U.S. Department of Health and Human Services

Office of Inspector General

Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs

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January 2023, OEI-04-21-00190

U.S. Department of Health and Human Services
Office of Inspector General
Report in Brief
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Why OIG Did This Review

Vaccines help reduce disease-related illnesses, hospitalizations, and deaths. The Centers for Disease Control and Prevention (CDC) assists and funds State and local immunization programs—to which we refer as awardees—to support vaccine programs that immunize individuals in their jurisdictions against vaccine-preventable diseases (e.g., measles and influenza). CDC's COVID-19 vaccination program is an extension of these efforts. As vaccine supply increased in March 2021—during the early stages of COVID-19 vaccination programs—awardees faced challenges in meeting their goals of immunizing the U.S. population amid an ongoing pandemic.

As CDC makes ongoing program improvements, it can be assisted by understanding the challenges that awardees experienced with the COVID-19 vaccination program and the mitigation strategies they took. This understanding can also help CDC enhance routine immunization programs and better prepare for vaccination programs for future pandemics.

How OIG Did This Review

The Office of Inspector General (OIG) collected data on the challenges and mitigation strategies that 56 State and large metropolitan area awardees reported in March 2021. We also interviewed CDC officials, officials from other Department of Health and Human Services (HHS) agencies, and other Federal officials, and we reviewed written responses and documentation across HHS. To support ongoing vaccination efforts, OIG shared preliminary analysis with CDC in late March and early April 2021.

Key Takeaway

State and local immunization programs distributing COVID 19 vaccines faced numerous challenges, including (1) achieving logistical efficiency, (2) obtaining complete vaccine data from providers, (3) combating vaccine hesitancy with public health messaging, and (4) overseeing vaccine providers.

What OIG Found

In the early stages of their COVID-19 vaccination programs, awardees consistently reported challenges that affected their ability to administer COVID-19 vaccines efficiently and equitably. Specifically, awardees reported logistical challenges that impacted efficiency, including large minimum order sizes for vaccines, requirements for ultra-cold storage, and insufficient ancillary supplies. Additionally, awardees reported challenges in obtaining complete, timely, and accurate vaccine data from both Federal program and jurisdictional providers, which affected their ability to determine community needs efficiently and equitably. Finally, awardees also reported wanting more Federal government support for public health messaging and for their oversight of providers.

For each type of challenge, awardees also reported using a variety of strategies to mitigate the challenge. For example, awardees reported breaking down large minimum order sizes to improve vaccine access. Awardees also reported having less experienced providers shadow each other to improve provider understanding of data systems.

What OIG Recommends and How the Agency Responded

COVID-19 vaccination efforts are ongoing, and CDC continues to take steps to address many awardee challenges. However, areas for improving the efficiency and equity of the vaccination program remain. Specifically, we recommend that CDC update its plans for mass vaccination programs with strategies that address awardee-reported logistical challenges and strengthen reporting of vaccine allocation data and administration data. In addition, we recommend that CDC clarify roles and responsibilities within HHS for vaccine public health messaging during a pandemic. Finally, we recommend that CDC work with awardees to enhance current and future capabilities for provider training and oversight. CDC concurred with all four recommendations.

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BACKGROUND

OBJECTIVES

1. To describe awardee-reported challenges in the early stages of their COVID-19 vaccination programs.
2. To describe awardee-reported mitigation strategies for addressing challenges in the early stages of their COVID-19 vaccination programs.

Rationale

The Department of Health and Human Services (HHS) plays a critical role in the distribution and administration of routine and pandemic vaccines to the public.[1] The Centers for Disease Control and Prevention (CDC) provided funding to 64 State, local and territorial immunization programs (hereinafter referred to as "awardees") through its *Immunization and Vaccines for Children Cooperative Agreement*.[2] Through this cooperative agreement, CDC provided $350 million on average each year between fiscal years (FYs) 2017 and 2021 for awardees to plan for and oversee routine vaccination programs.[3] Additionally, HHS and CDC have developed various pandemic vaccination planning guides, such as the *2005 HHS Pandemic Influenza Plan*, which also provide guidance to awardees.[4]

The COVID-19 vaccination program is a joint Federal, State and local initiative to provide safe and effective COVID-19 vaccines to the public.[5] To ensure wide access to COVID-19 vaccines, the Federal government uses multiple programs to get vaccines into communities, including both directly through the awardee, and through providers participating in Federal programs (i.e., programs run by the Federal government rather than by awardees).[6] Therefore, providers may receive COVID-19 vaccines through an awardee, a Federal program, or a combination of both.

CDC assisted awardees in developing and implementing plans that built upon existing routine immunization program efforts and past pandemic planning.[7] Moreover, CDC has provided $7.2 billion in COVID-19 supplemental funding to awardees between FY 2020 and FY 2021. As a result, Federal, State, and local personnel have carried out one of the largest mass vaccination efforts in U.S. history to combat the COVID-19 pandemic.[8] This included enrolling many providers who do not routinely administer vaccines (hereinafter referred to as "nontraditional providers"), in addition to traditional vaccine providers, to meet the demand for the COVID-19 vaccines. As of October 2022, CDC reported that approximately 68 percent of the U.S. population

(i.e., adults and children) had received at least two doses of Moderna or Pfizer vaccines or one dose of Johnson & Johnson.

Stakeholders reported several initial challenges when vaccine distribution and administration began in late 2020. These included limited vaccine supply; vaccine hesitancy; and storage and handling requirements.[9] Stakeholders acknowledged that some of these initial challenges would likely evolve, or new challenges would emerge, as vaccine supply increased.

This report provides a national view of challenges that 56 awardees reported experiencing in the early stages of their vaccination program, as well as any mitigation strategies implemented to address those challenges. To improve COVID-19 vaccination programs while they were ongoing, we issued preliminary, nonpublic analysis of reported challenges to CDC in late March and early April 2021. This preliminary analysis allowed CDC to address awardee challenges in a time-sensitive manner. This report builds upon that preliminary analysis, by using additional data and qualitative analysis, and includes formal recommendations to improve COVID-19 and future vaccination programs.

COVID-19 vaccination program logistics

In the *COVID-19 Vaccination Program Interim Operation Guidance*, CDC outlines various sections related to vaccination program logistics, including vaccine allocation; vaccine packaging; vaccine distribution; vaccine storage, handling, and administration; and critical populations.[10]

During our data collection, the Countermeasures Acceleration Group (CAG), a joint HHS and Department of Defense (DoD) effort, led the logistics associated with the development, manufacturing of COVID-19 vaccines, and distribution of those vaccines to awardees and their communities.[11] In March 2022, HHS replaced CAG with a permanent office, called the HHS Coordination Operations and Response Element (H-CORE), within the Administration for Strategic Preparedness and Response (ASPR).[12, 13, 14]

Vaccine allocation

Vaccines generally enter communities in one of two ways. A push model "pushes" vaccines into communities on the basis of a pre-determined vaccine allocation. Within a push model, an entity, such as the Federal government, determines vaccine allocations, or the number of vaccines doses made available, and manufacturers package and distribute vaccines. A pull model is typically used for routine vaccinations.[15] Within a pull model, there is not an entity allocating vaccines, as manufacturers package and distribute vaccines to providers on the basis of the number of vaccines doses that the provider requests.[16]

Since the COVID-19 vaccination program began, and as of May 2022, COVID-19 vaccines have entered communities using a push model. When we collected data in March 2021, CAG was responsible for allocating vaccines.[17, 18] As of March 2022, H-Core had taken over this responsibility.

Vaccine packaging

COVID-19 vaccine manufacturers determine how to package and determine minimum order sizes for vaccines. Minimum order sizes are the smallest number of vaccine doses that the manufacturer sends within each order. See Exhibit 1 for each COVID-19 vaccine's minimum order size during the time period for which we collected data (i.e., March 2021).

Exhibit 1: Minimum order sizes for COVID-19 vaccines in March 2021.

Vaccine	Minimum Order Size
Pfizer	1170 doses*
Moderna	100 doses
Johnson & Johnson	100 doses

Source: OIG analysis of CDC documentation, 2022.
* Initially, Pfizer orders contained 975 doses of vaccines. However, it was later determined that providers can obtain an extra dose out of each vial with a certain syringe, which increased the quantity of doses from 975 to 1170.

As of this report's release, the Pfizer vaccine was the only vaccine for which the minimum order size had changed, from 1170 doses to 300 doses.

Vaccine distribution

Using the number of vaccines doses they are allocated and the manufacturer-determined minimum order size, awardees manage and distribute vaccines to the providers enrolled in their jurisdiction using one of two methods.[19] Awardees have manufacturers ship vaccines to either (1) enrolled providers directly or (2) a central depot or warehouse where awardees repackage vaccines into smaller shipment sizes using their own resources.[20]

CDC notes several things to consider when establishing a depot or warehouse to break down vaccine shipments. CDC recommends that, when possible, vaccines be shipped directly from the manufacturer to the location where they will be administered.[21] This approach follows the vaccine manufacturer's quality system and minimizes opportunities for breaks in the temperature-controlled supply chain (i.e., cold chain), which could compromise the vaccine and cause the vaccine to be less effective.[22] However, repackaging vaccine shipments, rather than shipping vaccines directly to some providers who may not need a full minimum order amount, reduces the potential for vaccine waste by sending only the quantity that providers need. In addition, this helps ensure vaccine access for areas with smaller needs (e.g., smaller provider offices and mobile vaccination clinics). While this targeted approach ensures access for smaller providers (i.e., increases equitable access), repackaging vaccine

shipments also may decrease the distribution throughput, as it would add time to get vaccines to providers (i.e., delay patient access to the vaccine).

Vaccine storage, handling, and administration

Vaccine storage and handling requirements for each COVID-19 vaccine varied from refrigerated (36°F to 46°F) to frozen (-13°F to 5°F) to ultra-cold (-112°F to -76°F). Maintaining each vaccine within its required temperature range is important to maximize the potential potency and viability of the vaccine. Storing vaccines at freezing temperatures requires a standard pharmaceutical freezer, while storing vaccines at ultra-cold temperatures requires additional equipment that most providers typically do not have. See Appendix A for additional information on the specific storage and handling requirements for each COVID-19 vaccine when we collected data from awardees.

To administer the COVID-19 vaccine, providers need ancillary supplies, which are shipped in kits with the vaccines. These kits include needles, low dead-volume syringes, alcohol pads, vaccination cards, needle information cards, and personal protective equipment for providers.[23, 24] Each ancillary kit included enough supplies to administer the number of doses in each minimum order size, with overage to allow for breakage and loss.[25]

Critical population prioritization

Initially, CDC recommended in its playbook that awardees ensure that populations in their jurisdiction that are at higher risk for COVID-19 illness or death have priority access to vaccines.[26] In December 2020, CDC published its Advisory Committee on Immunization Practices (ACIP) recommendations for allocation of COVID-19 vaccines.[27] This recommendation included prioritizing COVID-19 vaccines for health care personnel to protect these workers and keep health care facilities operating.[28] In addition, CDC recommended prioritizing other vulnerable populations, such as residents in long-term care facilities; populations over the age of 65; populations with underlying medical conditions; and essential worker groups, some of which have high proportions of some racial and ethnic minority populations.[29] Awardees used these CDC recommendations and established their own priority groups with some variations.[30, 31, 32]

Vaccine data reporting

Given the multiple programs through which providers can obtain COVID-19 vaccines, data on where vaccines are distributed (i.e., vaccine allocation data) and the people receiving those vaccines (i.e., vaccine administration data) are important for ensuring an efficient and equitable vaccine campaign. Vaccine allocation data is important for vaccine access planning, while vaccine administration data is important for monitoring vaccine uptake.

Vaccine allocation data

The Federal government provides awardees with projections of the expected number of COVID-19 vaccines that will be allocated to them (i.e., allocation data). Awardees access allocation data through Tiberius, which is a system developed for the COVID-19 vaccine campaign. Allocation data are used by awardees, particularly when vaccine supply is limited, to plan distribution of allocated doses to providers.

Vaccine administration data

Each awardee has an immunization information system (IIS) that is used by its providers to report vaccine administration data. CDC requires that COVID-19 vaccine providers receiving vaccines through an awardee report data into awardee IISs for each dose administered. The data must be entered into the provider's system of record within 24 hours and reported to the jurisdiction's IIS within 72 hours.[33] The required data include the vaccine recipient's date of birth, address, race, and ethnicity, as well as vaccine administration date, location, and manufacturer.[34] Awardees then upload the data from their IISs into CDC's immunization system, according to State and local laws.

