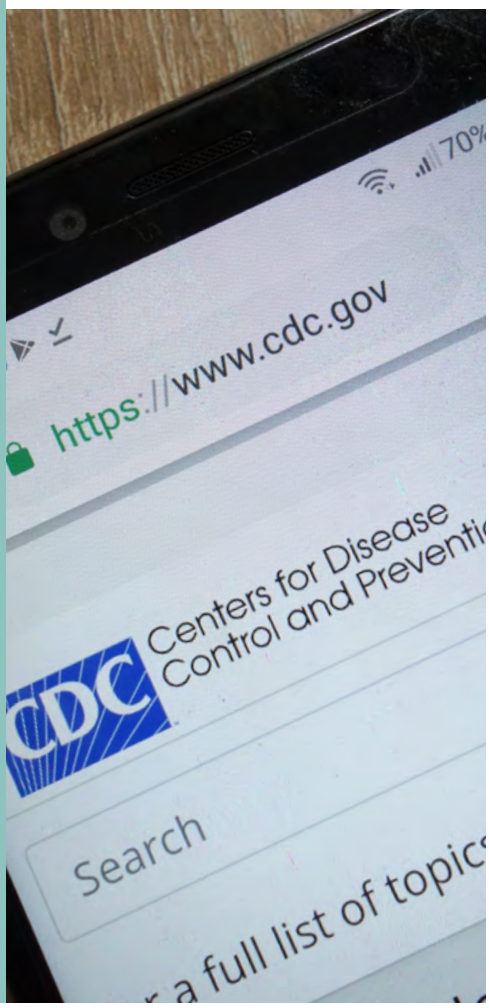
Plan for how diagnostic testing guidance will be updated over time



- Establish and communicate a process for determining the amount of new information needed to trigger new public guidance.
- Develop a website that communicates real-time updates of diagnostic testing guidance to the public.
- Revise policies to allow diagnostic test developers, in collaboration with the Food and Drug Administration, to provide additional information on the different ways antigen test results can be used.

Plan for how diagnostic testing guidance will be updated over time

Establish and communicate a process for determining the amount of new information needed to trigger new public guidance.

Frequent changes in guidance can lead to confusion about the reason for these changes. Experts suggested HHS should establish in advance and communicate a process for determining when diagnostic testing guidance will be updated based on new information. One expert said this action is important because the public may misinterpret changes to diagnostic testing guidance as due to indecision or bad information. Sharing a plan with the public about when and under what circumstances guidance will be updated would help manage public expectations, according to another expert.

Related recommendations

GAO, HHS-OIG, and the National Academies made recommendations related to transparency in communications. GAO recommended in November 2020 that CDC clearly disclose the scientific rationale for changes in diagnostic testing guidance. HHS concurred with this recommendation, which CDC implemented by creating a public health guidance development framework that describes the importance of providing scientific evidence to support public health guidance, such as diagnostic testing guidance updates.[xxv] Additionally, in May 2024, GAO recommended that ASPR develop procedures outlining how and when guidance documents will be updated. HHS concurred with this recommendation. As of February 2025, it had not yet been implemented.[xxvi] In October 2022, HHS-OIG recommended, in part, that CDC should document how it will assess and adjust its implementation of travel-related containment measures as more information is gathered about an infectious disease.[xxvii] According to HHS-OIG, as of February 2025, CDC has not implemented this recommendation. Additionally, in November 2021, the National Academies noted the importance of transparent communication mechanisms broadly.[xix]

HHS response

CDC officials stated that any criteria for determining the amount of new information needed to trigger additional updated guidance will vary based on the specific public health emergency. It is not possible to determine the amount of new information needed prior to the emergency, according to CDC officials.

Plan for how diagnostic testing guidance will be updated over time

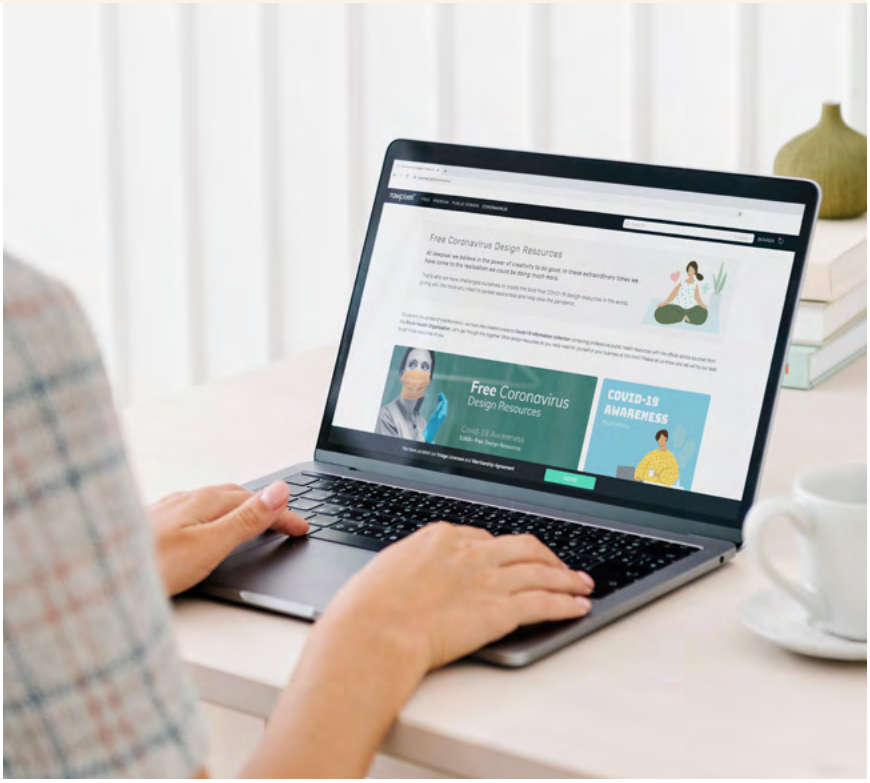
Photo: Rawpixel.com/stock.adobe.com

Develop a website that communicates real-time updates of diagnostic testing guidance to the public.

Updates to guidance during an evolving public health emergency can be difficult to communicate. Experts suggested HHS should develop a website that publishes real-time updates of diagnostic testing guidance to the public. One expert noted that one professional society used a similar strategy, which the expert found helpful. According to another expert, such communication would ensure that the public can see when there have been changes, and what those changes are, in an efficient way.

HHS response

CDC officials said that during the COVID-19 public health emergency, CDC published regular guidance for COVID-19 testing on its website, while HHS maintained a website with public information about accessing free diagnostic tests.[xxviii]



Plan for how diagnostic testing guidance will be updated over time

Revise policies to allow diagnostic test developers, in collaboration with FDA, to provide additional information on the different ways antigen test results can be used.

Keeping up with changing information in an evolving public health emergency can be challenging. Experts suggested HHS—specifically, FDA—should consider ways to provide additional information to the public about how results from diagnostic testing can be used over time. One expert described how, during the COVID-19 public health emergency, science evolved to support additional uses of antigen test results, such as serial testing, where people take additional diagnostic tests after receiving an initial negative test result to confirm their status. However, diagnostic test manufacturers were limited by the FDA-approved label, which did not describe this use. This expert suggested that a more flexible process could allow for more information about the use of diagnostic test results to be shared with consumers as science evolves during a public health emergency.

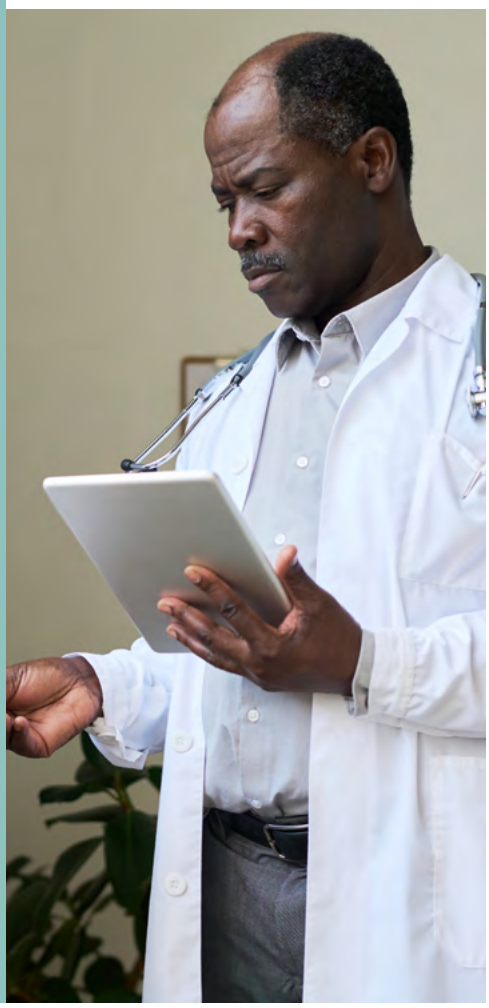
HHS response

FDA officials said that EUAs for diagnostic tests included a condition that test manufacturers could make additional information available to users. Officials also noted that FDA recently issued draft guidance regarding the factors it would use in the future when deciding whether to issue an enforcement policy for devices under an EUA.[ii] This would include enforcement policies related to the unapproved use of approved tests, such as for different purposes than originally intended.

FDA officials also said that one lesson learned during the COVID-19 public health emergency was the need for continuing education of the public about appropriate uses of different diagnostic tests, such as antigen and PCR tests, for different purposes. Officials said that it was important to provide this information to both physicians and communities.

Photo: pressmaster/stock.adobe.com

Continue and expand communication with stakeholders on diagnostic testing guidance



- Continue offering educational webinars and calls for health care professionals through existing Centers for Disease Control and Prevention programs.
- Increase communication with health care systems and hospitals when updating diagnostic testing guidance.
- Ensure coordination of diagnostic testing guidance with Tribal Nations and Tribal Epidemiology Centers.

Continue and expand communication with stakeholders on diagnostic testing guidance

Continue offering educational webinars and calls for health care professionals through existing CDC programs.

Provider and public health stakeholders have expressed that frequent changes to guidance can lead to confusion. Experts suggested HHS—specifically, CDC—should continue its existing educational efforts that target health care professionals, such as the Clinician Outreach and Communication Activity, the Laboratory Outreach Communication System, and joint webinars with the Infectious Disease Society of America. Experts said this outreach is useful to communicate with specific audiences, such as clinicians and public health professionals. One expert noted that these efforts were particularly successful during the COVID-19 public health emergency because they combined communications for specific groups within the health care sector, with the broader, consistent messaging coming out of CDC.

Related recommendations

In July 2020, the National Academies recommended that CDC use strategies to ensure that its recommendations reach its target audiences.[xxix] The National Academies suggested this could be done in several ways, including through publishing in CDC communications platforms and partnering with professional organizations to disseminate information.

HHS response

CDC has used the Clinician Outreach and Communication Activity and the Laboratory Outreach Communication System, as well as other methods, to foster collaboration and consistent messaging during public health response efforts, according to officials. Other methods used include briefings, webinars, and communication toolkits.

Continue and expand communication with stakeholders on diagnostic testing guidance

Photo: tuastockphoto/stock.adobe.com

Increase communication with health care systems and hospitals when updating diagnostic testing guidance.

Guidance may change frequently, necessitating changes in clinical practice. Experts suggested HHS should increase communication with health care systems and hospitals around diagnostic testing guidance updates, similar to how they communicate with jurisdictional health departments. One expert noted that during the COVID-19 public health emergency, CDC had regular calls with jurisdictional health departments at which they would share impending updates to current guidance and highlight specific changes. According to this expert, establishing similar practices to share updated guidance with health care systems and hospitals would allow these entities to adapt any updated guidance more quickly to their settings and communicate that information to their staff and patients.

Related recommendations

In July 2024, GAO recommended that CDC should document its intention to share certain finalized public health guidance with entities responsible for its implementation ahead of public release.[xxx] Doing so would enhance understanding and support quick implementation, which is essential during a public health response. HHS agreed with this recommendation, which CDC implemented by documenting its plan to share an embargoed copy of updated public health guidance with those who will implement it at least 24 hours in advance of its release.

