



November 2021

# COVID-19

## HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives



A Century of Non-Partisan Fact-Based Work

# GAO@100 Highlights

Highlights of [GAO-22-104457](#), a report to congressional committees

## Why GAO Did This Study

Vaccination remains critical in the federal response to the COVID-19 pandemic. Vaccine implementation—prioritizing, allocating, distributing, and administering doses—requires coordination among federal, state, and local levels and other stakeholders. HHS agencies—including CDC and HRSA—set up federal vaccine distribution programs, such as CDC’s retail pharmacy program that sends doses directly to pharmacies. The federal government also sends vaccine doses to states for further distribution.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report examines (1) stakeholder perspectives on federal programs to distribute and administer COVID-19 vaccines, (2) efforts to inform health officials, providers, and the public about vaccination, and (3) actions HHS agencies are taking to evaluate their vaccine implementation efforts.

GAO reviewed data and documents from HHS, CDC, and HRSA, and reviewed information from and interviewed state and local health officials in four states and one city selected, in part, for geographic variation. GAO also interviewed other stakeholders, including 12 national associations representing health care providers and others.

## What GAO Recommends

GAO is making four recommendations, including that CDC and HRSA obtain input from and share lessons learned with key stakeholders as they conduct their future reviews. HHS concurred with GAO’s recommendations.

View [GAO-22-104457](#). For more information, contact Alyssa M. Hundrup at 202-512-7114 or [hundrupa@gao.gov](mailto:hundrupa@gao.gov)

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# HHS Agencies’ Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives

## What GAO Found

In late 2020 and early 2021, agencies within the Department of Health and Human Services (HHS) set up federal programs for vaccine distribution and administration. State and local health officials and other stakeholders GAO interviewed said these programs helped higher-risk populations access COVID-19 vaccination. For example, the Health Resources and Services Administration’s (HRSA) health center program provided vaccinations in medically underserved areas. However, these stakeholders also cited challenges, such as initially having limited or no information on the doses federal programs were sending to pharmacies and health centers in their communities. They said this made it difficult to decide which sites, including pharmacies and health centers, to send their own allocated doses when supply was limited.

Stakeholders told GAO the Centers for Disease Control and Prevention’s (CDC) education materials, such as provider toolkits, were useful to address the public’s concerns about the safety of COVID-19 vaccines, but providers would have liked them sooner to be able start promoting vaccination earlier. These stakeholders, including health officials, said they had difficulty managing public expectations and responding to questions about vaccine availability when they did not receive advance notice about changes in federal priority groups for vaccination.

### Individual Being Vaccinated as Part of a Federal Program



Source: Defense Visual Information Distribution Service. | [GAO-22-104457](#)

Officials from HHS agencies—CDC and HRSA—stated they intend to conduct after action reviews to identify lessons learned from their COVID-19 vaccine distribution and communication efforts. However, officials said they have not finalized their plans for conducting such reviews, nor do they plan to do so while they continue to respond to the pandemic and have ongoing programs. Thus, it is uncertain whether they will gather input, including on an ongoing basis, from key stakeholders instrumental in vaccine distribution and communication efforts, such as state and local health officials, or whether the results will be shared with those stakeholders. Doing so will help ensure CDC and HRSA learn what worked well and identify areas for improvement to inform future vaccination efforts.

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### Abbreviations

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
DOD	Department of Defense
EUA	emergency use authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
health center vaccine program	Health Center COVID-19 Vaccine Program
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
LTC pharmacy program	Pharmacy Partnership for Long-Term Care Program
retail pharmacy program	Federal Retail Pharmacy Program for COVID-19 Vaccination
vaccination center pilot program	Community Vaccination Center Pilot Site and Mobile Vaccination Program
VAMS	Vaccine Administration Management System

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November 4, 2021

Congressional Committees:

More than a year and a half after the United States declared the Coronavirus Disease 2019 (COVID-19) pandemic a public health emergency, the nation continues to grapple with and respond to the pandemic. After an overall decline in the numbers of COVID-19 cases, hospitalizations, and deaths from their peaks in early 2021, cases began to surge again in the summer of 2021 as a new variant of the virus emerged.<sup>1</sup> Hospitalization and deaths attributed to COVID-19 also increased, primarily among those unvaccinated, according to federal health officials.<sup>2</sup> Increasing COVID-19 vaccination coverage among the public remains a critical priority for the federal government. As of October 8, 2021, about 66 percent of the U.S. population aged 12 years and older (about 187 million individuals) had been fully vaccinated, according to data from the Centers for Disease Control and Prevention (CDC).<sup>3</sup>

COVID-19 vaccine implementation—which includes prioritizing, allocating, distributing, and administering vaccine doses—is a highly complex undertaking, requiring coordination among multiple federal agencies, the private sector, jurisdictions, tribal officials, and health care

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<sup>1</sup>According to the Centers for Disease Control and Prevention (CDC), viruses, such as COVID-19, constantly change through mutation, and new variants are expected to occur. Sometimes new variants emerge and disappear, while at other times, new variants persist. The Delta variant (which, as of this report, is the dominant strain) spreads much faster than previous variants and may cause more severe cases of illness than other variants.

<sup>2</sup>For example, one study published by CDC showed new COVID-19 hospitalization rates in New York between May and July 2021 were considerably higher among unvaccinated adults than fully vaccinated adults. See Department of Health and Human Services, Centers for Disease Control and Prevention, “New COVID-19 Cases and Hospitalizations among Adults by Vaccination Status—New York, May 3–July 25, 2021,” *Morbidity and Mortality Weekly Report*, vol. 70, no. 34 (Atlanta, Ga.: Aug. 27, 2021).

<sup>3</sup>As of October 22, 2021, three COVID-19 vaccines were available in the United States but none of them was available for children under 12 years. Two of the three COVID-19 vaccines available for use were two-dose vaccine regimens and the third one was a single-dose vaccine. According to CDC, the count of fully vaccinated individuals represents the number of people who have received the second dose of a two-dose COVID-19 vaccine regimen and those who received one dose of the single-dose COVID-19 vaccine.

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providers.<sup>4</sup> At the federal level, the Department of Health and Human Services (HHS), along with its component agencies, has been a key department responsible for vaccine implementation efforts. For example, HHS, in partnership with the Department of Defense (DOD), has supported the development, manufacturing, allocation, and distribution of COVID-19 vaccine doses to states and other jurisdictions and to other federal vaccine distribution programs.

Since June 2020, we have cited the critical importance of planning for the development, manufacturing, distribution, and administration of COVID-19 vaccines.<sup>5</sup> In September 2020, we recommended that the Secretary of Health and Human Services, with support from the Secretary of Defense, develop a national plan for distributing and administering COVID-19 vaccines that outlines an approach for how efforts would be coordinated across federal agencies and nonfederal entities.<sup>6</sup> CDC issued initial planning documents in September and October 2020, and in January 2021, the White House issued a national COVID-19 response strategy that broadly outlined various programs for vaccine distribution. These documents contain general information on federally supported vaccine distribution activities, but do not provide details related to how the federal government is coordinating its efforts or information on the specific roles of the federal agencies and non-federal entities.

When COVID-19 vaccination began in December 2020, the federal government provided the majority of the limited supply of vaccine doses to the 50 states and other jurisdictions to further distribute to health care providers located in their jurisdictions. In December 2020, the federal government also began a vaccine distribution program targeting residents and staff in long-term care facilities. Then, in February 2021, it began three additional vaccine distribution programs focused on providing COVID-19 vaccine doses to pharmacies, federally supported health centers, and mass vaccination sites for administration.

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<sup>4</sup>Jurisdictions include all 50 states, the District of Columbia, eight U.S. territories, and a small number of major cities.

<sup>5</sup>GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, [GAO-20-625](#) (Washington, D.C.: June 25, 2020).

<sup>6</sup>The Secretary neither agreed nor disagreed with our recommendation. See GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, [GAO-20-701](#) (Washington, D.C.: Sept. 21, 2020).

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For COVID-19, CDC has played a key role in informing health care providers and the public about COVID-19 vaccination. A key component of any successful vaccination effort is timely, clear, and consistent communication to stakeholders like state, territorial, and local health officials and health care providers, as well as to the public about vaccine availability, effectiveness, and safety. Communication that is responsive to the public's questions and concerns can help increase public confidence and trust in vaccines and in vaccination.

Additionally, in our 2011 review of the federal response to the H1N1 influenza pandemic, we raised the importance of capturing lessons learned from the federal government's response. We reported on the importance of identifying response actions that worked well and those that could be improved, so the nation could be better prepared when the next pandemic occurred.<sup>7</sup>

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic.<sup>8</sup> This report is part of our body of work in response to the CARES Act and focuses on the federal government's efforts related to the distribution and administration of and communication about COVID-19 vaccines.<sup>9</sup> In this report, we

1. describe state and local health officials' and other stakeholders' perspectives on federal efforts to distribute and administer COVID-19 vaccines, including four federal vaccine distribution programs;
2. describe state and local health officials' and other stakeholders' perspectives on federal efforts, including CDC's efforts, to inform health officials, health care providers, and the public about COVID-19 vaccination; and

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<sup>7</sup>GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, [GAO-11-632](#) (Washington, D.C.: June 27, 2011).

<sup>8</sup>Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020).

<sup>9</sup>We have regularly issued government-wide reports on the federal response to COVID-19. For the latest report, see GAO, *COVID-19: Additional Actions Needed to Improve Accountability and Program Effectiveness of Federal Response*, [GAO-22-105051](#) (Washington, D.C.: Oct. 27, 2021). Our next government-wide report will be issued in January 2022 and will be available on GAO's website at <https://www.gao.gov/coronavirus>. Also, see the GAO Related Products section at the end of this report for additional work we have done on COVID-19 vaccines.



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3. examine actions HHS agencies are taking to evaluate their efforts to distribute and administer COVID-19 vaccines and to communicate about COVID-19 vaccination.

To address the first objective, we reviewed information from and interviewed selected state and local health officials and other stakeholders about federal efforts to distribute and administer COVID-19 vaccines, generally covering the period of December 2020 through May 2021. We focused our review on the four federal vaccine distribution programs that together distributed the most vaccine doses to the public, outside of vaccine doses distributed through states and other jurisdictions. These four programs included

- CDC's Pharmacy Partnership for Long-Term Care Program (LTC pharmacy program),
- CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination (retail pharmacy program),
- the Health Resources and Services Administration's (HRSA) Health Center COVID-19 Vaccine Program (health center vaccine program),<sup>10</sup> and
- the Federal Emergency Management Agency's (FEMA) Community Vaccination Center Pilot Site and Mobile Vaccination Program (vaccination center pilot program).<sup>11</sup>

We also obtained stakeholder perspectives on federal efforts to support the administration of COVID-19 vaccines, including the use of DOD and National Guard personnel, and additional categories of individuals qualified to administer vaccines with liability protections, such as dentists and veterinarians. The selected state and local health officials and other stakeholders we spoke to are described below; the perspectives of these officials and other stakeholders are not generalizable but provided valuable insight on these issues.

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<sup>10</sup>CDC coordinated with HRSA on the health center vaccine program, but for the purposes of this report, we refer to this program as a HRSA-operated vaccine distribution program since HRSA was the primary agency responsible for implementing the program.

<sup>11</sup>CDC coordinated with FEMA on the vaccination center pilot program, but for the purposes of this report, we refer to this program as a FEMA-operated vaccine distribution program since FEMA was the primary agency responsible for implementing the program.

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- **Selected state and local health officials.** We reviewed information from and interviewed or obtained written responses from health officials from five selected jurisdictions—four states (Connecticut, Georgia, Minnesota, and Washington) and one city (Philadelphia).<sup>12</sup> Within each of the four states, we also interviewed health officials from one local health department that had one or more vaccination site receiving vaccine doses through one of the four federal vaccine distribution programs we examined. We conducted these interviews between late March and early May 2021.
  - **Other stakeholders.** Within each of the four selected states noted above, we also interviewed representatives from the state’s medical association and hospital association to obtain the perspectives of health care providers. In addition, we reviewed information from and interviewed or obtained written responses from representatives from 12 national associations who represented different stakeholder groups, including state and local health officials, tribal health organizations, health care providers involved in vaccine administration, and others.<sup>13</sup> We conducted these interviews between April and May 2021.

To address the second objective, we obtained information from CDC’s website and from written responses on the agency’s efforts to inform health officials, health care providers, and the public about COVID-19 vaccination, generally covering the period of November 2020 to August 2021. We also conducted interviews with the selected state and local health officials and other stakeholders described above to get their perspectives on CDC’s efforts and about recommendations from CDC’s

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<sup>12</sup>We selected jurisdictions to reflect variation in geographic location and the degree to which state public health infrastructures were centralized or decentralized. We also selected one major city that received vaccine allocations directly from the federal government and is considered a jurisdiction.

<sup>13</sup>We interviewed officials or obtained written responses from: American Hospital Association, American Medical Association, Association of Immunization Managers, Association of State and Territorial Health Officials, National Association of Community Health Centers, National Association of Chain Drug Stores, National Association of County and City Health Officials, National Community Pharmacists Association, National Council of Urban Indian Health, National Governors Association, National Indian Health Board, and National Rural Health Association.

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Advisory Committee on Immunization Practices (ACIP) on which groups to initially prioritize and target when vaccine supply was limited.<sup>14</sup>

For both the first and second objectives, we also reviewed documentation from and interviewed officials from federal agencies involved in federal COVID-19 vaccine distribution, administration, or communication efforts. These agencies included CDC, FEMA, HRSA, and the HHS-DOD partnership tasked with supporting COVID-19 vaccine development, manufacturing, and distribution to states and other jurisdictions and selected federal entities.<sup>15</sup>

To address the third objective, we interviewed officials from HHS, including CDC and HRSA, and reviewed written responses from CDC and HRSA about their plans for conducting and sharing the results of after action reviews of federal COVID-19 vaccine implementation efforts. We compared CDC's and HRSA's plans for after action reviews to federal internal control standards regarding information and communication, and the underlying principle that management should externally communicate the necessary quality information to achieve the entity's objectives.<sup>16</sup> We also compared the agencies' plans with the Project Management Institute's program management standards, which similarly call for program managers to engage with key stakeholders.<sup>17</sup> Finally, we compared the agencies' plans to prior GAO work on lessons learned from and after action reports on the federal response to prior emergencies, including the 2009 H1N1 pandemic.<sup>18</sup>

Finally, we analyzed data from CDC's COVID-19 Data Tracker on the number of COVID-19 vaccine doses delivered, by distribution channel, as of August 19, 2021, and on doses administered and new cases of COVID-19 (the 7-day average of the new cases each day) as of October

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<sup>14</sup>ACIP is comprised of medical and public health experts who make recommendations on the use of vaccines in the civilian population of the United States.

<sup>15</sup>This partnership was initially known as Operation Warp Speed, but since May 2021, is named the HHS-DOD COVID-19 Countermeasures Acceleration Group.

<sup>16</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014).

<sup>17</sup>Project Management Institute, Inc., *The Standard for Program Management, Fourth Edition*, 2017.

<sup>18</sup>GAO, *Disaster Response: HHS Should Address Deficiencies Highlighted by Recent Hurricanes in the U.S. Virgin Islands and Puerto Rico*, [GAO-19-592](#) (Washington, D.C.: Sept. 20, 2019) and [GAO-11-632](#).

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8, 2021. We interviewed agency officials about the data on vaccine doses distributed and administered, and reviewed available documentation on these sources and on COVID-19 case rate data. We determined these data were sufficiently reliable for the purpose of providing context on COVID-19 vaccinations.

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

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## Background

As of October 22, 2021, three COVID-19 vaccines were available in the United States. One vaccine was licensed by the Food and Drug Administration (FDA) for individuals aged 16 years and older and was also available for individuals aged 12 to 15 years under an emergency use authorization (EUA), which allows for the temporary use of vaccines without FDA licensure, provided certain statutory criteria are met.<sup>19</sup> Two additional vaccines were authorized for emergency use for individuals

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<sup>19</sup>Typically, FDA must license a vaccine before it can be marketed in the United States. See 42 U.S.C. § 262. On August 23, 2021, FDA licensed the COVID-19 vaccine developed by Pfizer and BioNTech (marketed as Comirnaty) for the prevention of COVID-19 disease. For the purposes of this report, we refer to the COVID-19 vaccine that Pfizer and BioNTech developed together as the Pfizer vaccine.