While CDC encourages Federal program providers to report vaccine administration data to awardee IISs, some of these providers do not have the technological infrastructure and/or a data-sharing agreement to do so.[35] As a result, some of these Federal program providers submit vaccine administration data to CDC directly.

See Appendix B for more information on various immunization data systems used to collect and report COVID-19 vaccination data.

Vaccine public health messaging

Vaccine public health messaging is essential for building the public's confidence in vaccines, as highlighted in prior pandemic vaccine planning and routine vaccination programs.[36] Prior pandemic planning outlines steps for the Federal government and awardees to take to develop and disseminate public health messaging regarding vaccine safety and the benefits of being vaccinated.[37]

Educating the public and providing a clear, consistent message regarding vaccination is a joint Federal, State, and local effort. For routine vaccines, outbreaks, and other emergencies, CDC's primary role is developing and sharing core messages that reflect the latest science so that, in turn, health departments, clinical partners, and communities can hone those messages to reach the communities they serve.[38] CDC also assists awardees in strategies to combat vaccine hesitancy. In 2019, CDC developed a *Vaccinate with Confidence* strategy to build trust in populations that may be hesitant to receive routine vaccines.[39]

CDC also develops health messaging materials including frequently asked questions, flyers, testimonial videos, fact sheets, and social media posts regarding routine

immunizations. CDC tailors these materials to health care providers; State and local health departments; and the general public to enhance their applicability. CDC may also coordinate with nonprofits and/or professional organizations to develop public health messaging materials, such as public service announcements, social media campaigns, or radio ads, to encourage the public to get vaccinated.[40] Finally, CDC also provides resources to State and local health departments and health care providers to assist vaccine providers in developing their own public health messaging materials.[41]

In its *COVID-19 Vaccine Playbook*, CDC provides guidance to awardees on developing specific COVID-19 vaccine public health messaging. This includes creating messaging that encourages people to receive the COVID-19 vaccine, educates the public on the COVID-19 vaccine development process, and addresses COVID-19 vaccine misinformation.[42] CDC guidance states that COVID-19 public health messaging should be inclusive and consider the culture of the target audience.[43] Additionally, CDC recommends that awardees consider tailoring messaging for specific critical, high-risk populations.[44] Awardees have discretion on how public health messaging is shared, such as through print, radio, social media or television.[45]

Vaccine manufacturers also created vaccine-specific fact sheets for vaccine recipients to help ensure that patients understand any potential risks associated with the vaccine.[46] Vaccine manufacturers translated these fact sheets into multiple languages and posted them online for the public.[47] COVID-19 vaccine providers are responsible for disseminating these fact sheets to individuals receiving the vaccine.[48]

Vaccination program training and oversight

Training and oversight of providers administering vaccines are critical aspects of both routine and pandemic vaccination programs to ensure compliance with program requirements. Adherence to program requirements is necessary to ensure vaccines are properly distributed, stored, and handled and are administered equitably and efficiently. Failure to adhere to program requirements may contribute to lower overall vaccination coverage and may cause individuals to lose confidence in vaccines and providers.

Provider training

CDC requires awardees to train its enrolled providers to ensure that they understand the COVID-19 vaccination program requirements.[49] Training is especially important to ensure the success of the vaccination program. CDC provides educational resources to awardees, but awardees may develop their own materials.[50] CDC notes that awardees should determine the most efficient method for training delivery (e.g., online videos, webinars, or in-person instruction) and tracking the completion of those trainings.[51]

CDC expects awardees to train all of its providers on several topics, including:

- storing and handling COVID-19 vaccines,
- administering COVID-19 vaccines with appropriate ancillary supplies,
- reporting COVID-19 vaccine administration into the IIS, and
- providing COVID-19 vaccine fact sheets to vaccine recipients.[52]

Awardees may also leverage resources from CDC and other external sources to train providers. For example, vaccine manufacturers developed training resources that awardees may use to train providers on vaccine storage and handling.[53]

Provider oversight

CDC primarily relies on awardee-led site visits to ensure that providers adhere to program requirements. For COVID-19 vaccine providers, CDC requires awardees to conduct site visits each year for a fixed number of vaccination sites based on the population of the jurisdiction (i.e., 25, 50, 70, or 100 site visits).[54] Awardees with fewer than 25 enrolled providers are required to conduct site visits for all enrolled providers.[55] CDC recommends that awardees prioritize site visits on the basis of the number of vaccines administered and the amount of inventory onsite. CDC also requires that awardees conduct site visits for all depot or warehouse locations where vaccines are redistributed.[56]

Currently, COVID-19 vaccine provider site visits are only a one-time requirement (rather than an annual requirement).[57, 58] CDC requires that awardees conduct either in-person or virtual site visits, with in-person being the preferred method.[59]

Site visits involve reviewing and assessing COVID-19 provider operations with the following goals, as outlined in CDC's playbook:

- Assessing provider adherence to program requirements;
- Identifying and addressing areas in which providers are doing well and areas needing additional follow-up;
- Identifying and addressing provider educational needs to help providers meet program requirements;
- Ensuring that vaccine recipients are receiving properly managed and viable vaccine;[60] and
- Ensuring that vaccines are distributed equitably and according to State and local priorities.[61]

Awardees may, but are not required to, implement other oversight mechanisms, such as data quality checks.

As of October 2021, awardees were also required to conduct site visits for some provider types enrolled in Federal programs.[62]

Related work

OIG has conducted several prior studies on pandemic vaccine preparedness. In a series of reports from 2009, OIG found gaps in awardees' influenza vaccine distribution plans, as well as medical surge planning.[63] OIG made recommendations to both CDC and ASPR, all of which have been implemented since 2014.[64]

OIG has a companion report that provides a deeper analysis of the challenges that awardees reported experiencing with Federal program provider vaccination data.[65] In this review, OIG found that awardees did not receive comprehensive data for more than 250 million COVID-19 vaccine doses administered by Federal agencies and retail pharmacies that partnered with the Federal government. OIG recommended that CDC (1) work with State and local immunization programs and pharmacy partners, to improve data gaps and timeliness challenges and (2) provide educational outreach to ensure State and local immunization programs are aware of existing tools to address campaign needs. This report complements the information highlighted in this review, as we describe similar challenges that awardees reported to us at a higher level.

The Government Accountability Office (GAO) also reviewed the COVID-19 vaccination program in several recent reports. GAO found that vaccine companies had limited manufacturing capacity, challenging their ability to scale up COVID-19 vaccine production.[66] GAO also found that HHS's use of multiple vaccination programs improved high-risk populations' access to the COVID-19 vaccine, but cited coordination challenges.[67] Finally, GAO also released a report examining the transition from CAG to HHS's H-CORE.[68] At the time of this report's release, all of GAO's recommendations from these reports remain unimplemented.

Methodology

Scope

This evaluation was designed to describe awardee-reported challenges and mitigation strategies in the early stages of their COVID-19 vaccination programs. To do so, we collected and analyzed qualitative data from a variety of stakeholders, including 56 State and large metropolitan area awardees. The term "awardees" refers to 56 State and large metropolitan immunization programs included in our data collection.[69, 70] We collected data from awardees between March 12 and 24, 2021, which we refer to as the early stages of the COVID-19 vaccination program because vaccines were not widely available at this time.

Data sources and collection

We collected qualitative data from awardees, as well as from officials within HHS, including CDC and CAG, and other Federal agencies. We acquired these data via surveys, interviews, and submitted documentation.

Awardee data. We conducted email surveys or phone interviews with all 56 awardees to understand their challenges and any mitigation strategies they implemented to address the challenges.[71, 72] To do so, we first asked awardees to report the top three challenges they were facing in the early stages of their COVID-19 vaccination programs. Then, to ensure that we were capturing a comprehensive picture of all challenges, we asked awardees questions about whether they were experiencing challenges in six specific COVID-19 vaccination program-related areas. We asked awardees whether they were experiencing challenges in each area and, if so, to describe the challenges. The six areas were (1) provider enrollment; (2) establishing and distributing public messaging; (3) addressing disparities and inequities; (4) vaccine allocation, ordering, distribution, and inventory management; (5) administering the vaccine; and (6) Federal vaccine data systems.[73] We also asked awardees to describe any other COVID-19 vaccination program-related challenges. Finally, we asked awardees to identify ways in which the Federal government could help awardees address these challenges, as well as mitigation strategies awardees implemented on their own to address them.

HHS and other Federal agency data. We conducted two interviews with CDC and CAG in May 2021. The purpose of these interviews was to obtain CDC and CAG perspectives on the challenges that awardees reported, including any actions CDC or CAG had taken or planned to take to address the reported challenges. We also received additional written responses and documentation from CDC to clarify their actions and plans in May 2022. The documentation we received contained both internal and publicly available information related to both routine and COVID-19 vaccine programs.

Data analysis

We compiled and reviewed all the qualitative data to determine thematic challenges. Most awardees (i.e., more than 43 of the 56) reported challenges in each of the six specific targeted areas. However, some awardees reported challenges that applied to more than one of the six areas and some awardees reported challenges that did not align with our six areas. As such, we synthesized the data into meaningful themes about programmatic issues but do not provide quantitative counts in the report. See Appendix C for the raw counts of how many awardees reported challenges and associated mitigation strategies in the six specific COVID-19 vaccination program-related areas.

In determining which themes to report on, we focused on those themes that met two criteria: (1) the issue was currently challenging COVID-19 vaccination efforts, would challenge future pandemic vaccination efforts, or both; and (2) awardees alone could not implement potential solutions.

Limitations

Wherever possible, we compared interview and written responses to facts we could determine from our review of publicly available information, as well as other documentation provided by awardees, CDC, and CAG.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Awardees reported logistical challenges that affected their ability to administer vaccines equitably and efficiently

In March 2021 (i.e., the early stages of COVID-19 vaccination programs), awardees reported logistical challenges, such as large minimum order sizes for vaccines; requirements for ultra-cold vaccine storage; and insufficient ancillary supplies. Awardees reported that challenges in these areas hindered their ability to vaccinate their communities equitably and efficiently. For example, large minimum order sizes for vaccines and requirements for ultra-cold storage limited the ability of some smaller and rural providers to receive, store, and administer COVID-19 vaccines. Awardees reported that these providers were critical to ensuring equitable vaccine access and increasing vaccination rates within their jurisdictions. Further, awardees reported that some providers did not always have sufficient ancillary supplies when administering vaccines, which hindered efficiency and increased the potential for vaccine waste.

Awardees reported that large minimum order sizes and ultra-cold storage requirements hindered equitable and efficient vaccine distribution

The Pfizer vaccine—which was the first COVID-19 vaccine to be authorized for use — initially had a minimum order size that was about 10 times greater than that for the other 2 vaccines.[74] Further, while FDA authorized less restrictive temperature requirements in certain circumstances by early February 2021, the Pfizer vaccine still required ultra-cold storage if the vaccines were not used in 2 weeks. Therefore, if a provider received Pfizer vaccines and did not have ultra-cold storage, the provider had to use all 1,170 doses in 2 weeks to avoid wasting vaccines.

In March 2021, awardees reported that the Pfizer vaccine's large minimum order size and requirements for ultra-cold storage were particularly challenging for some providers. Awardees reported challenges in distributing the Pfizer vaccine to providers that did not have the ability to use all doses in a minimum order within the required timeframe or did not have the equipment to store the doses for longer periods of time. As a result, awardees reported that some providers and subsequently the populations they served had limited vaccine access.[75] For example, one awardee reported, "Many of our providers who serve the most vulnerable populations cannot manage large quantities of vaccines…. These are the providers that these populations trust."