HHS response

CDC is continuing to improve their communications by leveraging multiple communication streams and prioritizing public health communications, according to officials. During the COVID-19 public health emergency, CDC utilized their extensive network across health care settings to conduct ongoing outreach to health care facilities, providers, laboratories, and the public, according to officials.

Continue and expand communication with stakeholders on diagnostic testing guidance

Photo: Rosemarie Mosteller/stock.adobe.com

Ensure coordination of diagnostic testing guidance with Tribal Nations and Tribal Epidemiology Centers.

Sovereign Tribal Nations can enact different laws and policies than what is being enacted in the states. Experts suggested HHS should ensure coordination with Tribal Nations and Tribal Epidemiology Centers when developing diagnostic testing guidance. Without coordination with HHS, there may be inconsistencies in policies among tribal populations.

HHS response

NIH and CDC officials responded to this action. NIH officials agreed this was an effective and necessary strategy. They noted that their RADx initiative emphasized tribal sovereignty. NIH funded several projects that were guided by Tribes, according to officials, such as one project in which schools decided on COVID-19 testing strategies in collaboration with tribal governments and jurisdictional public health departments. Additionally, CDC officials said diagnostic testing guidance is intended for broad use by various laboratories and health care facilities, which would include tribal facilities and Tribal Epidemiology Centers.

Data Collection

Seek and exercise new authorities related to diagnostic testing data collection

- Seek legislation granting the Centers for Disease Control and Prevention (CDC) the authority to mandate that jurisdictions report diagnostic testing data.
- Seek legislative authority to enforce any requirements for jurisdictions to report race and ethnicity data related to diagnostic testing.

Increase standardization of diagnostic testing data collection

- Establish common and standardized demographic data elements for diagnostic testing data.
- Ensure that standardized demographic data elements align with best practices for the collection of race and ethnicity data.
- Continue efforts to standardize submission of any required diagnostic testing data across jurisdictions.
- Require reporting mechanisms for at-home diagnostic tests.

Increase efficiency in the collection of diagnostic testing data

- Continue to prioritize funding for CDC's Data Modernization Initiative.
- Establish a process for the direct, centralized reporting of diagnostic testing data to CDC.
- Support the integration of diagnostic testing data collection and reporting into existing workflows.
- Prioritize the collection of diagnostic testing data needed to inform the deployment of testing resources into communities.
- Consider collecting diagnostic testing data from sources already connected to the federal government.
- Establish preapproved data use agreement templates for diagnostic testing.

Build and expand partnerships with nonfederal entities around diagnostic testing data collection

- Build partnerships with health information exchanges to address incomplete demographic elements in diagnostic testing data.

Build and expand partnerships with nonfederal entities around diagnostic testing data collection (continued)

- Work with Tribal Nations to ensure that Tribal Epidemiology Centers have access to federal diagnostic testing data as required by law.
- Build partnerships with external entities to collect demographic data from diagnostic testing at traditional and non-traditional test sites.

Photo: Bill Perry/stock.adobe.com

Seek and exercise new authorities related to diagnostic testing data collection

- Seek legislation granting the Centers for Disease Control and Prevention (CDC) the authority to mandate that jurisdictions report diagnostic testing data.
- Seek legislative authority to enforce any requirements for jurisdictions to report race and ethnicity data related to diagnostic testing.

Seek and exercise new authorities related to diagnostic testing data collection

Seek legislation granting CDC the authority to mandate that jurisdictions report diagnostic testing data.

CDC receives diagnostic testing data based on individual, voluntary data-sharing agreements with jurisdictions. Experts suggested HHS should seek legislation that would give CDC the authority to mandate that jurisdictions report diagnostic testing data. Otherwise, experts said, CDC faces the challenge of being expected to report diagnostic testing data on behalf of the federal government, but does not have the authority to require jurisdictions to submit such data. Some related authority may be granted during public health emergencies, but does not exist outside of such circumstances. For example, during the COVID-19 public health emergency, the CARES Act required laboratories to submit COVID-19 diagnostic testing data.[xxxi] However, this requirement expired at the end of the COVID-19 public health emergency.

HHS response

CDC officials said that new data authority would allow for better quality and timely data reporting, while reducing burden on providers. HHS's fiscal year 2025 budget proposal included a legislative proposal to provide the department with such authority.

Seek and exercise new authorities related to diagnostic testing data collection

Seek legislative authority to enforce any requirements for jurisdictions to report race and ethnicity data related to diagnostic testing.

Accurate data on race and ethnicity are important to identify and address disparate impacts on certain populations during a public health emergency. Experts suggested HHS should seek legislative authority to enforce any requirements that are implemented to report race and ethnicity data to the federal government. During the COVID-19 public health emergency, the CARES Act required laboratories to submit COVID-19 diagnostic testing data to CDC, including patient race and ethnicity.[xxxii] Despite this requirement, HHS faced challenges in collecting complete race and ethnicity data. Experts suggested this was due, in part, to a lack of an accountability mechanism within the requirement to ensure compliance. Without including accountability mechanisms in any new diagnostic testing data requirements, HHS could encounter the same incomplete data challenges in future public health emergencies.

Related recommendations

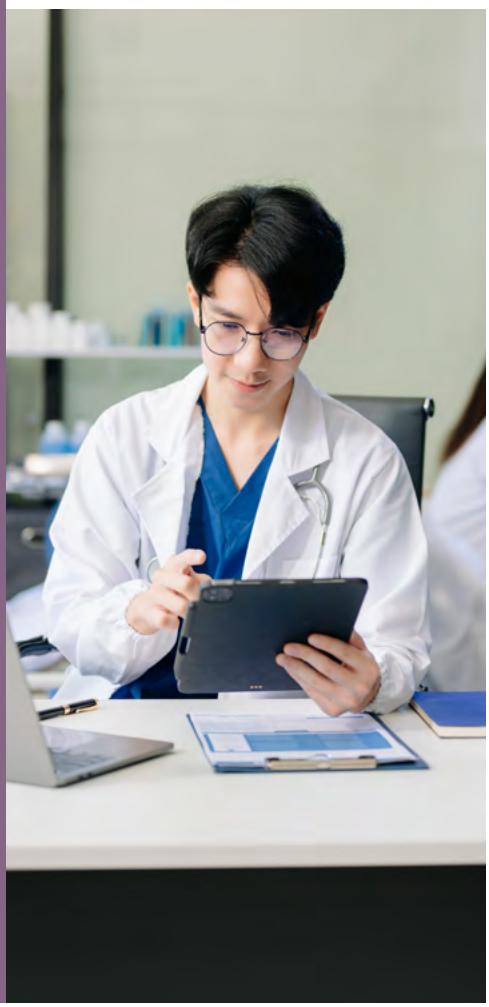
GAO and the National Academies have made related recommendations. In September 2020, GAO recommended that CDC determine whether having the authority to require jurisdictions to report race and ethnicity information for COVID-19 cases is necessary for ensuring more complete data, and if so, seek such authority from Congress.[xxii] CDC agreed with this recommendation, and in 2021, the agency determined that such additional legal authorities would improve race and ethnicity information for diseases. In its budget proposals for fiscal years 2024 and 2025, HHS requested new data authorities from Congress.[xxxiii] Additionally, in November 2021, the National Academies recommended that national public health agencies, such as CDC, work toward removing any barriers to making full and accurate data reports.[xiv]

HHS response

HHS officials did not have any comments regarding this action.

Photo: Nuttapong punna/stock.adobe.com

Increase standardization of diagnostic testing data collection



- Establish common and standardized demographic data elements for diagnostic testing data.
- Ensure that standardized demographic data elements align with best practices for the collection of race and ethnicity data.
- Continue efforts to standardize submission of any required diagnostic testing data across jurisdictions.
- Require reporting mechanisms for at-home diagnostic tests.

Increase standardization of diagnostic testing data collection

Establish common and standardized demographic data elements for diagnostic testing data.

During the COVID-19 public health emergency, HHS collected incomplete and inconsistent diagnostic testing data. Experts suggested HHS should establish common and standardized data elements to use for diagnostic testing data, especially for race and ethnicity data fields. For example, CDC data reporting instructions for COVID-19 generally used standard race and ethnicity categories established by the Office of Management and Budget. However, jurisdictions could choose to use different categories or implement these categories in different ways, such as by combining categories.[xxxiv] Experts said that the use of common data elements for demographic characteristics would help providers and researchers collect and report complete and consistent data.

Related recommendations

GAO, HHS-OIG, and the National Academies have made related recommendations. GAO and the National Academies, in January 2021 and July 2020, respectively, recommended the alignment and standardization of data collected during public health emergencies.[xiii, xii] HHS partially concurred with GAO's recommendation in this area. Additionally, in July 2022, HHS-OIG recommended during the COVID-19 pandemic that CDC expand its efforts to improve its collection of race and ethnicity data, which could include encouraging or incentivizing jurisdictions to use the Office of Management and Budget's standard race and ethnicity categories.[xxxiv] According to HHS-OIG, in February 2025, CDC implemented this recommendation.

HHS response

CDC, FDA, and NIH officials responded to this action. Specifically, CDC officials agreed that standardized data elements are important during a public health emergency and indicated the agency has taken steps related to this action. CDC established the minimal data set needed for public health emergency response for laboratory diagnostic testing data, which included demographic data elements, according to officials. CDC officials also said this data set is being further developed as part of an initiative to establish and advance the use of interoperable public health data elements through the Office of the National Coordinator for Health Information Technology. However, officials noted that there are difficulties implementing such standards because test orders that health care providers send to laboratories often do not include demographic data.

Additionally, both FDA and NIH identified efforts in this area, though FDA officials noted that implementing such standards

Increase standardization of diagnostic testing data collection

Establish common and standardized demographic data elements for diagnostic testing data. (continued)

HHS response (continued)

across federal, state, and local levels has been difficult. For example, NIH maintains the Common Data Element Repository, a freely available source of standard, structured, machine-readable definitions of data elements, variables, and measures used in NIH-funded clinical research. This repository includes common demographic data elements, such as race and ethnicity, for COVID-19 research. One expert from the roundtable we convened discussed working on an NIH-funded initiative and said the common data elements were helpful in standardizing the collection of demographic information.

Increase standardization of diagnostic testing data collection

Photo: Bavorndej/stock.adobe.com

Ensure that standardized demographic data elements align with best practices for the collection of race and ethnicity data.

Accurate data on race and ethnicity are important to identify and address disparate impacts on certain populations during a public health emergency. Experts suggested HHS should ensure that any common and standardized data elements they establish align with best practices for collecting data on race and ethnicity. One expert explained that using a single race category, instead of allowing participants to select multiple racial identities, could distort results. This expert gave the example of the category used for the American Indian and Alaska Native population. According to the expert, this category counts those who identify as only American Indian and Alaska Native, which leaves out individuals within the American Indian and Alaska Native population who are multiracial. Such exclusion could decrease resource allocation to this group.

Related recommendations

In January 2021, GAO recommended that HHS consult with an expert committee to inform its reporting standards for key health indicators.[xiii] HHS partially concurred with this recommendation and implemented it by taking steps to involve external stakeholders in its efforts to prepare for data collection and reporting standards in future pandemics.

HHS response

CDC and NIH officials responded to this action. CDC officials said that current national laboratory data exchange standards include the ability to record multiple racial identities. NIH officials also reported that when developing common data elements recommended or required in their funded research, they consider factors such as multi-dimensional identities and hesitancy to share certain demographic information. The common data elements maintained by NIH include a category for “more than one race” as well as “prefer not to answer.”