The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products, such as vaccines. Once a declaration of an emergency has been made, FDA may temporarily allow use of unlicensed vaccines through an EUA. For FDA to issue an EUA for a vaccine, it must be reasonable to believe that the vaccine may be effective and that the known and potential benefits of the vaccine outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3. FDA has indicated that issuance of an EUA for a COVID-19 vaccine for which there is adequate manufacturing information would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

Any COVID-19 vaccine that initially receives an EUA from FDA is expected to work toward submission of a biologics license application, according to FDA guidance. See Department of Health and Human Services, Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry*, (Silver Spring, Md.: May 2021).

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aged 18 years and older.<sup>20</sup> (See app. I for more information on COVID-19 vaccines available in the United States.) As of October 22, 2021, no vaccines had been authorized or licensed for children under 12 years, but one vaccine company (Pfizer) had requested that FDA authorize its COVID-19 vaccine for children aged 5 years to 11 years.<sup>21</sup>

As of October 8, 2021, about 66 percent of the U.S. population eligible for vaccination (i.e., those aged 12 years and older) was fully vaccinated—that is, they had received the second dose of a two-dose COVID-19 vaccine or had received the single-dose COVID-19 vaccine—but vaccination rates varied among different population groups. For example, more than 80 percent of those aged 65 years and older were fully vaccinated, compared with less than 60 percent of individuals under 40 years of age, according to CDC data. (See fig. 1.)

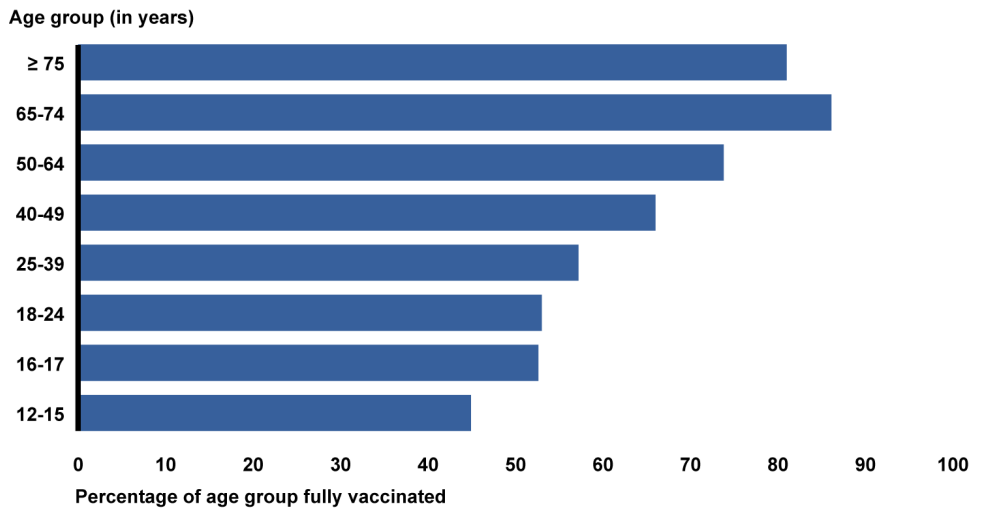
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<sup>20</sup>On June 10, 2021, one vaccine company, Moderna, requested FDA amend the EUA for its COVID-19 vaccine for use in adolescents aged 12 years to 17 years; as of October 22, 2021, FDA had not issued a decision in response. The other authorized COVID-19 vaccine was by Janssen Pharmaceutical Companies, which is part of Johnson & Johnson.

Additional or booster doses have also been authorized and recommended for fully vaccinated individuals. In August 2021, FDA authorized, and CDC recommended, the use of an additional dose of the Pfizer and Moderna COVID-19 vaccines in certain immunocompromised individuals. In September and October 2021, FDA authorized and CDC recommended that certain populations receive a booster dose of either the Pfizer, Moderna, or Janssen vaccine. In October 2021, FDA also authorized “mix and match” for the booster dose—that is, authorizing the use any available COVID-19 vaccine for use as a booster dose regardless of which COVID-19 vaccine was used as the primary series or single-dose primary series. According to CDC, an additional dose is administered when the initial immune response following a primary vaccine series is likely to be insufficient and a booster dose is administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

<sup>21</sup>As of October 22, 2021, FDA’s Vaccines and Related Biological Products Advisory Committee was scheduled to meet on October 26, 2021, to discuss a request for authorization of Pfizer’s COVID-19 vaccine for children aged 5 through 11 years.

**Figure 1: Percentage of Those Fully Vaccinated in the United States, by Age Group, as of October 8, 2021**

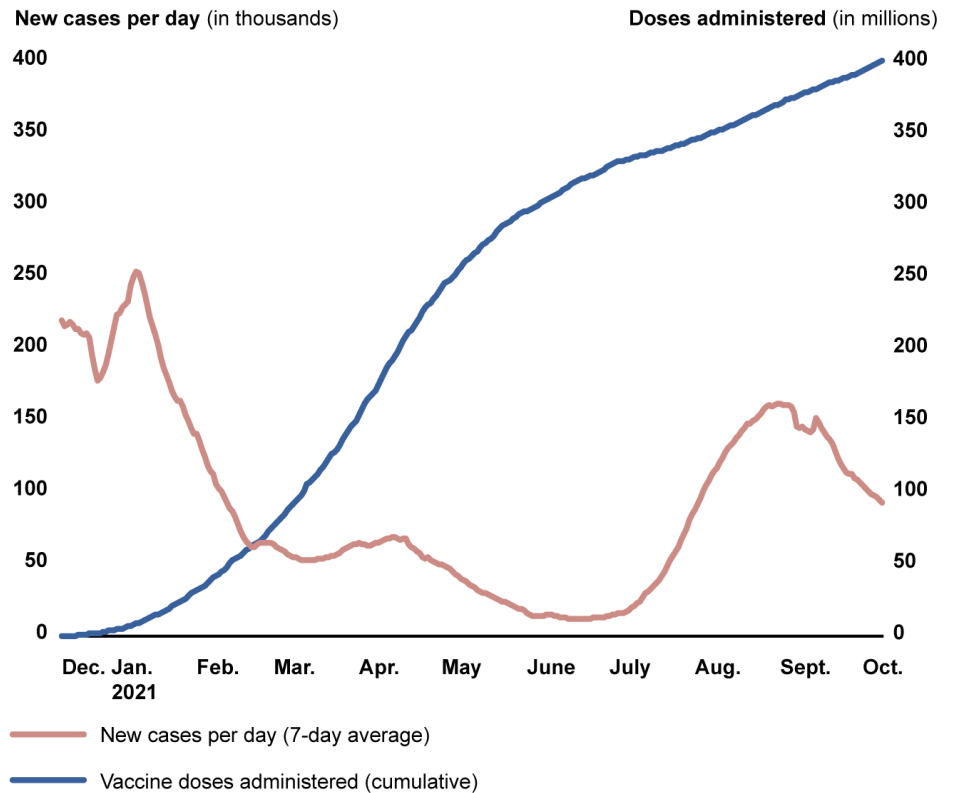


Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO-22-104457

Notes: The figure does not include data for Texas or for individuals under age 18 years from Idaho, due to limitations in these states' reporting of demographic data to CDC. As of October 8, 2021, three COVID-19 vaccines were available in the United States. One vaccine was authorized for emergency use in individuals aged 12 years to 15 years on May 10, 2021, and was licensed for individuals aged 16 years and older. The two remaining vaccines were authorized for emergency use for individuals aged 18 years and older. As of October 8, 2021, there were no vaccines authorized or licensed for children under 12 years. In this figure, fully vaccinated refers to those individuals who have received the second dose in a two-dose COVID-19 vaccine regimen and those who received one dose of the single-dose COVID-19 vaccine.

Over time, as the number of COVID-19 vaccine doses administered increased, COVID-19 case rates fell steadily through mid-June 2021. (See fig. 2.) In late June, however, the average number of cases per day began to increase as the more transmissible Delta variant was circulating. After September 2021, the average number of cases per day generally declined; as of October 8, 2021, the average number of cases per day was 93,437.

**Figure 2: Number of COVID-19 Vaccine Doses Administered and Reported COVID-19 Cases per Day in the United States, December 14, 2020 to October 8, 2021**



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO-22-104457

Notes: Data begin on December 14, 2020, when the first dose of COVID-19 vaccine was administered in the United States. Data on the number of COVID-19 vaccine doses administered reflect the cumulative number of doses administered as reported to CDC by state, local, and territorial immunization information systems and other sources. Data on COVID-19 case rates reflect the 7-day moving average for the number of new cases reported per day and are based on aggregate case reporting to CDC on probable and confirmed cases by states and jurisdictions. According to CDC, the actual number of COVID-19 cases is unknown for a variety of reasons, including that people who have been infected may not have been tested, or may not have sought medical care.

The pace of COVID-19 vaccinations in the United States has fluctuated over time. In the first 4 months after vaccination began, as vaccine supply increased, the average number of doses administered daily climbed steadily, peaking in April 2021. In the following months, the average number of doses administered daily declined steeply and then in July 2021, began to increase once more, after COVID-19 cases had begun to surge again. As of October 8, 2021, about 34 percent of the U.S. population aged 12 years and older was not fully vaccinated.

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Those unvaccinated may include people who desire to be vaccinated but face access barriers, such as lacking transportation to a vaccination site or not having the ability to take time off from work to get vaccinated. Others may be uncertain or reluctant to be vaccinated (sometimes referred to as vaccine hesitancy) for different reasons, such as having concerns about the safety of COVID-19 vaccines or believing vaccination is unnecessary because COVID-19 is not a serious threat to their health.<sup>22</sup>

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## Federal Efforts to Allocate and Distribute COVID-19 Vaccines

COVID-19 vaccine implementation—that is, prioritizing, allocating, distributing, and administering vaccine doses—has been a key component in mitigating the disease’s effect on the public’s health, societal functioning, and the economy. (See text box below.) The federal government began distributing COVID-19 vaccine doses on December 12, 2020, and 2 days later, the first dose of vaccine was administered.<sup>23</sup>

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<sup>22</sup>While different models exist for categorizing attitudes toward vaccination, a common conception is that these attitudes run along a continuum that ranges from full acceptance of vaccines on one end to full opposition to vaccines on the other. The term “vaccine hesitancy” has been used to refer to a delay in acceptance of vaccines, including the COVID-19 vaccine, despite the availability of vaccination services. An individual’s level of vaccine hesitancy can vary by vaccine and over time. See National Academies of Sciences, Engineering, and Medicine, *The Critical Public Health Value of Vaccines: Tackling Issues of Access and Hesitancy: Proceedings of a Workshop* (Washington, D.C.: 2021).

<sup>23</sup>See app. II for a timeline of these efforts and other key events related to COVID-19 vaccine implementation.



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## COVID-19 Vaccine Implementation

COVID-19 vaccine implementation includes the prioritization, allocation, distribution, and administration of vaccine doses and relies on communication and coordination between the federal government and stakeholders, including states and other jurisdictions, local health departments, the private sector, and health care providers.

**Prioritization** refers to the identification of groups prioritized for vaccination when vaccine supply is limited. Within priority groups are separate target groups, which are added as vaccine supply increases. CDC's Advisory Committee on Immunization Practices issued its recommendations for priority groups and target groups for COVID-19 vaccination in December 2020.

**Allocation** refers to the number of vaccine doses the federal government made available through different vaccine distribution programs, such as to states and other jurisdictions. States and other jurisdictions used part of their allocations of vaccine doses from the federal government for CDC's Pharmacy Partnership for Long-Term Care Program; the other doses were directed to health care providers within their jurisdictions. In contrast, three additional federal vaccine distribution programs—(1) CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination, (2) the Health Resources and Services Administration's (HRSA) Health Center COVID-19 Vaccine Program, and (3) the Federal Emergency Management Agency's (FEMA) Community Vaccination Center Pilot Site and Mobile Vaccination Program—were implemented as separate distribution programs, and each program received a direct allocation of vaccine doses from the federal government.

**Distribution** refers to the delivery of COVID-19 vaccine doses to health care providers, as directed by states and other jurisdictions; federal entities, such as FEMA and HRSA; and other entities that have partnered with the federal government, such as pharmacies.

**Administration** refers to the administering of COVID-19 vaccine doses at various sites, including long-term care facilities, pharmacies, health centers, mass vaccination sites, and physician offices, by authorized health care providers.

Source: GAO summary of information from the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services, and the Department of Defense. | GAO-22-104457

When COVID-19 vaccine implementation began in December 2020, the federal government allocated and distributed nearly all available vaccine

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doses to the 50 states and other jurisdictions.<sup>24</sup> Jurisdictions then decided how to further distribute their allocated vaccine doses to authorized health care providers within their boundaries, including to pharmacies, health centers, local health departments, mass vaccination sites, hospitals, physician offices, and others.<sup>25</sup> Initially, the vaccine supply was limited and not all health care providers that wanted to administer COVID-19 vaccines received doses, and people who wanted to be vaccinated experienced challenges doing so, according to multiple stakeholders. We previously reported that state, territorial, and local health officials and health care providers experienced multiple challenges when distribution of COVID-19 vaccines first began in mid-December 2020.<sup>26</sup> For example, health officials and health care providers said they lacked information on vaccine shipments, such as the number of doses being delivered, which was needed to assist their on-the-ground planning for vaccine administration.

In December 2020, the federal government initiated CDC's LTC pharmacy program. Under this program, CDC worked with selected pharmacy partners to vaccinate residents and staff at participating nursing homes and other long-term care facilities.<sup>27</sup> To implement this

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<sup>24</sup>In December 2020, the federal government began providing allocations of COVID-19 vaccine doses to 62 jurisdictions, including all 50 states, the District of Columbia, three major cities (Chicago, New York City, and Philadelphia), and eight territories (American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands), generally on a weekly basis. A jurisdiction could then order vaccine doses from the federal government to be distributed to authorized health care providers for administration, up to the allocated number of doses (order cap). Although there are 64 jurisdictions implementing COVID-19 vaccination and receiving federal funding for these efforts, allocations of vaccine doses were made to 62 jurisdictions because two major cities considered jurisdictions—Houston and San Antonio—had their allocations consolidated with Texas. On June 24, 2021, the federal government stopped allocating COVID-19 vaccine doses to jurisdictions and federal vaccine distribution programs because vaccine supply had increased to sufficient levels to meet the needs of jurisdictions and other federal programs, according to federal officials.

<sup>25</sup>As of October 22, 2021, all COVID-19 vaccines in the United States have been purchased by the U.S. Government for administration exclusively by authorized health care providers enrolled in CDC's COVID-19 Vaccination Program. Only health care providers enrolled as vaccination providers can legally store, handle, and administer COVID-19 vaccines in the United States.

<sup>26</sup>GAO, *COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation*, [GAO-21-443](#) (Washington, D.C., Apr. 14, 2021).

<sup>27</sup>For the LTC pharmacy program, CDC worked with CVS, Walgreens, and Managed Health Care Associates, Inc., as pharmacy partners.

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program, pharmacies used vaccine doses from states' and other jurisdictions' allocations to conduct three on-site vaccination clinics at each participating facility.

In February 2021, as the vaccine supply began increasing, the federal government implemented three additional vaccine distribution programs.<sup>28</sup> These three federal programs were outlined in the White House's national strategy for the COVID-19 response and received their own allocations of vaccine doses from the federal government.<sup>29</sup> According to federal officials, the number of vaccine doses the federal government allocated to CDC's retail pharmacy program, HRSA's health center vaccine program, and FEMA's vaccination center pilot program were determined by the White House COVID-19 Response Team.<sup>30</sup> The programs were

- **CDC's retail pharmacy program**, which distributed vaccine doses directly to national pharmacy partners and independent pharmacy networks,

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<sup>28</sup>In addition to allocations of vaccine doses made to states and other jurisdictions and these three federal programs, the federal government allocated and distributed vaccine doses to five federal entities (the Bureau of Prisons, DOD, Department of State, Indian Health Service, and the Veterans Health Administration). The federal government also allocated vaccine doses to HHS/National Institutes of Health for a small program managing doses allocated to federal departments and agencies for administration to critical infrastructure personnel and made a one-time allocation of 751,140 vaccine doses to the Federal Dialysis Center Program to distribute to participating dialysis centers to administer vaccines to patients and health care personnel.

<sup>29</sup>The *National Strategy for the COVID-19 Response and Pandemic Preparedness* includes a goal of mounting a safe, effective, and comprehensive vaccination campaign. See White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021). Earlier planning documents, including CDC's COVID-19 interim guidance for states and other jurisdictions, identified the LTC pharmacy partnership and outlined plans for direct partners such as retail pharmacy chains that would enroll directly with CDC to order and receive COVID-19 vaccines. See Department of Health and Human Services, Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, version 2.0* (Atlanta, Ga: Oct. 29, 2020).

