

Testimony

Before the Committee on Homeland Security, House of Representatives

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Key Insights from GAO's Oversight of the Federal Public Health Response

Statement of A. Nicole Clowers, Managing Director, Health Care Team



GAO@100 Highlights

Highlights of GAO-21-396T, a testimony before the Committee on Homeland Security, House of Representatives

Why GAO Did This Study

As of February 17, 2021, the U.S. had about 27 million cumulative reported cases of COVID-19 and more than 486,000 reported deaths, according to the Centers for Disease Control and Prevention. The country also continues to experience serious economic repercussions.

Five relief laws, including the CARES Act, have appropriated \$3.1 trillion to address the public health and economic threats posed by COVID-19. The CARES Act also includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to COVID-19.

This testimony summarizes GAO's insights from its oversight of the federal government's pandemic response in a series of comprehensive reports issued from June 2020 through January 2021. In particular, the statement focuses on the public health response, including testing, vaccines and therapeutics, medical supply chain, health disparities, and health data.

GAO reviewed data, documents, and guidance from federal agencies about their activities and interviewed federal and state officials and stakeholders for the series of reports on which this testimony is based. See https://www.gao.gov/coronavirus/.

What GAO Recommends

GAO has made 44 recommendations for agencies and four matters for congressional consideration in its comprehensive series of bimonthly reports on the federal response to COVID-19 over the last year. GAO will issue its next report in this series in March 2021.

View GAO-21-396T. For more information, contact A. Nicole Clowers, (202) 512-7114 or clowersa@gao.gov.

February 24, 2021

COVID-19

Key Insights from GAO's Oversight of the Federal Public Health Response

What GAO Found

More than a year after the U.S. declared COVID-19 a public health emergency, the pandemic continues to result in catastrophic loss of life and substantial damage to the economy. It also continues to lay bare the fragmented nature of our public health sector, the fragility of the nation's medical supply chain, and longstanding disparities in health care access, treatment, and outcomes.

GAO has made 44 recommendations to federal agencies. Of these recommendations, 16 relate to the following public health topics:

<u>COVID-19 Testing</u>. GAO has made two recommendations to date to improve the federal government's efforts in diagnostic testing for COVID-19, critical to controlling the spread of the virus. In January 2021, GAO recommended that the Department of Health and Human Services (HHS) develop and make publicly available a comprehensive national COVID-19 testing strategy.

<u>Vaccines and Therapeutics</u>. GAO has made two recommendations to improve transparency, communication, and coordination around the government's efforts to develop, manufacture, and distribute vaccines and therapeutics to prevent and treat COVID-19. For example, in September 2020, GAO recommended that HHS establish a time frame for a national vaccine distribution and administration plan that follows best practices, with federal and nonfederal coordination.

Medical Supply Chain. GAO has made seven recommendations for the federal government to respond to vulnerabilities highlighted by the pandemic in the nation's medical supply chain, including limitations in personal protective equipment and other supplies necessary to treat individuals with COVID-19. In January 2021, GAO recommended that HHS establish a process for regularly engaging with Congress and nonfederal stakeholders as the agency refines and implements its supply chain strategy for pandemic preparedness, to include the role of the Strategic National Stockpile.

<u>COVID-19 Health Disparities</u>. GAO has made three recommendations to improve COVID-19 data by race and ethnicity, as available data show communities of color bear a disproportionate burden of COVID-19 positive tests, cases, hospitalizations, and deaths. In September 2020, GAO recommended that the Centers for Disease Control and Prevention involve key stakeholders to help ensure the complete and consistent collection of demographic data.

<u>COVID-19 Data</u>. GAO has made two recommendations to improve the collection of data needed to respond to COVID-19 and prepare for future pandemics. GAO recommended in January 2021 that HHS establish an expert committee to help systematically define and ensure the collection of standardized data across the relevant federal agencies and related stakeholders; the absence of such data hinders the ability of the government to respond to COVID-19, communicate the status of the pandemic with citizens, or prepare for future pandemics.

Although the responsible agencies generally agreed with the majority of the 16 recommendations, only one has been fully implemented. GAO maintains that implementing these recommendations will improve the federal government's public health response and ability to recover as a nation.