However, in March 2021, vaccine availability was limited, and vaccine access and uptake of those limited vaccines was a priority. As a result, awardees reported spending significant resources to either procure additional equipment for ultra-cold

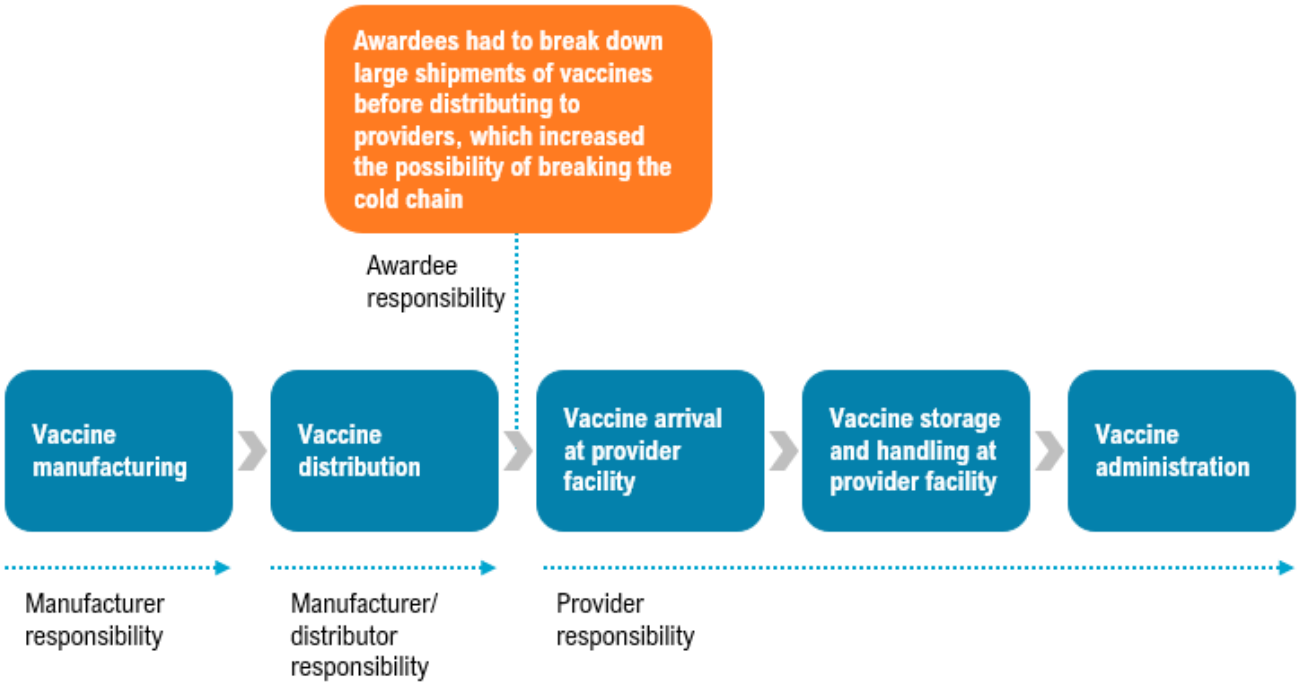
storage that was not always readily available and/or breaking down and redistributing Pfizer vaccine orders into smaller quantities to improve vaccine access and reduce the potential for vaccine waste.

AWARDEE REPORTED CHALLENGE: Ultra cold storage is a challenge in rural areas with smaller providers due to the need for special storage equipment.

AWARDEE REPORTED MITIGATION STRATEGY: We are a small State. Not every provider can use Pfizer. We end up as a warehouse receiving shipments and break them apart. We are doing about 50 customized deliveries daily.

More specifically, awardees reported breaking down the large vaccine orders into smaller quantities at a central warehouse or depot and then distributing these smaller amounts to providers in their jurisdictions. Using this method, awardees ensured that more providers received vaccines that they could use in the required timeframe without having to procure additional equipment for ultra-cold storage or waste vaccines. See Exhibit 2 below for the cold chain management steps for COVID-19 vaccination programs and the additional step that some awardees had to take to ensure vaccine access for providers who could not store or administer the large minimum order sizes during the required timeframe.

Exhibit 2: Due to large minimum order sizes, awardees reported adding a step to the standard cold chain management process to improve COVID-19 vaccine access.



Source: OIG adapted this graphic from CDC's Vaccine Storage and Handling Toolkit. Accessed at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf on August 6, 2021.

While breaking down large minimum orders sizes mitigated some equity challenges, awardees also reported concerns with this approach. Awardees reported that adding another step to the cold chain increased risk to vaccine potency and of vaccine spoilage. Awardees also reported challenges with the amount of staffing and transportation resources required for this additional step. As of October 2021, CDC required that awardees conduct site visits for all depots and warehouses.[76] The purpose of these site visits was to ensure that providers understood the COVID-19 vaccination program requirements and were adhering to such requirements, such as ensuring the proper handling of the vaccine.

In May 2021, CDC and CAG reported to OIG that they were working with COVID-19 vaccine manufacturers to make smaller minimum order sizes available. This resulted in a limited inventory of 450 minimum order size shipments of the Pfizer vaccine in Summer 2021 only. CDC reported to OIG in written responses that as of December 2021, the Pfizer vaccine was available in 300 dose minimum order size for adults, and 100 dose minimum order size for pediatrics.

Awardees reported that providers did not have sufficient ancillary supplies to efficiently administer vaccines

Awardees also reported that the contents of their ancillary supply kits were not sufficient for efficient vaccine administration. Awardees reported that providers needed more low dead-volume syringes to maximize the number of doses they could administer from each vial. Awardees also reported that their providers needed additional needles, more generally. Explaining the need for additional needles, including variety of needles, one awardee specifically reported that "the standard needles in the ancillary kits are often too large for elderly [and] frail populations."[77] Not having sufficient ancillary supplies limit a provider's ability to administer vaccines, even if the doses themselves are available.

CDC reported to OIG that ancillary supply kits contained 5-percent overage for training needs, breakage, and errors. CDC further reported that it independently reviewed awardee claims of insufficient ancillary supplies and determined that awardees not having enough needles was primarily due to the large number of nontraditional providers, which resulted in more needle breakage and errors. In follow-up interviews, CAG also reported that the supply chain could not support providing additional supplies beyond the overage already supplied when we collected data in 2021.

In May 2022, CDC reported to OIG that CDC had received feedback that insufficient ancillary supplies had become less pervasive a challenge as more individuals had been vaccinated, thereby decreasing demand. However, CDC did not report identifying and/or implementing a solution for future pandemic vaccination efforts, for which many nontraditional providers may be needed.

Awardees reported that data challenges affected their ability to allocate and distribute vaccines equitably and efficiently

Awardees described challenges in obtaining complete, timely, and accurate data in the following areas: (1) doses allocated to and administered by their own providers; (2) doses allocated to and administered by providers enrolled in Federal programs; and (3) demographic information (e.g., race and ethnicity) across all providers. Not having complete, timely, and accurate vaccine allocation and administration data hindered awardees' ability to vaccinate their communities equitably and efficiently, as it challenged awardees' ability to plan and prioritize vaccine distribution, particularly for vulnerable and underserved populations. One awardee reported,

> Having that data, visibility, and data support really matters when steering the State in the right direction. Having all that visibility on all those moving components is important particularly as we shift away from those that show up at the door [to be vaccinated] to those that are truly the most vulnerable and we have to go to them [to get them vaccinated].

Awardees reported completeness, accuracy and timeliness challenges with allocation and administration data for their enrolled providers

Awardees reported experiencing challenges in obtaining vaccine allocation data from the Federal government and obtaining vaccine administration data from their providers, which hindered awardees' ability to ensure equitable and efficient vaccination among their various communities. These challenges included gaps in both the timeliness and accuracy of allocation data visible to awardees, as well as gaps in the timeliness and completeness of administration data that awardees received from their providers.[78]

Provider allocation data. In March 2021, awardees reported challenges in obtaining accurate vaccine allocation data from the Federal government.[79] Awardees noted that they could see allocation projections 3 weeks in advance, which was a helpful improvement from prior projections they received. However, awardees still reported inaccuracies with the data, as sometimes they received less, and sometimes they received more, vaccine doses than expected. Both scenarios made it difficult to plan how and where to distribute vaccines to providers. Specifically, awardees expressed that the number of doses shipped directly to them changed substantially from week to week and often did not match their previously advised allocations for which they had planned. One awardee reported, "CDC told us that we could have 3 weeks of visibility. With that we get 3 weeks of static allocation numbers. But the day before [the vaccines are scheduled to arrive], they tell us the allocation must change, which still doesn't give us the ability to plan ahead."

AWARDEE REPORTED CHALLENGE: There s dramatic variation in the number of doses we could receive. We are trying to plan for as little as 3,600 doses and as many as 50,000 with not much turnaround time.

AWARDEE REPORTED MITIGATION STRATEGY: [Our jurisdiction] uses GIS maps to generate heat maps displaying vaccine allocation as it relates to the prioritized zip codes identified by [us]. Collectively, these strategic tools allow [us] to assess situational awareness as it relates to vaccine allocation.

Having accurate and timely allocation data is important with regard to prioritizing vulnerable and underserved populations and providers, such as those in rural areas. For example, awardees often used complex algorithms that considered certain equity measures (e.g., CDC's social vulnerability index and demographic information) when determining where to distribute doses.[80] However, when the number of vaccine doses

received was different from the allocation projections, awardees had to move quickly to figure out how and where to distribute the new number of vaccine doses. This was challenging when awardees received fewer vaccine doses than previously projected. It was also challenging when awardees received more vaccine doses than expected. Awardees reported downstream challenges with locating providers who could fill vaccine appointments and administer these doses efficiently. As one awardee reported,

> The problem is that the [allocation] projection changes. We are using a central scheduler to register patients and set up appointments. So, when you [have]…less than a week's notice [that] we get an additional 8,000 vaccines, that is an additional 8,000 more appointments that have to be built out and new providers need to be identified to do that.

Administration data from jurisdictional providers. Awardees reported challenges obtaining timely and complete vaccine administration data from their providers. These data are critical for understanding where gaps in vaccination coverage exist. Awardees attributed this data challenge to having limited resources to sufficiently train providers on how to use their data systems, including how to input data in the various data systems in a timely and accurate way. Specifically, these awardees reported that training providers to use data systems, including IISs, was particularly challenging and burdensome when some providers had minimal to no prior vaccine experience.

AWARDEE REPORTED CHALLENGE: We do not have the bandwidth to provide coaching and technical assistance to 1,200 providers.

AWARDEE REPORTED MITIGATION STRATEGY: We are exploring strategies like a buddy system or shadowing to mitigate incongruent information and experience.

Awardees also attributed their challenges in receiving and reporting vaccine administration data to technological infrastructure limitations at the provider and State levels. These challenges were further exacerbated by the large volumes of COVID-19 vaccine administration data needing to be reported in a short time period. For example, some providers were unable to use specific data exchanges, such as Health Level 7, due to their electronic health record systems being outdated or not compatible.[81] Having these exchanges allows data to automatically flow between provider electronic health records and jurisdictional immunization systems (i.e., IISs).

Without these connections, providers had to upload vaccine administration data manually into jurisdictional immunization systems, which was resource-intensive and caused delays in uploading data.

Awardees reported not having visibility into Federal program provider allocation and administration data

In March 2021, awardees also reported not having data on how many doses Federal program providers were being allocated. Awardees further reported that gaps in allocation data hindered their planning efficiencies because without knowing how many vaccines were going to which providers, awardees reported not having a full picture on their jurisdiction's vaccine campaign. Further, planning inefficiencies could lead to vaccine waste.

AWARDEE REPORTED CHALLENGE: We do not know how much supply is in our State and what is given out. There are providers getting vaccines from us and from Health Resources & Services Administration (HRSA). We get total number of doses administered, but we do not know [what supply the doses came from], which makes data reporting messy.

AWARDEE REPORTED MITIGATION STRATEGY: We have some visibility going, mostly with the pharmacies. We have weekly check ins with Rite Aid, Walmart, Walgreens, CVS.

In May 2021, CDC and CAG reported in a joint interview that they were aware of this challenge but that no improvements had been made to allow awardees visibility into allocation data from Federal program providers. In May 2022, CDC subsequently reported that awardees now have access to this information.

In addition to challenges with allocation data, awardees reported challenges with vaccine administration data. While awardees reported being able to see aggregate vaccine administration data from Federal program providers, awardees reported not having access to individual-level vaccine administration data. One awardee reported,

> Getting access to the Federal doses administered is important. We can't understand what proportion has been covered because we only see what is going into our IIS. The rest of the data is going into the CDC Clearinghouse, but we don't have the ability to query that and to get that data.

Some awardees specifically attributed this challenge to delays in implementing full functionality of the IZ Gateway, which is one technology solution for administration data sharing between awardees and Federal program providers. In 2020, prior to any COVID-19 vaccines being distributed and administered, CDC reported that its goal

was to have all IISs onboarded onto the IZ Gateway by September 30, 2020.[82] However, in March 2021, one awardee reported that even if connected to the IZ Gateway, it still could not query data to meet its needs for obtaining individual-level vaccine administration data from all Federal program providers.