<sup>30</sup>Since January 2021, the White House COVID-19 Response Team has been responsible for coordinating across the federal government on the COVID-19 response, including COVID-19 vaccine implementation, and for communicating to the public, state, and local public health officials and other stakeholders about these efforts through regular public briefings.

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- **HRSA’s health center vaccine program**, which distributed vaccine doses to federally supported health centers,<sup>31</sup> and
  - **FEMA’s vaccination center pilot program**, which distributed vaccine doses to federally operated community vaccination centers and to mobile vaccination units.<sup>32</sup>

The federal government initiated these four federal vaccine distribution programs, in part, to focus on vaccinating higher-risk populations who might experience worse health outcomes associated with COVID-19. The programs were put in place to supplement states’ and jurisdictions’ vaccination efforts, according to federal officials. When the federal programs were initiated, some pharmacies and health centers were already receiving vaccine doses from the states or other jurisdictions in which they were located, as jurisdictions distributed their allocated vaccine doses to health care providers in their communities. Thus, some pharmacies and health centers could receive vaccine doses from both their jurisdiction and a federal vaccine distribution program.

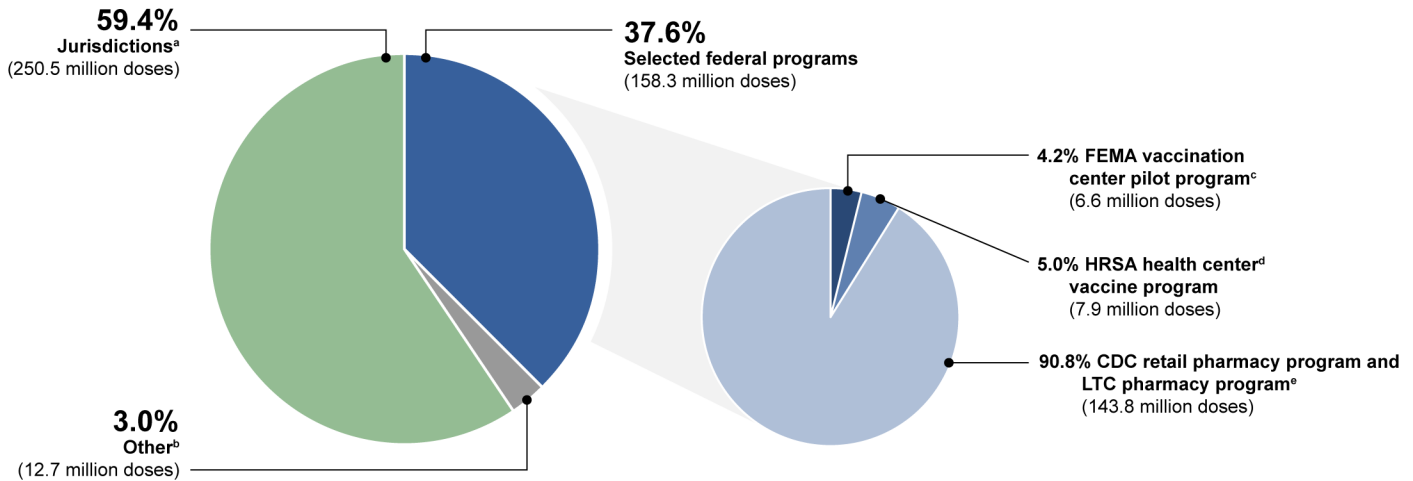
As of August 19, 2021, the federal government had distributed over one-third of all COVID-19 vaccine doses through the four federal vaccine distribution programs, with most doses going to pharmacies (through CDC’s LTC pharmacy program and its retail pharmacy program). (See fig. 3.)

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<sup>31</sup>Federally supported health centers generally receive Health Center Program grants from HRSA under section 330 of the Public Health Service Act (42 U.S.C. § 254b) and provide primary care services in medically underserved communities. Some organizations meet all Health Center Program requirements but do not receive federal grant funding through the section 330 program. However, these centers, which are known as “look-alikes,” receive other benefits, such as higher reimbursement rates from the Medicare and Medicaid programs and may receive grants through other federal programs. We use the term “federally supported health centers” to refer to both “look-alikes” and those health centers that receive grants under section 330 of the Public Health Service Act.

<sup>32</sup>On June 20, 2021, the last mass vaccination site under FEMA’s vaccination center pilot program closed, according to federal officials. However, after that date, agency officials reported that they continued to support mobile vaccination units and community vaccination centers managed and operated by states and other jurisdictions (using doses allocated to the jurisdictions) by providing federal personnel, funding, and material, such as medical equipment and supplies.

**Figure 3: Percentage of COVID-19 Vaccine Doses Distributed through Four Federal Vaccine Distribution Programs Compared to the Percentage Distributed through Jurisdictions, as of August 19, 2021**



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO-22-104457

Notes: Figure shows cumulative number and percentage of COVID-19 vaccine doses distributed through four federal and other vaccine distribution programs from the time vaccine doses were first distributed in December 2020 to August 19, 2021.

<sup>a</sup>A total of 62 jurisdictions—including all 50 states, the District of Columbia, three major cities (Chicago, New York City, and Philadelphia), and eight territories (American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands)—received allocations of COVID-19 vaccine doses, generally on a weekly basis. Although there are 64 jurisdictions implementing COVID-19 vaccination and receiving federal funding for these efforts, allocations of vaccine doses were made to 62 jurisdictions because two major cities considered jurisdictions—Houston and San Antonio—had their allocations consolidated with Texas.

<sup>b</sup>Other includes other federal vaccine distribution programs that received direct allocations from the federal government—(1) four federal entities (the Bureau of Prisons, Department of Defense, Indian Health Service, and the Veterans Health Administration); (2) Department of Health and Human Services/National Institutes of Health for a small program managing doses allocated to federal departments and agencies for administration to critical infrastructure personnel; and (3) a one-time allocation of vaccine doses to the Federal Dialysis Center Program to distribute to participating dialysis centers to administer vaccines to patients and health care personnel. Although the Department of State received allocations of vaccine doses from the federal government, data for this department are not included in CDC’s data on distribution.

<sup>c</sup>CDC coordinated with the Federal Emergency Management Agency (FEMA) on the Community Vaccination Center Pilot Site and Mobile Vaccination Program (vaccination center pilot program); for the purposes of this report, we refer to this program as a FEMA-operated vaccine distribution program. On June 20, 2021, the last mass vaccination site under this program closed, according to agency officials.

<sup>d</sup>CDC coordinated with the Health Resources and Services Administration (HRSA) on the Health Center COVID-19 Vaccine Program (health center vaccine program); for the purposes of this report, we refer to this program as a HRSA-operated vaccine distribution program.

<sup>e</sup>The number of doses attributed to CDC’s Federal Retail Pharmacy Program for COVID-19 Vaccination (retail pharmacy program) includes doses distributed through its Pharmacy Partnership for Long-Term Care Program (LTC pharmacy program). The LTC pharmacy program ended on April 23, 2021.

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Although the federal government distributed the majority of vaccine doses through states and other jurisdictions when COVID-19 vaccine implementation began, this changed over time. For example, between April and July 2021, the proportion of vaccine doses distributed through states and other jurisdictions decreased from 62 percent in early April 2021, to 6 percent in mid-July 2021. During that same time, the proportion of vaccine doses distributed through CDC’s retail pharmacy program increased from 29 percent to 92 percent, according to our analysis.<sup>33</sup>

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## CDC’s Efforts to Inform Health Officials, Health Care Providers, and the Public about COVID-19 Vaccination

Before COVID-19 vaccine implementation began, CDC took steps to inform jurisdictional health officials, health care providers, and the public about COVID-19 vaccines. For example, CDC created its first COVID-19 Vaccine Toolkit in November 2020.<sup>34</sup> The agency created several other Toolkits targeted to various audiences, such as health care providers, health centers, pharmacies, and schools, which included materials for communicating about the potential and known benefits, safety, side effects, and effectiveness of COVID-19 vaccines. In addition, CDC partnered with the Ad Council to create public service announcements to encourage vaccination.<sup>35</sup> Providing information on safety and efficacy is important to help inform the public about COVID-19 vaccines and to address any concerns about vaccination.<sup>36</sup>

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<sup>33</sup>Our analysis compared the proportion of vaccine doses CDC reported as distributed through the different federal vaccine distribution programs between April 1–18, 2021, and July 8–23, 2021. Our analysis began in April 2021, because this is when CDC began making data on COVID-19 vaccine doses distributed through the different federal vaccine distribution programs publicly available. Our analysis ended in July 2021, because these were the most recent data available at the time of our analysis.

<sup>34</sup>CDC also developed tools to help the public locate where COVID-19 vaccines were available and to schedule a vaccination appointment—VaccineFinder and the Vaccine Administration Management System (VAMS). See app. III for more information on these tools.

<sup>35</sup>The Ad Council is a nonprofit and nonpartisan organization that uses advertising, media, technology, and marketing to develop public service campaigns to raise awareness and to solve social issues on a national scale.

<sup>36</sup>For example, one survey conducted between March and May 2021 found that most people aged 18 to 39 years who responded that they probably or definitely would not get vaccinated said it was because they did not trust COVID-19 vaccines or were concerned about possible side effects. Brittney N. Baack et al., “COVID-19 Vaccination Coverage and Intent among Adults Aged 18–39 Years—United States, March–May 2021,” *Morbidity and Mortality Weekly Report*, vol. 70, no. 25 (2021).

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CDC also provided guidance on which segments of the population should be prioritized for vaccination when initial vaccine supply was limited, when the agency adopted ACIP's recommendations. In December 2020, ACIP recommended that COVID-19 vaccines be allocated through a phased approach and identified broad priority groups that should be offered COVID-19 vaccines first while vaccine supply was limited.<sup>37</sup> ACIP recommendations generally serve as public guidance for safe use of vaccines and states and other jurisdictions may adopt different approaches.

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## State and Local Health Officials and Others Said Federal Programs Helped Higher-Risk Populations Gain Access to COVID-19 Vaccination, but Cited Coordination Challenges




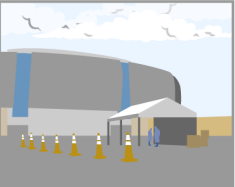
### Federal Programs Helped Higher-Risk Populations Gain Access to Vaccination, according to Selected Health Officials and Other Stakeholders

The four federal distribution programs helped higher-risk populations gain access to vaccinations and assisted with logistical aspects of administering COVID-19 vaccines, according to selected state and local health officials and other stakeholders we interviewed between late March and early May 2021. (See fig. 4 for descriptions of the four programs.)

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<sup>37</sup>ACIP is comprised of medical and public health experts who make recommendations on the use of vaccines in the civilian population of the United States. To inform its policy options, the committee established a COVID-19 Vaccines Work Group in April 2020, comprised of experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics. The Work Group has held numerous meetings to review data regarding vaccine candidates, COVID-19 surveillance, modeling of allocation scenarios, and vaccine implementation issues.

**Figure 4: Four Federal Distribution Programs for COVID-19 Vaccination**

Federal program	Description
<p><b>CDC's LTC pharmacy program</b></p> 	<p><b>Vaccination site:</b> Long-term care facilities</p> <p><b>Description:</b> CDC partnered with selected pharmacy partners to conduct three vaccination clinics at each site of 62,243 participating long-term care facilities, using vaccine doses the federal government directly allocated to states and other jurisdictions.<sup>a</sup></p> <p><b>Target population:</b> Residents and staff at long-term care facilities.</p> <p><b>Dates active:</b> December 2020 – April 2021</p> <p><b>Number of vaccine doses administered by program end:</b> 8.1 million</p>
<p><b>CDC's retail pharmacy program</b></p> 	<p><b>Vaccination site:</b> Pharmacies</p> <p><b>Description:</b> CDC partnered with 21 national pharmacy and independent pharmacy networks to distribute vaccine doses to 39,473 pharmacies, using vaccine doses directly allocated from the federal government.</p> <p><b>Target population:</b> Initial pharmacy partners were selected based on several factors, including the number of stores and the ability to reach populations at risk of severe illness (e.g., elderly, socially vulnerable communities).<sup>b</sup></p> <p><b>Dates active:</b> February 2021 – Ongoing</p> <p><b>Number of vaccine doses administered as of October 6, 2021:</b> about 133 million</p>
<p><b>HRSA's health center vaccine program</b></p> 	<p><b>Vaccination site:</b> Federally supported health centers</p> <p><b>Description:</b> HRSA distributed vaccine doses to 866 participating health centers for 2,362 sites, as of September 15, 2021, using vaccine doses directly allocated from the federal government. Participating health centers could use mobile vans or help pop-up clinics or school-based clinics to administer vaccines at community-based events.</p> <p><b>Target population:</b> Initial health centers were selected based on their service to disproportionately affected populations, such as migrant and seasonal agricultural workers. All federally supported health centers serve patients in medically underserved communities.<sup>c</sup></p> <p><b>Dates active:</b> February 2021 – Ongoing</p> <p><b>Number of vaccine doses administered as of September 15, 2021:</b> 6.4 million</p>
<p><b>FEMA's vaccination center pilot program</b></p> 	<p><b>Vaccination site:</b> Pilot community vaccination centers, including mass vaccination sites<sup>d</sup></p> <p><b>Description:</b> FEMA partnered with states to support 39 pilot community vaccination centers and 225 satellite sites across 27 states, using vaccine doses directly allocated from the federal government. These pilot community vaccination centers were managed and operated by FEMA personnel. The satellite sites brought vaccine doses to the community through mobile sites or pop-up clinics.</p> <p><b>Target population:</b> Sites were selected to reach socially vulnerable communities.</p> <p><b>Dates active:</b> February 2021 – June 2021</p> <p><b>Number of vaccine doses administered by program end:</b> 5.6 million</p>

Source: GAO analysis of data and information from the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Federal Emergency Management Agency (FEMA). | GAO-22-104457

Notes: This figure provides information on four federal vaccine distribution programs: (1) CDC's Pharmacy Partnership for Long-Term Care Program (LTC pharmacy program), (2) CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination (retail pharmacy program), (3) HRSA's Health



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Center COVID-19 Vaccine Program (health center vaccine program), and (4) FEMA's Community Vaccination Center Pilot Site and Mobile Vaccination Program (vaccination center pilot program).

CDC coordinated with HRSA on the health center vaccine program and with FEMA on the vaccination center pilot program, but for the purposes of this report, we refer to these programs as HRSA- and FEMA-operated vaccine distribution programs since these agencies were the primary agencies responsible for implementing these programs.

In addition, the federal government allocated and distributed vaccine doses to five federal entities (the Bureau of Prisons, Department of Defense, Department of State, Indian Health Service, and the Veterans Health Administration). The federal government also allocated vaccine doses to the Department of Health and Human Services/National Institutes of Health for a small program managing doses allocated to federal departments and agencies for administration to critical infrastructure personnel and made a one-time allocation of vaccine doses to the Federal Dialysis Center Program to distribute to participating dialysis centers to administer vaccines to patients and health care personnel.

<sup>a</sup>A total of 62 jurisdictions—including all 50 states, the District of Columbia, three major cities (Chicago, New York City, and Philadelphia), and eight territories (American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands)—received allocations of COVID-19 vaccine doses, generally on a weekly basis. Although there are 64 jurisdictions implementing COVID-19 vaccination and receiving federal funding for these efforts, allocations of vaccine doses were made to 62 jurisdictions because two major cities considered jurisdictions—Houston and San Antonio—had their allocations consolidated with Texas.

<sup>b</sup>According to CDC, social vulnerability refers to the potential negative effects on communities caused by external stresses on human health, such as natural or human-caused disasters or disease outbreaks.

<sup>c</sup>Federally supported health centers generally receive Health Center Program grants from HRSA under section 330 of the Public Health Service Act (42 U.S.C. § 254b) and provide primary care services in medically underserved areas. Some organizations meet all Health Center Program requirements but do not receive federal grant funding through the section 330 program. However, these centers, which are known as "look-alikes," receive other benefits, such as higher reimbursement rates from the Medicare and Medicaid programs and may receive grants through other federal programs. We use the term "federally supported health centers" to refer to both "look-alikes" and those health centers that receive grants under section 330 of the Public Health Service Act.

<sup>d</sup>On June 20, 2021, the last mass vaccination site under FEMA's vaccination center pilot program closed. However, after that date, the agency continued to support mobile vaccination units and community vaccination centers managed and operated by states and other jurisdictions (using doses allocated to the jurisdictions) by providing federal personnel, funding, and material, such as medical equipment and supplies, according to agency officials.