Increase standardization of diagnostic testing data collection

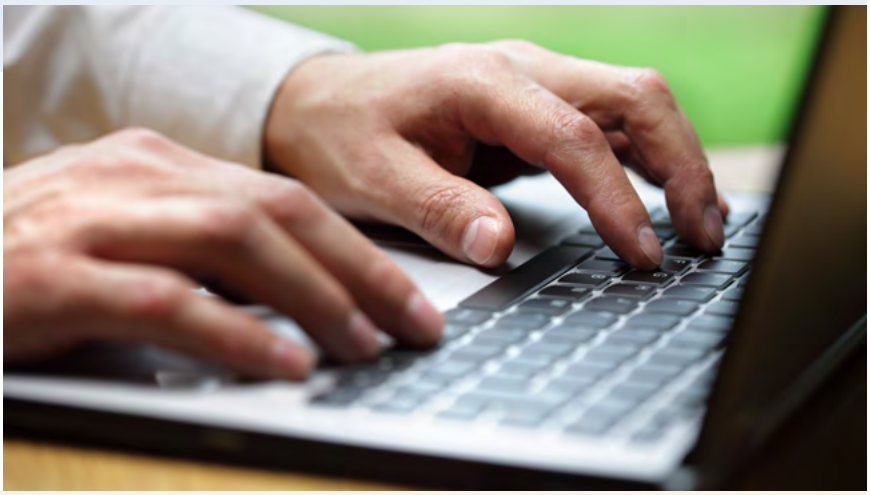
Photo: Brian Jackson/stock.adobe.com

Continue efforts to standardize submission of any required diagnostic testing data across jurisdictions.

During the COVID-19 public health emergency, HHS received data through various submission methods, such as by fax, by email, and in different formats. Some of these methods are burdensome, requiring more time for input. Experts suggested HHS, specifically CDC, should continue to move toward the standardization of data submission. Further standardization could also benefit laboratories and providers because, as one expert explained, they must manage several different methods for submitting data across different reporting systems.

Related recommendations

In July 2020, the National Academies recommended that HHS invest in a data infrastructure that promotes standardization.[xii]



HHS response

CDC and FDA officials responded to this action. FDA officials said that the agency is working to increase diagnostic testing data standardization. FDA has funded several contracts and awards to improve the collection and transmission of diagnostic testing data inside and outside of laboratories through its Diagnostic Data Program. CDC officials said that the agency continues to pursue standardization through efforts such as electronic laboratory and case reporting, which allow for a standard protocol for data exchange across partners and vendors.

Increase standardization of diagnostic testing data collection

Require reporting mechanisms for at-home diagnostic tests.

During the COVID-19 public health emergency, federal testing data reported on the HHS website did not generally include home test results due to incomplete reporting of results from these tests. Experts suggested HHS should require that developers of diagnostic tests designed for at-home use include a mechanism for reporting results with their tests. In describing such a mechanism, one expert said it should be easy to use at home, able to be integrated into the workflow of point-of-care testing, and not further burden state and local public health systems. One mechanism suggested was a QR code included with tests and used for direct reporting.

Other experts noted considerations related to this action. For example, one expert said that HHS and test developers should consider challenges in certain areas where mechanisms like a QR code may not be as effective due to limited internet access. Another expert said that enhancing data collection and reporting from diagnostic tests designed for home use could discourage people from using them due to privacy concerns.

HHS response

ASPR, FDA, and NIH officials responded to this action. ASPR officials said that automated test reporting capabilities for at-home tests is part of their current test development program. FDA officials said that during the COVID-19 public health emergency, FDA added data reporting mechanisms as a post-market requirement for at-home and point-of-care tests. Additionally, FDA's Diagnostic Data Program includes a focus on this issue. The work in this area includes collaborating with the diagnostic testing industry to develop innovative approaches to standardizing, collecting, and transmitting data from these types of tests. Additionally, NIH noted that the RADx initiative includes a program to promote a standards-based approach to reporting at-home test results and to establish best practices for future reporting from such tests. One result of this program was the Make My Test Count website, which allows individuals to voluntarily report results from at-home diagnostic tests.

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Increase efficiency in the collection of diagnostic testing data

- Continue to prioritize funding for CDC's Data Modernization Initiative.
- Establish a process for the direct, centralized reporting of diagnostic testing data to CDC.
- Support the integration of diagnostic testing data collection and reporting into existing workflows.
- Prioritize the collection of diagnostic testing data needed to inform the deployment of testing resources into communities.
- Consider collecting diagnostic testing data from sources already connected to the federal government.
- Establish preapproved data use agreement templates for diagnostic testing.

Increase efficiency in the collection of diagnostic testing data

Continue to prioritize funding for CDC's Data Modernization Initiative.

Complete and consistent data is important to inform public health responses to emergencies. Experts suggested HHS should continue to prioritize funding for CDC's Data Modernization Initiative, noting that it is a long-term initiative requiring continued funding. CDC's Data Modernization Initiative, which launched in 2020, aims to improve data collection and sharing, strengthen data reporting and analytics, and advance surveillance of future public health threats, among other goals. We previously reported that CDC has made progress toward its goals of modernizing public health data infrastructure through this initiative, such as by implementing the COVID-19 Electronic Laboratory Reporting System in 2020.[xxxv] This system allowed for the electronic reporting of COVID-19 diagnostic testing data from laboratories.

Related recommendations

In November 2021, the National Academies recommended that national public health agencies, such as CDC, should strengthen public health data infrastructure to support accurate and rapid data reporting.[xiv]

HHS response

CDC and FDA officials responded to this action. CDC officials agreed that continued and sustained investment in public health data modernization is important. CDC continues to invest resources in data modernization, which are guided by the agency's public health data strategy, according to officials. CDC officials also described the importance of funding and maintaining platforms that enable streamlined diagnostic test reporting, such as CDC's ReportStream, to ensure preparedness for future public health emergencies. Additionally, FDA officials noted that building and maintaining data infrastructure across HHS is important, as interagency data sharing enhances each agency's ability to meet their mission.

Increase efficiency in the collection of diagnostic testing data

Photo: Zoriana/stock.adobe.com

Establish a process for direct, centralized reporting of diagnostic testing data to CDC.

To increase efficiency, experts suggested HHS should establish a system by which laboratories could report diagnostic testing data directly to CDC, which experts said could also lead to more complete and consistent data reporting. One expert explained that because laboratories perform diagnostic testing for patients across different states, they must report data to multiple different health departments. Reporting to one central authority, like CDC, would make it easier to report data. However, experts also cautioned that it would be important to ensure that state and local public health authorities have simultaneous access to these data to inform their decision-making. Experts also acknowledged that this type of major change in the country's public health reporting system could require new legislative authority to implement.

HHS response

CDC and FDA officials responded to this action. Specifically, CDC receives data directly from four national, commercial laboratories, according to officials. These data are available to jurisdictions through the National Syndromic Surveillance Program, CDC officials said. Other intermediary platforms also exist that can route diagnostic testing data to CDC and to state health departments, according to officials. However, CDC officials acknowledged challenges inherent in the use of these tools due to differences in state reporting requirements. Additionally, FDA officials noted that any improvements to data completeness would benefit other HHS agencies that share data with CDC, such as FDA and NIH.

Increase efficiency in the collection of diagnostic testing data

Support the integration of diagnostic testing data collection and reporting into existing workflows.

Manual data collection and reporting is burdensome to health departments and providers. Experts suggested HHS should support the integration of data collection and reporting into the existing workflows of health care providers to improve efficiency and reduce reliance on manual reporting. Experts suggested that this integration could be done through automated systems that pull relevant data from electronic health records for reporting. However, they acknowledged that current data systems may not have this capacity.

Related recommendations

In July 2020, the National Academies recommended that HHS invest in a national data system that allows for the linkage of data across various sources to inform public health response and noted that such a system should not overly burden those who collect data.[xii]

HHS response

FDA, CDC, and ASPR officials responded to this action. Specifically, FDA officials acknowledged the importance of integrating data collection and reporting into diagnostic testing workflows, noting that integrated solutions have the greatest potential to solve related data challenges. They highlighted FDA's Diagnostic Data Program, which includes a focus on collaboration with the diagnostic testing industry to develop approaches to standardizing, collecting, and transmitting data from point-of-care and at-home tests.

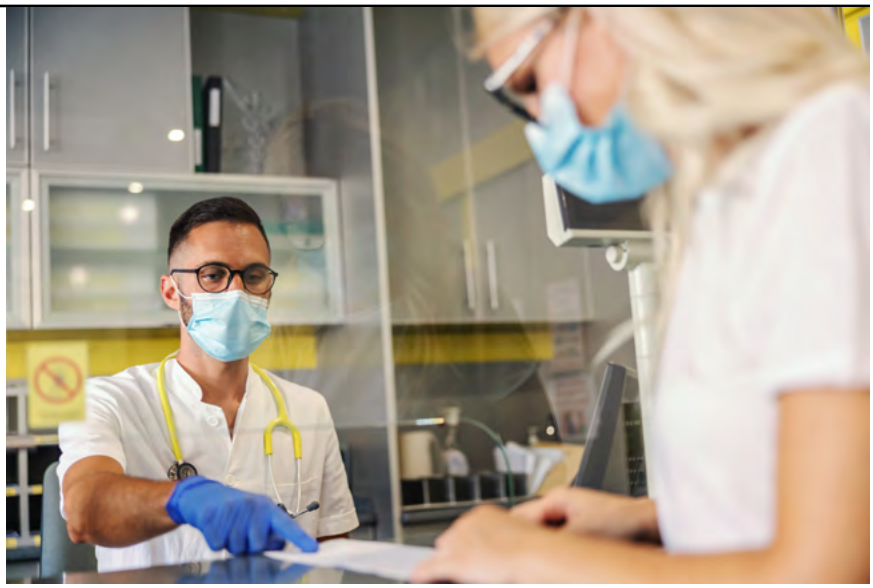
CDC officials also agreed with this action and said that integrating diagnostic testing data into existing health information technology systems would improve the quality and timeliness of these data. They also noted that for such integration to be successful, its use must be incentivized across all parts of the health care system, including hospitals, pharmacies, and nursing facilities, among others.

Additionally, HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. Officials said this plan would address various aspects of diagnostic testing and would aim to improve diagnostic test result reporting. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation.

Increase efficiency in the collection of diagnostic testing data

Dusan Petkovic/stock.adobe.com

Prioritize the collection of diagnostic testing data needed to inform the deployment of testing resources into communities.



During the COVID-19 public health emergency, one expert observed that agency officials had to streamline initial data collection efforts, such as surveys, because officials found that respondents did not want to take long surveys. Experts suggested HHS should prioritize the collection of diagnostic testing data needed to immediately inform the public health response over additional data that might be needed later for clinical studies.

HHS response

CDC officials said that the agency contracts with national pharmacy chains to provide COVID-19 and influenza diagnostic testing to uninsured and at-risk communities. Data from these activities is available to inform the deployment of testing resources, according to officials.

Increase efficiency in the collection of diagnostic testing data

Consider collecting diagnostic testing data from sources already connected to the federal government.

Experts suggested HHS should address challenges related to incomplete diagnostic testing data, especially for demographic data, by utilizing sources already available to the federal government. For instance, experts suggested that data could be available from Medicare's and Medicaid's data systems. According to experts, this could alleviate some burden on providers.

Related recommendations

GAO, HHS-OIG, and the National Academies made recommendations related to using additional data sources to supplement diagnostic testing data during the COVID-19 public health emergency. In December 2020, GAO recommended that the Department of Veterans Affairs could use data from CMS to inform their collection of COVID-19 case and death data from state veterans' home.[xxv] The Department of Veterans Affairs generally concurred with this recommendation, and as of September 2021, the agency updated its COVID-19 cases and deaths on its website to reflect complete data. HHS-OIG also recommended in July 2022 that CDC supplement its COVID-19 race and ethnicity data with additional data sources.[xxxiv] According to HHS-OIG, in February 2025, CDC implemented this recommendation. Finally, in a July 2020 recommendation, the National Academies recommended HHS develop a national data infrastructure that allows for the practical linkage of data across multiple sources.[xii]

HHS response

FDA and CDC officials responded to this action. HHS has used multiple data sources for these purposes, but there are challenges related to data standards and infrastructure that impede real-time, high-quality data sharing, according to FDA officials. They noted that it would be beneficial to establish and maintain interagency data sharing ahead of public health emergencies. Officials said that investing in data modernization would help make that possible. Additionally, CDC officials said that using multiple sources could lead to duplicate data. Officials said that obtaining diagnostic testing data directly from laboratories is an effective and more timely approach.