In May 2021, CDC and CAG reported in a joint interview that they were aware of this challenge. As an interim solution, CDC and CAG reported they actively encouraged Federal program providers to report administration data into awardee IISs, which would enhance visibility for awardees into administration data from providers enrolled in Federal programs. In May 2022, CDC further reported that it continues working to address legal and technological infrastructure challenges to allow for data sharing between Federal program providers and awardees. CDC also reported that it is working on policy agreements to onboard more parties to the IZ gateway, as well as enabling interoperability when there may be different data standards by jurisdictions.

Awardees reported challenges obtaining and reporting comprehensive race and ethnicity data for vaccine recipients

Awardees reported challenges obtaining comprehensive demographic data, such as race and ethnicity, on individuals receiving a COVID-19 vaccine.[83] Awardees reported that gaps in this data hindered their efforts to identify and address inequities in vaccine distribution and administration. Awardees attributed challenges in this area to a hesitancy to report personally identifiable information and some States not having standards for collecting demographic information.

AWARDEE REPORTED CHALLENGE: With regards to race, ethnicity, and inequity, it comes down to data. If you can t prove it, it didn t happen. Having consistent data that is collected across thousands of providers in one state can be a challenge.

AWARDEE REPORTED MITIGATION STRATEGY: For providers that don't collect race or ethnicity, we are matching with other databases to see if we can backfill any of that [vaccine data]

Despite initial challenges in collecting demographic data, improvements have been made in the number of States including race and ethnicity data within their reported vaccination rates since we collected data in March 2021. According to the Kaiser Family Foundation, in January 2021, only 17 States reported race and ethnicity data for vaccination rates, while as of July 2022, this had increased to 41 States and Washington, D.C.[84]

In addition to challenges collecting race and ethnicity data, one awardee reported technological limitations in the data reporting systems did not allow awardees to make changes to demographic data if they collected it after uploading the information into CDC's systems. CDC reported to OIG that as of July 2021, awardees have the ability to manually edit, and re-upload previously submitted records. CDC reported that awardees also have the ability to use an automated upload solution rather than manually editing and re-uploading their vaccine administration data. However, CDC reported that not all awardees had elected to implement this solution yet due to time constraints at the jurisdictional level requiring prioritization of resources.

Awardees reported challenges with public health messaging to combat vaccine hesitancy

In March 2021, awardees reported challenges with public health messaging to combat vaccine hesitancy. Awardees reported wanting more Federal government support in two areas: (1) a unified public health message and (2) adaptable public health messaging materials.[85] A unified public health message is critical to building trust with the public and ensuring that individuals receive the same information regarding the vaccine regardless of where they live or who delivers the message. Adaptable public health messaging materials ensure consistency in messaging, while also allowing awardees to tailor the message to their jurisdiction's populations. Combating vaccine hesitancy and building vaccine confidence with unified and adaptable public health messaging may make communities more willing to receive the COVID-19 vaccine.

AWARDEE REPORTED CHALLENGE: The importance of a national, public media campaign cannot be overlooked. States may have funding for smaller campaigns but something comprehensive and overarching that will reach most Americans will be important to sustain interest and demand for the vaccine.

AWARDEE REPORTED MITIGATION STRATEGY: [We are] using community health workers to educate and promote vaccine knowledge and to develop and air targeted media messaging to those same racial/ethnic groups and communities after assessing their attitudes and beliefs about the vaccine.

Awardees reported various reasons for wanting more Federal government support for public health messaging. These reasons included having limited funding to develop public messaging campaigns themselves; wanting to reach a greater audience in vaccine messaging; wanting to minimize duplication of efforts when developing materials; and wanting to decrease variation across jurisdictions in the framing and

content of messages. For example, one awardee discussed the need for the public to hear the same message from all partners, including the Federal government. One awardee reported,

> I'd like to see some generic public service announcements being created so that States can use the same messaging. I know the messages will need to be tailored to different areas and populations, but I think the Vaccines for Children program has sent public service announcements that we use and publicize so that messaging is consistent across the nation.

CDC reported several ways in which it was taking steps to mitigate awardee-reported public health messaging challenges. For example, CDC reported that it developed several "plug-and-play" public health messaging resources that health departments can use for their jurisdictional-specific public health messaging campaigns, including a communication toolkit that is available in 33 languages.[86] CDC also reported developing social media posts and other advertisements to promote the COVID-19 vaccine program. In addition, CDC reported building a website for health care providers to compile various materials for easy access and dissemination. CDC also creates and disseminates reports on vaccine confidence to provide awardees and other partners with information on the public's questions regarding the vaccine as well as on misinformation that may be prevalent in communities. These reports aim to help awardees and partners develop materials to combat vaccine hesitancy. Finally, CDC reported providing public messaging technical assistance to awardees on a daily basis through regional coordinators and project officers.

Finally, CDC also reported that the COVID-19 vaccine public health messaging strategy did not follow the standard approach used for routine vaccination, outbreaks, and other emergencies. Rather, HHS's Assistant Secretary for Public Affairs (ASPA), not CDC, is the lead for COVID-19 vaccine messaging. While CDC reported not having its own national public health messaging campaign for the COVID-19 vaccination program, CDC noted that it was engaging with and supporting ASPA's "We Can Do This" national, public health messaging campaign as a technical advisor.[87] The "We Can Do This" campaign launched in April 2021, which was after we collected data from awardees.

Awardees reported lacking resources to sufficiently oversee COVID-19 vaccination program providers

In March 2021, awardees reported having limited resources, such as personnel and equipment, to conduct provider site visits. Between December 1, 2020, and December 31, 2021, awardees and CDC conducted 5,495 site visits (5,399 and 96 respectively) at both mass and non-mass vaccination sites.[88, 89] However, less than 3 percent (i.e., 149 of 5,495) of these site visits occurred between December 1, 2020, and May 31, 2021. This is concerning because by the end of May, nearly 50 percent of the U.S. population had received at least one dose of a COVID-19 vaccine.[90, 91] Of further concern is that during these site visits, both awardees and CDC found

deficiencies that pose vulnerabilities to patient health. These deficiencies included lacking a temperature monitoring device to monitor vaccine storage units and noncompliance with training requirements for vaccination staff who manage or administer the COVID-19 vaccine.[92]

AWARDEE REPORTED CHALLENGE: With the inclusion of the site visit requirement for COVID 19 vaccine providers and the increasing number of enrolled COVID 19 vaccine providers, more site visits are going to need to be completed....it poses a staffing challenge to meet all of the site visit requirements.

AWARDEE REPORTED MITIGATION STRATEGY: "We are trying to partner with the State Pharmacy Board that already does compliance visits.

Site visits are an important tool for ensuring that patients are not at risk of receiving vaccines that are spoiled or compromised due to improper storage, handling, and administration (e.g., not being held within the required temperature ranges). During site visits, CDC found that half (48 of 96) of providers did not adhere to storage and handling requirements. Vaccines that are not maintained within their required temperature storage ranges may be less potent and effective and may not provide maximum protection to vaccine recipients. Moreover, patients may lose confidence in vaccines and their providers if the vaccines are less effective than reported.

CDC requires awardees to conduct site visits for a fixed number of providers. CDC reported establishing a fixed number because awardees did not have the resources to conduct site visits for all enrolled providers. CDC also reported using a fixed number because the number of providers administering COVID-19 vaccines changed over time, as some vaccination sites were only temporary. However, a fixed numbered approach poses vulnerabilities in that at least hundreds of COVID-19 vaccine providers were not subject to site visits at a time when much of the U.S. population was receiving vaccines. For example, in March 2021, Delaware reported having over 400 enrolled COVID-19 vaccine providers. According to CDC's requirement based on the jurisdiction's population, Delaware was required to visit only 25 providers in 2021, which means that over 375 providers were not required to have a site visit.

Moreover, site visits also serve an educational purpose for some providers (i.e., these providers may not know if they are or are not adhering to vaccination program requirements), and when site visits do not happen, that educational opportunity is lost. While awardees recognized the importance of site visits and meeting CDC's minimum requirements, awardees also reported challenges acquiring the staffing

resources necessary to conduct provider site visits to all enrolled providers in a timely manner.

In addition to challenges conducting provider site visits, awardees reported not being able to obtain a sufficient number of digital data loggers. Proper monitoring of provider adherence to the temperature requirements helps ensure that vaccines are viable for administration to the public. These devices also allow for remote monitoring of the storage temperatures of vaccines by awardees, which is another valuable safeguard.

This challenge generally applied to nontraditional vaccine providers, as they may not have needed these devices prior to this vaccine campaign. As a result of the 5,399 site visits awardees conducted between December 1, 2020, and December 31, 2021, awardees issued 441 citations for a lack of digital data loggers for vaccine transport and/or storage unit monitoring.[93] This challenge was magnified by worldwide supply shortages of digital data loggers, which resulted in the use of less accurate temperature monitoring devices. During the supply shortage, CDC allowed awardees to use minimum/maximum or traditional digital thermometers as an alternative until digital data logger supply issues were resolved.

CONCLUSION AND RECOMMENDATIONS

CDC has long funded State, Territory, and large metropolitan area immunization programs to support vaccine programs that immunize individuals in their jurisdictions against vaccine-preventable diseases (e.g., measles and influenza). The COVID-19 vaccination program is an extension of these efforts with a goal to immunize the U.S. population amid an ongoing pandemic. The COVID-19 vaccination program is one of the largest mass vaccination efforts in recent U.S. history. In late 2020, awardees, in coordination with Federal partners, began preparing to stand up COVID-19 vaccination programs, with the first vaccines being administered in December 2020. By mid-March 2021, COVID-19 vaccine supply and demand continued to increase, and challenges implementing these vaccination programs continued to change and evolve.

We found that during the early stages of the COVID-19 vaccination program (i.e., March 2021), awardees were experiencing challenges administering COVID-19 vaccines efficiently and equitably due to multiple factors. Specifically, awardees reported challenges with vaccine logistics, such as large minimum order sizes for vaccines, requirements for ultra-cold storage, and insufficient ancillary supplies. Additionally, awardees reported challenges in obtaining complete, timely, and accurate vaccine allocation and administration data from both their providers and Federal program providers, which impacted their ability to efficiently determine community needs. Further, awardees reported challenges in obtaining comprehensive race and ethnicity information on doses administered, which impacted their ability to monitor equitable distribution. Finally, awardees reported wanting more Federal government support for public health messaging and provider oversight.

To improve COVID-19 vaccination programs while they were ongoing, we issued preliminary, non-public analysis of reported challenges to CDC in late March and early April 2021. This preliminary analysis allowed CDC to address awardee challenges in a time-sensitive manner. This report builds upon that preliminary analysis, by using additional data and qualitative analysis, and includes formal recommendations to improve COVID-19 and future vaccination programs.

Understanding awardee-reported challenges with the COVID-19 vaccination program, as well as the mitigation strategies awardees took, can assist CDC in ongoing program improvements. It can also assist CDC with improving routine immunization programs, as well as with preparing for future pandemic vaccination programs.

To continue to drive vaccination program improvement, we recommend that CDC:

Update its plans for mass vaccination programs with strategies that address awardee-reported logistical challenges

CDC should update its plans for mass vaccination programs with strategies that address awardee-reported challenges with vaccine minimum order sizes and ancillary supply kits. We offer ways in which CDC can continue to drive improvement for the ongoing COVID-19 vaccination campaign, and drive improvement for future pandemic vaccination efforts.

Vaccine minimum order sizes and vaccine storage requirements. To address ongoing COVID-19 vaccine challenges, while noting the reductions made to the Pfizer vaccine's minimum order size, CDC should first determine whether these reductions are sufficient to address awardee-reported challenges. If awardees still report challenges with the Pfizer vaccine's minimum order size, CDC should coordinate with the Biomedical Advanced Research and Development Authority (BARDA) to determine the feasibility of solutions that will address awardee challenges. As of this report's release, COVID-19 vaccines are not packaged in a similar way to routine vaccinations (i.e., customizable order sizes and/or pre-filled syringes). Ensuring that providers can obtain the number of vaccine doses that they need for their jurisdiction's population in a timeframe that does not require the procurement of additional storage equipment will help address challenges with vaccine access and waste.