- **Helped higher-risk populations gain access to vaccinations.** The four federal vaccine programs did well in distributing vaccine doses to sites aimed at reaching populations at higher-risk for COVID-19, according to selected state and local health officials. For example,
  - CDC's LTC pharmacy program helped state health departments by facilitating the vaccination of higher-risk residents and staff of long-term care facilities, according to some state and local health officials. Some health officials said CDC's LTC pharmacy program made health care providers available to vaccinate residents and

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staff in long-term care facilities in their jurisdictions.<sup>38</sup> A few of these officials said vaccinating these higher-risk residents and staff would have otherwise been a large undertaking.

- CDC's retail pharmacy program and FEMA's vaccination center pilot program used CDC's social vulnerability index, which measures the relative vulnerability of the populations in every Census tract. CDC's retail pharmacy program used this index when initially deciding which pharmacies to add, and FEMA's vaccination center pilot program used the index, in part, to select mass vaccination sites.<sup>39</sup>
- Additionally, some stakeholders, including state and local health officials, noted that federally supported health centers—which provide primary care services in medically underserved areas—added vaccination access points for populations at higher risk for COVID-19 because they have limited access to care.
- HRSA's health center vaccine program and FEMA's vaccination center pilot program had flexibilities to provide more equitable access to vaccination sites. For example, HRSA's health center vaccine program was helpful because participating health centers in their area could schedule vaccination appointment times on weekends or evenings, according to health officials from one local health department. Officials from another local health department told us FEMA officials worked with them to extend operating hours to include early mornings, evenings, and Saturdays. These local health officials said the extended hours allowed them to administer up to 8,000 vaccinations a day at the FEMA site instead of the up to 6,000 vaccinations a day typically administered at this type of mass vaccination site.<sup>40</sup> (See fig. 5 for photos of FEMA mass vaccination sites.) Additionally, health

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<sup>38</sup>More than 62,000 long-term care facilities participated in CDC's LTC pharmacy program, according to CDC.

<sup>39</sup>CDC's social vulnerability index further groups the 15 social factors into four related themes: socioeconomic status, household composition and disability, race and ethnicity and language, and housing type and transportation. Each Census tract receives a ranking for each Census variable and for each of the four themes as well as an overall ranking. Census tracts are subdivisions of counties for which the Census collects statistical data.

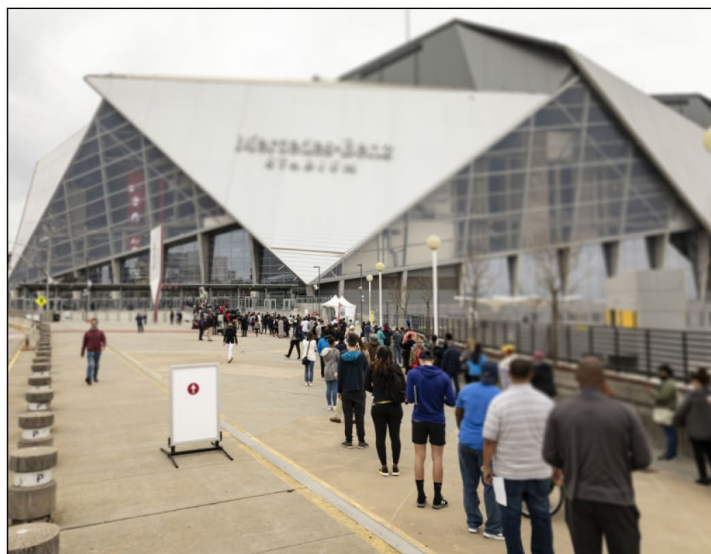
<sup>40</sup>Under FEMA's vaccination center pilot program, vaccination centers were available in five different types, generally depending on the approximate number of vaccinations that could be administered each day. These included type 1 (approximately 6,000 vaccinations per day), type 2 (approximately 3,000 vaccinations per day), type 3 (approximately 1,000 vaccinations per day), type 4 (approximately 250 vaccinations per day), and type 5 (approximately 250 vaccinations per day via mobile clinic).

officials from two states we interviewed told us they used FEMA's mobile vaccination units, which provided access to vaccinations by meeting individuals where they were located.

**Figure 5: FEMA Vaccination Center Pilot Program Sites**



Cars in line at a mass vaccination site in Los Angeles, California, for FEMA's vaccination center pilot program. (Photo by Spc. Jacob Ward)



People in line at a mass vaccination site for FEMA's vaccination center pilot program in Atlanta, Georgia. (Photo by Spc. Robert P. Wormley III)



Nurses and U.S. Navy hospital corpsmen administering COVID-19 vaccine at FEMA's vaccination center pilot program in Boston, Massachusetts. (Photo by Sgt. Matthew Lumagui)



People waiting at a mass vaccination site capable of administering 3,000 doses per day as part of FEMA's vaccination center pilot program. (Photo by K.C. Wilsey)

Source: Defense Visual Information Distribution Service. | GAO-22-104457

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Note: On June 20, 2021, the last mass vaccination site under FEMA's Community Vaccination Center Pilot Site and Mobile Vaccination Program (vaccination center pilot program) closed. However, after that date, the agency continued to support mobile vaccination units and community vaccination centers managed and operated by states and other jurisdictions (using doses allocated to the jurisdictions) by providing federal personnel, funding, and material, such as medical equipment and supplies, according to agency officials

- **Assisted with logistical aspects of COVID-19 vaccinations.** Some of the federal programs supported COVID-19 vaccinations by helping jurisdictions with administrative and logistical aspects of administering vaccines, according to state and local health officials we interviewed. For example,
  - CDC's retail pharmacy program helped state health departments by allowing the federal government to enroll pharmacies as COVID-19 vaccine providers, selected state health officials told us.<sup>41</sup> For example, officials from one jurisdiction said CDC's retail pharmacy program enrolled as vaccine providers all 77 pharmacies located in the jurisdiction that belonged to one pharmacy partner. Thus, officials from most state health departments we interviewed said they did not have to enroll those pharmacies as individual vaccine providers, easing an administrative burden on state health departments.
  - DOD and National Guard personnel provided critical assistance and efficient administration of vaccines for FEMA's vaccination center pilot program, according to selected state health officials and other stakeholders. For example, such personnel provided traffic control and security, and helped to set up mass vaccination sites, including for FEMA's vaccination center pilot program. (See fig. 6.) Because mass vaccination sites require a large number of staff to operate, the availability of DOD and National Guard personnel was critical to their operation, according to two state health officials. According to DOD, at the highest point of support by DOD active-duty personnel in the week of April 23–30, 2021, 4,731 active-duty personnel were supporting vaccination sites in over 25 states and territories. DOD reported that by June 22, 2021, active-duty personnel had administered about 5 million vaccinations.

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<sup>41</sup>Health care providers who want to administer COVID-19 vaccines have to enroll either through their jurisdictional immunization program (as part of CDC's COVID-19 Vaccination Program) or through the federal program in which they are participating. To enroll in these programs, providers have to, among other things, sign the respective program's provider agreement.

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In addition, health officials from most of the states in our review reported that the National Guard supported vaccine distribution and administration efforts. Additionally, two stakeholders representing health care providers said these personnel helped to efficiently administer vaccines at FEMA sites when demand for vaccinations was high.<sup>42</sup> As of July 22, 2021, over 21,000 National Guard personnel had assisted with vaccine-related activities, such as distributing vaccines, providing transportation support, and administering vaccines at 721 vaccination sites, according to DOD.

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<sup>42</sup>Before vaccine distribution began, stakeholders representing state and local health officials noted the importance of considering if uniformed military vaccinators would improve or undermine confidence in a COVID-19 vaccine, particularly among certain racial and ethnic groups and underserved communities where trust in government is strained. However, some stakeholders we interviewed said this concern was important to note, but did not use or experience issues with using military personnel.

**Figure 6: DOD and National Guard Personnel Provide Assistance at FEMA Vaccination Sites**



U.S. Army soldiers administering COVID-19 vaccines in Los Angeles, California. (Photo by Capt. Daniel Parker)



National Guard personnel assists with traffic control at a drive-through vaccine clinic in Louisville, Kentucky. (Photo by Dale Greer)



U.S. Army soldier administering COVID-19 vaccines in Houston, Texas. (Photo by Jose Rodriguez)



U.S. Navy sailors unpack and store medical supplies. (Photo by Steve Zumwalt)

Source: Defense Visual Information Distribution Service. | GAO-22-104457

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In addition, the federal government’s expansion of liability protections to additional categories of personnel for administering COVID-19 vaccines was helpful, according to some local health officials and representatives of health care providers we interviewed.<sup>43</sup> Specifically, in March 2021, HHS authorized additional categories of personnel to dispense and administer COVID-19 vaccines, with liability protections under the Public Readiness and Emergency Preparedness Act, including dentists, emergency medical technicians, optometrists, and others.<sup>44</sup> Representatives of health care providers in one state told us that it was a burden for facilities to pull nurses out of direct patient care to administer vaccines and that having the flexibility on who could provide vaccinations was important to make sure their facilities could vaccinate as many people as possible and remain in operation.

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### Stakeholders Identified Challenges Coordinating with Federal Vaccine Distribution Programs that Eased as Vaccine Supply Increased and as States and CDC Made Adjustments

Initially when vaccine supply was limited, state and local health officials faced challenges coordinating their vaccine-related efforts with the four federal vaccine programs, according to state and local health officials and other stakeholders we interviewed. Selected state and local health officials said they had to spend time and resources answering questions from the public and program participants about some of the federal programs, which officials from one state said further burdened their already limited staff and resources. However, as these vaccine distribution programs continued operating and vaccine supply increased in the spring of 2021, these coordination challenges eased. State and local health officials, representatives of health care providers, and other stakeholders we interviewed reported the following examples of the challenges they experienced coordinating with the federal programs:

- **Limited initial information on where vaccine doses were allocated and amounts allocated.** State and local health officials, health care providers, and other stakeholders said they had limited or no information about where vaccine doses were going or the amounts of doses allocated through CDC’s retail pharmacy program and

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<sup>43</sup>Some stakeholders we interviewed said additional health care providers available to administer vaccines did not address the vaccination challenge of a limited vaccine supply.

<sup>44</sup>Under this act, licensed health professionals and other individuals authorized to administer a countermeasure under state law are protected from liability under federal and state law for administering covered countermeasures against COVID-19, including the COVID-19 vaccines. HHS may identify additional categories of persons, known as “qualified persons”, to be afforded such protections. See Pub. L. No. 109-148, div. C, 119 Stat. 2680, 2818 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d et seq.). See HRSA Notice, 86 Fed. Reg. 14462 (Mar. 16, 2021).

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HRSA's health center vaccine program when these programs were initiated. Some of these officials told us the limited information on where vaccine doses were going made it difficult for states to optimally and equitably allocate and distribute their own limited supply of vaccine doses.<sup>45</sup> In some cases, a state's distribution of doses to a HRSA-supported health center was already high and additional federal doses provided under HRSA's health center vaccine program resulted in more doses being distributed than the health center could administer in a timely manner, according to most state health officials we interviewed.

For CDC's retail pharmacy program, most state health officials we spoke with reported experiencing challenges with determining which pharmacy sites would receive vaccine doses from the program's pharmacy partners (i.e., the 21 national pharmacy partners and independent pharmacy networks). For example, pharmacy partners in one state chose to distribute vaccine doses to pharmacy sites the state had not identified as priorities because they were located in areas with a sufficient number of existing vaccine providers. Health officials in the state said they had to negotiate with pharmacy partners participating in CDC's retail pharmacy program to send vaccine doses to pharmacy sites in higher-need areas of their state.

Additionally, representatives of health care providers said their members often did not know which pharmacies had received vaccine doses when CDC's retail pharmacy program was initiated, so health care providers were unable to refer their patients to pharmacies with available vaccine doses. As vaccine supply increased and there were enough vaccine doses available for all of the federal vaccine distribution programs, information on where vaccine doses were allocated and the amounts allocated became less important. On June 24, 2021, the federal government stopped its weekly allocation of COVID-19 vaccine doses to jurisdictions and federal vaccine distribution programs, including CDC's retail pharmacy program and HRSA's health center vaccine program, because vaccine supply had increased to sufficient levels to meet the needs of jurisdictions and other federal programs, according to federal officials.

- **Higher than needed vaccine allocation for LTC pharmacy program.** CDC overestimated the number of vaccine doses needed for CDC's LTC pharmacy program when vaccine supply was limited in

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<sup>45</sup>As we reported in April 2021, this information was critical for vaccination planning, especially when states were determining where to send their own allocated doses when supply was limited and demand for vaccinations was high. See [GAO-21-443](#).



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early 2021, according to state health officials we interviewed. For example, health officials from one state said CDC set aside about 40,000 doses a week from their state's overall allocation to be allocated to the LTC pharmacy program. However, not all of the doses were used by the LTC pharmacy program because the number of residents and staff at long-term care facilities being vaccinated was not as high as CDC had expected. These officials said the inability to use those doses elsewhere affected their ability to vaccinate other residents in their state in a timely manner. According to health officials from another state, the higher-than-needed allocation of vaccine doses to the LTC pharmacy program delayed other vaccination efforts. These officials said their jurisdiction could not use the extra doses until state health officials negotiated with pharmacy partners to make the extra doses available for use by the jurisdiction instead of the LTC pharmacy program. These negotiations affected the timely availability of those vaccine doses when vaccine supply was limited. Once states recognized the LTC pharmacy program had excess vaccine doses, some state health officials we interviewed said they worked with CDC to determine how to make available the extra vaccine doses to other populations in their areas.

- **Lack of initial planning for continuing vaccinations at long-term care facilities.** Initially, CDC did not have a plan in place to vaccinate new staff and residents of long-term care facilities who arrived after the pharmacy partners had completed their three required clinics in CDC's LTC pharmacy program, according to selected stakeholders, including jurisdictional and local health officials. Some of these stakeholders said this was a challenge because of the frequent turnover of patients and staff in long-term care facilities. For example, local health officials from one health department said there were outbreaks of COVID-19 in long-term care facilities after the LTC pharmacy program had concluded, when new patients who were not vaccinated were admitted to the facilities. In mid-March 2021, CDC began working with four pharmacy partners to provide a direct allocation of vaccine doses to long-term care pharmacies participating in CDC's retail pharmacy program.

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## Health Officials and Others Said Federal Efforts to Inform about Vaccination Were Helpful, but Cited Challenges Implementing Recommendations on Priority Groups

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### State and Local Health Officials and Other Stakeholders Said CDC's Education Materials about Vaccination Were Useful, but Would Have Liked the Information Sooner

CDC's education materials were useful in informing health officials, health care providers, and the public about COVID-19 vaccination, according to selected state and local health officials and other stakeholders. CDC's education materials included its COVID-19 Vaccine Toolkits, public service announcements, print advertisements, and other online resources that the agency released starting in late-November 2020.

State and local health officials and other stakeholders we interviewed reported the following benefits of CDC's education materials:

- **CDC's online, education materials, including its Toolkits, addressed COVID-19 vaccine safety concerns.** CDC's online, educational materials helped state and local health officials and health care providers address the public's concerns about the safety of COVID-19 vaccines, according to selected health officials and other stakeholders. For example, to inform health care providers and the public about vaccination, CDC produced several COVID-19 Vaccine Toolkits. (See table 1.) These Toolkits were useful for health care providers to discuss COVID-19 vaccines with patients, according to representatives of providers from selected state hospital and medical associations we interviewed.

**Table 1: COVID-19 Vaccination Toolkits Published by CDC, November 2020 to October 2021**

<b>Toolkit title</b>	<b>Initial publication date</b>
<b>Target audience and purpose</b> <b>Recipient Education Toolkit</b> For health care providers and workers to educate people getting vaccinated about the importance of COVID-19 vaccination	November 25, 2020
<b>Vaccination Communication Toolkit</b> For health centers, pharmacies, and health care providers to build confidence in COVID-19 vaccination among health care staff	December 9, 2020
<b>Long-Term Care Facility Vaccination Toolkit</b> For the leadership and administrators of long-term care facilities to inform staff, residents and their families about COVID-19 vaccinations in long-term care facilities	December 30, 2020
<b>Essential Worker Vaccination Toolkit</b> For employers of essential workers to help plan for and inform employees about COVID-19 vaccination	January 15, 2021
<b>Community-Based Organization Vaccination Toolkit</b> For staff of organizations serving communities to educate communities about COVID-19 vaccination and address common questions and concerns	January 15, 2021
<b>School Settings and Childcare Programs Toolkit</b> For education and childcare professionals to provide information about COVID-19 vaccines and increase confidence in vaccines among education and childcare staff	March 8, 2021
<b>Health Departments and Public Health Partner Vaccination Toolkit</b> For health departments and public health officials to educate and inform communities about COVID-19 vaccination	April 2, 2021 <sup>a</sup>

Source: GAO summary of the Centers for Disease Control and Prevention (CDC) information. | GAO-22-104457

<sup>a</sup>As of October 22, 2021, this Toolkit was the most recent one specific to COVID-19 vaccination published by CDC on the agency's website.