Increase efficiency in the collection of diagnostic testing data

Photo: DC Studio/stock.adobe.com

Establish preapproved data use agreement templates for diagnostic testing.

Delays in diagnostic testing data collection can hinder the government's ability to make informed decisions about public health threats. Experts suggested HHS should develop data use agreement templates for diagnostic testing data ahead of a public health emergency. Experts said that having a preexisting administrative structure that addresses what data elements will be required and how data will be used would increase efficiency and improve timeliness of diagnostic testing data collection and reporting during a public health emergency.

Related recommendations

In November 2021, the National Academies recommended that national public health agencies strengthen local authorities to be able to accurately and rapidly report data about pathogens.[xiv]

HHS response

CDC and FDA officials responded to this action. CDC has established an agency-wide data use agreement that includes an addendum for diagnostic testing data, according to CDC officials. Officials said this kind of preapproval could help streamline data-sharing and build trust and collaboration between CDC and jurisdictions. Additionally, FDA officials agreed that data use agreements should be in place ahead of public health emergencies. They noted that based on FDA's role evaluating test performance and other regulatory responsibilities, they would benefit from having access to these data in real-time.

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Build and expand partnerships with nonfederal entities around diagnostic testing data collection

- Build partnerships with health information exchanges to address incomplete demographic fields in diagnostic testing data.
- Work with Tribal Nations to ensure that Tribal Epidemiology Centers have access to federal diagnostic testing data as required by law.
- Build partnerships with external entities to collect demographic data from diagnostic testing at traditional and non-traditional test sites.

Build and expand partnerships with nonfederal entities around diagnostic testing data collection

Build partnerships with health information exchanges to address incomplete demographic elements in diagnostic testing data.

During the COVID-19 public health emergency, the diagnostic testing data that HHS collected did not include consistent and complete information on race and ethnicity. Experts suggested HHS should partner with health information exchange organizations—which electronically move data among health care entities—to enhance the completeness of demographic elements in diagnostic testing data. Health information exchange organizations can facilitate data exchange at the national level through electronic health record networks, or at the regional, state, or local level. For example, one expert said that the state's health information exchange, which included data from hospitals and public health departments, was able to assist in increasing diagnostic testing data completeness.

Related recommendations

HHS-OIG and the National Academies made related recommendations on improving the collection of data needed to respond to public health emergencies. In July 2022, HHS-OIG recommended that CDC improve the completeness of its COVID-19 data, including diagnostic testing data, on race and ethnicity by supplementing with data from additional sources.[xxxiv] According to HHS-OIG, in February 2025, CDC implemented this recommendation. Additionally, in July 2020, the National Academies also recommended that HHS invest in data infrastructure that allows for the linkage of clinical and other data across multiple sources to enhance its public health response.[xii]

HHS response

CDC officials said that strengthening health information exchange partnerships could improve completeness and timeliness, as well as reduce provider burden, when it comes to collecting data. However, the variation in use of health information exchanges in and across jurisdictions creates challenges to implementing this action, according to officials. At the time of our review, officials said CDC was seeking jurisdictions to conduct demonstrations.

Build and expand partnerships with nonfederal entities around diagnostic testing data collection

Work with Tribal Nations to ensure that Tribal Epidemiology Centers have access to federal diagnostic testing data as required by law.

Tribal Epidemiology Centers face challenges accessing data from CDC and the Indian Health Service. For example, experts cited our prior work on this topic, which found that tribal access to COVID-19 diagnostic testing data varied, and officials at Tribal Epidemiology Centers said lacking data access can limit Tribes' ability to address public health needs.[xxxvi] Experts suggested HHS should take action to ensure that Tribal Epidemiology Centers have access to HHS data, including from CDC and the Indian Health Service, for public health purposes as required by law.[xxxvii]

Related recommendations

GAO and HHS-OIG have made related recommendations. In March 2022, GAO made several related recommendations, including that CDC and the Indian Health Service develop guidance for making and responding to Tribal Epidemiology Centers data requests and that HHS clarify through policy the data to which Tribal Epidemiology Centers have access. HHS concurred with and implemented these recommendations. CDC and the Indian Health Service have released guidance on these topics and, as of December 2024, HHS finalized its departmentwide policy in this area. HHS-OIG found similar data access challenges and in July 2022 recommended that CDC take action to ensure that Tribal Epidemiology Centers have timely access to public health data, as required by law.[xxxiv] According to HHS-OIG, in February 2023, CDC implemented this recommendation.

HHS response

NIH officials noted their commitment to supporting tribal data activities related to public health. Officials also described efforts to expand tribal data access through NIH's RADx repository of tribal data, which allows data to be shared among tribal communities on a peer-to-peer basis. Access to this data can help communities better understand and address the impact of health disparities, according to officials.

Build and expand partnerships with nonfederal entities around diagnostic testing data collection

Build partnerships with external entities to collect demographic data from diagnostic testing at traditional and non-traditional test sites.

During the COVID-19 public health emergency, the diagnostic testing data that HHS collected did not include consistent and complete information on race and ethnicity. Experts suggested HHS should take action to increase the completeness of demographic data by working with external entities who collect this data. One expert noted that collecting demographic data was particularly difficult at mass testing sites because they did not have the plans or systems for data collection. Another expert noted that this was also a challenge in health care settings, where ordering providers needed to be better engaged in collecting demographic data.

Related recommendations

GAO, HHS-OIG, and the National Academies made related recommendations. In September 2020, GAO recommended that CDC work with stakeholders to ensure the complete and consistent collection of demographic data.[xxii] CDC agreed with this recommendation and implemented it through listening sessions with community health workers, as well as engagement with public health partners. In July 2022 and November 2021, respectively, HHS-OIG and the National Academies also recommended that CDC expand efforts to improve accurate data collection and reporting, including of demographic data.[xxxiv, xiv] According to HHS-OIG, in February 2025, CDC implemented its recommendation.

HHS response

CDC officials agreed that improved data collection would enhance public health decision-making and noted the agency had developed resources to enhance reporting from testing sites. One such resource is a web application called SimpleReport that enables a user to enter diagnostic testing data, which is automatically converted into the appropriate format and securely submitted to the relevant public health department. As of July 2024, SimpleReport was available in 41 states and four territories, and can be used to report results from any diagnostic test. This tool is especially useful for non-traditional or under-resourced testing sites, according to officials. CDC officials also noted that the completeness of diagnostic testing data can be increased through the case investigation process that takes place at the jurisdictional level.

Cross-Cutting

Develop a national diagnostic testing strategy	• Develop a national diagnostic testing strategy. • Define the stages of a public health emergency. • Define roles and responsibilities of federal, public, and private partners in diagnostic testing. • Develop a plan for re-evaluating the role and use of the Laboratory Response Network. • Develop a plan for determining the most effective use of the International Reagent Resource. • Build in redundancy in initial diagnostic test development. • Support diversification in diagnostic test types and characteristics.
Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources	• Create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners. • Develop structured plans for scientific diagnostic studies to inform test development and testing guidance. • Invest resources to understand the human behavior drivers that could increase the likelihood of compliance with diagnostic testing guidance.
Assess and exercise preparedness	• Conduct work to understand current capabilities for diagnostic testing. • Conduct preparedness exercises to practice and identify problems with quickly developing and deploying diagnostic tests. • Expand Hospital Preparedness Program and Public Health Emergency Preparedness cooperative agreement funding to include training exercises for diagnostic testing.

Foster relationships with other federal agencies with other capabilities	• Build relationships with relevant federal agencies that may be able to access financial resources more quickly than the Department of Health and Human Services. • Build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change. • Build relationships with relevant federal agencies to prepare for potentially receiving clinical samples for test validation from international partners.
Prioritize developing a robust laboratory workforce	• Cross train National Disaster Medical System staff to supplement the public health workforce. • Incentivize individuals to become laboratory workers.
Better align federal funds with local needs	• Seek legislative authority to improve federal funding flexibilities to better align with specific local needs.

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Develop a national diagnostic testing strategy

- Develop a national diagnostic testing strategy.
- Define the stages of a public health emergency.
- Define roles and responsibilities of federal, public, and private partners in diagnostic testing.
- Develop a plan for re-evaluating the role and use of the Laboratory Response Network.
- Develop a plan for determining the most effective use of the International Reagent Resource.
- Build in redundancy in initial diagnostic test development.
- Support diversification in diagnostic test types and characteristics.

Develop a national diagnostic testing strategy

Develop a national diagnostic testing strategy.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies, such as access to testing in certain areas during the mpox response. Experts suggested HHS should develop a federally endorsed national diagnostic testing strategy to address various aspects of diagnostic testing for infectious diseases with pandemic potential. While the specific circumstances of a pandemic may vary, one expert noted certain steps should be taken regardless, and the many partners involved will need direction. As this expert explained, an important function of developing a national diagnostic testing strategy is to reach agreement on "who does what when." In developing a national strategy, experts said HHS should plan for meaningful consultation with Tribal Nations, as well as incorporate input from jurisdictions, and community-based and faith-based organizations.

Related recommendations

GAO and HHS-OIG have made recommendations related to a national diagnostic testing strategy. In January 2021, GAO recommended HHS develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporated all six characteristics of an effective national strategy.[xiii] In April 2024, GAO closed the recommendation as not implemented because GAO no longer believes HHS should engage in additional efforts for a testing strategy exclusive to COVID-19, with COVID-19 becoming endemic and with the circulation of other infectious diseases, such as H5N1 avian influenza. In this report, GAO is recommending HHS develop a national diagnostic testing strategy for infectious diseases with pandemic potential. In September 2022, HHS-OIG recommended FDA work with federal partners to implement lessons learned about a national testing strategy.[i] According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

ASPR, FDA, and CDC officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. ASPR officials expected the completion of this plan would fulfill the intent of the action experts suggested, but as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. ASPR officials also said the plan is being developed with input from technical experts and response personnel across HHS and the federal government, and is expected to address challenges

Develop a national diagnostic testing strategy

Photo: Milos/stock.adobe.com

Develop a national diagnostic testing strategy. (continued)

HHS response

identified during prior public health emergencies. FDA officials added that FDA is participating in the development of the diagnostics joint capabilities plan. 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 diagnostics joint capabilities plan being developed under the leadership of the Executive Office of the President.

Drafting a strategy

Although 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 2022 *National Biodefense Strategy* requirement, they were unable to provide documentation of the plan as of May 2025. Neither HHS nor White House officials provided details regarding its content or completion date. In this report, we recommend that 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 an effective strategy, among other things.

Develop a national diagnostic testing strategy

Photo: Kate Wilcox/stock.adobe.com

Define the stages of a public health emergency.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies. Experts suggested HHS should define the different stages of a public health emergency related to diagnostic testing. For example, the stages could be defined using the Federal Emergency Management Agency's mission areas (prevention, protection, mitigation, response, and recovery) or using outbreak response (preparedness, containment, mitigation, suppression, and recovery), as one expert noted. Establishing common terminology can improve collaboration on issues that cross agencies and industries, such as diagnostic testing. Experts suggested that this action could be addressed via a national diagnostic testing strategy.

HHS response

ASPR and FDA officials responded to this action. ASPR officials referred to *Presidential Policy Directive 8: National Preparedness*, which establishes prevention, protection, mitigation, response, and recovery as components of a national preparedness system that could address a public health emergency. FDA officials also commented on defining stages, noting that the strengths and limitations of different diagnostic testing technologies may change depending on the stage of the public health emergency.

Develop a national diagnostic testing strategy

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Define roles and responsibilities of federal, public, and private partners in diagnostic testing.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies, including coordinating with jurisdictions and other partners. Experts suggested HHS should define the roles and responsibilities of federal, public, and private partners in diagnostic testing for infectious diseases with pandemic potential. In defining roles and responsibilities, HHS should also prioritize and sequence these roles and responsibilities for different stages of an emergency, experts said. For example, there may be certain partners the federal government would call on for surge capacity during certain stages. Experts suggested that this action could be addressed via a national diagnostic testing strategy.