To address future pandemic vaccination efforts, CDC should update mass vaccination planning to include guidance that advises BARDA on vaccine manufacturer contract parameters for packaging quantities of vaccines.[94] This guidance should advise on how vaccine storage requirements intersect with vaccine minimum order sizes, as well as changes needed in these parameters as the pandemic evolves. For example, while large minimum order sizes may be efficient early in a mass vaccination effort, smaller order sizes may make vaccine distribution more efficient and equitable later in a mass vaccination effort.

As a part of updating mass vaccination planning, CDC should also consider including guidance on the establishment of centralized, Federal depots to break down large order sizes into smaller ones to reduce the burden on awardee resources. CDC reported that it would need to consider the following risks when considering this option: (1) compromised vaccine quality/effectiveness, as the breakdown activity may be difficult to accomplish manually at ultracold temperatures; (2) increased risk for the U.S. Government as removing vaccine from the manufacturer's quality system shifts responsibility for this complex process to the U.S. Government; and (3) a significant decrease in distribution throughput. It is worth noting that these risks also apply to awardees setting up their own depots for breaking down vaccines. Therefore, CDC should consider providing guidance to awardees on how they can conduct this risk benefit analysis for breaking down vaccines themselves.

Ancillary supply kits. While challenges with COVID-19 vaccine ancillary supply kit contents have subsided, CDC should use lessons learned from this effort to update future planning that includes:

(1) determining the projected ancillary supply kit needs during future mass vaccination efforts and

(2) determining ways to ensure sufficient overages of these supplies that accounts for potential global supply chain shortages.

For example, CDC could work with ASPR to determine whether, and in what quantity, items that were challenging for awardees to obtain (e.g., needles in a variety of sizes and low dead-volume needles) should be included in the Strategic National Stockpile. CDC could also consider supplementing awardee provider training with its own training to help reduce provider error and thus the need for additional supplies.

Strengthen reporting of vaccine allocation data and administration data

CDC should strengthen reporting of vaccine allocation data and administration data in two ways:

Improve vaccine allocation data accuracy. CDC should work with relevant partners (e.g., vaccine manufacturers) to determine why awardees are receiving inaccurate projections of their expected vaccine shipments and take steps to address this issue. We recognize that these projections are of less importance now that the COVID-19 vaccination effort is well underway and ample vaccine supply exists. However, there is value in understanding that the need to ensure that this challenge does not occur during any future mass vaccination campaigns when vaccine supply may be initially limited.

Develop strategies to improve vaccine administration data. CDC should define and communicate data quality standards for providers and require that awardees develop an approach to provide routine data quality feedback to all providers for IIS reporting. This will allow awardees to more consistently check the quality of the data reported to their IISs. This can, in turn improve the completeness and accuracy of the vaccine data.

Further, OIG has a companion work in this area regarding improvements needed for vaccine administration data submitted by providers enrolled in Federal programs. In that report, OIG recommends that CDC (1) work with State and local immunization programs and pharmacy partners, to improve data gaps and timeliness challenges and (2) provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address campaign needs. This report's findings also support those OIG recommendations.

In addition to supporting those recommendations, this report makes one additional recommendation regarding strategies to improve vaccine administration data more broadly. CDC should also continue to work with awardees on the collection of complete and accurate race and ethnicity data. This will allow jurisdictions to have better visibility on the extent to which disparities exist in vaccination rates and subsequently allocate resources towards improving vaccination rates in those populations.

In implementing these recommendations, CDC could consider requiring that awardees ensure that their vaccine administration data systems and processes can be scalable during an emergency. Doing so will decrease the time to operationalize systems and processes during an emergency, as involved parties will already have an understanding of the underlying systems and processes in place and how to scale them as needed.

To the extent that any new data systems are created, or existing data systems are modified for vaccine allocation and administration data during ongoing and future vaccine campaigns, CDC should ensure that these recommendations are still addressed, as appropriate.

Clarify roles and responsibilities within HHS for vaccine public health messaging during a pandemic

CDC should clarify agency roles and responsibilities within HHS (including, at a minimum, ASPA, ASPR, and FDA) for vaccine public health messaging during a pandemic. In doing so, CDC should use lessons learned from the COVID-19 response, including the awardee-reported challenges outlined in this report. Doing so will help take steps towards a more unified, national message, and will limit the delays in making vaccine public health messaging materials available nationwide and to the awardees, in particular.

Work with awardees to enhance current and future capabilities for provider training and oversight

Training and oversight of providers administering vaccines are critical aspects of mass vaccination programs to ensure compliance with program requirements. However, conducting provider training and site visits are resource-intensive activities, especially when hundreds of new, and often inexperienced, providers are enrolled to help facilitate a mass vaccination effort. As a result, CDC should identify ways to support awardees in training and overseeing providers both during the current COVID-19 vaccination campaign, and in future mass vaccination efforts. These could include:

Establishing and maintaining a pandemic-ready vaccine provider roster. CDC should work with awardees to establish a plan for expedited provider training during

a pandemic when more inexperienced, nontraditional providers may need to be leveraged. This could include annual, abbreviated training so that a "pandemic-ready" roster of nontraditional providers is available. Such a plan would ensure that a group of nontraditional providers are sufficiently trained on items such as, awardee data systems and vaccine administration techniques, prior to the start of a mass vaccination campaign, thereby reducing the burden on awardee resources during a critical time. It also could mitigate awardee-enrolled provider vaccine administration data challenges.

Implementing a risk-based approach for conducting provider site visits. CDC could consider requiring that awardees use a risk-based approach to determine the priority and frequency of provider site visits. For example, awardees may consider whether the provider is experienced or inexperienced; prior site visits results; how many vaccines the provider is administering; and what type of technology the provider has (e.g., digital data loggers) to remotely monitor adherence to program requirements.

Providing supplemental Federal resources for conducting provider oversight. In addition to the resources that CDC provided early in the COVID-19 vaccination effort, CDC could continue to provide Federal personnel to assist with conducting provider site visits. In addition, CDC could work with ASPR to ensure that temperature monitoring devices, such as data digital loggers, are available to awardees and providers through the Strategic National Stockpile or ancillary supply kits.

AGENCY COMMENTS AND OIG RESPONSE

CDC concurred with all four of OIG's recommendations.

CDC concurred with our first recommendation, to update CDC plans for mass vaccination programs with strategies that address awardee-reported logistical challenges. While CDC agreed with some of our suggestions for implementation, it disagreed with others. CDC agreed with our suggestion that future vaccine contract requirements should provide for multiple vaccine presentations, including a large presentation for mass vaccination clinics and a smaller presentation(s) appropriate for other health care settings. CDC also agreed with our suggested methods to address vaccine ancillary supply kit challenges. However, CDC disagreed with OIG's suggestion that, as a part of updating its planning, CDC consider including guidance on the establishment of centralized, Federal depots to break down large order sizes into smaller ones. CDC stated that there are numerous risks involved with the Federal government setting up its own depots, which OIG acknowledges in its suggestion. Further, CDC stated that implementing OIG suggestion's that future contract requirements allow for multiple presentation sizes of vaccines reduces the need for centralized depots to break down larger presentations, as well as reduces the risks to the Federal government. OIG agrees that updating CDC planning to include guidance on how future vaccine contracts should allow for multiple presentation sizes of vaccine will address the root cause of this issue. However, there are no guarantees that a vaccine contract will unfold exactly as expected during an emergency response. Therefore, OIG believes that it would be beneficial for CDC to prepare for multiple possibilities, including the possibility that centralized Federal depots will be needed to break down vaccines during future pandemics. Further, this guidance could focus on assisting awardees who may need to set up their own centralized depots, as they did during the COVID-19 response.

CDC concurred with our second recommendation, to strengthen reporting of vaccine allocation data and administration data. CDC stated it will continue to work with relevant partners to improve projections of expected vaccine shipments and continue to improve data quality standards for reporting.

CDC concurred with our third recommendation, to clarify roles and responsibilities within HHS for vaccine public health messaging during a pandemic. CDC suggested further agency-specific and HHS-wide communication hot washes, to include representatives from State and local public health stakeholders.

CDC concurred with our fourth recommendation, to work with awardees to enhance current and future capabilities for provider training and oversight. CDC had concerns with the suggestions that OIG offered to support vaccination provider training and oversight. OIG's goal with this recommendation is to ensure providers have the training and oversight needed to ensure vaccines are stored, handled, and administered properly. Beyond the suggestions OIG offered, CDC should identify

practical and effective ways to support and address awardee-reported challenges with provider training and oversight.

For the full text of CDC's comments, see Appendix D. We also addressed all of CDC's technical comments.

APPENDIX

Appendix A: Storage and Handling Requirements for COVID-19 Vaccines in March 2021

Each COVID-19 vaccine authorized for use in the United States has specific storage and handling requirements to ensure viability and potency of the vaccine. These requirements include ensuring cold chain conditions, using digital data loggers to check temperatures, monitoring storage unit temperatures, monitoring vaccine expiration dates, and preserving records for vaccines.[95, 96] See Exhibit 3 for the COVID-19 vaccine storage requirements for the time during which we collected data from awardees (i.e., between March 12 and 24, 2021). The COVID-19 vaccine storage requirements have been updated since March 2021, when we collected data.

Exhibit 3: COVID-19 vaccines had varying storage and handling requirements during our data collection.

Vaccine	Storage and Handling Requirements
Pfizer-BioNTech (requirements in effect March 3, 2021, through May 21, 2021)[97]	This vaccine may be stored in an ultra-cold freezer between -112°F and -76°F until ready to thaw. Before mixing with adjuvant, this vaccine can be stored in freezer (i.e., between -13°F and 5°F) for up to 2 weeks or in a refrigerator (i.e., between 36°F and 46°F) for up to 5 days. Once the vaccine is mixed with the adjuvant, the vaccine may be stored at room temperature (i.e., between 35 °F and 77 °F) and subsequently used within 6 hours. Mixed vaccines may not be returned to freezer storage.
Moderna (requirements in effect December 20, 2020, through April 23, 2021)[98]	This vaccine does not require use of an ultra-cold freezer. This vaccine may be stored in a freezer between -13°F and 5°F. This vaccine must be thawed before using. Once thawed, this vaccine can be stored in the refrigerator between 36°F and 46°F for up to 30 days. Unpunctured vials may be stored at room temperature (i.e., between 46.4°F and 77°F) for up to 12 hours.
Johnson & Johnson (requirements in effect March 5, 2021, through April 12, 2021)[99]	This vaccine is not frozen. This vaccine is stored in a refrigerator between 35.6°F and 46.4°F until expiration date. If vials are punctured, the vaccine they contain must be used within 6 hours.

Appendix B: State and Federal Data Systems

COVID-19 vaccine administration data flows from the provider to the national-level through several different State and Federal data systems, including the following:

- Immunization Information System (IIS): a confidential, population-based database that records all vaccine doses administered by participating health care providers to persons residing within a specific geographical location.[100] Awardees manage the IIS and enroll their providers into it. Providers must report data elements to an IIS within 24 hours of a vaccine being administered.[101]

- IZ Gateway: a gateway that enables exchange between IISs, other provider systems and Immunization (IZ) Data Lake.[102] Federal program providers or other non-IIS-connected entities may submit administration data directly to the IZ Gateway. CDC is currently in the process of setting up this data exchange, which is not yet operational.

- IZ Data Clearinghouse: a cloud-hosted data repository that receives, deduplicates, and redacts COVID-19 vaccine administration data for the IZ Data Lake. This data is patient record-level and identifiable. Federal program providers or other non-IIS-connected entities may submit administration data directly to the clearinghouse if they do not report to the State IIS. Until the IZ Gateway is stood up, awardees upload IIS file extracts to the clearinghouse manually.

- IZ Data Lake: a cloud-hosted data repository to receive, store, manage, and analyze a limited dataset for COVID-19 vaccine data, including administration, ordering, inventory, and allocation data. This data is record-level and redacted. No personal health information is stored in this dataset.

- Tiberius: an HHS platform that visualizes administration data, among other data points, from the IZ Data Lake.

Appendix C: More Details on Awardee-Reported Challenges and Mitigation Strategies

Below is data regarding how many awardees reported challenges in one of the six broad areas that we asked them about, as well as mitigation strategies that awardees reported using to address challenges in those six areas. These six areas include: (1) provider enrollment; (2) establishing and distributing public messaging; (3) addressing disparities and inequities; (4) vaccine allocation, ordering, distribution, and inventory management; (5) administering the vaccine; and (6) Federal vaccine data systems.