CDC also produced other materials, such as online resources, about COVID-19 vaccines' safety and effectiveness and the potential for allergic reactions, which multiple stakeholders used to inform the public about vaccination. For example, officials from one local health department said this information was helpful when answering questions from the public about health and safety concerns about receiving a vaccine while pregnant.<sup>46</sup> CDC also created materials to help address misinformation, which included information on how to find credible resources about

<sup>46</sup>On August 11, 2021, CDC recommended COVID-19 vaccination for people who are pregnant, breastfeeding, trying to become pregnant, or might become pregnant in the future. See Department of Health and Human Services, Centers for Disease Control and Prevention, "COVID-19 Vaccines While Pregnant or Breastfeeding," (Atlanta, Ga.: Aug. 11, 2021), accessed Aug. 19, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>.

### COVID-19 Vaccination Public Service Announcements

In November 2020, CDC, the Department of Health and Human Services, and other stakeholders partnered with the Ad Council to inform the public about COVID-19 vaccination by providing information about available vaccines and the benefits of vaccination. The partnership used research about the public's intentions to be vaccinated to guide its messaging, among other considerations. The public service announcements were released to the public starting in February 2021. Many announcements were available in Spanish and English to reach greater proportions of the public and were released as video ads, radio ads, print, and on other mediums.

Examples included:

Well-known children's television characters discussing the benefits of vaccination.

The experience of hugging loved ones again after vaccination.

Former U.S. presidents discussing their motivations to get vaccinated.

Information about how vaccines provide protection against COVID-19.



Screenshot of a televised video that are part of CDC and the Ad Council's COVID-19 vaccine education campaign.

Source: GAO summary of information from the Centers for Disease Control and Prevention (CDC) and the Ad Council. | GAO-22-104457

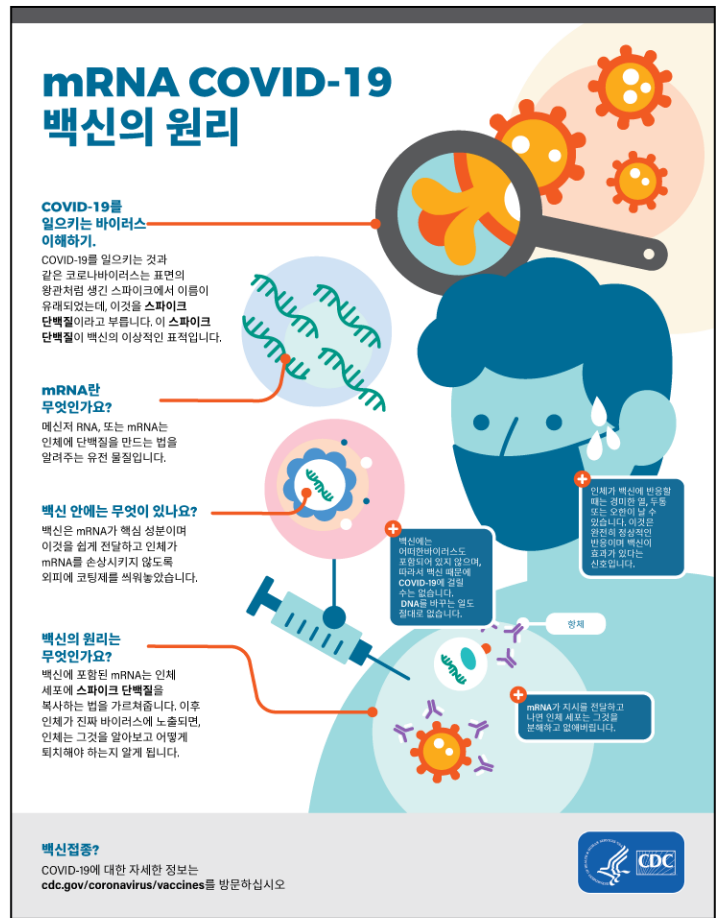
COVID-19 vaccines.<sup>47</sup> Multiple stakeholders reported using such materials to inform hard-to-reach populations about the safety of available COVID-19 vaccines.

- **Public service announcements promoted COVID-19 vaccination.** The public service announcements created by CDC and the Ad Council were helpful in informing the public about COVID-19 vaccination, according to state and local health officials we interviewed. (See side bar.) These announcements were particularly helpful because local governments did not always have the resources to create such messages to inform the public about vaccination, according to selected state and local health officials. These announcements targeted specific groups and provided information on the different reasons for getting vaccinated. For example, one announcement targeted those who might not consider getting vaccinated against COVID-19 as important for themselves by encouraging them to get vaccinated for others, such as their family members. Another announcement featured country music stars talking about the importance of vaccination and was directed at those who admire such celebrities.
- **CDC's materials could be tailored to reach specific communities.** CDC's education materials have been useful because they could be easily modified to meet the needs of particular communities, according to state and local health officials and other stakeholders we interviewed. For example, officials from a national association representing American Indian and Alaska Native populations reported using CDC education materials to develop culturally appropriate messages for their communities. State and local health officials we interviewed similarly reported modifying federal education materials to disseminate specific messages to encourage vaccination among specific communities in their respective areas. CDC also provided translations of various federal education materials, such as information about the different COVID-19 vaccines available and frequently asked questions, which were helpful, according to health officials from one state. (See fig. 7.) Health officials said these

<sup>47</sup>CDC defines misinformation as false information shared by people not intending to mislead others, and disinformation as false information shared by people with the intent to mislead others. See Department of Health and Human Services, Centers for Disease Control and Prevention, "How to Address COVID-19 Vaccine Misinformation," accessed August 19, 2021, <https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html>.

materials allowed their staff to provide information about COVID-19 vaccination to greater proportions of the public, including higher-risk populations.<sup>48</sup>

Figure 7: Examples of Federal Education Materials about COVID-19 Vaccines in Multiple Languages



Portion of a comic strip in Haitian Creole.

Infographic in Korean.

Source: Centers for Disease Control and Prevention (CDC). | GAO-22-104457

<sup>48</sup>In our work examining the federal response to the H1N1 influenza pandemic, we found that education materials and other vaccination information were more effective when available in multiple languages in order to reach some non-English speaking populations. See [GAO-11-632](#).

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### Vaccinate with Confidence Strategic Framework

In 2019, CDC developed its Vaccinate with Confidence strategic framework to help build confidence in vaccines generally and help prevent outbreaks of vaccine-preventable diseases in the United States. CDC explained that this was a new approach with three key priorities to increase confidence in vaccines:

- protecting at-risk communities,
- empowering families with information about vaccines, and
- stopping myths about vaccines.

According to CDC, vaccine confidence is the trust that patients, their families, and health care providers have in recommended vaccines, providers who administer vaccines, and the processes and policies that lead to vaccine development, licensure or authorization, manufacturing, and recommendations for use.

In late 2020, CDC tailored its Vaccinate with Confidence strategic framework to provide specific information about COVID-19 vaccines to health care providers and the public. In this specific framework, CDC prioritized

- building trust in the vaccine, health care providers, and public health officials;
- promoting confidence in the vaccine among health care personnel; and
- engaging communities and individuals in equitable and inclusive ways.

Source: GAO summary of Centers for Disease Control and Prevention (CDC) information | GAO-22-104457

- **CDC’s strategic framework and consultations informed state communication strategies about COVID-19 vaccination.** Selected state health officials also reported using CDC’s Vaccinate with Confidence strategic framework and consultations in developing community-specific messaging strategies to inform health care providers and the public about vaccination. (See sidebar.) As of July 2021, CDC provided 23 states with a “Confidence Consult” at the request of those states to identify potential strategies to improve vaccine confidence in their states.<sup>49</sup> For example, health officials from one state said they used the results from a CDC consultation to address communities’ concerns about COVID-19 vaccination. These officials organized smaller community- and faith-based vaccination events after learning this was an effective way of communicating. The public tends to trust information about vaccines from local leaders and community members, according to state and local health officials we interviewed.<sup>50</sup>

However, state and local health officials and other stakeholders indicated that CDC’s education materials were not always available when it would have been most helpful. CDC began releasing its COVID-19 Vaccine Toolkits in late November 2020. These Toolkits would have been more useful if CDC had released them earlier so health officials and health care providers could have used them to discuss COVID-19 vaccines with the public earlier, according to selected health officials and other stakeholders. For example, health officials from one state health department said it would have been helpful for providers to have some materials in early fall 2020 to provide information about vaccination to their patients before COVID-19 vaccine distribution and administration began in December 2020. Having information about COVID-19 vaccines earlier, such as information on the development and authorization process, might have made some health care providers more comfortable promoting vaccinations and might have increased some individuals’

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<sup>49</sup>If requested, CDC will provide state and local health departments with Confidence Consults in which the agency examines and develops solutions to increase confidence in COVID-19 vaccine. As of July 2, 2021, CDC reported it had completed 23 Confidence Consults. CDC may offer state and local health departments additional support through rapid community assessments and Vaccine Confidence Bootcamps, both of which aim to create specific strategies to increase confidence and COVID-19 vaccinations.

<sup>50</sup>Experts have also suggested that some individuals may be more likely to get vaccinated if recommended by a trusted figure. See, for example, National Academies of Sciences, Engineering, and Medicine, *Strategies for Building Confidence in the COVID-19 Vaccines*, (Washington, D.C.: Feb. 3, 2021) and Scott Ratzan et al., “Missing the Point—How Primary Care Can Overcome Covid-19 Vaccine Hesitancy,” *The New England Journal of Medicine*, vol. 384, no. 100 (2021).

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comfort with the vaccines when they became available, according to some stakeholders.

According to CDC, the agency timed the release of education materials to coordinate with ACIP's December 2020 release of recommendations for priority groups and target groups and based on the vaccination rates of specific communities. For example, CDC reported it released the Toolkit for long-term care facility workers in late December 2020 because ACIP's recommendations prioritized these workers for early vaccination efforts around that time.

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### Health Officials and Others Reported Challenges Implementing Federal Recommendations on Vaccine Priority Groups

In December 2020, as vaccines were first becoming available, CDC adopted ACIP's recommendations on whom state and local health officials should prioritize and target with initial doses when vaccine supply was limited.<sup>51</sup> According to CDC, the ACIP recommendations were designed to be fluid and to allow states and local health departments to adapt the recommendations to meet their specific needs.

Selected state and local health officials told us that health care providers and the public were confused about when and where to get vaccinated in part because of federal changes regarding ACIP's recommended priority groups and differences among states and other jurisdictions on who should be prioritized and targeted for vaccination. In particular,

- **States and localities were not given advanced notice about federal changes regarding priority groups.** Selected stakeholders, including state and local health officials, reported they were not given advanced notice when the federal government made changes on prioritizing and targeting COVID-19 vaccines. (See table 2.) Having advanced notice of federal changes would have given them time to better adjust their vaccination plans and to prepare how to answer questions from health care providers and the public. For example, officials from a state association representing health care providers reported their members did not always know whom to prioritize for vaccination after federal changes were made. Health officials from one jurisdiction stated that while they understood why eligibility changes were recommended, they would have appreciated having this information before the public was told in order to explain how these changes affected vaccine availability in their communities. For

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<sup>51</sup>ACIP recommendations for COVID-19 vaccines were reviewed by the CDC Director and were published as official HHS/CDC recommendations in the *Morbidity and Mortality Weekly Report*.

example, not having this information sooner made it challenging for health officials and health care providers to manage the public's expectations about when individuals could get vaccinated while information from the federal government about who should be eligible kept changing, according to selected stakeholders we interviewed.

**Table 2: Examples of Changes in Information from the Federal Government on Prioritizing and Targeting COVID-19 Vaccines between December 2020 and March 2021**

Date	Event
December 1, 2020	CDC's Advisory Committee on Immunization Practices (ACIP) recommended that for the initial phase of vaccine implementation (phase 1a) when vaccine supply was limited, vaccines be offered to those at risk of contracting COVID-19, which included (1) health care personnel and (2) residents of long-term care facilities. <sup>a</sup>
December 20, 2020	CDC's ACIP recommended that after phase 1a, vaccines should be offered in phase 1b to: (1) persons aged 75 years and older and (2) frontline essential workers (non-health care) and in phase 1c to: (1) persons aged 65-74 years, (2) persons aged 16-64 years with high-risk medical conditions, and (3) other essential workers. <sup>b</sup> For phase 2, ACIP prioritized all people at least 16 years of age not yet recommended for vaccination in phase 1.
January 12, 2021	The Secretary of Health and Human Services announced at a press briefing that jurisdictions should open vaccination to all persons age 65 and older and all people under age 65 with a documented co-morbidity.
January 21, 2021	The White House released a national strategy for the COVID-19 response that encouraged states and other jurisdictions to open vaccination to persons age 65 years and older and essential workers. <sup>c</sup>
March 2, 2021	The President directed states to prioritize educators for vaccination with a goal of every educator, school staff member, and childcare worker receiving at least one shot by the end of March, using CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination.
March 11, 2021	The White House announced in a press release that it was directing states, tribes, and territories to make all adults (those aged 18 years and older) in the United States eligible to receive a COVID-19 vaccine by May 1, 2021.

Source: GAO analysis of Centers for Disease Control and Prevention (CDC) information and press releases by the White House and Department of Health and Human Services. | GAO-22-104457

<sup>a</sup>ACIP defines health care personnel as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. See Kathleen Dooling et al., "The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020," *Morbidity and Mortality Weekly Report*, vol. 69, no. 49 (2020).

<sup>b</sup>For the purposes of ACIP's recommendations, non-health care frontline essential workers include firefighters, police officers, corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, those who are in the education sector (teachers and support staff) as well as daycare workers. According to CDC, about 49 million persons, including non-health care frontline essential workers and individuals aged 75 years and older were recommended for vaccination in phase 1b, and an additional 129 million persons were recommended for vaccination in phase 1c (including about 28 million individuals aged 65 through 74 years). See Kathleen Dooling et al., "The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine—United States, December 2020," *Morbidity and Mortality Weekly Report*, vol. 69, no. 51-52 (2021).

<sup>c</sup>White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021).



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- **Health care providers were uncertain whom to vaccinate because states and jurisdictions differed in their implementation of federal recommendations for vaccine priority groups.** Health care providers and the public were confused about who was eligible to be vaccinated, especially when vaccine supply was limited, according to selected health officials and other stakeholders. For example, stakeholders representing health care providers reported their members received conflicting information about who was eligible for vaccination, which affected their ability to vaccinate particular groups because they did not always know whom to vaccinate. Further, variation among states' target groups affected the public's confidence in COVID-19 vaccination because they received inconsistent information about when they were eligible for vaccination, according to one stakeholder we interviewed.

We previously reported similar issues regarding variation among states and who they prioritized for vaccination during the 2009 H1N1 pandemic.<sup>52</sup> At that time, we noted that state and local health officials appreciated the flexibility in being able to modify ACIP recommendations to meet state and local needs, but that the variation also caused confusion. Similarly, state and local health officials from one state noted their appreciation for ACIP's COVID-19 vaccine recommendations. For example, these state health officials said the recommendations were useful to communicate with the public about prioritization for vaccines. However, officials from a state association representing health care providers said there was more confusion regarding eligibility for COVID-19 vaccination because they were trying to vaccinate more people for COVID-19 and the risk for not doing so was greater compared to the 2009 H1N1 pandemic.

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<sup>52</sup>See [GAO-11-632](#).

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## HHS Agencies Intend to Complete After Action Reviews to Identify Lessons Learned, but Are Uncertain about Plans to Incorporate Information from, and Share Results with, Stakeholders

Two HHS component agencies involved in COVID-19 vaccine implementation—CDC and HRSA—told us that they intend to conduct after action reviews to identify lessons learned from their COVID-19 vaccine distribution and communication efforts. Specifically,

- **CDC** noted that its Center for Preparedness and Response’s Division of Emergency Operations, in collaboration with CDC subject matter experts, plans to develop an agency-wide COVID-19 after action review. Historically, such reviews have included lessons learned and recommendations for making improvements within its areas of responsibility, according to CDC. CDC indicated that its review will entail gathering information from CDC responders that participated throughout the duration of the response as well as collaborating with interagency partners, such as FEMA and the HHS/DOD partnership (formerly known as Operation Warp Speed).