Related recommendations

GAO, HHS-OIG, and the National Academies have made recommendations recognizing the importance of defining roles and responsibilities. For example, in July 2021, GAO recommended CDC should develop a plan to enhance laboratory surge testing capacity, and that this plan should include defining agency and stakeholder roles and responsibilities.[xi] CDC agreed with the recommendation and implemented it in May 2022 by collaborating with external partners to develop such a plan. HHS-OIG recommended in October 2023 that CDC integrate roles and responsibilities that provide effective oversight of a response effort.[xxxviii] According to HHS-OIG, in May 2024, this recommendation was implemented. In November 2021, the National Academies recommended that PHEMCE should develop, document, and clearly define roles and responsibilities among federal, nonfederal, and private sector partners and stakeholders vital to testing, among other medical countermeasures.[xix]

Develop a national diagnostic testing strategy

Define roles and responsibilities of federal, public, and private partners in diagnostic testing. (continued)

HHS response

ASPR and CDC officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. ASPR officials expected the plan would include roles and responsibilities, but as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. ASPR officials suggested an effective role for HHS could be as a coordinator of equitable testing access and distribution through both commercial and federal programs, especially in the event of testing supply constraints.

CDC officials added that taking action to define roles and responsibilities would help minimize duplication of effort and delays in test deployment, as well as strengthen coordination. According to officials, CDC convened a group of other federal agencies and private and public health laboratory organizations to discuss ways to better organize a national response testing framework and coordinate across partners during a public health emergency. Officials anticipated the completion of a draft plan in early 2025.

Develop a national diagnostic testing strategy

Photo: Alessandro Biascioli/stock.adobe.com

Develop a plan for re-evaluating the role and use of the Laboratory Response Network.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies, including challenges related to coordinating the use of existing resources. Experts suggested that HHS should develop a plan to re-evaluate the role and use of the Laboratory Response Network in diagnostic testing. Experts suggested that in re-evaluating the role of the Laboratory Response Network, HHS could consider, for example, whether it should be used to aid in test validation or whether it should be expanded to include academic and private laboratories to increase surge capacity. The plan for re-evaluation could be a part of a national diagnostic testing strategy.

HHS response

According to CDC officials, the agency has considered whether to expand the Laboratory Response Network to include academic and private laboratories. Following discussion within the Laboratory Response Network governance group and with critical partners, CDC decided not to expand the network at this time, given resource limitations and other challenges, officials said. An example of a challenge is the lack of financial incentive for private laboratories to maintain diagnostic testing capabilities for emerging infectious diseases, which officials described as a rare occurrence. However, academic and private laboratories will engage with the Laboratory Response Network regarding how all of the nation's laboratories could be a part of a system that can respond to emergencies.

Develop a national diagnostic testing strategy

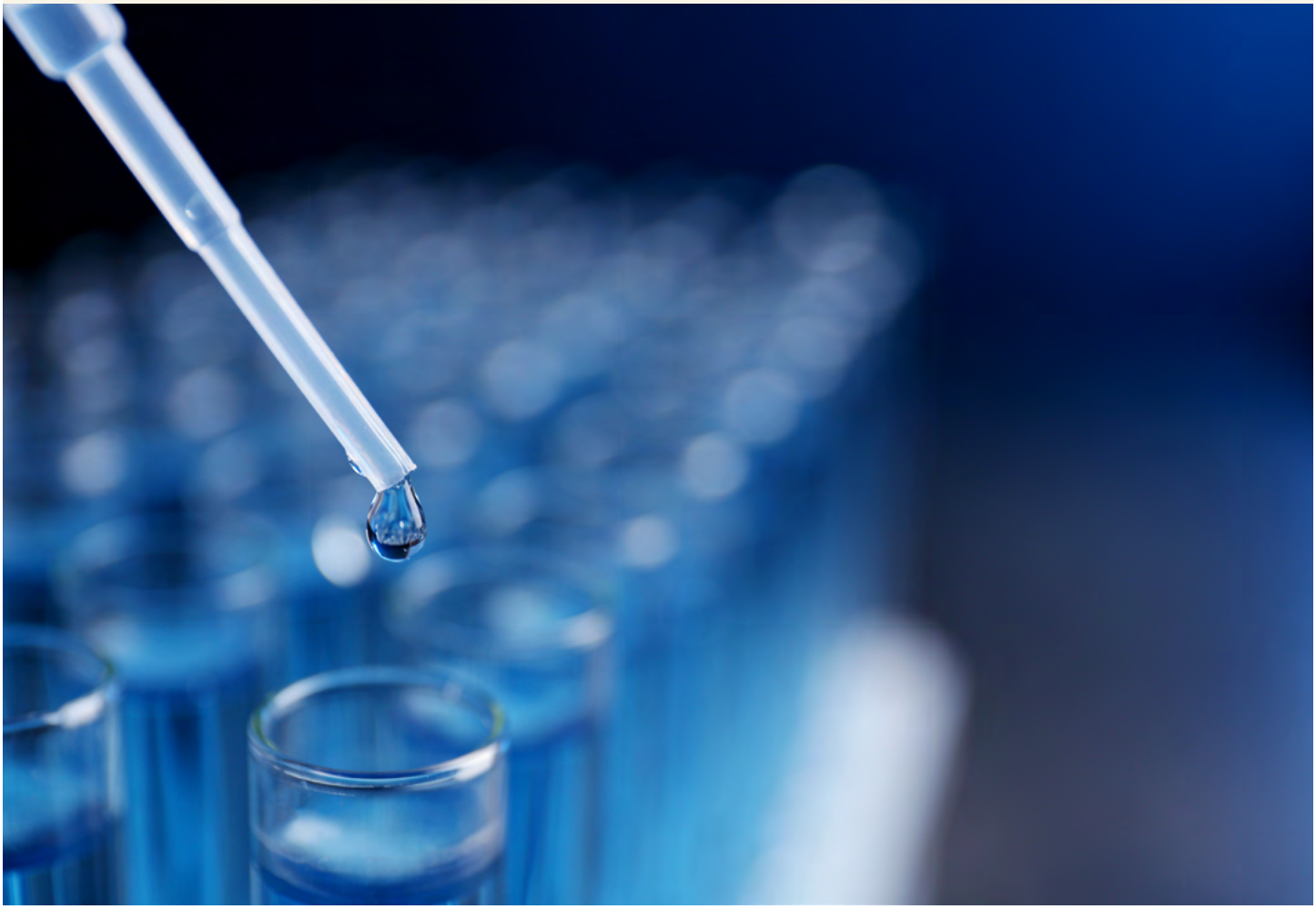
Photo: New Africa/stock.adobe.com

Develop a plan for determining the most effective use of the International Reagent Resource.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies, including challenges related to coordinating the use of existing resources. Experts suggested that HHS should develop a plan for determining the most effective use of the International Reagent Resource. For example, during the COVID-19 pandemic, the list of items provided to laboratories through this resource expanded to include additional diagnostic supplies beyond reagents. Such a plan could be a part of a national diagnostic testing strategy.

HHS response

CDC is proposing a contract that would centralize International Reagent Resource activities to streamline and standardize resource allocations and information sharing, as well as avoid duplication of resources, according to officials.



Develop a national diagnostic testing strategy

Build in redundancy in initial diagnostic test development.

CDC's initial test failed to work as expected, resulting in limited testing capacity in the United States during the critical early weeks of the pandemic when the nation needed to understand the spread of the novel virus. Experts suggested HHS should build in redundancy in its plans for initial diagnostic test development. Historically, CDC has led the development of diagnostic tests for new diseases, and the distribution of the tests to public health laboratories. Experts suggested instead that multiple other developers, such as clinical laboratories, public health laboratories, and manufacturers, should work at the same time to develop tests. This redundancy could reduce the risk that the failure of any one of these tests would impede efforts to decrease disease transmission. Experts added that building in redundancy could be a component of a national diagnostic testing strategy.

Related recommendations

GAO and HHS-OIG have made recommendations related to this action. In July 2021, GAO recommended CDC should assess the agency's needs for goods and services for the manufacturing and deployment of diagnostic tests in public health emergencies.[xi] GAO recommended this assessment should incorporate lessons learned from COVID-19 and evaluate how establishing contracts in advance of an emergency could help quickly and cost-effectively provide these capabilities. CDC agreed with the recommendation and implemented it in March 2022 by completing an assessment and instituting additional flexibilities and contract options for existing, new, and future contract mechanisms. In September 2022, HHS-OIG recommended FDA determine the feasibility of contracting with test manufacturers in advance of the next emergency.[i] HHS-OIG stated that this could potentially circumvent testing delays if one test or manufacturer encountered problems. According to HHS-OIG, as of February 2025, this recommendation had not been implemented.

HHS response

ASPR, CDC, NIH, and FDA officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. ASPR officials expected this document would include plans for the simultaneous development of multiple tests using multiple technologies by multiple developers, but as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation.

Develop a national diagnostic testing strategy

Build in redundancy in initial diagnostic test development. (continued)

HHS response (continued)

CDC officials added that they anticipated the completion of a draft plan regarding a national response testing framework—expected in early 2025—would include plans for test development by multiple organizations during large outbreaks, as well as for working with commercial laboratories to develop tests when needed.

In addition, NIH officials agreed with the action suggested by experts, mentioning the agency's success in taking this approach through the RADx initiative. According to officials, the RADx initiative was designed to support innovative testing by quickly assessing the viability of tests and then closely reviewing to identify those tests with the most potential to achieve commercialization. This initiative supported over 100 laboratories, developers, and manufacturers in their efforts to develop COVID-19 diagnostic tests, resulting in 64 FDA authorizations over 4 years, officials said. The RADx initiative has also expanded beyond COVID-19; however, officials acknowledged that the initiative lacks sustained funding, challenging NIH's ability to continue it.

FDA officials also commented that multiple developers working at the same time often happens naturally, but they acknowledged that manufacturers may be hesitant until the financial incentives of developing a test are clear. FDA officials also mentioned the agency has contributed to building in redundancy by coordinating with NIH on the RADx initiative.

Develop a national diagnostic testing strategy

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Support diversification in diagnostic test types and characteristics.

Lack of diversity in diagnostic test types can limit testing capacity during a public health emergency. Experts suggested that HHS should support diversification in diagnostic test types and characteristics. Experts said such diversification could include diagnostic tests that

- use various reagents and types of instrumentation,
- require various specimen types (e.g., nasal swab, blood sample), and
- can be performed in various settings (e.g., laboratory, point of care, at home).

Diversity in test types and characteristics could alleviate challenges such as shortages of testing supplies and therefore increase testing capacity. For example, if some diagnostic tests require specimen collection via nasal swabs, but others require blood samples, supply chain pressures are spread out across several testing supplies instead of concentrated on only a few. Experts suggested that a plan for diversification could be included as part of a national diagnostic testing strategy.

HHS response

ASPR, CDC, NIH, and FDA officials responded to this action. ASPR is planning a Broad Agency Announcement on novel manufacturing modalities for diagnostic tests. A Broad Agency Announcement may be used by agencies to fulfill requirements for scientific study and experimentation directed toward

Develop a national diagnostic testing strategy

Support diversification in diagnostic test types and characteristics. (continued)

increasing knowledge or understanding, rather than focusing on a specific system or hardware solution. In addition, HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. Officials expected the document to include plans for the development and use of diagnostic testing technologies not used during prior public health emergencies that officials anticipated would speed up the availability of early testing in the event of a novel pathogen. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. ASPR officials said they expect such technologies would be replaced by more traditional testing as it becomes available, due to lower costs and greater usability.

CDC officials agreed with this action, noting that diversification can enhance accessibility, accuracy, scalability, and adaptability. For example, diversification can increase the adaptability of tests because some may perform better against certain variants than others. NIH officials also agreed with this action. Diversification could lessen supply chain issues for diagnostic tests due to the different test components, officials said.

NIH implemented a similar strategy during the COVID-19 public health emergency through its RADx initiative, according to NIH officials. For example, the initiative supported the development of tests using saliva, nasal swabs, breath, and blood samples, officials said. However, officials noted that for COVID-19, not all sample types were able to produce quality test results. Additional research into these other sample types and alternative diagnostic testing methods would require additional funding, according to NIH officials.