Chairman Thompson, Ranking Member Katko, and Members of the Committee:

Thank you for the opportunity to discuss the federal government's ongoing response to Coronavirus Disease 2019 (COVID-19). The pandemic has resulted in catastrophic loss of life and substantial damage to the global economy, and to the stability and security of our nation. As of February 17, 2021, the U.S. had more than 27 million reported cases and 486,000 reported deaths, according to the Centers for Disease Control and Prevention (CDC).

The country also continues to experience serious economic repercussions. In January 2021, there were more than 10.1 million unemployed individuals, compared to nearly 5.8 million individuals in January 2020.

Over the past 2 weeks, case counts and deaths have slowed since peaking in January 2021. But public health officials warn that we should not become complacent in our efforts, as new variants of virus appear across the country. Until the country better contains the spread of the virus, the pandemic will continue to lay bare the fragmented nature of our public health sector, the fragility of our medical supply chain, and longstanding disparities in health care access, treatment, and outcomes, as well as impeding a more robust economic recovery.

In response to this ongoing public health emergency, and the resulting economic challenges, Congress and the administration have taken a series of actions to protect the health and well-being of Americans. Notably, in March 2020, Congress passed, and the President signed into law, the CARES Act, which provided over \$2 trillion in emergency assistance and health care response for individuals, families, and

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businesses affected by COVID-19.1 To date, the five enacted COVID-19 relief laws, including the CARES Act, have appropriated \$3.1 trillion.

The CARES Act includes a provision for us to conduct monitoring and oversight of the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic, including issuance of bimonthly reports to Congress.² We are to report on, among other things, the effect of the pandemic on public health and the economy. To date, our work in response to this provision includes five comprehensive issued reports from June 2020 through January 2021; we will issue our next government-wide report on the federal response to the COVID-19 pandemic at the end of March.

In our five reports we have made 44 recommendations to federal agencies, and raised four matters for congressional consideration to improve the federal government's response efforts.³ Our recommendations are tailored to specific federal programs and initiatives, and, if implemented, will strengthen the efficiency, effectiveness, and accountability of these federal efforts. We urge the new Congress and administration to consider these recommendations as well as the principles of an effective federal response that we have previously identified.

My comments today will summarize the key findings and recommendations from our oversight of the federal government's continued efforts to respond to and recover from the COVID-19 pandemic. I will focus my comments on our findings related to the public health response, including COVID-19 testing, vaccines and therapeutics,

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¹Pub. L. No. 116-136, 134 Stat. 281 (2020). As of January 1, 2021, four other relief laws were also enacted in response to the COVID-19 pandemic: the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182 (2020); Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020); Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020); and the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146. We refer to these five laws, each of which was enacted as of January 1, 2021, and provides appropriations for the COVID-19 response, as "COVID-19 relief laws," and the funding appropriated by these laws as "COVID-19 relief funds." In January 2020, the novel coronavirus was declared a public health emergency.

²Pub. L. No. 116-136, § 19010, 134 Stat. at 579-81.

³See https://www.gao.gov/coronavirus/ for our comprehensive reports and other COVID-19 related reports.

the medical supply chain, COVID-19 health disparities, and COVID-19 health data.

We conducted the work on which this statement is based, which was completed on January 15, 2021, with updates to federal agency data, as available, in accordance with generally accepted government auditing standards.⁴ 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.

Key Insights from GAO's Oversight of the Federal Response to COVID-19

In February 2020, at the outset of the COVID-19 pandemic, we identified key principles that are essential for an effective federal response. Specifically, based on our prior work examining responses to large-scale catastrophic disasters or public health emergencies, we emphasized the need for federal agencies to coordinate, establish, and define roles and responsibilities among those responding to the crisis, and to provide clear, consistent communication. In June 2020, we reinforced the importance of these key principles and also emphasized the need to collect and analyze data to inform decision-making and future preparedness; establish clear goals; establish mechanisms for accountability and transparency to help ensure program integrity; and address fraud risks. Incorporating these principles into ongoing or new COVID-19-related programs and policies will improve the effectiveness of the federal government's response.

Of the 44 recommendations we have made to date, 16 fall into one of the following public health areas: COVID-19 testing, vaccines and therapeutics, medical supply chain, COVID-19 health disparities, and COVID-19 health data.