However, as of August 2021, CDC had not identified the specific topics related to vaccine distribution and communication that it intends to include in its review, or to what extent, if any, it plans to gather feedback or perspectives from external stakeholders, such as state and local health officials and providers. CDC explained that typically, its reviews are primarily focused on internal response operations and that coordinating with other departments and agencies may occur once topics are finalized. Additionally, CDC indicated that its review would result in a final report that would be vetted through leadership, but it would be for internal use only; the agency did not indicate plans to share the final report with key stakeholders outside CDC.

- **HRSA** stated that it plans to conduct an after action review and develop a final report documenting successful strategies, challenges, recommendations and considerations for future public health emergencies. HRSA noted that since the inception of its health center vaccine program, it has regularly used available data, including program survey data; vaccine allocation, distribution, and administration data; and stakeholder feedback to assess and continuously improve the program’s operations in real time. In conducting an after action review, HRSA stated that it anticipates that any findings would be informed by and shared as appropriate with the CDC and health center programs as well as key rural health and other stakeholders. However, as of August 2021, the agency did not specify whether state and local health officials would be included as stakeholders in this effort, how it was maintaining such feedback for the purposes of an after action review, or what specific topics would be covered related to vaccine distribution and communication.

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CDC and HRSA did not provide additional details on their forthcoming after action reviews because, according to agency officials, they have yet to finalize their plans for conducting such reviews. Officials from both agencies explained that they have yet to do so, because they are still involved in the pandemic response. The agencies indicated they would initiate their reviews once the public health emergency ends or, in the case of HRSA, when the health center vaccine program and rural health clinic vaccine program end, if that occurs before the end of the public health emergency.

Federal internal control standards state that management should externally communicate the necessary quality information to achieve an entity's objectives, such as by obtaining quality information from external parties so those external parties can help the entity achieve its objectives and address related risks.<sup>53</sup> Additionally, as we have previously reported, *The Standard for Program Management*, produced by the Project Management Institute, Inc., states that program managers should actively engage key stakeholders throughout the life cycle of a program, which would include evaluation activities, such as completing after action reviews.<sup>54</sup> State and local health officials were key stakeholders in COVID-19 vaccine distribution and communication efforts as they were responsible for critical tasks, such as receiving vaccine allocations from the federal government; identifying the providers in their communities to receive and administer available doses; and communicating with health care providers and the public about vaccination.

Given the challenges state and local health officials and other stakeholders have faced throughout COVID-19 vaccine implementation, and especially early on when vaccine supply was limited, obtaining stakeholder perspectives to inform the after action review process would provide valuable information to CDC and HRSA. For example, as previously noted, when supply was limited, state and local health officials often were not aware of the number of vaccine doses being allocated to vaccination sites within their jurisdictions through federal programs, which affected the officials' ability to plan where to send their own allocated doses. Gathering perspectives from key stakeholders on challenges such

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<sup>53</sup>[GAO-14-704G](#).

<sup>54</sup>See GAO, *Disaster Response: HHS Should Address Deficiencies Highlighted by Recent Hurricanes in the U.S. Virgin Islands and Puerto Rico*, [GAO-19-592](#) (Washington, D.C.: Sept. 20, 2019). Project Management Institute, Inc., *The Standard for Program Management, Fourth Edition*, 2017.

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as these—encompassing federal distribution and administration activities as well as efforts to inform the public about COVID-19 vaccination throughout the life cycle of the response—would provide CDC and HRSA with a more comprehensive understanding of what worked well and areas for improvement to inform future efforts. Gathering this information as the pandemic response is ongoing is particularly important because these stakeholder perspectives could be lost or forgotten over time as vaccine implementation continues.

Moreover, given the highly complex undertaking involved with vaccine implementation spanning multiple federal agencies and key stakeholders across state and local governments and the private sector, sharing the results of after action reviews and lessons learned with stakeholders is equally imperative.<sup>55</sup> Any lessons learned or recommendations that CDC and HRSA identify through their reviews may also be more broadly relevant or applicable to other key stakeholders, such as state and local governments, which were also instrumental in vaccine distribution and communication activities. By sharing such information, stakeholders may also be able to learn from and adjust their related efforts, critical to ensuring an effective response for any additional vaccine efforts that may be needed related to COVID-19 or in future pandemics.

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## Conclusions

The administration of COVID-19 vaccines across the nation has played a vital role in the U.S. response to the pandemic. With the pandemic now well into its second year, vaccination efforts remain critically important, especially as the Delta variant has emerged and vaccines are anticipated to be made available for children. Federal agencies, including CDC and HRSA, have provided higher-risk populations access to vaccines through the implementation of several federal programs. But, state and local health officials and other stakeholders cited challenges, such as the ability to consider federal efforts when making decisions for their own vaccination programs, particularly when supply was limited.

CDC and HRSA plan to conduct after action reviews of their vaccine distribution and communication efforts, which could provide valuable information on any benefits, challenges, and lessons learned. However, the agencies indicated they do not plan to undertake such reviews until the end of the public health emergency or, in the case of HRSA, when their vaccine distribution programs end, and it is uncertain whether their

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<sup>55</sup>We previously reported on the importance of sharing the relevant findings of after action reports with key stakeholders, such as state and local governments. [GAO-11-632](#).

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plans will include gathering input from key stakeholders, such as state and local health officials, or whether the results will be shared with such stakeholders. By gathering perspectives throughout the life cycle of the response from key stakeholders—including state and local health officials—and incorporating their feedback as part of these reviews, CDC and HRSA will help ensure they obtain a more comprehensive understanding of what worked well and areas for improvement to inform future efforts.

It is particularly important to gather stakeholder perspectives on an ongoing basis, given the critical need to continue vaccination efforts, including to address threats of any new variants or to vaccinate children if those vaccines become available. Since agencies do not plan to complete after action reviews until their federal response efforts or programs end, obtaining key stakeholder perspective on an ongoing basis will help ensure those perspectives will not be lost or forgotten by the time the agencies conduct their reviews.

Moreover, by sharing the results of their reviews with such stakeholders, CDC and HRSA will help ensure a successful and effective response across federal, state, and local levels for any additional vaccine efforts that may be needed in the future.

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## Recommendations for Executive Action

We are making a total of four recommendations, including two to CDC and two to HRSA:

- As CDC finalizes its plans for an after action review related to its COVID-19 vaccine distribution and communication efforts, the Director of the Centers for Disease Control and Prevention should ensure the agency obtains feedback during the life cycle of the response from key stakeholders, including state and local health officials, and incorporates their perspectives as it conducts its review. (Recommendation 1)
- The Director of the Centers for Disease Control and Prevention should share relevant findings of its after action review related to vaccine distribution and communication with key stakeholders, such as state and local health officials, and other federal agencies, as appropriate. (Recommendation 2)
- As HRSA finalizes its plans for an after action review related to its COVID-19 vaccine distribution and communication efforts, the Administrator of the Health Resources and Services Administration should ensure the agency obtains feedback during the life cycle of the

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response from key stakeholders, including state and local health officials, and incorporates their perspectives as it conducts its review. (Recommendation 3)

- The Administrator of the Health Resources and Services Administration should share relevant findings of its after action review related to vaccine distribution and communication with key stakeholders, such as state and local health officials. (Recommendation 4)

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## Agency Comments

We provided a draft of this report to DOD, FEMA, and HHS for review and comment. In written comments provided by CDC and HRSA through HHS (reproduced in appendix IV), CDC and HRSA concurred with our recommendations. In its written comments, HHS stated that the GAO study provided valuable feedback on the implementation of CDC's and HRSA's programs and that the agencies are committed to the continuous improvement of their vaccine programs. CDC stated a timeline for an after action review had not been established as it remains involved in the COVID-19 response, and agreed the agency should share relevant findings with key stakeholders, as appropriate, from its after action review once it is completed. CDC also stated that in the meantime, it continues to incorporate continuous feedback from stakeholders. HRSA stated that it plans to incorporate feedback from key stakeholders in its after action review and anticipates sharing results as appropriate with key stakeholders, such as state and local health officials. HRSA also provided technical comments, which we incorporated as appropriate. FEMA and DOD stated they had no comments on the draft report.

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We are sending copies of this report to the appropriate congressional committees, the Secretary of Defense, the Administrator of FEMA, 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>.

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If you or your staff have any questions about this report, please contact Alyssa M. Hundrup at (202) 512-7114 or [hundrupa@gao.gov](mailto:hundrupa@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 major contributions to this report are listed in appendix V.



Alyssa M. Hundrup  
Director, Health Care

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*List of Addressees*

The Honorable Patrick Leahy  
Chairman  
The Honorable Richard Shelby  
Vice Chairman  
Committee on Appropriations  
United States Senate

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

The Honorable Patty Murray  
Chair  
The Honorable Richard Burr  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Gary C. Peters  
Chairman  
The Honorable Rob Portman  
Ranking Member  
Committee on Homeland Security and Governmental Affairs  
United States Senate

The Honorable Rosa L. DeLauro  
Chairwoman  
The Honorable Kay Granger  
Ranking Member  
Committee on Appropriations  
House of Representatives



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The Honorable Frank Pallone, Jr.  
Chair  
The Honorable Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce  
House of Representatives

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

The Honorable Carolyn B. Maloney  
Chairwoman  
The Honorable James Comer  
Ranking Member  
Committee on Oversight and Reform  
House of Representatives

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

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# Appendix I: COVID-19 Vaccines Authorized in the United States, as of October 22, 2021

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As of October 22, 2021, three COVID-19 vaccines were available in the United States. One vaccine was licensed by the Food and Drug Administration (FDA) for individuals aged 16 years and older and was also available to individuals aged 12 through 15 years under an emergency use authorization (EUA).<sup>1</sup> An EUA allows for the temporary use of vaccines without FDA licensure, provided certain statutory criteria are met.<sup>2</sup> Two additional vaccines were authorized for emergency use for individuals aged 18 years and older.<sup>3</sup> As of October 22, 2021, no vaccines had been authorized or licensed for children under 12 years, but one vaccine company (Pfizer) had requested that FDA authorize its COVID-19 vaccine for children aged 5 years to 11 years.<sup>4</sup>

On August 12, 2021, FDA amended the EUAs for two COVID-19 vaccines to allow for the use of an additional dose in certain immunocompromised individuals, specifically in solid organ transplant recipients or those who are diagnosed with conditions that are considered

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<sup>1</sup>Typically, FDA must license a vaccine before it can be marketed in the United States. See 42 U.S.C. § 262. On August 23, 2021, FDA licensed the COVID-19 vaccine developed by Pfizer and BioNTech (marketed as Comirnaty) for the prevention of COVID-19 disease. For the purposes of this report, we refer to the COVID-19 vaccine that Pfizer and BioNTech developed together as the Pfizer vaccine.

<sup>2</sup>The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products, such as vaccines. Once a declaration of an emergency has been made, FDA may temporarily allow use of unlicensed vaccines through an EUA. For FDA to issue an EUA for a vaccine, it must be reasonable to believe that the vaccine may be effective and that the known and potential benefits of the vaccine outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3. FDA has indicated that issuance of an EUA for a COVID-19 vaccine for which there is adequate manufacturing information would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

Any COVID-19 vaccine that initially receives an EUA from FDA is expected to work toward submission of a biologics license application, according to FDA guidance. See FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry*, (Silver Spring, Md.: May 2021).

<sup>3</sup>On June 10, 2021, one vaccine company, Moderna, requested that FDA amend the EUA for its COVID-19 vaccine for use in adolescents aged 12 years to 17 years; as of October 22, 2021, FDA had not issued a decision in response. The other authorized COVID-19 vaccine was developed by Janssen Pharmaceutical Companies, which is part of Johnson & Johnson.

<sup>4</sup>As of October 22, 2021, FDA's Vaccines and Related Biological Products Advisory Committee was scheduled to meet on October 26, 2021, to discuss a request for authorization of Pfizer's COVID-19 vaccine for children aged 5 through 11 years.

**Appendix I: COVID-19 Vaccines Authorized in the United States, as of October 22, 2021**

to have an equivalent level of immunocompromise.<sup>5</sup> In September and October 2021, FDA authorized a booster dose of either the Pfizer, Moderna, or Janssen vaccine for certain populations.<sup>6</sup> In October 2021, FDA also authorized “mix and match” for the booster dose—that is, authorizing the use of any available COVID-19 vaccine for use as a booster regardless of which COVID-19 vaccine was used as the primary series or single-dose primary series.

The three available COVID-19 vaccines have varying storage requirements that may affect the setting where each vaccine can be administered. For example, some vaccine administration settings may not have equipment, such as freezers, to store vaccine doses at ultra-cold temperatures, the recommended storage method for the Pfizer vaccine.<sup>7</sup> Table 3 shows the age groups authorized for each of the three COVID-19 vaccines, as well as each vaccine’s dosing schedules, and storage and handling requirements.

**Table 3: COVID-19 Vaccines FDA Authorized for Emergency Use, as of October 22, 2021**

Vaccine company	Date FDA initially issued or amended EUA <sup>a</sup>	Individuals for whom vaccine is permitted for emergency use	Dosing and schedule	Storage requirements (doses per vial and minimum lot size)
Pfizer <sup>b</sup>	12/11/2020	12 through 15 years <sup>c</sup>	2 doses, 3 weeks apart	Stored frozen at ultra-cold temperatures <sup>d</sup>
	8/12/21	Certain immunocompromised individuals aged 12 years and older <sup>e</sup>	1 dose, at least 28 days after the initial 2-dose regimen <sup>f</sup>	Once thawed and diluted, must be used within 6 hours. (6 doses per vial, minimum lot size 450 doses)
	9/22/21	65 years and older; 18 through 64 years at high risk of severe COVID-19; 18 through 64 years with frequent institutional or occupational exposure to the virus that causes COVID-19 <sup>g</sup>	1 dose (booster) at least 6 months after the initial 2-dose regimen <sup>h</sup>	

<sup>5</sup>According to CDC, an additional dose is administered when the initial immune response following a primary vaccine series is likely to be insufficient.

<sup>6</sup>According to CDC, a booster dose is administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

<sup>7</sup>Alternatively, Pfizer vaccine vials may be stored frozen at a slightly higher temperatures of -13 to 5 degrees Fahrenheit for up to 2 weeks.

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Moderna	12/18/2020	18 years and older <sup>i</sup>	2 doses, 1 month apart	Stored frozen, but may be refrigerated for up to 30 days once thawed.
	8/12/21	Certain immunocompromised individuals aged 18 years and older <sup>e</sup>	1 dose, at least 28 days after the initial 2-dose regimen <sup>f</sup>	Once first dose is withdrawn from vial, other doses must be used within 12 hours.
	10/20/21	65 years and older; 18 through 64 years at high risk of severe COVID-19; 18 through 64 years with frequent institutional or occupational exposure to the virus that causes COVID-19	1 dose (booster) at least 6 months after the initial 2-dose regimen <sup>h</sup>	(2 vial sizes: maximum 11 doses per vial (range 10-11) or 15 doses per vial (range 13-15), minimum lot size 10-multi-dose vials)
Janssen <sup>j</sup>	2/27/2021 <sup>k</sup>	18 years and older	1 dose	Refrigerated, but may be stored at room temperature for up to 12 hours.
	10/20/21	18 years and older	1 dose (booster) at least 2 months after completion of the single-dose primary regimen <sup>h</sup>	Once first dose is withdrawn from vial, other doses may be stored at 36 to 46 degrees Fahrenheit for up to 6 hours or at room temperature for up to 2 hours.  (5 doses per vial, minimum lot size 100 doses)

Source: GAO analysis of vaccine company and Food and Drug Administration (FDA) information. | GAO-22-104457

<sup>a</sup>Typically, FDA must license a vaccine before it can be marketed in the United States. See 42 U.S.C. § 262. The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products, such as vaccines. Once a declaration of an emergency has been made, FDA may temporarily allow use of unlicensed vaccines through an emergency use authorization (EUA). For FDA to issue an EUA for a vaccine, it must be reasonable to believe that the vaccine may be effective and that the known and potential benefits of the vaccine outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3. FDA has indicated that issuance of an EUA for a COVID-19 vaccine for which there is adequate manufacturing information would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

Any COVID-19 vaccine that initially receives an EUA from FDA is expected to work toward a submission of a biologics license application, according to FDA guidance. See Department of Health and Human Services, Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry*, (Silver Spring, Md.: May 2021). On August 25, 2021, Moderna announced completion of its submission of a biologics license application to FDA. As part of the application, Moderna requested the application be given priority review.

<sup>b</sup>Pfizer and BioNTech developed this COVID-19 vaccine together, which for the purposes of this report we refer to as the Pfizer vaccine. On August 23, 2021, FDA licensed the two-dose Pfizer vaccine for those aged 16 years and older; this vaccine had been available for emergency use since December 11, 2020. FDA licensed the Pfizer vaccine (marketed as Comirnaty) for the prevention of COVID-19 disease. Under the authorization in effect at the time of licensure, the vaccine remains available for adolescents aged 12 through 15 years.