Moreover, FDA officials cautioned that diversity in diagnostic test types and characteristics can only occur when there is supporting evidence to ensure quality test performance. For example, not all specimen types are suitable for at-home testing, and not all specimen types are appropriate for all pathogens.

HHS response (continued)

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Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

- Create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners.
- Develop structured plans for scientific diagnostic studies to inform test development and testing guidance.
- Invest resources to understand the human behavior drivers that could increase the likelihood of compliance with diagnostic testing guidance.

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

Create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners.

HHS's testing efforts in recent public heath emergencies have experienced a variety of issues due to a lack of coordination. Experts suggested HHS should create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners. A national diagnostic testing forum would provide real-time coordination among all levels of government and provide partners with insight into government decision-making, according to experts. For example, experts said a forum would help test developers and laboratories learn which types of tests to prioritize, how to access clinical samples, and the number of tests needed. Another benefit of a forum that experts noted is building institutional relationships between relevant federal agencies and relevant non-federal testing stakeholders that could then be quickly called upon during a public health emergency. These experts emphasized that the relationships that could be built via a forum are important to establish before a public health emergency occurs. In establishing a forum, experts said HHS should plan for meaningful consultation with Tribal Nations, as well as appropriate engagement with jurisdictions.

Experts also suggested that a national diagnostic testing forum should have the authority necessary to make decisions and take actions, such as developing a national testing strategy, and allocate resources to the areas most in need during an emergency. For instance, during the COVID-19 public health emergency, there was no established framework for determining where to deploy tests, so test manufacturers deployed the limited number of tests to states based on population, experts said. This was an imperfect approach, and states were often competing for testing resources and supplies, according to experts. Experts suggested that a national diagnostic testing forum should have the authority to allocate resources to the regions where there is greatest demand, which could be useful for managing the distribution of tests.

Related recommendations

The National Academies made a related recommendation about making use of the expertise of nonfederal and private-sector partners. In November 2021, the National Academies recommended that PHEMCE should establish an advisory committee of nonfederal and private-sector partners and stakeholders to garner their expertise and ensure transparency in PHEMCE activities.[xix] In this report, GAO is recommending HHS develop a national diagnostic testing forum for infectious diseases with pandemic potential.

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

Photo: Rawpixel.com/stock.adobe.com

Create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners. (continued)

HHS response

ASPR, FDA, and CDC officials responded to this action. ASPR officials commented that they could support such a forum, but would not be an appropriate departmental lead. ASPR officials added that it would not be appropriate to allocate products without requests from the jurisdictions. Officials said HHS should instead develop an allocation strategy that ensures resources, especially constrained resources, are available for request by jurisdictions across the country to meet shifting demands. This would likely involve phased allocation or threshold strategies, according to officials. ASPR officials said they have used this approach for COVID-19 and mpox testing during both emergency responses. As of June 2024, ASPR's Center for Industrial Base Management and Supply Chain has conducted direct distribution of diagnostic supplies to more than 30,000 locations weekly and has delivered more than 1.8 billion devices to the American public, according to officials. Officials said distributing these supplies is supported by 250 million devices in the stockpile, as well as a dozen procurement contracts through mid-2025.

FDA officials told us that the proposed forum, as described by the experts, would have responsibilities and authorities that are currently the mission and purview of various federal agencies, including coordinating actions among government agencies, developing a national testing strategy, and allocating resources.

CDC officials told us there are existing forums for CDC and other federal agencies to discuss diagnostic testing, such as the Testing Coordination Group, the Tri-Agency Task Force for Emergency Diagnostics, and PHEMCE. Charters have been drafted or established for these forums to explain their function and interaction with nongovernmental organizations, according to officials. CDC officials said private sector, public health organizations, and academia will be invited to engage as needed and per the Federal Advisory Committee Act rules. Additionally, CDC developed a plan to enhance surge diagnostic testing capability during

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

Create a permanent national diagnostic testing forum made up of federal, public health, academic, and private sector partners. (continued)

HHS response (continued)

public health emergencies, including engaging private sector partners in supporting the public health emergency response. These efforts provide opportunities for private sector partners to express concerns and work collaboratively with the federal government to solve problems, according to officials. CDC officials also said a forum could be part of a federally endorsed national strategy to address various aspects of diagnostic testing for infectious diseases with pandemic potential. CDC officials told us a forum involving external stakeholders needs to comply with the Federal Advisory Committee Act.[xxxix] Officials noted the agency must be unbiased when engaging with private sector stakeholders who could potentially receive competitive funding from the agency.

About coordination groups

Our review of these coordinating groups found that they did not include all relevant federal agencies. We also identified concerns that many of these groups did not include relevant external stakeholders. In this report, we recommend that 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—that includes 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.

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

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Develop structured plans for scientific diagnostic studies to inform test development and testing guidance.

Advanced plans can provide 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. Experts suggested that HHS should develop structured plans for scientific diagnostic studies to inform test development and testing guidance. For example, experts suggested HHS develop studies that can help define testing characteristics (e.g., sample types) and symptomatic features to monitor variants and lead to evidence-based guidelines. One expert suggested that this action could be addressed via a national diagnostic testing forum.

Related recommendations

In July 2020, the National Academies recommended that CDC develop a national public health emergency and response science framework to translate science to the practice community; establish infrastructure to support ongoing public health emergency preparedness and response evidence reviews; and ensure the translation, dissemination, and implementation of public health emergency preparedness and response research to practice.[xxix]

HHS response

FDA and NIH officials responded to this action. FDA provides guidance to manufacturers seeking to develop tests. FDA also provides template guidance with recommendations on appropriate validation studies. FDA officials noted that implementing this action would likely require efforts from FDA related to regulating the test, and CDC related to guidance on performing the test, as well as other governmental and non-governmental entities (e.g., professional societies).

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

Develop structured plans for scientific diagnostic studies to inform test development and testing guidance. (continued)

HHS response (continued)

NIH officials responded that NIH views this as an effective strategy. Officials provided examples of initiatives to develop studies that inform test development. The RADx initiative includes a program that conducts studies to address test performance and inform testing guidance. Officials said a primary challenge is maintaining this work. Officials said it is difficult to develop structured plans and timelines for unknown pathogens and affected populations, even though this work is necessary so technology development can continue and the government is ready to respond quickly to emerging threats. NIH also supported the development of new diagnostic testing types and characteristics for any future COVID-19 pandemics through the RADx initiative. Officials said NIH has been soliciting and awarding proposals to develop diagnostic platforms for wide coverage of potential emerging pathogen threats, including platforms for point-of-care and laboratory testing. Finally, NIH officials said they are committed to working with the White House Office of Pandemic Preparedness and Response Policy on advancing development initiatives needed for diagnostic test readiness ahead of the next emerging pathogen threat.

Establish a permanent national diagnostic testing forum with authority to develop plans and allocate resources

Invest resources to understand the human behavior drivers that could increase the likelihood of compliance with diagnostic testing guidance.

Poorly communicated testing guidance can create confusion and erode the public's trust in government. Experts suggested that HHS should invest resources to understand the human behavior drivers that could increase compliance with diagnostic testing guidance. One expert noted that guidelines are not effective if individuals ignore them, so research needs to be done to understand what models work and do not work for encouraging compliance with diagnostic testing guidance. Experts suggested that this action could be addressed via a national diagnostic testing forum.

Related recommendations

In July 2020, the National Academies recommended that CDC develop a national public health emergency and response science framework to translate science to the practice community.[xxix] The National Academies also recommended CDC establish infrastructure to support ongoing public health emergency preparedness and response evidence reviews, and appoint a public health emergency preparedness and response evidence-based guidelines group. These mechanisms could identify evidence gaps in the research on the effectiveness of public health practices, including social science research on behavioral drivers.

HHS response

NIH officials told us that NIH views this as an effective strategy because it improves understanding of and informs best approaches for testing compliance. NIH officials described their success implementing a similar strategy during the COVID-19 pandemic through the RADx initiative. This initiative identified racial, ethnic, and socioeconomic status disparities in testing motivation. Investing resources to identify these motivations and barriers will increase the likelihood of compliance within specific communities, according to NIH officials. In particular, the officials said many of the projects that were part of this initiative focused on identifying and overcoming potential barriers to compliance in underserved communities, including geographic barriers, inability to take sick leave, long waits, and inability to access transportation.

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Assess and exercise preparedness

- Conduct work to understand current capabilities for diagnostic testing.
- Conduct preparedness exercises to practice and identify problems with quickly developing and deploying diagnostic tests.
- Expand Hospital Preparedness Program and Public Health Emergency Preparedness cooperative agreement funding to include training exercises for diagnostic testing.

Assess and exercise preparedness

Conduct work to understand current capabilities for diagnostic testing.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies. Experts suggested HHS should conduct work to understand current capabilities for scaling up development and deployment of diagnostic testing under various potential infectious disease pandemic scenarios, such as whether the pathogen is known or unknown. One expert suggested that in conducting this work, HHS should include laboratories beyond public health laboratories, such as those located in hospitals, which may have additional capabilities not available elsewhere.

Related recommendations

GAO has previously made recommendations related to understanding current capabilities and needs. For example, in July 2021, GAO recommended CDC (1) work with appropriate stakeholders to develop a plan to enhance laboratory surge capacity, and (2) assess the agency's needs for goods and services for the manufacturing and deployment of diagnostic test kits in public health emergencies.[xi] CDC agreed with both recommendations. CDC implemented the first recommendation in May 2022 by collaborating with external partners to develop a plan to enhance surge testing capacity at laboratories other than CDC and public health laboratories. CDC implemented the second recommendation in March 2022 by completing an assessment and instituting additional flexibilities and contract options for existing, new, and future contracts for goods and services used in diagnostic testing.

HHS response

ASPR, NIH, and FDA officials responded to this action. ASPR has invested approximately $2 billion in domestic manufacturing of tests and test components, according to ASPR officials. In addition, NIH officials agreed that conducting work to understand current testing capabilities is an effective strategy. NIH officials noted NIH's RADx initiative established a group charged with supporting manufacturing, deployment, and implementation of diagnostics that received RADx funds. Additionally, FDA officials said the agency has been engaged in efforts to incentivize pathogen agnostic tests, which could be used in various infectious disease scenarios. Officials said these plans could also consider whether there are existing tests for known pathogens and be updated on a periodic basis.

Assess and exercise preparedness

Conduct preparedness exercises to practice and identify problems with quickly developing and deploying diagnostic tests.

Conducting exercises of plans is a key component of response preparedness because exercises help to identify what works and what does not. Experts suggested HHS should conduct preparedness exercises to practice and identify problems with quickly developing and deploying diagnostic tests. One expert proposed the exercises could be used to practice logistics such as developing tests, including obtaining control material for test validation. This expert suggested such an exercise could be done for an infectious disease with pandemic potential that the government has prioritized for test development, which could serve a dual purpose of identifying areas for improvement and achieving a working test for a particular infectious disease.

Related recommendations

GAO and the National Academies have made recommendations to HHS related to preparedness exercises. For example, GAO recommended in April 2021 that HHS plan and conduct regular exercises with relevant stakeholders to test certain plans related to pandemic response and update relevant plans based on lessons learned.[xi] HHS agreed with this recommendation and partially addressed it in May 2022 by conducting 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 annual reviews, including scenario-based simulations to identify capacity gaps and promote process improvement.[xii]

HHS response

ASPR and FDA officials responded to this action. HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, according to ASPR officials, which is a requirement of the *National Biodefense Strategy*. Officials said the joint capabilities plan includes exercises to demonstrate the ability to produce diagnostic tests and key materials required for testing. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. In addition, in May 2023, ASPR held a tabletop exercise with seven test manufacturers and other HHS agencies, including CDC, FDA, and NIH, ASPR officials said. The focus of the exercise, according to ASPR officials, was on accelerating the development and production of certain tests during the early stages of a public health emergency. The exercise provided an opportunity for industry and government officials to discuss ways to enhance information sharing and coordination, officials said. FDA officials added that after-action activities related to COVID-19 and future preparedness efforts across the federal government are addressing this action.