These challenges and mitigation strategies are self-reported. Further, OIG did not independently assess the accuracy or effectiveness of these strategies in addressing awardee challenges.

Exhibit 4: Most awardees reported experiencing challenges in all six areas.

Challenge Area	Awardee Count (N=56)
Addressing disparities and inequities	53
Vaccine allocation, ordering, distribution, and inventory management	52
Establishing and distributing public messaging	50
Federal vaccine data systems	49
Administering the vaccine	48
Provider enrollment	43

Source. OIG analysis of awardee interview and survey data, 2022.

Exhibit 5: Awardees reported using a variety of mitigation strategies to address challenges in all six areas.

Challenge Area	Awardee-Reported Example Mitigation Strategies
Provider enrollment	• Holding "office hours" for providers to be a ready source of assistance, information, and troubleshooting for enrolled providers • Partnering with pharmacy boards and the National Guard to onboard providers
Establishing and distributing public messaging	• Conducting a massive door-to-door campaign to promote the benefits and accessibility of the vaccine

Challenge Area	Awardee-Reported Example Mitigation Strategies
	• Administering a survey to assess what are the issues related to vaccine hesitancy and how the jurisdiction can educate the public on those issues • Partnering with community-based organizations and faith-based organizations to conduct vaccine outreach
Addressing disparities and inequities	• Sending out letters to individuals in priority groups that have not yet been identified as vaccinated in State vaccine registry systems • Creating teams to deploy to underserved communities to ensure vaccine access • Targeting the Johnson & Johnson vaccine to at-risk communities who might be difficult to locate for a second dose
Vaccine allocation, ordering, distribution, and inventory management	• Updating training for new providers on inventory management • Centralizing vaccine scheduling systems to increase visibility in vaccine supply, uptake, and allocation
Administering the vaccine	• Purchasing ultra-cold freezers for regional hubs before distribution • Formation of "strike teams" that are ready to administer vaccines at mass vaccination sites • Holding weekly stakeholder calls to discuss issues, such as ancillary kits and maximizing use of syringes
Federal vaccine data systems	• Updating State IISs to include validation steps to improve completeness and accuracy of reported vaccine data • Using the National Guard for data entry • Creating a Memorandum of Understanding in order to share data with other jurisdictions

Source: OIG analysis of awardee interview and survey data, 2022.

Appendix D: Agency Comments

Following this page are the official comments from CDC.

Centers for Disease Control and Prevention (CDC)'s planned actions in response to the Office of the Inspector General's (OIG) draft report, "Early Challenges Highlight Areas of Improvement in COVID-19 Vaccination Programs, OEI-04-21-00190" (the Report)

CDC appreciates OIG's ongoing work on the Report and agrees with the need to continue to support awardees in provider training and oversight. CDC will build upon the framework established for provider-ready training resources. Having tools and references developed for the current response allows for adjustments for the future. CDC will continue to encourage awardees to maintain a roster of trained vaccination providers for rapid assistance to the extent feasible and disseminate available funding to awardees to enhance their ability to properly hire and train staff, purchase supplies, and train providers. CDC is currently reviewing and updating its immunization program field staff structure and recruitment processes to ensure awardees and staff are more adequately supported in the future. As recommended, CDC can work with Administration for Strategic Preparedness and Response (ASPR) to ensure temperature-monitoring devices are available through the Strategic National Stockpile or ancillary supply kits.

OIG Recommendation 1:

CDC should update its plans for mass vaccination programs with strategies that address awardee-reported challenges with vaccine minimum order sizes and ancillary supply kits. We offer ways in which CDC can continue to drive improvement for the ongoing COVID-19 vaccination campaign, as well as drive improvement for future pandemic vaccination efforts:

- Vaccine minimum order sizes and vaccine storage requirements
- Ancillary supply kits

CDC Response:

OIG has two recommendations regarding vaccine minimum order size and storage requirements:

- To address future pandemic vaccination efforts, CDC should update mass vaccination planning to include guidance that advises Biomedical Advanced Research and Development Authority (BARDA) on vaccine manufacturer contract parameters for packaging quantities of vaccines.[93]
- As a part of updating mass vaccination planning, CDC should consider including guidance on the establishment of centralized, federal depots to breakdown large order sizes into smaller ones to reduce the burden on awardee resources.

CDC concurs with the first recommendation about updating guidance/collaborating with BARDA around COVID-19 vaccine contract requirements. Specifically, those requirements should provide for multiple vaccine presentations, including a large presentation that is appropriate for mass vaccination clinics and a smaller presentation(s) appropriate for provider sites, health departments, pharmacies, etc., as vaccine administration options that are complementary to mass vaccination clinics. Having more than one sized presentation available reduces the burden on awardees by decreasing the redistribution required. Finalizing the details of these requirements must consider the inherent trade-offs between larger presentations and manufacturing throughput (i.e., larger presentations, such as Pfizer's 1170 dose presentation allow vaccine to be produced more quickly, which is especially important in the early

weeks and months of a vaccine response.) In addition, the COVID-19 vaccine contract requirements about vaccine presentations should include a time component: (1) initially, the majority of vaccine shall be provided as a large presentation and a small proportion of vaccine shall be provided in the smaller presentation(s), and (2) at a specified point in time, the proportion of vaccine to be provided as a large presentation decreases and the proportion of vaccine to be provided as a smaller presentation increases.

CDC does not concur with the recommendation to consider the establishment of centralized, federal depots to breakdown large order sizes into smaller ones. There are numerous risks involved with the second recommendation (provided by CDC in prior feedback to OIG). Further, implementation of the first OIG recommendation (updating COVID-19 vaccine contract requirements to include multiple presentation sizes of vaccine) reduces the need to break down larger presentations and allows the government to avoid the risks associated with the second recommendation related to minimum order size. Implementing the first OIG recommendation in this section allows government to require the appropriate combination of vaccine large and smaller presentations rather than purchasing vaccine in only a single, large presentation and then implementing (and paying for) a separate mechanism to convert a large presentation into smaller ones.

CDC concurs with the recommendation to use lessons learned from the COVID-19 vaccine ancillary supply kit challenges. CDC has and will continue to use the lessons learned from this response to update planning efforts.

OIG Recommendation 2:

CDC should strengthen reporting of vaccine allocation data and administration data in two ways:

- Improve vaccine allocation data accuracy
- Develop strategies to improve vaccine administration data

CDC Response:
CDC concurs with the recommendation to strengthen reporting of vaccine allocation data and administration data in two ways: improve vaccine allocation data accuracy and develop strategies to improve vaccine administration data. CDC has and will continue to work with relevant partners to improve projections of expected vaccine shipments, and CDC has and will continue to improve data quality standards for reporting.

OIG Recommendation 3:

CDC should clarify agency roles and responsibilities within the Department of Health and Human Services (HHS) (which includes, at a minimum; Office of the Assistant Secretary for Public Affairs [ASPA], ASPR, and the Food and Drug Administration [FDA]) for vaccine public health messaging during a pandemic. In doing so, CDC should use lessons learned from the COVID-19 response, including the awardee-reported challenges outlined in this report.

CDC Response:

CDC concurs with the recommendation to clarify HHS-wide agency roles and responsibilities and for setting public communication and outreach priorities and implementing activities.

- CDC recommends further agency-specific (CDC, ASPA, ASPR, FDA, etc.) and HHS-wide communication hot washes that include representatives from organizations that represent state and local public health stakeholders such as the National Public Health Information Coalition, the Association of Immunization Managers, the Association of State and Territorial Health Officials, and the National Association of City and County Health Officials.
- While reported as a mitigation strategy, CDC recommended and actively supported the use of community health workers, vaccine ambassadors, and other trusted community leaders and messengers as the foundation of any successful vaccine confidence, communication, or media strategy. CDC recommends and is supporting strengthening local, state, and federal capacity to evaluate and strengthen and community health worker, vaccine ambassador, and other trusted community leader and messenger activities to reinforce vaccine confidence and education, combat misinformation, support public health community pandemic recovery, and prepare for future emergencies.

OIG Recommendation 4:

CDC should identify ways to support awardees in training and overseeing providers both during the current COVID-19 vaccination campaign, as well future mass vaccination efforts. These could include establishing and maintaining a pandemic-ready vaccine provider roster, implementing a risk-based approach for conducting provider site visits, and providing supplemental federal resources for conducting provider oversight.

CDC Response:

CDC concurs with the recommendation to identify ways to support awardees in vaccination provider training and oversight; however, the specific examples listed have been implemented or may not be a practical solution.

1. Establishing and maintaining a pandemic-ready vaccine provider roster is an activity that awardees have been asked to do in preparedness planning for many years. The frequent change in ownership or organizational structure to healthcare provider organizations as well as the rapid turnover of healthcare provider staff makes this extremely difficult, if not impossible, to achieve on a large scale. Within only months, a provider's vaccine coordinator (position generally responsible for vaccine ordering, storage, and handling, etc.) and back-up staff can completely change, resulting in the need for full training for the organization again. Additionally, much of the training is centered around the specific vaccine storage, handling, and administration requirements by product and can only occur when products to be used have been authorized and that information along with each product's specifications can be made publicly available. CDC developed and provided numerous training materials and resources posted to the CDC website that providers could use for self- and staff-training purposes.

   The limitations with training influence the ability to have oversight (i.e., compliance site visit materials) ready early on. During site visits, providers are assessed to ensure they are adhering to the storage, handling, and administration requirements for each specific product. With COVID-19 vaccine, getting vaccine out and administered as quickly as possible was the primary focus

and one that required "all hands on deck." Once vaccine was distributed, then some resources were freed so that efforts could be devoted to beginning oversight activities.

2. A risk-based approach to site visits was implemented in that awardees were instructed to prioritize providers who were administering the greatest number of vaccine doses. CDC's intent with this approach was to assess providers whose vaccination practices were impacting the greatest portion of the population. CDC agrees that the proportion of required number of visits to enrolled providers was less than ideal, but the staffing challenges described in this report at all levels (federal, state, local) posed a major barrier to increasing the number or frequency. This also contributed to the reasoning behind prioritizing those providers impacting the greatest number of vaccine recipients. CDC could have instructed that awardees perform more visits than defined (and some did), but many would have not been able to do so due to lack of available staff. Even awardee staff who routinely conducted Vaccines For Children visits were pulled to perform other response-related roles that were just as critical.

   CDC agrees experienced providers would theoretically be able to perform more readily, but vaccine administration, storage, and handling requirements for some COVID-19 vaccine products were vastly different than other vaccines providers routinely administered.

   CDC allows allow virtual visits and, in fact, suspended all in-person visits for a period. Once local travel restrictions were lifted and staff were considered to not be at risk due to local virus transmission, in-person visits were prioritized so that all aspects of the provider operations could be better observed. Screen sharing provided limited viewing ability of all that was happening within a provider location. (NOTE: There were Health Insurance Portability and Accountability Act concerns around photos/streaming of vaccine administration in progress.)

3. Supplemental federal resources were made available for conducting provider oversight. Approximately $3 billion in supplemental funding was made available to jurisdictions, and required activities included implementation of site visits, purchase of supplies (e.g., digital data loggers to monitor vaccine storage temperatures, appropriate storage equipment), provider training, and many others. CDC allowed jurisdictions to fund contractors or local health department staff to perform site visits, and many jurisdictions took advantage of such an arrangement. Through the CDC Foundation, CDC funded additional field staff to be placed in jurisdictions; jurisdictions were allowed to request staff to perform site visits through this mechanism. Additionally, ~70 CDC field staff were already embedded in state/local immunization programs that could be used to perform site visits. For added support, CDC held trainings that were recorded and posted online and regular office hours for jurisdiction site visit reviewers.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Lauren Buss served as the team leader for this study, and Rebekah Schwartz served as the lead analyst. Others in the Office of Evaluation and Inspections who conducted the study include Margaret Dore and Alicia Stevens. Office of Evaluation and Inspections headquarters staff who provided support include Jennifer Gist, Althea Hosein, and Christine Moritz.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Victoria Coxon, Kaliane Davidson, Adam Freeman, Samantha Handel-Meyer, Jonathan Jones, Kayla Phelps, Kelsey Ridenour, Lucio Verani, and Brianna Weldon.