<sup>c</sup>On December 11, 2020, FDA authorized the Pfizer vaccine for emergency use in individuals aged 16 years and older, and on May 10, 2021, FDA amended the EUA to include adolescents aged 12-15 years.

<sup>d</sup>Alternatively, Pfizer vaccine vials may be stored frozen at a slightly higher temperatures of -13 to 5 degrees Fahrenheit for up to 2 weeks. On May 19, 2021, FDA authorized an increased storage time for thawed vials of Pfizer's COVID-19 vaccine prior to dilution. Thawed, undiluted vials can be stored in the refrigerator at 35 to 46 degrees Fahrenheit for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.

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<sup>e</sup>According to FDA, immunocompromised individuals refers to solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

<sup>f</sup>According to CDC, an additional dose is administered when the initial immune response following a primary vaccine series is likely to be insufficient.

<sup>g</sup>FDA's initial authorization included individuals 18 through 64 years of age whose frequent institutional or occupational exposure to the virus that causes COVID-19 put them at high risk of serious complications, including severe COVID-19. On October 20, 2021, FDA amended the Pfizer EUA to clarify that individuals aged 18 through 64 years with frequent institutional or occupational exposure to the virus that causes COVID-19 were eligible for a booster dose, without reference to whether that exposure put them at high risk of severe COVID-19.

<sup>h</sup>According to CDC, a booster dose is a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. On October 20, 2021, FDA amended the EUAs for COVID-19 vaccines to allow each of the available COVID-19 vaccines to be used "mix and match" for the booster dose—that is, authorizing the use of any available COVID-19 vaccine for use as a booster dose regardless of which COVID-19 vaccine was used as the primary series or single-dose primary series.

<sup>i</sup>On June 10, 2021, Moderna requested that FDA amend the EUA for its vaccine to include adolescents aged 12-17 years. As of October 22, 2021, FDA had not issued a decision in response.

<sup>j</sup>Janssen Pharmaceutical Companies are a part of Johnson & Johnson.

<sup>k</sup>On April 13, 2021, the Centers for Disease Control and Prevention (CDC) and FDA recommended a pause in the use of the Janssen vaccine so the agencies could review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving this vaccine. CDC and FDA lifted the pause on April 23, 2021, following a safety review, and revised the Janssen vaccine fact sheets for health care providers and recipients and caregivers to include information about the risk.

# Appendix II: Timeline of Key Events Related to COVID-19 Vaccine Implementation through October 21, 2021

**Table 4: Timeline of Key Events Related to COVID-19 Vaccine Implementation, November 25, 2020 through October 21, 2021**

Date	Event
November 25, 2020	CDC published its first COVID-19 Vaccination Toolkit for health care providers and workers on vaccine recipient education. The Toolkit included quick references for COVID-19 vaccinators to share with those being vaccinated, including information on the mRNA COVID-19 vaccines.
December 1, 2020	CDC's Advisory Committee on Immunization Practices (ACIP) recommended that for the initial phase of vaccine implementation (phase 1a) when vaccine supply was limited, vaccines be offered to those at risk of contracting COVID-19, which included (1) health care personnel and (2) residents of long-term care facilities. <sup>a</sup>
December 2, 2020	CDC Director adopted ACIP's recommendation for priority groups for the initial phase of the COVID-19 vaccine implementation.
December 10, 2020	FDA's Vaccines and Related Biological Products Advisory Committee met to discuss emergency use authorization request for Pfizer vaccine. Committee voted to recommend the vaccine for emergency use.
December 11, 2020	Pfizer vaccine authorized for emergency use in individuals aged 16 years and older. <sup>b</sup>
December 12, 2020	Initial doses of Pfizer vaccine shipped to health care providers, as directed by states and other jurisdictions and five federal entities (the Bureau of Prisons, Department of Defense, Department of State, Indian Health Service, and the Veterans Health Administration).
December 14, 2020	First dose of COVID-19 vaccine administered; vaccine administration begins.
December 17, 2020	FDA's Vaccines and Related Biological Products Advisory Committee met to discuss emergency use authorization request for the Moderna vaccine. Committee voted to recommend the vaccine for emergency use.
December 18, 2020	Moderna vaccine authorized for emergency use in individuals aged 18 years and older.
December 20, 2020	CDC's ACIP recommended that after phase 1a, vaccines should be offered in phase 1b to: (1) persons aged 75 years and older and (2) frontline essential workers (non-health care) and in phase 1c to: (1) persons aged 65-74 years, (2) persons aged 16-64 years with high-risk medical conditions, and (3) other essential workers. <sup>c</sup> For phase 2, ACIP prioritized all people at least 16 years of age not yet recommended for vaccination in phase 1.
December 21, 2020	CDC Director adopted ACIP's updated recommendation for priority groups for the initial phase of the COVID-19 vaccine implementation.
Week of December 21, 2020	Vaccine doses first distributed through CDC's Pharmacy Partnership for Long-Term Care Program began.
January 11, 2021	CDC published an annex to its interim playbook for jurisdictions that provided new guidance and considerations to jurisdictions regarding when and how to transition from vaccinating initial populations of focus to increasing vaccinations among additional priority populations. It also included a framework for balancing equitable access, service delivery, and vaccine demand; tools for engaging priority populations and increasing vaccine confidence; and strategies for leveraging private-public partnerships. <sup>d</sup>
January 12, 2021	The Secretary of Health and Human Services announced at a press briefing that jurisdictions should open vaccination to all persons age 65 and older and all people under age 65 with a documented co-morbidity.
January 21, 2021	The White House released a national strategy for the COVID-19 response that encouraged states and other jurisdictions to open vaccination to persons age 65 years and older and essential workers. <sup>e</sup>
February 4, 2021	FEMA published the agency's initial guidance on community vaccination centers. <sup>f</sup>
February 9, 2021	Vaccine doses first distributed through CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination.
February 12, 2021	DOD's announced deploying first team of 222 personnel to support FEMA's Community Vaccination Centers Pilot Site and Mobile Vaccination Program.

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<b>Date</b>	<b>Event</b>
February 15, 2021	First FEMA Community Vaccination Centers Pilot Site and Mobile Vaccination Program sites established in Oakland and Los Angeles, California.
Week of February 22, 2021	Vaccine doses first distributed through HRSA's Health Center COVID-19 Vaccine Program. <sup>g</sup>
February 27, 2021	Janssen vaccine authorized for emergency use in individuals aged 18 years and older. <sup>h</sup>
March 2, 2021	The President directed states to prioritize educators for vaccination with a goal of every educator, school staff member, and childcare worker receiving at least one shot by the end of March, using CDC's Federal Retail Pharmacy Program for COVID-19 Vaccination.
March 11, 2021	The White House announced in a press release that it was directing states, tribes, and territories to make all adults (those aged 18 years and older) in the United States eligible to receive a COVID-19 vaccine by May 1, 2021.
March 12, 2021	HHS authorized additional categories of personnel to dispense and administer COVID-19 vaccines, including dentists, emergency medical technicians, optometrists, and others. <sup>i</sup>
March 29, 2021	The White House announced in a press release that (1) 90 percent of adults should be eligible for vaccination by April 19, 2021 and (2) 90 percent of adults should have a vaccination site within 5 miles of where they live.
April 9, 2021	Pfizer requested that FDA amend the EUA for its vaccine to include adolescents aged 12-15 years.
April 13, 2021	CDC and FDA recommended a pause in the use of Janssen vaccine so the agencies could review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving this vaccine.
April 23, 2021	CDC and FDA lifted the pause in the use of Janssen vaccine following a safety review, and revised the Janssen vaccine fact sheets for health care providers and recipients and caregivers to include information about the risk.
April 23, 2021	CDC's Pharmacy Partnership for Long-Term Care Program ended.
May 1, 2021	CDC launched a national hotline (1-800-232-0233) to assist with scheduling appointments.
May 4, 2021	The White House announced efforts to make appointments for COVID-19 vaccinations more accessible. For example, the President encouraged pharmacies participating in CDC's retail pharmacy program to begin offering walk-in appointments and redirected FEMA resources to support smaller vaccination sites and more mobile clinics to meet people where they are instead of requiring them to come to a designated site to be vaccinated.  The White House also announced the Vaccines.gov website to assist the public in finding vaccination appointments.
May 7, 2021	Pfizer submitted a biologics license application with FDA for its COVID-19 vaccine for those 16 years and older.
May 10, 2021	Pfizer vaccine authorized for emergency use for adolescents aged 12-15 years.
Week of May 17, 2021	HRSA's Rural Health Clinic COVID-19 Program began (vaccine doses first distributed for this program). <sup>j</sup>
June 1, 2021	Moderna submitted a biologics license application for its COVID-19 vaccine for those 18 years and older.
June 2, 2021	The White House announced that June 2021 would be a "National Month of Action," which included a variety of events surrounding COVID-19 vaccinations. For example, the federal government entered into partnerships with the private sector to facilitate vaccination, such as with Major League Baseball, which offered on-site vaccinations at games and gave free tickets to those who were vaccinated.
June 10, 2021	Moderna requested that FDA amend the EUA for its vaccine to include adolescents aged 12-17 years.
June 20, 2021	FEMA's Community Vaccination Centers Pilot Site and Mobile Vaccination Program ended. <sup>k</sup>
June 22, 2021	DOD halted deployment of active-duty servicemembers to support federal vaccination efforts.

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<b>Date</b>	<b>Event</b>
July 1, 2021	HRSA's Rural Health Clinic Vaccine Confidence Program began supporting vaccine outreach in rural communities. Funding could be used for a variety of activities including conducting educational and outreach efforts on the benefits and safety of vaccines, providing information to rural residents about how and where to get vaccinated, and coordinating with existing vaccination sites and public health partners to identify isolated populations.
July 6, 2021	The White House announced plans to mobilize COVID-19 surge response teams, federal personnel focused on increasing vaccination rates in communities with low rates, by, for example, filling in gaps in staffing.
July 15, 2021	U.S. Surgeon General issued advisory warning about the threat of health misinformation to the U.S. response to COVID-19, including preventing people from getting vaccinated.
July 16, 2021	FDA accepted Pfizer's application requesting licensure for its COVID-19 vaccine and granted the application priority review (meaning that FDA will aim to make a decision on the application within 6 months, compared to the 10 months for standard review).
August 11, 2021	CDC recommended COVID-19 vaccination for people who are pregnant, breastfeeding, trying to become pregnant, or might become pregnant in the future. CDC stated that there was no evidence that COVID-19 vaccines cause fertility problems in women or men.
August 12, 2021	HHS announced mandating COVID-19 vaccination for staff who serve in federally operated health care and clinical research facilities and interact with, or have the potential to come into contact, patients. HHS staff included employees, contractors, trainees, and volunteers as well as members of the U.S. Public Health Service Commissioned Corps.
August 12, 2021	FDA amended both the Pfizer and Moderna EUAs to allow for the use of an additional dose in certain immunocompromised individuals, specifically in solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. <sup>l</sup>
August 13, 2021	ACIP recommended using an additional dose of Pfizer and Moderna COVID-19 vaccines in certain immunocompromised individuals. CDC Director adopted ACIP's recommendations.
August 16, 2021	Pfizer submitted phase 1 data to FDA to support the evaluation of a booster dose of its COVID-19 vaccine. <sup>m</sup>
August 18, 2021	HHS recommended booster shots for those that have received the Pfizer or Moderna vaccines, pending an FDA review and ACIP recommendations. HHS said it was prepared to offer booster shots beginning the week of September 20 and starting 8 months after an individual's second dose.
August 18, 2021	The White House announced that HHS would develop new regulations requiring nursing homes to require that all of their workers be fully vaccinated against COVID-19 as a condition of participating in the Medicare and Medicaid programs.
August 23, 2021	FDA licensed the Pfizer vaccine for those aged 16 years and older (marketed as Comirnaty) for the prevention of COVID-19 disease. The vaccine remained available under an emergency use authorization for use in individuals aged 12 to 15 years.
August 25, 2021	Moderna submitted a completed biologics license application to FDA. As part of the application, Moderna requested the application be given priority review.
September 1, 2021	Moderna initiated its submission of data to FDA for the evaluation of a booster dose of its COVID-19 vaccine. <sup>m</sup>



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Date	Event
September 9, 2021	<p>The White House announced that</p> <ul style="list-style-type: none"> <li>• HHS would develop regulations requiring health care workers in hospitals, home health care facilities, or other medical facilities that treat Medicare and Medicaid patients be fully vaccinated;</li> <li>• the Department of Labor was developing an emergency rule to require all employers with 100 or more employees to ensure their workforce were fully vaccinated or showed a negative COVID-19 test at least once a week;</li> <li>• the Department of Labor would require employers with 100 or more workers to give those workers paid time off to get vaccinated;</li> <li>• the President would sign an executive order requiring all executive branch federal employees be vaccinated; and</li> <li>• the President would sign an executive order requiring all federal contractors be vaccinated.</li> </ul>
September 17, 2021	<p>FDA's Vaccines and Related Biological Products Advisory Committee met to discuss EUA request for a booster dose of the Pfizer vaccine. Committee voted against recommending the authorization of a booster dose for those aged 16 years and older citing data demonstrating an increased risk for adverse cardiac events, particularly among males aged 16 to 17 years, and limited data on whether this risk may be increased after a booster dose. Committee voted for recommending the authorization of a single booster dose at least 6 months after completion of the primary series for use in individuals aged 65 years and older.<sup>m</sup></p>
September 22, 2021	<p>FDA amended the Pfizer EUA to allow for use of a single booster dose to be administered at least 6 months after completion of the primary series in</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older;</li> <li>• individuals aged 18 through 64 years at high risk of severe COVID-19; and</li> <li>• individuals aged 18 through 64 years whose frequent institutional or occupational exposure puts them at high risk of serious complications of COVID-19 including severe illness.<sup>m</sup></li> </ul>
September 23, 2021	<p>ACIP recommended a booster dose of the Pfizer vaccine at least 6 months after the completion of the primary series for</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older,</li> <li>• residents of long-term care facilities,</li> <li>• individuals aged 50 through 64 years with underlying medical conditions, and</li> <li>• individuals aged 18 through 49 years with underlying medical conditions, based on their individual risk-benefit analysis.<sup>m</sup></li> </ul>
September 24, 2021	<p>CDC recommended the following groups should receive a booster dose of the Pfizer vaccine at least 6 months after the completion of a primary series:</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older,</li> <li>• residents in long-term care settings, and</li> <li>• individuals aged 50 through 64 years with underlying medical conditions.</li> </ul> <p>CDC also recommended the following groups may receive a booster dose of the Pfizer vaccine 6 months after the completion of a primary series, based on their individual benefits and risks:</p> <ul style="list-style-type: none"> <li>• individuals aged 18 through 49 years with underlying medical conditions and</li> <li>• individuals aged 18 through 64 years who are at increased risk of COVID-19 exposure and transmission because of occupational or institutional setting.<sup>m</sup></li> </ul>
October 5, 2021	<p>Johnson &amp; Johnson announced that it had submitted data for the Janssen COVID-19 vaccine to FDA for the evaluation of a booster dose of its COVID-19 vaccine.<sup>m</sup></p>
October 6, 2021	<p>Pfizer submitted a request to FDA to amend its EUA for its COVID-19 vaccine to include those aged 5 through 11 years.</p>

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Date	Event
October 14, 2021	<p>FDA's Vaccines and Related Biological Products Advisory Committee met to discuss EUA request for a booster dose of the Moderna vaccine. Committee voted to recommend authorizing a single booster dose to be administered at least 6 months after completion of the primary series in</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older;</li> <li>• individuals aged 18 through 64 years at high risk of severe COVID-19; and</li> <li>• individuals aged 18 through 64 years whose frequent institutional or occupational exposure puts them at high risk of serious complications of COVID-19 including severe illness.<sup>m</sup></li> </ul>
October 15, 2021	<p>FDA's Vaccines and Related Biological Products Advisory Committee met to discuss EUA request for a booster dose of the Janssen vaccine. Committee voted to recommend authorizing a single booster dose to be administered at least 2 months after completion of the single-dose primary regimen in individuals aged 18 years and older.<sup>m</sup></p>
October 20, 2021	<p>The White House announced a plan for distributing and communicating about COVID-19 vaccinations for children aged 5 through 11 years, if authorized by FDA and recommended by CDC.<sup>n</sup></p>
October 20, 2021	<p>FDA amended the Moderna EUA to allow for use of a single booster dose to be administered at least 6 months after completion of the primary series in</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older;</li> <li>• individuals aged 18 through 64 years at high risk of severe COVID-19; and</li> <li>• individuals aged 18 through 64 years with frequent institutional or occupational exposure to the virus that causes COVID-19.<sup>m</sup></li> </ul> <p>FDA amended the Janssen EUA to allow for use of a single booster dose to be administered at least 2 months after completion of the single-dose primary regimen in individuals 18 years of age and older</p> <p>FDA authorized "mix and match" for the booster dose—that is, authorizing the use of any available COVID-19 vaccine for use as a booster dose regardless of which COVID-19 vaccine was used as the primary series or single-dose primary series.</p> <p>FDA amended the Pfizer EUA to clarify that individuals aged 18 through 64 years with frequent institutional or occupational exposure to the virus that causes COVID-19 were eligible for a booster dose, without reference to whether that exposure put them a high risk of severe COVID-19.</p>
October 21, 2021	<p>ACIP recommended a booster dose of the Moderna vaccine at least 6 months after the completion of the primary series and a booster dose of the Janssen vaccine at least 2 months after the completion of the single-dose primary regimen, as authorized by FDA.<sup>m</sup></p>
October 21, 2021	<p>CDC adopted ACIP's recommendations, stating that individuals in the following groups who received the Pfizer vaccine or the Moderna vaccine were eligible for a booster dose 6 months or more after their the completion of a primary series:</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years and older,</li> <li>• individuals aged 18 years and older living in long-term care settings,</li> <li>• individuals aged 18 years and older who have underlying medical conditions, and</li> <li>• individuals aged 18 years and older who work or live in high-risk settings.<sup>m</sup></li> </ul> <p>CDC also recommended a single booster dose to be administered 2 months or more after receiving the Janssen single-dose primary regimen for individuals 18 years of age and older</p> <p>CDC stated its recommendations allowed for the "mix and match" of a booster dose—that is, the use of any available COVID-19 vaccine for use as a booster dose regardless of which COVID-19 vaccine was used as the primary series or single-dose primary series.</p>

Source: GAO analysis of information from the Department of Defense (DOD), the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), CDC's ACIP, the Federal Emergency Management Agency (FEMA), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and transcripts of press conferences by White House and HHS officials. | GAO-22-104457

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**Appendix II: Timeline of Key Events Related to  
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Note: The timeline represents selected events related to COVID-19 vaccine implementation—prioritizing, allocating, distributing, and administering vaccine doses—and federal communication efforts from November 2020 through October 21, 2021.