Assess and exercise preparedness

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Expand Hospital Preparedness Program and Public Health Emergency Preparedness cooperative agreement funding to include training exercises for diagnostic testing.

Conducting exercises of plans is a key component of response preparedness because exercises help to identify what works and what does not. Experts suggested HHS should expand some of its preparedness programs to include training exercises. Experts specifically referenced

- the Hospital Preparedness Program, which provides leadership and funding through cooperative agreements to increase the ability of hospitals to plan for and respond to large-scale emergencies; and
- the Public Health Emergency Preparedness cooperative agreement, which provides assistance to jurisdictional public health departments to build and strengthen their abilities to effectively respond to various public health threats, including infectious diseases.

Related recommendations

GAO and the National Academies have made recommendations to HHS related to preparedness exercises. For example, GAO recommended in April 2021 that HHS plan and conduct regular exercises with relevant stakeholders to test certain plans related to pandemic response and update relevant plans based on lessons learned.[xi] HHS agreed with this recommendation and partially addressed it in May 2022 by conducting a related exercise. Expanding programs to support training 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 annual reviews, including scenario-based simulations to identify capacity gaps and promote process improvement.[xii]

Assess and exercise preparedness

Expand Hospital Preparedness Program and Public Health Emergency Preparedness cooperative agreement funding to include training exercises for diagnostic testing. (continued)

HHS response

ASPR officials agreed that conducting training exercises for diagnostic testing would be a useful activity. While Hospital Preparedness Program funding cannot be used to provide direct clinical care services, officials said the cooperative agreement includes requirements related to this action. Specifically, funding recipients must:

- collaborate with relevant partners to build capacity to perform diagnostic testing for novel and high-consequence infectious diseases, which could include infectious diseases with pandemic potential;
- develop, update, and submit a training exercise plan that includes partnerships and training resources to support preparedness for special pathogens, such as those that cause infectious diseases with pandemic potential; and
- include professionals with expertise in preventing health care-associated infections in planning, training, and exercises.

ASPR officials also noted that the Hospital Preparedness Program recommends funding recipients look to Regional Emerging Pathogen Treatment Centers and the National Emerging Special Pathogens Training and Education Center for additional guidance, as these programs have specific expertise and are focused on best practices for special pathogens.

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Foster relationships with other federal agencies with other capabilities

- Build relationships with relevant federal agencies that may be able to access financial resources more quickly than the Department of Health and Human Services.
- Build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change.
- Build relationships with relevant federal agencies to prepare for receiving clinical samples for test validation from international partners.

Foster relationships with other federal agencies with other capabilities

Photo: Chris Allan/stock.adobe.com

Build relationships with relevant federal agencies that may be able to access financial resources more quickly than the Department of Health and Human Services.

HHS has faced challenges obtaining funding in a timely manner during recent public health emergencies. Experts suggested that HHS should build relationships with relevant federal agencies that may be able to access financial resources for public health emergency response more quickly than HHS. For example, experts noted that the Department of Defense played a major role early in the COVID-19 public health emergency because it had resources readily available to contract with companies to develop and manufacture diagnostic tests. Experts also noted the important role of the Federal Emergency Management Agency in mobilizing its resources to support testing. However, one expert noted that there was sometimes imperfect communication between HHS and the Federal Emergency Management Agency, leading to supply chain challenges.

Related recommendations

GAO and the National Academies have previously made recommendations related to coordination between HHS and other federal agencies. For example, in September 2020, GAO recommended HHS work with the Federal Emergency Management Agency to (1) develop and communicate plans to help mitigate medical supply gaps, and (2) document roles and responsibilities for supply chain management functions to stabilize the supply chain and address emergent supply issues for the duration of the COVID-19 pandemic.[xxii] Although HHS disagreed, the department took steps to fulfill the intent of these recommendations. HHS implemented the first recommendation by taking several steps to help mitigate supply gaps, such as forming a new office to address deficiencies in medical supplies and releasing a *National Strategy for a Resilient Public Health Supply Chain*. HHS implemented the second recommendation

Foster relationships with other federal agencies with other capabilities

Build relationships with relevant federal agencies that may be able to access financial resources more quickly than the Department of Health and Human Services. (continued)

Related recommendations (continued)

by taking several steps to define roles and responsibilities, such as signing a memorandum of understanding with the Department of Defense for continued acquisition assistance and releasing an updated *National Biodefense Strategy*. In July 2021, GAO recommended HHS coordinate with the Secretaries of Defense and Homeland Security to ensure that input from contracting officials on interagency contracting lessons learned in response to COVID-19 is collected and shared as part of government-wide efforts to collect, analyze, and report on lessons learned.[xli] HHS agreed with this recommendation, and in July 2024, HHS implemented it by finalizing a report in coordination with the Department of Defense and the Department of Homeland Security that consolidated the interagency contracting lessons learned by the agencies in response to COVID-19. In addition, in November 2021, the National Academies recommended that PHEMCE establish mechanisms for transparent communications across the government.[xix]

HHS response

ASPR officials told us they work closely with interagency partners, including the Department of Defense, to implement test development programs, including joint development of products and utilization of each other's funding mechanisms when expeditious. Specifically, ASPR partners with the Department of Defense to utilize the Defense Production Act and with the Federal Emergency Management Agency in all Stafford Act events to access additional financial resources, according to ASPR officials. Officials said that these types of actions are highly effective, including during the COVID-19 response when HHS utilized the Defense Production Act for the first time. Additionally, ASPR officials said PHEMCE routinely engages with interagency partners at various technical, programmatic, and executive levels through a variety of mechanisms. Officials said the federal agencies primarily involved in the medical countermeasure life cycle—which encompasses diagnostics—include HHS components, including ASPR, CDC, FDA, and NIH. Officials said PHEMCE also includes additional federal partners, including the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, the Department of Agriculture, the Office of the Director of National Intelligence, and the White House's Office of Pandemic Preparedness and Response Policy. Officials said the PHEMCE multi-year budget represents HHS's current estimates for the basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the U.S. government's civilian medical countermeasure enterprise, including for diagnostic testing.

Foster relationships with other federal agencies with other capabilities

Photo: danielfela/stock.adobe.com

Build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies. Experts suggested HHS should build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change. One expert specifically mentioned the important roles the Federal Emergency Management Agency, the Department of Defense, and White House played resolving supply chain issues early in the COVID-19 public health emergency. Building relationships could include practices such as offering details for employees to work across agencies. One expert noted that cross-agency detailing can help build lasting in-house skillsets as a contingency, should coordinating efforts cease as administrations and priorities change.

Related recommendations

GAO and the National Academies have previously made recommendations related to coordination between HHS and other federal agencies. For example, in September 2020, GAO recommended HHS work with the Federal Emergency Management Agency to (1) develop and communicate plans to help mitigate medical supply gaps, and (2) document roles and responsibilities for supply chain management functions to stabilize the supply chain and address emergent supply issues for the duration of the COVID-19 pandemic.[xxii] Although HHS disagreed, the department took steps to fulfill the intent of these recommendations. HHS implemented the first recommendation by taking several steps to help mitigate supply gaps, such as forming a new office to address deficiencies in medical supplies and releasing the *National Strategy for a Resilient Public Health Supply Chain*. HHS implemented the second recommendation by taking several steps to define roles and responsibilities, such as signing a memorandum of understanding with the Department of Defense for continued acquisition assistance. In addition, in November 2021, the National Academies recommended that PHEMCE establish mechanisms for transparent communications across the government.[xix]

Foster relationships with other federal agencies with other capabilities

Photo: U.S. National Guard, A. Danielle Thomas

Build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change. (continued)

HHS response

FDA, ASPR, and CDC officials responded to this action. FDA officials said it is challenging to always identify the point-of-contact for a topic at an agency given natural turnover and re-organization. Officials said efforts to identify specific departments and agencies to both lead and support discrete tasks can help organize roles and responsibilities more quickly during public health emergencies. For instance, officials suggested each agency could share an updated proposed public health emergency command structure with each other annually. Officials added that this would help staff at different levels know who to connect with across agencies, at the appropriate level, as well as know which groups between agencies are expected to interact. Officials said one challenge during COVID-19 was that information was shared at the top level of the command structure. Pertinent information did not always make it down to the lower levels, or the information had changed or was not accurate by the time the information made it down.

ASPR officials added that HHS is involved in an interagency effort led by the Executive Office of the President to develop a diagnostics joint capabilities plan, which is a requirement of the *National Biodefense Strategy*. Officials expected the completion of this plan to fulfill the intent of the action experts suggested. The joint capabilities plan is a document being developed with active participation of the Federal Emergency Management Agency, the Department of Defense, the Department of

Foster relationships with other federal agencies with other capabilities

Build relationships with other relevant federal agencies to improve coordination regarding diagnostic testing, including when administrations change. (continued)

HHS response (continued)

Agriculture, and many other federal agencies, according to ASPR officials. However, as of May 2025, HHS officials were unable to provide documentation of the plan for confirmation. In addition, ASPR officials told us HHS has a Testing and Coordination Group, an interagency group that comprises senior leaders from HHS, including ASPR, CDC, CMS, FDA, and NIH. This group works closely with the White House on testing and diagnostic development, independent of the administration, according to ASPR officials.

CDC officials further described the work of the Testing Coordination Group. Officials said that CDC serves as the group's chair and facilitates meetings, tracks actions, and maintains records. According to officials, the group has been a useful forum for the federal government to

- discuss testing needs in advance of and during public health emergencies;
- coordinate solutions;
- create and maintain a state of readiness; and
- improve the speed, capacity, and efficiency of diagnostic testing during public health emergencies.

In addition, CDC is working to engage with relevant agencies to ease the transition between administrations and agencies, according to CDC officials.

Foster relationships with other federal agencies with other capabilities

Build relationships with relevant federal agencies to prepare for potentially receiving clinical samples for test validation from international partners.

The federal government has faced challenges coordinating diagnostic testing during recent public health emergencies. Experts suggested HHS should build relationships with relevant federal agencies to better prepare for potentially receiving clinical samples for test validation from international partners. Experts noted the importance of sharing clinical samples across international borders, as some places may have access to more samples than others, particularly early in a public health emergency. However, one expert noted that moving these samples internationally is a significant challenge. Therefore, it is necessary to involve relevant federal agencies, such as Customs and Border Patrol and the Department of Homeland Security.

HHS response

ASPR and CDC officials responded to this action. According to ASPR officials, CDC routinely receives clinical samples from international partners and has relationships with Customs and Border Patrol, the Department of Homeland Security, and the Department of Agriculture to facilitate receipt. ASPR officials also said that delays in receiving clinical samples from international partners are rarely due to challenges at the border and are instead because international partners are reluctant to share samples until their own domestic needs are met.

CDC officials responded that CDC works closely with Customs and Border Patrol and the Department of Homeland Security to facilitate the receipt of clinical samples from international partners through a number of programs. For example:

- CDC's Port Health Stations are part of a comprehensive Port Health Protection system that serves to limit the introduction and spread of infectious diseases into the United States. Through these stations, CDC works with Customs and Border Patrol and the Department of Homeland Security to provide support and verify that imported biologics, such as clinical samples, meet CDC standards.
- The Import Permit Program reviews importer requests for biologic importations and grants permits.
- The Border Infectious Disease Surveillance Program has provided support to jurisdictions and universities in acquiring import permits and complying with international shipping regulations, according to CDC officials

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Prioritize developing a robust laboratory workforce

- Cross train National Disaster Medical System staff to supplement the public health workforce.
- Incentivize individuals to become laboratory workers.

Prioritize developing a robust laboratory workforce

Cross train National Disaster Medical System staff to supplement the public health workforce.

The demand for diagnostic tests early in a pandemic can quickly exceed a nation's testing capacity. Experts suggested HHS should cross train National Disaster Medical System staff to supplement the public health workforce. One expert specifically proposed that HHS provide credentialing and licensing for National Disaster Medical System staff to support the public health laboratory workforce, such as by helping to collect and analyze test samples.