COVID-19 Testing

Diagnostic testing for COVID-19 is critical to controlling the spread of the virus, according to CDC. We have made two recommendations to improve the federal government's COVID-19 testing efforts, as shown in

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⁴We reviewed data, documents, and guidance from federal agencies about their activities and interviewed federal and state officials and stakeholders for the series of reports on which this testimony is based.

⁵A. Nicole Clowers, Managing Director of GAO's Health Care team, *Roundtable: Are We Prepared? Protecting the U.S. from Global Pandemics,* testimony before the Senate Committee on Homeland Security and Governmental Affairs. 116th Cong., 2nd sess., Feb. 12, 2020.

table 1. Most recently, in January 2021, we found that the Department of Health and Human Services (HHS) had not issued a comprehensive and publicly available national testing strategy. For example, stakeholders involved in the response efforts told us that they either were unaware of the national strategy or did not have a clear understanding of it. Without a comprehensive, publicly available national strategy, HHS is at risk of key stakeholders and the public lacking crucial information to support an informed and coordinated testing response.

In January 2021, we recommended that HHS develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy. Such a strategy could build upon existing strategy documents that HHS has produced for the public and Congress to allow for a more coordinated pandemic testing approach. (See table 1.)

Table 1: GAO's Recommendations Related to COVID-19 Testing

Recommendation

The Secretary of Health and Human Services (HHS) should develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy. Such a strategy could build upon existing strategy documents that HHS has produced for the public and Congress to allow for a more coordinated pandemic testing approach (January 2021)

The Secretary of Health and Human Services should ensure that the Director of the Centers for Disease Control and Prevention (CDC) clearly discloses the scientific rationale for any change to testing guidelines at the time the change is made (November 2020 report).

Status

Open. HHS partially concurred with our recommendation. HHS agreed that the department should take steps to more directly incorporate some of the elements of an effective national strategy, but expressed concern that producing such a strategy at this time could be overly burdensome on the federal, state, and local entities that are responding to the pandemic, and that a plan would be outdated by the time it was finalized or potentially rendered obsolete by the rate of technological advancement.

Open. HHS concurred with our recommendation, noting that CDC officials typically consult with scientific stakeholders when issuing guidance and that HHS will continue to evaluate its processes in this area.

Source GAO I GAO-21-396T

report).

Vaccines and Therapeutics

Multiple federal agencies support the development and manufacturing, and now distribution, of vaccines and therapeutics to prevent and treat COVID-19. Agencies involved in the federal partnership (formerly called Operation Warp Speed) include the Department of Defense (DOD) and HHS, including HHS's Biomedical Advanced Research and Development Authority (BARDA), Food and Drug Administration (FDA), CDC, and the National Institutes of Health (NIH). DOD is supporting HHS in nationwide distribution efforts of any licensed or authorized vaccine. As of February 18, 2021, two of the six Operation Warp Speed vaccine candidates had been authorized by FDA for emergency use, and vaccine distribution and vaccine administration began in December 2020. A third company

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submitted a request for emergency use authorization for its vaccine to FDA on February 4, 2021.

In addition, the Federal Emergency Management Agency (FEMA) provides funding to states (including D.C.), tribes and territories, for expenses related to COVID-19 vaccination. In accordance with a January 21, 2021, presidential memorandum, FEMA will reimburse states, territorial, local, and tribal governments for costs associated with vaccine distribution and administration through the Disaster Relief Fund, which had a balance of more than \$12.2 billion, as of February 7, 2021, according to FEMA.⁶ The agency has also deployed staff across the nation to support vaccine centers with federal personnel and technical assistance.

As shown in table 2, we have made two recommendations to improve the government's efforts related to vaccines and therapeutics. In particular, in September 2020, we reported that clarity on the federal government's plans for distributing and administering vaccine, as well as timely, clear, and consistent communication to stakeholders and the public about those plans, is essential. In September 2020, we recommended that HHS, with the support of DOD, establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccines that, among other things, outlines an approach for how efforts would be coordinated across federal agencies and nonfederal entities.

In our January 2021 report, we noted that vaccine distribution and administration had, as of January, fallen short of expectations. We reiterated the importance of fully implementing our September 2020 recommendation. (See table 2.)