<sup>a</sup>ACIP defines health care personnel as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. See Kathleen Dooling et al., “The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020,” *Morbidity and Mortality Weekly Report*, vol. 69, no. 49 (2020).

<sup>b</sup>Pfizer and BioNTech developed this COVID-19 vaccine together, which this report refers to as the Pfizer vaccine. The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products, such as vaccines. Once a declaration of an emergency has been made, FDA may temporarily allow use of unlicensed vaccines through an emergency use authorization (EUA). For FDA to issue an EUA for a vaccine, it must be reasonable to believe that the vaccine may be effective and that the known and potential benefits of the vaccine outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3. FDA has indicated that issuance of an EUA for a COVID-19 vaccine for which there is adequate manufacturing information would require a determination by FDA that the vaccine’s benefits outweigh its risks based on data from at least one well-designed phase 3 clinical trial that demonstrates the vaccine’s safety and efficacy in a clear and compelling manner.

Typically, FDA must license a vaccine before it can be marketed in the U.S. See 42 U.S.C. § 262. Any COVID-19 vaccine that initially receives an EUA from FDA is expected to work toward submission of a biologics license application, according to FDA guidance. See Department of Health and Human Services, Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry*, (Silver Spring, Md.: May 2021).

<sup>c</sup>For the purposes of ACIP’s recommendation, non-health care frontline essential workers include firefighters, police officers, corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, those who are in the education sector (teachers and support staff) as well as daycare workers. According to CDC, about 49 million persons, including non-health care frontline essential workers and individuals aged 75 years and older were recommended for vaccination in phase 1b, and an additional 129 million persons were recommended for vaccination in phase 1c (including about 28 million individuals aged 65-74 years). See Kathleen Dooling et al., “The Advisory Committee on Immunization Practices’ Updated Interim Recommendation for Allocation of COVID-19 Vaccine—United States, December 2020,” *Morbidity and Mortality Weekly Report*, vol. 69, no. 51-52 (2021).

<sup>d</sup>Department of Health and Human Services, Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex—Considerations for Increasing COVID-19 Vaccination: Reaching and Increasing Uptake in Priority Populations, version 1.0*, (Atlanta, Ga.: Jan. 11, 2021). According to CDC, this document was a supplement to CDC’s interim playbooks to assist state and other jurisdictions with COVID-19 vaccine implementation. See Department of Health and Human Services, Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, version 1.0* (Atlanta, Ga.: Sept. 16, 2020) and *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, version 2.0* (Atlanta, Ga.: Oct. 29, 2020).

<sup>e</sup>White House, National Strategy for the COVID-19 Response and Pandemic Preparedness (Washington, D.C.: Jan. 21, 2021).

<sup>f</sup>In addition to its initial guidance on community vaccination centers, FEMA published five additional versions of its guidance on community vaccination centers between February 2021 and April 2021. For the final version, see Department of Homeland Security, Federal Emergency Management Agency, *Community Vaccination Centers Playbook, Final* (Washington, D.C.: April 23, 2021).

<sup>g</sup>Federally supported health centers generally receive Health Center Program grants from HRSA under section 330 of the Public Health Service Act (42 U.S.C § 254b) and provide primary care services in medically underserved areas. Some organizations meet all Health Center Program requirements but do not receive federal grant funding through the section 330 program. However, these centers, which are known as “look-alikes,” receive other benefits, such as higher reimbursement rates from the Medicare and Medicaid programs and may receive grants through other federal programs. We use the term “federally supported health centers” to refer to both “look-

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**Appendix II: Timeline of Key Events Related to  
COVID-19 Vaccine Implementation through  
October 21, 2021**

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alikes” and those health centers that receive grants under section 330 of the Public Health Service Act.

<sup>h</sup>Janssen Pharmaceutical Companies are a part of Johnson & Johnson.

<sup>i</sup>Under the Public Readiness and Emergency Preparedness (PREP) Act, licensed health professionals and other individuals authorized to administer a countermeasure under state law are protected from liability under federal and state law for administering covered countermeasures against COVID-19, including the COVID-19 vaccines. HHS may identify additional categories of persons, known as “qualified persons”, to be afforded such protections. See Pub. L. No. 109-148, div. C, 119 Stat. 2680, 2818 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d et seq.). See HRSA Notice, 86 Fed. Reg. 14462 (Mar. 16, 2021).

<sup>j</sup>The Rural Health Clinic COVID-19 Vaccine Distribution Program distributed 99,760 vaccine doses to 141 rural health clinics, as of September 15, 2021, according to HHS.

<sup>k</sup>Although FEMA’s vaccination center pilot program ended, the agency continued to support community vaccination centers managed and operated by states and other jurisdictions (using doses allocated to the jurisdictions) by providing federal personnel, funding, and material, such as medical equipment and supplies, according to agency officials.

<sup>l</sup>According to CDC, an additional dose is administered when the initial immune response following a primary vaccine series is likely to be insufficient.

<sup>m</sup>According to CDC, a booster dose is a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

<sup>n</sup>As of October 21, 2021, no vaccines had been authorized or licensed for children under 12 years, but Pfizer had requested FDA to authorize its COVID-19 vaccine children aged 5 years to 11 years. FDA’s Vaccines and Related Biological Products Advisory Committee was scheduled to meet on October 26, 2021, to discuss a request for authorization of Pfizer’s COVID-19 vaccine for children aged 5 through 11 years.

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# Appendix III: Vaccine Finder and the Vaccine Administration Management System

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The Centers for Disease Control and Prevention (CDC) developed tools to help the public locate where vaccines were available and to schedule a vaccination appointment. Specifically:

**VaccineFinder** is an online tool previously developed by CDC and Boston's Children's Hospital to provide users information on the locations of providers offering vaccinations, such as for seasonal influenza. As the national supply of COVID-19 vaccine increased, CDC updated VaccineFinder to include information about COVID-19 vaccines. VaccineFinder, however, provided no or limited information on COVID-19 vaccines in March 2021 when vaccine demand was increasing. The public also could not schedule appointments on VaccineFinder; instead, users were given a link to a second website or a phone number to schedule appointments. When information was not available on COVID-19 vaccines on VaccineFinder, some states created their own platforms to help health care providers and the public find available vaccination appointments, according to selected health officials. In May 2021, CDC updated VaccineFinder for COVID-19 vaccines with a new website, <https://www.vaccines.gov>, which is dedicated specifically to COVID-19 vaccines.

**Vaccine Administration Management System (VAMS)** is an online tool CDC developed that states or other jurisdictions, federal agencies, or other organizations could opt to use to help manage COVID-19 vaccine administration. For example, in jurisdictions that used the system, the public could use VAMS to schedule vaccination appointments. Ten jurisdictions, three federal agencies, and one multi-state health system were using VAMS as of June 2021, according to CDC officials. State health officials from one state using VAMS said health care providers reported some problems with VAMS, including difficulties completing their registration, which is needed to upload information about vaccination appointments into VAMS, and correcting record errors in a timely manner in some instances. VAMS was initially only available in English; it was made available in Spanish in April 2021, according to health officials from one state.

# Appendix IV: Comments from the Department of Health & Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

October 19, 2021

Alyssa M. Hundrup  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Hundrup:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, ***"COVID-19: HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives"*** (GAO-22-104457).

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

Sincerely,

A handwritten signature in blue ink that reads "Melanie Anne Egorin".

Melanie Anne Egorin  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19: HHS AGENCIES' PLANNED REVIEWS OF VACCINE DISTRIBUTION AND COMMUNICATION EFFORTS SHOULD INCLUDE STAKEHOLDER PERSPECTIVES (GAO-22-104457)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

The GAO study provided valuable feedback on the implementation of the Health Resources and Services Administration's (HRSA) Health Center COVID-19 Vaccine Program and the Rural Health Clinic COVID-19 Vaccine Distribution Program, as well as the Centers for Disease Control and Prevention's (CDC) Long-Term Care Partnerships Pharmacy Program and Federal Retail Pharmacy Program. HRSA and CDC are committed to continuous improvement of their vaccine programs and appreciate this opportunity to further inform those improvements.

HRSA and CDC launched the [Health Center COVID-19 Vaccine Program](#) and the [Rural Health Clinic COVID-19 Vaccine Distribution Program](#) to allocate a limited supply of COVID-19 vaccine to select health centers and rural health clinics. This was done to ensure our nation's underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against the virus and to improve vaccine access and vaccination rates to medically underserved rural communities. Additionally, starting in February of 2021, the Federal Retail Pharmacy Program was initiated and now includes over 40,000 retail and long-term care pharmacy locations nationwide and 21 national pharmacy partners and independent pharmacy networks.

To participate in the HRSA and CDC vaccine programs, participants must agree to the Conditions of Participation, which includes data reporting (i.e., required vaccine supply and administration data reported to state/other jurisdictions, as required in the CDC COVID-19 Vaccine Provider Agreement). HHS' Tiberius system is the central platform for sharing vaccine related information. Since the platform capabilities were enabled, vaccine data from these programs has been shared with jurisdictions to facilitate coordination at state and local levels through Tiberius.

HRSA and CDC are aware of the importance of continuous stakeholder engagement to ensure collaboration between vaccine programs and jurisdictions overseeing state and local immunization programs. For example, during the initial phase of the Health Center COVID-19 Vaccine Program, in order to maximize coordination, HRSA and CDC hosted weekly hour-long office hours with CDC regional coordinators and state and local immunization programs to share program updates and to address questions and solicit feedback. HRSA staff also communicated with CDC regional coordinators and state and local immunization programs on an almost daily basis to answer questions and joined regional calls with immunization programs to provide tailored opportunities for bidirectional information sharing.

As of September 15, 2021, the Health Center COVID-19 Vaccine Program distributed 6,389,574 vaccine doses to 866 participating HRSA-supported health centers for 2,362 sites. During the same time period, the Rural Health Clinic COVID-19 Vaccine Distribution Program distributed 99,760 vaccine doses to 141 rural health clinics. HRSA designed its vaccine programs as separate, direct allocations for health centers and rural health clinics and are intended to supplement – not supplant – existing vaccine distributions that health centers and rural health

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19: HHS AGENCIES' PLANNED REVIEWS OF VACCINE DISTRIBUTION AND COMMUNICATION EFFORTS SHOULD INCLUDE STAKEHOLDER PERSPECTIVES (GAO-22-104457)**

clinics are receiving from states. As of September 29, 2021, CDC's Federal Retail Pharmacy Program distributed almost 137 million vaccine doses (including those administered through the Pharmacy Partnership for Long-term Care Program).

**Recommendation 1**

As CDC finalizes its plans for an after-action review related to its COVID-19 vaccine distribution and communication efforts, the Director of the Centers for Disease Control and Prevention should ensure the agency obtains feedback during the life cycle of the response from key stakeholders, including state and local health officials, and incorporates their perspectives as it conducts its review. (Recommendation 1)

**HHS Response**

CDC concurs with the GAO's recommendation. CDC anticipates the development of an after-action report on vaccine distribution and communication efforts. A timeline for an after-action report has not been established as CDC remains activated for the COVID-19 response. In the meantime, CDC continues to incorporate continuous feedback from stakeholders.

**Recommendation 2**

The Director of the Centers for Disease Control and Prevention should share relevant findings of its after action review related to vaccine distribution and communication with key stakeholders, such as state and local health officials, and other federal agencies, as appropriate. (Recommendation 2)

**HHS Response**

CDC concurs with the GAO's recommendation. CDC anticipates the development of an after-action report on vaccine distribution and communication efforts. A timeline for an after-action report has not been established as CDC remains activated for the COVID-19 response. In the meantime, CDC continues to incorporate continuous feedback from stakeholders.

**Recommendation 3**

As HRSA finalizes its plans for an after action review related to its COVID-19 vaccine distribution and communication efforts, the Administrator of HRSA should ensure the agency obtains feedback during the life cycle of the response from key stakeholders, including state and local health officials, and incorporates their perspectives as it conducts its review.

**HHS Response**

HRSA concurs with the GAO's recommendation. HRSA plans to conduct an after-action review and develop a final report documenting the key program accomplishments, including successful strategies, challenges, recommendations, and considerations for future public health emergencies at the conclusion of the HRSA vaccine programs. HRSA will seek to obtain feedback during the lifecycle of the response from key stakeholders to incorporate their perspectives in an after action review.



**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19: HHS AGENCIES' PLANNED REVIEWS OF VACCINE DISTRIBUTION AND COMMUNICATION EFFORTS SHOULD INCLUDE STAKEHOLDER PERSPECTIVES (GAO-22-104457)**

**Recommendation 4**

The Administrator of HRSA should share relevant findings of its after action review related to vaccine distribution and communication with key stakeholders, such as state and local health officials.

**Response**

HRSA concurs with GAO's recommendation. HRSA anticipates that any after action review findings would be shared as appropriate with the CDC, HRSA-supported health centers, rural health clinics, key rural health and other stakeholders, such as state and local health officials.

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

Alyssa M. Hundrup, (202) 512-7114, [hundrupa@gao.gov](mailto:hundrupa@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above Kim Yamane (Assistant Director), Gay Hee Lee (Analyst in Charge), Sam Amrhein, George Bogart, Linda McIver, Fatima Sharif, and Meghan Shrewsbury made key contributions to this report. Other contributors to this report were Anne Hopewell, Ethiene Salgado-Rodriguez, and Lillian Riehl Schultze.

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# Related GAO Products

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*COVID-19: Additional Actions Needed to Improve Accountability and Program Effectiveness of Federal Response.* [GAO-22-105051](#). Washington, D.C.: October 27, 2021.

*COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery and Program Integrity.* [GAO-21-551](#). Washington, D.C.: July 19, 2021.

*COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation.* [GAO-21-443](#). Washington, D.C.: April 14, 2021.

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

*Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges.* [GAO-21-319](#). Washington, D.C.: February 11, 2021.

*COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention.* [GAO-21-265](#). Washington, D.C.: January 28, 2021.

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

*COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations.* [GAO-21-207](#). Washington, D.C.: November 17, 2020.

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

*COVID-19: Opportunities to Improve Federal Response and Recovery Efforts.* [GAO-20-625](#). Washington, D.C.: June 25, 2020.

*Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning.* [GAO-11-632](#). Washington, D.C.: June 27, 2011.

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