HHS response

ASPR officials noted that in an emergency, a state can call on the National Disaster Medical System to help augment the affected medical health care system, via health care providers, support personnel, veterinary care, fatality management experts, equipment, and supplies. ASPR officials also referenced initiatives other than the National Disaster Medical System to supplement the public health workforce. Specifically, ASPR officials noted that the Public Health Service Act authorizes requesting states and tribal organizations to temporarily reassign state and local public health personnel funded under the act for purposes of addressing a public health emergency. This authority was utilized by every state during the COVID-19 public health emergency, according to officials. ASPR officials also mentioned the Medical Reserve Corps, a network of medical and public health professionals and other volunteers who can respond locally to emergencies. Officials suggested the use of temporary reassignment or activation of local Medical Reserve Corps units could be more effective and could provide surge relief at a lower cost than deploying National Disaster Medical System staff.

Prioritize developing a robust laboratory workforce

Incentivize individuals to become laboratory workers.

The demand for diagnostic tests early in a pandemic can quickly exceed a laboratory's testing capacity. Experts suggested HHS should incentivize individuals to become laboratory workers. Experts specifically suggested that HHS provide incentives similar to those used to encourage medical professionals to work in underserved areas, such as educational loan repayment programs.

HHS response

CDC has the option and flexibility to utilize available incentives for recruitment and retention, according to officials. Officials said that historically, usage of loan repayment and recruitment, retention, and relocation programs has been low. CDC has requested authority to waive tax liability on student loan repayment incentives, which would increase the percentage of funding used for these incentives relative to the tax liability, according to officials. In addition, CDC is developing a workforce action plan. Officials expected CDC's workforce action plan to (1) identify strategies to close gaps, (2) include plans to implement these strategies, and (3) define measures for assessing progress.

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Better align federal funds with local needs

- Seek legislative authority to improve federal funding flexibilities to better align with specific local needs.

Better align federal funds with local needs

Seek legislative authority to improve federal funding flexibilities to better align with specific local needs.

Different jurisdictions may have different needs, which experts said makes it difficult to provide funding in ways appropriate for every jurisdiction. Experts suggested HHS should seek legislative authority to improve federal funding flexibilities to better align with specific local needs. Experts explained that because jurisdictions have different needs, it is difficult to provide funding in ways appropriate for every jurisdiction. One expert explained that initially during the COVID-19 public health emergency, private laboratories could use federal funding to pay for temporary workers. However, this flexibility ended and funds could no longer be used this way unless specifically allocated. According to experts, this lack of continued funding flexibility hindered diagnostic testing.

HHS response

NIH and CDC officials responded to this action. NIH officials agreed improving federal funding flexibilities would be an effective strategy because it increases funding opportunities and allows for innovative, community-tailored research approaches that would not be possible otherwise. Officials described how NIH had success implementing a similar strategy during the COVID-19 public health emergency in the RADx initiative. Specifically, the RADx initiative utilized the Other Transactions Authority funding mechanism to provide flexibility to investigators performing COVID-19 testing within education systems, according to NIH officials. An Other Transaction Authority is a type of awarding instrument other than a contract, grant, or cooperative agreement that is not generally subject to grant regulations. Officials said RADx used this approach to award funds to 16 such projects in 2021. These projects would not have been possible using other grant funding options, according to officials.

In addition, CDC officials told us they used available authority to provide flexibility to jurisdictions where possible through the Public Health Infrastructure Grant. The Public Health Infrastructure Grant gives health departments the flexibility to direct funds toward specific organizational and community needs. CDC was also able to use supplemental and base funding to invest in supporting critical public health infrastructure, according to officials. CDC officials said supplemental appropriations were critical for supporting surge capacity. However, officials said CDC requires sustained, disease-agnostic funding to meet its core preparedness and response needs and build a stronger public health system ready for future public health emergencies.

Glossary

Clinical Laboratory Improvement Amendments of 1988

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and associated regulations provide the authority for the certification and oversight of clinical laboratories and laboratory testing. Under the CLIA program, clinical laboratories are required to have an appropriate certificate before they can accept human samples for testing. To obtain certain certificates, clinical laboratories undergo an inspection from the Centers for Medicare & Medicaid Services to assess compliance with the relevant requirements. The Food and Drug Administration (FDA) determines whether a test is moderate or high complexity by reviewing the package insert test instructions and using a criteria "scorecard." For example, FDA assesses whether minimal training and limited experience or specialized training and substantial experience are required of staff to successfully conduct a test. See 42 U.S.C. § 263a.

contrived samples

Contrived samples are made from viral material that may come from a range of sources.

control material

Control material can include clinical samples, from patients, or contrived samples.

Defense Production Act

The Defense Production Act gives agencies the authority to prioritize contracts for medical supplies so those orders get preference over others and expand domestic production of medical supplies. See 50 U.S.C. ch. 55.

emergency use authorization

An emergency use authorization allows for emergency use of unapproved medical products during a declared emergency, 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. Typically, before a medical device such as a diagnostic test can be marketed in the United States, 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 unapproved medical products. See 21 U.S.C. § 360bbb-3.

Laboratory Response Network

The Laboratory Response Network, organized by the Centers for Disease Control and Prevention, is an integrated network of state and local public health, veterinary, military, and international laboratories that can respond to emerging infectious diseases and other public health emergencies.

Medicare

Medicare is a federal health insurance program for people age 65 and older, certain individuals with disabilities, and individuals diagnosed with end-stage renal disease.

National Disaster Medical System

The National Disaster Medical System partners with health care facilities to ensure a network is in place to provide care for American citizens and military casualties requiring additional or complex care unavailable within an area impacted by a natural or man-made disaster, military health emergency, or other public health emergency.

polymerase chain reaction test

A polymerase chain reaction test is a type of diagnostic test that uses a genetic photocopier, copying a unique portion of the viral genetic material, if present, until there are enough copies to detect.

preemption

Preemption refers to the idea that a federal law will displace the law of a lower authority, such as a state, when the two authorities come into conflict.

Public Health Emergency Medical Countermeasures Enterprise

The Public Health Emergency Medical Countermeasures Enterprise is an interagency group of experts established by the Department of Health and Human Services to advance national preparedness by coordinating medical countermeasure efforts. Medical countermeasures refer to FDA-regulated products that may be used in the case of a public health emergency such as vaccines, diagnostic tests, and personal protective equipment.

Rapid Acceleration of Diagnostics

Rapid Acceleration of Diagnostics (RADx) is a National Institutes of Health initiative to speed innovation in diagnostic test development through various programs that focus on aspects such as supporting the development of new testing technology and developing community-engaged projects to expand testing for underserved populations.

reagent

A reagent is a substance used in testing for other substances, or for reacting with them in a particular way.

Stafford Act

The Stafford Act establishes the process to request a presidential major disaster or emergency declaration, which, if approved, triggers a variety of federal response and recovery programs. See 42 U.S.C. ch. 68.

test validation

Test validation refers to studies designed to assess a test's sensitivity (i.e., its ability to identify cases with the disease) and specificity (i.e., its ability to identify cases without the disease) among other things.

Endnotes

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

[ii]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* (Rockville, Md.: 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).

[iii]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).

[iv]See GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year,* GAO-21-387 (Washington, D.C.: Mar. 31, 2021).

[v]See Food and Drug Administration, *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff* (Rockville, Md.: Mar. 27, 2023).

[vi]See Department of Health and Human Services, Office of the Inspector General, *CMS Could Improve Its Procedures for Setting Medicare Clinical Diagnostic Laboratory Test Rates Under the Clinical Laboratory Fee Schedule for Future Public Health Emergencies,* A-01-21-00506 (Washington, D.C.: April 2024).

[vii]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).

[viii]See National Institutes of Health, National Institute of Allergy and Infectious Diseases, *NIAID Pandemic Preparedness Plan* (December 2021).

[ix]See Anne M. Deschamps, Amanda J. DeRocco, Karin Bok, and L. Jean Patterson, "Prototype Pathogens for Vaccine and Monoclonal Antibody Countermeasure Development: NIAID Workshop Process and Outcomes for Viral Families of Pandemic Potential," *The Journal of Infectious Diseases,* vol. 228, supplement 6 (2023): S355-S358.

[x]See GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk,* GAO-16-642 (Washington, D.C.: Aug. 30, 2016).

[xi]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).

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

[xiii]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).

[xiv]See 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).

[xv]See GAO, *Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues,* GAO-21-108 (Washington, D.C.: Nov. 19, 2020).

[xvi]See Department of Health and Human Services, Office of the Inspector General, *The Strategic National Stockpile Was Not Positioned to Respond Effectively to the COVID-19 Pandemic,* A-04-20-02028 (Washington, D.C.: October 2023).

[xvii]See Pub. L. No. 100-578, 102 Stat. 2903 (codified at 42 U.S.C. § 263a). See also 42 C.F.R. part 493.

[xviii]See Pub. L. No. 109-148, div. C, 119 Stat. 2818 (2005). HHS's Office of General Counsel issued an advisory opinion in May 2020 that concluded that the act preempted any state or local requirement that prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test authorized by FDA.

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

[xx]See 21 U.S.C. § 356j(g).

[xxi]See 21 U.S.C. § 356j(a); PREVENT Pandemics Act, Pub. L. No. 117-328, § 2514(c), 136 Stat. 5706, 5806 (2022). Food and Drug Administration, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act: Guidance for Industry and Food and Drug Administration Staff (Rockville, Md.: Jan. 7, 2025).

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

[xxiii]See Department of Health and Human Services, Office of the Inspector General, *Lessons Learned During the Pandemic Can Help Improve Care in Nursing Homes,* OEI-02-20-00492 (February 2024).

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

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

[xxvi]See GAO, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Coordination Challenges,* GAO-24-106260 (Washington, D.C.: May 2, 2024).

[xxvii]See Department of Health and Human Services, Office of the Inspector General, *During the Initial COVID-19 Response, HHS Personnel Who Interacted with Potentially Infected Passengers Had Limited Protections,* OEI-04-20-00360 (October 2022).

[xxviii]See Centers for Disease Control and Prevention, "COVID-19 Testing: What You Need to Know," accessed July 15, 2024, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html; and General Services Administration, "COVID-19 testing and vaccinations," accessed July 15, 2024, https://www.usa.gov/covid-tests-vaccinations.

[xxix]See National Academies of Sciences, Engineering, and Medicine, *Evidence-Based Practice for Public Health Emergency Preparedness and Response* (Washington, D.C.: July 14, 2020).

[xxx]See GAO, *Public Health Preparedness: HHS Should Assess Jurisdictional Planning for Isolation and Quarantine,* GAO-24-106705 (Washington, D.C.: July 25, 2024).

[xxxi]See CARES Act, Pub. L. No. 116-136, div. B, tit. VIII, § 18115, 134 Stat. 281, 574 (2020).

[xxxii]The CARES Act included a provision requiring laboratories to submit the result of each COVID-19 test in a manner specified by the Secretary of Health and Human Services. Pub. L. No. 116-136, § 18115, 134 Stat. 281, 574 (2020). HHS guidance required the reporting of test results by race and ethnicity. Department of Health and Human Services, *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* (June 4, 2020).

[xxxiii]See Department of Health and Human Services, *Fiscal Year 2025 Centers for Disease Control and Prevention Justification of Estimates for Appropriations Committee*.

[xxxiv]See Department of Health and Human Services, Office of the 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 (July 2022).

[xxxv]See GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments,* GAO-22-105397 (Washington, D.C.: Apr. 27, 2022).

[xxxvi]See GAO, *Tribal Epidemiology Centers: HHS Actions Needed to Enhance Data Access,* GAO-22-104698 (Washington, D.C.: Mar. 4, 2022).

[xxxvii]See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10221, 124 Stat. 119, 935 (2010) (codified at 25 U.S.C. § 1621m(e)).

[xxxviii]See Department of Health and Human Services, Office of the 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).

[xxxix]See 5 U.S.C. §§ 1001–14.

[xl]See GAO, *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).

[xli]See GAO, *COVID-19 Contracting: Opportunities to Improve Practices to Assess Prospective Vendors and Capture Lessons Learned,* GAO-21-528 (Washington, D.C.: July 29, 2021).

Other notes

All icons presented in Appendix II are sourced from RaulAlmu/ stock.adobe.com.

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.

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.