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ENDNOTES

[1] Routine immunizations refer to vaccines that are distributed and administered annually to certain individuals (normally children) to prevent against disease such as Hepatitis B, Measles, and Chickenpox, among others.

[2] These awardees include the 50 States, the District of Columbia, five large metropolitan areas (i.e., Chicago, Houston, New York City, Philadelphia, San Antonio), and eight Territories (i.e., American Samoa, Guam, Marshall Islands, Micronesia, Northern Marianas, Palau, Puerto Rico, and the Virgin Islands).

[3] This average amount does not include supplemental funding provided for COVID-19 activities. CDC has provided an additional $7.2 billion in COVID-19 supplemental response funding through its *Immunization and Vaccines for Children Cooperative Agreement* between Fiscal Years 2020 and 2021.

[4] For example, see: HHS, *Pandemic Influenza Plan*, November 2005. Accessed at https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf on January 26, 2022.

[5] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 5. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022.

[6] COVID-19 vaccines enter communities through Federal programs that include partnerships with retail pharmacies, Department of Defense (DoD), Indian Health Services (IHS), Health Resources and Services Administration (HRSA), Bureau of Prisons (BoP), and the Department of Veteran Affairs. These Federal programs target specific vulnerable, higher-risk populations, such as long-term care residents, people experiencing homelessness, incarcerated populations, and communities of color. CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 25-26. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on August 16, 2022.

[7] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 5. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022. CDC, *Interim Jurisdiction COVID-19 Vaccination Playbook Draft Executive Summaries*, last updated on August 11, 2022. Accessed at https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html#playbook-draft-summaries on August 26, 2022.

[8] Gross, J., *Five Past Vaccine Drives and How They Worked*, New York Times, January 25, 2021. Accessed at https://www.nytimes.com/2021/01/25/science/mass-vaccine-drives.html on February 11, 2022.

[9] We identified these challenges through discussions with relevant stakeholders (e.g., the Association of State and Territorial Health Officials and the National Association of County and City Health Officials) and a review of CDC guidance documents, White House strategy documents, and media articles on initial vaccine efforts.

[10] Vaccine allocations are covered in Section 5 and 7; vaccine packaging and distribution are covered in Section 7; vaccine storage, handling and administration are covered in Section 7 and Section 8; and critical populations are covered in Section 4. CDC, *COVID-19 Vaccination Program Interim Operational Guidance,* October 2020. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/Covid-19-Vaccination-Program-Interim_Playbook.pdf on August 26, 2022.

[11] CAG was formerly known as Operation Warp Speed.

[12] ASPR was formerly known as the Office of the Assistant Secretary for Preparedness and Response.

[13] On December 31, 2021, after we collected data from awardees, CAG was dissolved and transitioned fully to an HHS effort. In March 2022, HHS established H-CORE to build off CAG and Operation Warp Speed efforts. The White House, *Press Briefing by White House and HHS Public Health Officials*, March 2, 2022. Accessed at https://www.whitehouse.gov/briefing-room/press-briefings/2022/03/02/press-briefing-by-white-house-and-hhs-public-health-officials-march-2-2022/ on May 18, 2022.

[14] In January 2022, the Government Accountability Office (GAO) released a report examining that transition, as part of its ongoing obligation to monitor the Federal government's pandemic response. GAO, *HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues*, January 2022. Accessed at https://www.gao.gov/assets/gao-22-104453.pdf on March 29, 2022.

[15] CDC encourages manufacturers and distributors to use a strategy in which partial shipments are used to allow as many providers as possible to begin vaccination activities early in the vaccination season. Further, CDC recommends using manufacturer-filled syringes for large influenza vaccination clinics. CDC, *Frequently Asked Questions on Vaccine Supply*, last updated October 18, 2021. Accessed at https://www.cdc.gov/flu/prevent/vaxdistribution.htm on January 27, 2022. CDC, *Seasonal Influenza Vaccine Dosage and Administration*, last updated November 16, 2020. Accessed at https://www.cdc.gov/flu/about/qa/vaxadmin.htm on January 27, 2022.

[16] Huang, Hsin-Chan et al., "*Equalizing access to pandemic influenza vaccines through optimal allocation to public health distribution points*," August 30, 2017. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5576642/ on March 9, 2022.

[17] CAG determined these allocations using population size in each jurisdiction. Allocations changed over time based on recommendations for critical populations, vaccine production and availability, and overall jurisdictional population. CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 29, 2020, p. 29.

[18] Haung, P., *Government To Allocate Vaccine to States based on Population, not Risk*, November 2020. Accessed from https://www.npr.org/2020/11/25/939002641/government-to-allocate-vaccine-to-states-based-on-population-not-risk on December 21, 2021.

[19] Awardees recruited providers to administer the COVID-19 vaccine. As part of this process, providers who agree to administer the COVID-19 vaccine, enroll into their awardee's COVID-19 vaccination program. These providers must adhere to the CDC COVID-19 Vaccination Program Provider Agreement. CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 21. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022.

[20] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 31. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022.

[21] Ibid.

[22] A cold chain includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient. CDC, *Vaccine Storage and Handling Toolkit*, September 2021, p. 5. Accessed at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf on February 11, 2022.

[23] Additionally, because the Pfizer vaccine must be mixed before use, its ancillary supply kit also includes a mixing kit. CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 29, 2020, p. 30.

[24] A low dead-volume syringe is a specific type of syringe that is able to reduce what is known as "dead volume"—the amount of fluid remaining within in the syringe after an injection is completed. This allows providers to maximize the number of doses from one vial, as a low dead-volume syringe can withdraw six doses out of a vial, rather than five. Pfizer, *Information about Low Dead-Volume Syringes and/or Needles,* 2021. Accessed at https://www2.gnb.ca/content/dam/gnb/Departments/eco-bce/Promo/covid-19/ldv-info-pfizer-biontech-vaccine.pdf on March 3, 2022.

[25] ASPR, *COVID Vaccine Ancillary Supply and Mixing Kits,* August 9, 2021. Accessed at https://www.phe.gov/about/sns/COVID/Pages/covid19-ancillary-supplies-mixing-kits.aspx on March 4, 2022.

[26] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 29. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022.

[27] To ensure equitable distribution of the vaccine, CDC worked with various partners, including ACIP and the National Institutes of Health and the National Academies of Sciences, Engineering, and Medicine, to recommend how awardees

distribute the vaccination to reach critical populations. CDC, *The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020*, December 31, 2020. Accessed at https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm on February 11, 2022

[28] Ibid.

[29] Ibid.

[30] Kaiser Family Foundation, *State COVID-19 Vaccine Priority Populations*, April 19, 2021. Accessed at https://web.archive.org/web/20210129160408/https://www.kff.org/other/state-indicator/state-covid-19-vaccine-priority-populations/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D on February 11, 2022.

[31] In May 2021, all individuals aged 16 years and older became eligible to receive the COVID-19 vaccine. The White House, *Fact Sheet: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th*, March 11, 2021. Accessed at https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/11/fact-sheet-president-biden-to-announce-all-americans-to-be-eligible-for-vaccinations-by-may-1-puts-the-nation-on-a-path-to-get-closer-to-normal-by-july-4th/ on February 15, 2022.

[32] In late October 2021, all children and adults aged 5 and older became eligible to receive the COVID-19 vaccine. FDA authorized the Pfizer COVID-19 vaccine for emergency use in children 5-11 years old on October 29, 2021. For children 12-15 years old, FDA authorized the Pfizer vaccine on May 10, 2021. FDA, *Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic*, May 10,2021. Accessed at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use on February 15, 2022. FDA, *FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age*, October 29, 2021. Accessed at https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age on February 15, 2022.

[33] CDC, *CDC COVID-19 Vaccination Program Provider Agreement*, September 14, 2020. Accessed at https://scdhec.gov/sites/default/files/media/document/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf on September 23, 2022; CDC, *COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operation*, October 29, 2020, p. 35; CDC, *Immunization Information System Data Requirement Form*, December 11, 2020. Accessed at https://www.cdc.gov/vaccines/covid-19/reporting/downloads/IIS-data-requirement-form.pdf on September 23, 2022.

[34] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, p. 64. Accessed at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf on February 11, 2022.

[35] CDC written and verbal responses to OIG questions in February 2022.

[36] HHS, *Pandemic Influenza Plan*, November 2005, p. 280. Accessed at https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf on January 26, 2022.

[37] HHS agencies should develop and distribute communication materials for awardees to use during pandemic vaccination efforts, as outlined in prior pandemic planning. Prior planning states that Federal government, including HHS, should coordinate with awardees to disseminate consistent public health messages to the wider public. In addition, awardees should tailor those messages to local populations. HHS, *Pandemic Influenza Plan*, November 2005, Supplement 10, p. S10-1 through S10-21. Accessed at https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf on January 26, 2022.

[38] CDC, *VFC Parents Brief Answers to Common Questions*, June 17, 2020. Accessed at https://www.cdc.gov/vaccines/programs/vfc/parents/qa-flyer.html on February 15, 2022. CDC, *Educational Resources and CMEs for Healthcare Professionals*, July 13, 2020. Accessed at https://www.cdc.gov/vaccines/events/niam/hcp/educational-resources.html#maternal-vaccination on February 15, 2022. CDC, *Growing Up with Vaccines: What Should Parents Know?,* July 2018. Accessed at https://www.cdc.gov/vaccines/growing/images/global/CDC-Growing-Up-with-Vaccines.pdf on February 15, 2022. CDC, *CDC Digital Media Toolkit: 2021-22 Flu Season*, December 20, 2021. Accessed at https://www.cdc.gov/flu/resource-center/toolkit/index.htm on February 15, 2022. CDC, *What Vaccines are Recommended for You*, November 21, 2019. Accessed at https://www.cdc.gov/vaccines/adults/rec-vac/index.html on February 15, 2022. CDC,

Vaccines at 4 to 6 Years, February 25, 2020. Accessed at https://www.cdc.gov/vaccines/parents/by-age/years-4-6.html on February 15, 2022.

[39] CDC, *Vaccinate with Confidence*, 2019. Accessed at https://www.cdc.gov/vaccines/partners/downloads/Vaccinate-Confidently-2019.pdf on March 22, 2022.

[40] CDC, *VFC Awareness and Promotional Materials*, August 31, 2012. Accessed at https://www.cdc.gov/vaccines/programs/vfc/awardees/awareness.html on February 15, 2022; Ad Council, *COVID-19 Vaccine Education Initiative*. Accessed at https://www.adcouncil.org/covid-vaccine on February 15, 2022; GAO, *HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives*, November 2021. Accessed at https://www.gao.gov/assets/gao-22-104457.pdf on February 15, 2022. (pg. 36/68); Ad Council, *CDC, AMA, and Ad Council Urge Flu Vaccinations to Reduce Flu Hospitalizations Amid COVID-19 Concerns*, October 12, 2021. Accessed at https://www.adcouncil.org/press-releases/cdc-ama-and-ad-council-urge-flu-vaccinations-to-reduce-flu-hospitalizations-amid-covid-19-concerns on February 15, 2022; Ad Council, *No Time For Flu.* Accessed at https://www.adcouncil.org/asset/no-time-for-flu/203306523 on February 15, 2022; NACCHO, *Community Health.* Accessed at, https://www.naccho.org/programs/community-health on February 15, 2022.

[41] CDC, *How to Tailor COVID-19 Vaccine Information to Your Specific Audience*, November 3, 2021. Accessed at https://www.cdc.gov/vaccines/covid-19/hcp/tailoring-information.html on February 15, 2022.

[42] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 29, 2020, p. 43.

[43] Ibid.

[44] Ibid., p. 42.

[45] Ibid., p. 44.

[46] Ibid., p. 46.

[47] FDA, *Multilingual COVID-19 Resources,* January 31, 2022. Accessed at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/multilingual-covid-19-resources on February 11, 2022.

[48] CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 29, 2020, p. 46.

[49] Ibid., p. 23.

[50] Ibid.

[51] Ibid.

[52] Additional topics include ordering vaccine, managing, and reporting vaccine inventory, reporting vaccine wastage and spoilage, reporting adverse events, and submitting facility information and reports. CDC, *COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction* Operation, October 29, 2020, p. 23.

[53] CDC, *U.S. COVID-19 Vaccine Product Information*, May 26, 2022. Accessed at https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html on February 15, 2022.