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⁶White House, *Memorandum to Extend Federal Support to Governors' Use of the National Guard to Respond to COVID-19 and to Increase Reimbursement and Other Assistance Provided to States*, (Washington, D.C.: Jan. 21, 2021), accessed on February 4, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/extend-federal-support-to-governors-use-of-national-guard-to-respond-to-covid-19-and-to-increase-reimb ursement-and-other-assistance-provided-to-states/. According to FEMA, as of February 7, 2021, it had provided more than \$2.29 billion to 32 states, the District of Columbia, three territories, and two tribes for expenses related to COVID-19 vaccination efforts.

Table 2: GAO's Recommendations Related to COVID-19 Vaccines and Therapeutics

Recommendation

The Secretary of Health and Human Services should direct the Commissioner of the Food and Drug Administration (FDA) to identify ways to uniformly disclose to the public the information from FDA's scientific review of safety and effectiveness data—similar to the public disclosure of the summary safety and effectiveness data supporting the approval of new drugs and biologics—when issuing emergency use authorizations (EUA) for therapeutics and vaccines, and, if necessary, seek the authority to publicly disclose such information (November 2020 report on vaccine and therapeutics).

The Secretary of Health and Human Services, with support from the Secretary of Defense, should establish a time frame for documenting and sharing a national plan for distributing and administering a COVID-19 vaccine and, in developing such a plan, ensure that it is consistent with best practices for project planning and scheduling and outlines an approach for how efforts will be coordinated across federal agencies and nonfederal entities (September 2020 report).

Status

Closed. FDA developed a process for working with drug sponsors to disclose its scientific review documents for therapeutic EUAs and has released this information for the EUAs it has already issued. For vaccine EUAs, FDA is holding public Vaccines and Related Biological Products Advisory Committee meetings, through which FDA and sponsors are making information from scientific reviews publicly available. The agency also released decision memos with detailed information about the agency's review of safety and effectiveness data for the two vaccines authorized to date

Open. The Department of Health and Human Services (HHS) neither agreed nor disagreed with our recommendation. In November 2020, we reported that HHS and the Department of Defense had released initial planning documents for the distribution and administration of potential COVID-19 vaccines, but also reported that stakeholders indicated that they would like to see additional information as planning continued.

Source GAO Analysis I GAO-21-396T

Medical Supply Chain

The pandemic has highlighted vulnerabilities in the nation's medical supply chain, which includes personal protective equipment and other supplies necessary to treat individuals with COVID-19. Ensuring the availability of medical supplies to meet the continuing needs of state, local, tribal, and territorial governments, as well as point-of-care providers, such as nursing homes, has been a persistent challenge for federal agencies. Continued supply chain constraints may also hamper HHS's goal of building a 90-day supply of certain key items in the Strategic National Stockpile (SNS).

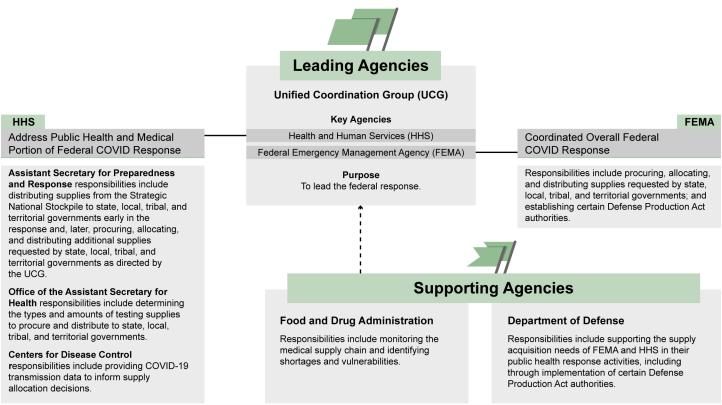
Multiple federal agencies have responsibility for coordinating and managing the medical supply chain, and HHS and FEMA lead the federal response through the Unified Coordination Group.⁷ HHS is designated as the lead agency to address the public health and medical portion of the response and FEMA is designated as the lead agency for coordinating the overall federal response. The agencies are responsible for supporting and informing decisions made by the Unified Coordination Group

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⁷The Unified Coordination Group (UCG) is the primary field entity for the federal response. The group integrates diverse federal authorities and capabilities and coordinates federal response and recovery operations. The UCG is jointly led by the Administrator of FEMA, the Assistant Secretary for Preparedness and Response, and a representative of CDC.

regarding the allocation, distribution, and procurement of COVID-related supplies (see fig. 1).

Figure 1: Key Federal Agencies Involved in Coordinating and Managing the Medical Supply Chain during the COVID-19 Pandemic



Source: GAO. | GAO-21-396T

We have made seven recommendations to improve the federal government's efforts to address medical supply challenges highlighted by the pandemic (see table 3.) In our January 2021 report, we focused on the role of the SNS, which is an important piece of HHS's strategy to improve the medical supply chain to enhance pandemic response capabilities and was being finalized during the course of our review. However, the department has yet to develop a process for engaging about the strategy with key nonfederal stakeholders that have a shared role for providing supplies during a pandemic, such as state and territorial governments and the private sector. Our work has noted the importance of directly and continuously involving key stakeholders, including

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Congress, in the development of successful agency reforms and in helping to harness ideas, expertise, and resources.

In January 2021, we recommended that HHS establish a process for regularly engaging with Congress and nonfederal stakeholdersincluding state, local, tribal, and territorial governments and private industry—as the agency refines and implements its supply chain strategy for pandemic preparedness, to include the role of the SNS.

Recommendation	Status
To improve the nation's response to and preparedness for pandemics, the Assistant Secretary for Preparedness and Response should establish a process for regularly engaging with Congress and nonfederal stakeholders—including state, local, tribal, and territorial governments and private industry—as the Department of Health and Human Services (HHS) refines and implements a supply chain strategy for pandemic preparedness, to include the role of the Strategic National Stockpile (January 2021 report).	Open. HHS generally concurred with our recommendation, and added that improving the pandemic response capabilities of state, local, tribal, and territorial governments is a priority.
The Assistant Secretary for Preparedness and Response, in coordination with the appropriate offices within HHS, should accurately report data in the federal procurement database system and provide information that would allow the public to distinguish between spending on other transaction agreements and procurement contracts (January 2021 report).	Open. HHS concurred with our recommendation and stated that it has taken steps to manually identify its other transaction agreements in its contract writing system to allow the public to distinguish between spending on agreements and procurement contracts in the Federal Procurement Data System-Next Generation. HHS also plans to update its contract writing system.
The Commissioner of the Food and Drug Administration (FDA) should, as the agency makes changes to its collection of drug manufacturing data, ensure the information obtained is complete and accessible to help it identify and mitigate supply chain vulnerabilities, including by working with manufacturers and other federal agencies (e.g., the Departments of Defense and Veterans Affairs), and, if necessary, seek authority to obtain complete and accessible information (January 2021 report).	Open. HHS neither agreed nor disagreed with our recommendation. In HHS's response, FDA said that as the agency continues efforts to enhance relevant authorities and close data gaps, it will consider GAO's recommendation.
The Secretary of Health and Human Services, in coordination with the Administrator of the Federal Emergency Management Agency(FEMA)—who head agencies leading the COVID-19 response through the Unified Coordination Group—should immediately document roles and responsibilities for supply chain management functions transitioning to the Department of Health and Human Services, including continued support from other federal partners, to ensure sufficient resources exist to sustain and make the necessary progress in stabilizing the supply chain, and address emergent supply issues for the duration of the COVID-19 pandemic (September 2020 report).	Open. HHS disagreed with our recommendation at the time the report was issued and noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability.

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Recommendation	Status
The Secretary of Health and Human Services in coordination with the Administrator of FEMA—who head agencies leading the COVID-19 response through the Unified Coordination Group—should further develop and communicate to stakeholders plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps necessary to respond to the remainder of the pandemic, including through the use of Defense Production Act authorities (September 2020 report).	Open. HHS disagreed with our recommendation at the time the report was issued and noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability.
The Secretary of Health and Human Services —who heads one of the agencies leading the COVID-19 response through the Unified Coordination Group—consistent with the department's roles and responsibilities, should work with relevant federal, state, territorial, and tribal stakeholders to devise interim solutions, such as systems and guidance and dissemination of best practices, to help states enhance their ability to track the status of supply requests and plan for supply needs for the remainder of the COVID-19 pandemic response (September 2020 report).	Open. HHS disagreed with our recommendation at the time the report was issued and noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability.
The Administrator of FEMA—who heads one of the agencies leading the COVID-19 response through the Unified Coordination Group—consistent with the department's roles and responsibilities, should work with relevant federal, state, territorial, and tribal stakeholders to devise interim solutions, such as systems and guidance and dissemination of best practices, to help states enhance their ability to track the status of supply requests and plan for supply needs for the remainder of the	Open. The Department of Homeland Security, on behalf of FEMA, disagreed with our recommendation at the time the report was issued and noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability

Source GAO I GAO-21-396T

COVID-19 Health Disparities

COVID-19 pandemic response (September 2020 report).