[54] CDC, *COVID-19 Provider Oversight FAQ*, v.1, June 24, 2021.

[55] Ibid.

[56] CDC, CDC COVID-19 Vaccination Program: Provider Oversight and Quality Assurance, October 12, 2021, p. 6

[57] CDC, COVID-19 Provider Oversight FAQ, v.1, June 24, 2021.

[58] In contrast, CDC requires awardees to conduct site visits of routine vaccine providers every 24 months. CDC, *Vaccines for Children Program vs. CDC COVID-19 Vaccination Program*, December 7, 2021. Accessed at https://www.cdc.gov/vaccines/covid-19/vfc-vs-covid19-vax-programs.html on February 15, 2022.

[59] CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex,* January 2021, p. 23. Accessed at https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vaccination-program-playbook-annex.pdf on February 15, 2022.

[60] As a part of this, CDC requires that every vaccine storage unit have a temperature monitoring device. CDC recommends providers use digital data loggers, a specific type of temperature monitoring device, as these devices provide the most accurate measure of vaccine storage temperatures while detecting the length of time during any temperature excursion. CDC, *Vaccine Storage and Handling Toolkit*, September 2021, p. 10.

[61] CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex,* January 2021, p. 23.

[62] As of October 2021, awardees are required to conduct site visits of 10 percent of provider locations of selected Federal-channel partner organizations within the jurisdiction (i.e., dialysis centers, HRSA federally qualified health centers, IHS facilities, HHS facilities, and BoP facilities. Awardees are not required to conduct sites visits of providers enrolled through DoD, Veterans Health Administration, Department of State, or the Federal Retail Pharmacy Program, as these programs conduct site visits internally. CDC, *CDC COVID-19 Vaccination Program: Provider Oversight and Quality Assurance*, October 12, 2021, p. 1-2.

[63] OIG, *Local Pandemic Influenza Preparedness: Vaccine and Antiviral Drug Distribution and Dispensing*, September 2009. Accessed at https://oig.hhs.gov/oei/reports/oei-04-08-00260.pdf on July 28, 2022. OIG, *State and Local Pandemic Influenza Preparedness: Medical Surge*, September 2009. Accessed at https://oig.hhs.gov/oei/reports/oei-02-08-00210.pdf on July 28, 2022.

[64] Ibid.

[65] HHS OIG, *Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19*, OEI-05-22-00010, January 2023.

[66] GAO, *Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, February 2021. Accessed at https://www.gao.gov/assets/gao-21-319.pdf on July 28, 2022.

[67] GAO, *HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives*, November 2021. Accessed at https://www.gao.gov/assets/gao-22-104457.pdf on July 28, 2022.

[68] GAO, *HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues*, January 2022. Accessed at https://www.gao.gov/assets/gao-22-104453.pdf on March 29, 2022.

[69] These six large metropolitan areas included Chicago, District of Columbia, Houston, Philadelphia, New York City, and San Antonio.

[70] We did not include U.S. territories (i.e., American Samoa, Guam, Marshall Islands, Micronesia, Northern Marianas, Palau, Puerto Rico, and the Virgin Islands) in this review, given their different infrastructure and relatively low number of allocated vaccines in March 2021.

[71] We gave awardees the option to respond to our questions either via email or phone. Both email surveys and phone interviews contained the same questions.

[72] We received contact information from CDC for each awardee and made initial contact with awardees through these individuals. We conducted surveys and interviews with one or more immunization program official, which sometimes included the initial contact person CDC provided. The immunization program officials who completed our surveys or interviews were typically Immunization Program Managers, Immunization Program Directors, or Immunization Program Branch Chiefs within the awardees' public health departments.

[73] We selected these broad areas based on our review of CDC's COVID-19 Vaccine Playbook, as well as challenges reported in the media and by stakeholders prior to when we collected data.

[74] FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, December 11, 2020. Accessed at https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 on April 20, 2022.

[75] Awardees reported having manufacturers send the large minimum orders primarily to sites that had a predictably large demand, such as metropolitan hospitals and mass vaccination sites with high volumes of people seeking vaccinations. This approach used standard cold chain management processes and fewer awardee resources. However, this presented challenges in ensuring vaccine access to populations who did not live near or were uncomfortable being vaccinated at these types of locations.

[76] CDC, *CDC COVID-19 Vaccination Program: Provider Oversight and Quality Assurance*, October 12, 2021, p. 6.

[77] CDC recommends different needle sizes based on individuals' age and the site of injection. CDC, *Vaccine Administration: Needle Gauge and Length,* August 4, 2020. Accessed at https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf on March 29, 2022.

[78] Tiberius provides awardees access to vaccine allocation data (i.e., the number of doses allotted to their jurisdiction). See Appendix B for more information on State and Federal data systems.

[79] Prior GAO reports found that State health officials reported lacking visibility into how many doses would be allocated to them and challenges in reporting vaccine administration data to CDC. GAO, *Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation*, GAO-21-443, https://www.gao.gov/assets/gao-21-443.pdf. Accessed on July 22, 2022.

[80] Zylla, E., Bernard, S., & Lukanen, E, *Ensuring Equity: State Strategies for Monitoring COVID-19 Vaccination Rates by Race and Other Priority Populations*, June 3, 2021. Accessed at https://www.shvs.org/ensuring-equity-state-strategies-for-monitoring-covid-19-vaccination-rates-by-race-and-other-priority-populations/ on February 15, 2022.

[81] Health Level 7 is a set of standards for the transfer of clinical or administrative data between software applications used by various health care providers. Health Level 7 allows providers to send data to their State's IIS from their electronic health record system. This saves time as providers do not have to enter data into two different data systems. The standards are produced by Health Level Seven International, an international standards organization. (Reference to "level 7" does not indicate that there are other levels not described here; rather, it reflects the name of the company that developed the standards.) CDC, *Implementation Guide for Immunization Messaging,* October 1, 2014. Accessed at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf on March 3, 2022.

[82] HHS Office of the Chief Technology Officer, *The Immunization Gateway*, August 11, 2020. Accessed at https://repository.immregistries.org/files/resources/5f3478b27ffc4/iz_gateway_aira_august_2020_final.pdf on May 24, 2022.

[83] HHS reported to GAO that COVID-19 vaccine administration data was missing race and ethnicity data for almost half of vaccine recipients from December 2020 to March 2021. GAO, *Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year,* GAO-21-387. Accessed at https://www.gao.gov/assets/gao-21-387.pdf on July 22, 2022. In another report released in February 2022, GAO also found Federal vaccination programs lacked completed race and ethnicity data for vaccination administration. GAO, *Federal Efforts to Provide Vaccines to Racial and Ethnic Groups*, GAO-22-105079. Accessed at https://www.gao.gov/assets/gao-22-105079.pdf on July 22, 2022.

[84] Kaiser Family Foundation, *Early State Vaccination Data Raise Warning Flags for Racial Equity*, January 21, 2021. Accessed at https://www.kff.org/policy-watch/early-state-vaccination-data-raise-warning-flags-racial-equity/ on July 14, 2022. Kaiser Family Foundation, *Latest Data on COVID-19 Vaccinations by Race/Ethnicity*, July 14, 2022. Accessed at https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-by-race-ethnicity/#endnote_link_538361-2 on August 30, 2022. Kaiser analyzed State COVID-19 vaccine dashboards to conduct this analysis. Therefore, the remaining four States may still collect race and ethnicity data but do not report it on national dashboards. Further, this analysis does not include an assessment of the accuracy nor completeness of this data.

[85] GAO found that despite CDC developing COVID-19 vaccine communication toolkits, State and local health officials reported a lack of availability of communication materials early in the COVID-19 vaccination program. GAO, *HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives,* GAO-22-104457. Accessed at https://www.gao.gov/assets/gao-22-104457.pdf on July 22, 2022.

[86] As part of these toolkits, CDC included a vaccine fact sheet with information on vaccine safety and efficacy to promote vaccine uptake. CDC, *Communication Toolkit,* August 17, 2021. Accessed at https://www.cdc.gov/immigrantrefugeehealth/resources/communication-toolkit.html on February 15, 2022.

[87] CDC reported that the "We Can Do This" campaign includes formative research, creative development, partnership engagement, media buying, earned media, and ongoing research and evaluation.

[88] We analyzed documentation provided by CDC and found that billing practices was the most common deficiency that awardees identified during their provider site visits. Thirty-six percent of providers (1960 of 5,399) were noncompliant with vaccine documentation, data reporting and/or vaccine recipient communication.

[89] We analyzed documentation provided by CDC and found that CDC conducted site visits only between December 1, 2020, and May 31, 2021. During site visits, CDC found that over half (54 of 96) providers did not adhere to vaccination procedures, such as vaccine preparation, administration, and adverse events reporting. Further, half (48 of 96) of providers did not adhere to storage and handling requirements.

[90] CDC, *COVID Data Tracker Weekly Review*, May 28, 2021. Accessed at https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/05282021.html on August 2, 2022.

[91] Between December 1, 2020, and December 1, 2021, awardees identified 22 percent of providers (i.e., 1191) as noncompliant with storage and handling requirements sitewide.

[92] After our review period, in one awardee's jurisdiction, hundreds of vaccines were spoiled due to a mishandling of vaccines which led to the vaccines to be stored at the incorrect temperature. Deville, T., Cohn, M. & Miller, H, *Whistleblower alleges Maryland health officials failed to alert hundreds of patients of potentially spoiled vaccines*, December 29, 2021. Accessed at https://www.baltimoresun.com/coronavirus/bs-md-truecare-whistleblower-20211229-5sof2rxtnvfpji4lks3pumiqd4-story.html?utm_source=&utm_medium=email&utm_campaign=45830 on February 15, 2022.

[93] We analyzed documentation provided by CDC and found that CDC did not provide granular data regarding citations in this area for site visits that it conducted. However, CDC did report that 48 (of 96) site visits were noncompliant with storage and handling per unit requirements, which includes "having a temperature monitoring device located on the storage unit at all time,", among other things.

[94] CDC reported to the OIG that the Biomedical Advanced Research and Development Authority (BARDA) is a key partner in coordinating with vaccine manufacturers. BARDA provides an integrated, systematic approach to the development of necessary vaccines and other tools for public health emergencies, including pandemics and emerging infectious diseases. For COVID-19, BARDA funded six COVID-19 vaccine candidates, which includes obligating funds to research and development, increased manufacturing capacity, and advanced purchases of the final vaccine. ASPR, *Biomedical Advanced Research and Development Authority*. Accessed at https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx on August 26, 2022. CRS, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials,* updated March 1, 2021. Accessed at https://crsreports.congress.gov/product/pdf/IN/IN11560 on August 26, 2022.

[95] Cold chain conditions refer to the temperature that a vaccine must be controlled at during various stages of distribution and administration to ensure the viability of the vaccine. CDC, *Vaccine Storage and Handling Toolkit,* March 4, 2021, p. 5. Accessed at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html on August 24, 2022.

[96] Digital data loggers are a temperature monitoring device used to monitor and record the temperature of a vaccine storage unit on a continuous basis. CDC, *Vaccine Storage and Handling*, last reviewed August 18, 2021. Accessed at https://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html on August 26, 2022.

[97] CDC, *Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary*, March 3, 2021

[98] CDC, *Moderna COVID-19 Vaccine Preparation and Administration Summary*, March 15, 2021; CDC, *Moderna COVID-19 Storage and Handling Summary,* December 20, 2020

[99] CDC, *Janssen COVID-19 Vaccine (Johnson & Johnson) Storage and Handling Summary*, March 5, 2021.

[100] CDC, *Data Use and Sharing Agreement to Support the United States Government's COVID-19 Emergency Response*, p. 3. Accessed at https://www.cdc.gov/vaccines/covid-19/reporting/downloads/vaccine-administration-data-agreement.pdf on March 30, 2022.

[101] These elements include date and location administered, recipient name, recipient date of birth, certain recipient demographic information, such as race, ethnicity and sex, and type of vaccine administered. CDC, *COVID-19 Vaccination Program Interim Operational Guidance*, October 2020, Appendix D, p. 63.

[102] Awardees are not required but are encouraged to use the IZ Gateway upon it being available. CDC, *Data Use and Sharing Agreement to Support the United States Government's COVID-19 Emergency Response*, p. 8. Accessed at https://www.cdc.gov/vaccines/covid-19/reporting/downloads/vaccine-administration-data-agreement.pdf on March 30, 2022.