Available data from CDC and others demonstrate disparities in COVID-19 indicators by race and ethnicity, with communities of color bearing a disproportionate burden of COVID-19 cases, hospitalizations, and deaths. For example, the available data on COVID-19 hospitalizations show that as of February 12, 2021, the rate of COVID-19-associated hospitalizations for non-Hispanic American Indian/Alaska Native persons is 3.7 times the rate for non-Hispanic White persons, when adjusting for

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age.⁸ Available data from CDC on the percentage of positive COVID-19 tests and on recipients of COVID-19 vaccinations also demonstrate racial and ethnic disparities.

Testing. As of January 7, 2021, among COVID-19 diagnostic test results reported to CDC from laboratories in 48 jurisdictions, the percent of tests that were positive by each racial and ethnic group was: 17.9 percent for Hispanic or Latino persons, 13.2 percent for non-Hispanic Native Hawaiian or Other Pacific Islander persons, 12.4 percent for non-Hispanic American Indian/Alaska Native, and 11.2 percent for non-Hispanic Black persons, compared to 9.5 percent for non-Hispanic White persons.⁹

Vaccinations. Data showed disparities by race and ethnicity in vaccine recipients who received at least one dose whose race and ethnicity was known as of February 8, 2021:

- 62.9 percent were non-Hispanic White (compared to 60.1 percent of the U.S. population),
- 8.9 percent were Hispanic or Latino (compared to 18.5 percent of the U.S. population), and

⁸Hospitalization data through January 30, 2021, are from CDC's COVID-19-Associated Hospitalization Surveillance Network (COVID-NET), which collects data on COVID-19 hospitalizations that are confirmed by laboratory testing from select counties in 14 states, representing 10 percent of the U.S. population. It includes data from hospitals in select counties in California, Colorado, Connecticut, Georgia, Iowa, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah. American Indian/Alaska Native, Asian, and Black, and White persons were non-Hispanic. Hispanic or Latino persons might be of any race.

Age-adjusted case, hospitalization, and death rates were standardized to the 2019 U.S. intercensal population. Age-adjusted rates, which hold constant the age distributions between different population groups, allow researchers to focus analyses on other demographics, such as race and ethnicity, without being concerned about differences that are due to different age distributions of the racial and ethnic groups. Age-adjusted rates are particularly important to consider for indicators of COVID-19 because persons in older age groups are more likely to experience hospitalizations and racial and ethnic groups have different age distributions in the U.S. population.

⁹Department of Health and Human Services, Centers for Disease Control and Prevention. Report to Congress on Paycheck Protection Program and Health Care Enhancement Act Disaggregated Data on U.S. Coronavirus Disease 2019 (COVID-19) Testing, 8th 30-Day Update (January 2021). CDC data represent viral COVID-19 laboratory test results from laboratories in the U.S., including commercial laboratories, public health laboratories, and other testing locations from 48 jurisdictions. The data represent total laboratory tests, not individual people, and exclude antibody and antigen tests.

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 5.9 percent were non-Hispanic Black (compared to 13.4 percent of the U.S. population).¹⁰

While CDC collects and makes race and ethnicity data on indicators of COVID-19 available to the public, we found gaps in the data for COVID-19 indicators. For example, as of February 2, 2021, race and ethnicity was missing for 48.8 percent of COVID-19 cases with case report forms received by CDC, or 61.5 percent of total cases reported. Additionally, as of February 8, 2021, data collected from states and jurisdictions on race and ethnicity for COVID-19 vaccine recipients were missing for almost half (45.6 percent) of recipients who received at least one dose.

We made three recommendations to address the gaps in race and ethnicity data (see table 4). CDC agreed with the recommendations.

Table 4. GAO's	Recommendations	Related to	COVID-19 Health	Disparities

Recommendation	Status
As the Center for Disease Control and Prevention (CDC) implements its COVID-19 Response Health Equity Strategy, the Director of CDC should determine whether having the authority to require states and jurisdictions to report race and ethnicity information for COVID-19 cases, hospitalizations, and deaths is necessary for ensuring more complete data and, if so, seek such authority from Congress (September 2020 report).	Open. CDC agreed with our recommendation. In response to our recommendation, CDC stated in January 2021 that the agency is committed to having discussions, both internally and with stakeholders, to assess whether having and implementing authority to require states and jurisdictions to report race and ethnicity information for COVID-19 cases would result in improved reporting.
As CDC implements its COVID-19 Response Health Equity Strategy, the Director of CDC should involve key stakeholders to help ensure the complete and consistent collection of demographic data (September 2020 report).	Open. CDC agreed with our recommendation. In response to our recommendation, CDC stated in January 2021 that the agency is working with state and local health departments, in addition to other stakeholders, to accelerate the reporting of demographic data and improve data quality, including for information on race and ethnicity.
As CDC implements its COVID-19 Response Health Equity Strategy, the Director of CDC should take steps to help ensure CDC's ability to comprehensively assess the long-term health outcomes of persons with COVID-19, including by race and ethnicity (September 2020 report).	Open. CDC agreed with our recommendation. In response to our recommendation, CDC noted in October 2020 that the agency is convening a team to develop a plan to monitor the long-term health outcomes of persons with COVID-19 by identifying health care surveillance systems that can electronically report health conditions to state and local health departments.

Source GAO I GAO-21-396T

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¹⁰CDC COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic, accessed February 9, 2021.

¹¹CDC officials reported that the number of cases with case report forms received by CDC is less than the total number of reported cases because there is generally a 2-week lag from when total cases are reported by state and jurisdictional health departments to when CDC receives the case report forms. Total cases reported by CDC include both probable and confirmed cases as reported by states or jurisdictions. A probable case does not have confirmatory laboratory evidence, but meets certain other criteria.

COVID-19 Data Collection and Standardization

The federal government does not have a process to help systematically define and ensure the collection of standardized data across relevant federal agencies and related stakeholders to help respond to COVID-19, communicate the status of the pandemic with citizens, or prepare for future pandemics. As a result, COVID-19 information that is collected and reported by states and other entities to the federal government is often incomplete and inconsistent.

The lack of complete and consistent data limits HHS's and others' ability to monitor trends in the burden of the pandemic across states and regions, make informed comparisons between such areas, and assess the impact of public health actions to prevent and mitigate the spread of COVID-19. Further, incomplete and inconsistent data have limited HHS's and others' ability to prioritize the allocation of health resources in specific geographic areas or among certain populations most affected by the pandemic. For example, HHS's data on COVID-19 in nursing homes do not capture the first 4 months of the pandemic, because the agency did not require nursing homes to report until May 8, 2020. The gaps in reporting limits the usefulness of data in helping to understand the effects of COVID-19 in nursing homes. GAO has made two recommendations to improve the collection of data needed to respond to COVID-19 and prepare for future pandemics.

In January 2021, we recommended that HHS immediately establish an expert committee comprised of knowledgeable health care professionals from the public and private sectors, academia, and nonprofits or use an existing one to systematically review and inform the alignment of ongoing data collection and reporting standards for key health indicators.

In addition, in September 2020, we recommended that HHS, in consultation with CMS and CDC, develop a strategy to capture more complete data on COVID-19 cases and deaths in nursing homes retroactively back to January 1, 2020.

In conclusion, we have made 16 recommendations to improve the government's pandemic response in the areas of COVID-19 testing, vaccines and therapeutics, medical supply chain, COVID-19 health disparities, and COVID-19 health data. Most of the recommendations have not been implemented. We maintain that doing so would improve the government's response. We will continue to monitor the implementation of our past recommendations as part of our ongoing

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oversight of the government's COVID-19 response and recovery efforts on behalf of Congress.

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

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact A. Nicole Clowers, Managing Director, Health Care at (202) 512-7114 or clowersa@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are Tim Bushfield, Assistant Director; Jill Center, Analyst-in-Charge; Jennie Apter, Robert Dougherty, Kelly Krinn, and Elaina Stephenson.

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