CDC COVID-19 vaccination program: Healthcare provider compliance with COVID-19 vaccine requirements and recommendations

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Abstract

The COVID-19 Vaccination Provider Oversight (CVPO) program was implemented by the Centers for Disease Control and Prevention (CDC) to ensure the proper management and administration of COVID-19 vaccines by healthcare providers participating in the CDC COVID-19 Vaccination Program. As part of the CVPO program, the 64 CDC-funded immunization program awardees conducted site visits with participating healthcare providers. We evaluated healthcare provider adherence to CVPO program requirements between May 2021 and May 2023. CVPO program site visit data was collected using a REDCap database. The proportion of site visits conducted by U.S. Department of Health and Human Services (HHS) region was calculated. Chi-square statistics for healthcare provider compliance with CVPO program requirements were presented to assess variation in compliance by provider type. The proportion of healthcare providers receiving a site visit ranged from 7.9 % to 37.2 % across HHS regions. Healthcare provider compliance was high for COVID-19 vaccine preparation, administration, and error reporting categories (>90 %). Healthcare provider compliance was lowest for vaccine storage and handling and reporting requirements (79.9 % and 82.6 %, respectively). Public health providers demonstrated significantly higher overall compliance as compared to all other included healthcare provider types (p-value < 0.05). The observed high healthcare provider compliance, coupled with thorough follow-up efforts by awardees to address any non-compliance concerns, highlights the success of

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jurisdictions supporting healthcare providers with proper vaccine management, administration, and safety procedures. Further research can strengthen vaccine storage, handling, and administration practices for future widespread vaccination efforts.

Keywords

COVID-19; Vaccination; Compliance; Adult vaccination

1. Introduction

In March 2020, the World Health Organization (WHO) declared COVID-19 a pandemic [1]. By December 2020, two mRNA vaccines for COVID-19 received emergency use authorization (EUA) from the Food and Drug Administration (FDA) [2]. As of May 2023, >984 million COVID-19 vaccine doses have been delivered in the U.S., with 270.2 million (81.4 %) individuals having received at least one dose [3]. The Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program, in coordination with state and local public health efforts, helped to ensure safe and equitable vaccine access and the achievement of this COVID-19 vaccination coverage milestone.

Prior to the commercialization of COVID-19 medical countermeasures to the traditional health care marketplace, all COVID-19 vaccines in the U.S. were purchased exclusively by the federal government. COVID-19 vaccination providers were required to enroll in the CDC COVID-19 Vaccination Program to administer COVID-19 vaccine [4]. The COVID-19 Vaccination Provider Oversight (CVPO) program was implemented to assist the 64 CDC-funded immunization program awardees (described herein as awardees) in supporting enrolled healthcare providers with proper vaccine management (e.g., vaccine storage and handling), administration, reporting, and safety procedures. Increased technical assistance and financial support via awardee supplemental funding were provided to recruit and onboard COVID-19 vaccination providers and address increased staffing needs to manage systems and provider education impacted by multiple COVID-19 vaccine products, frequent changes in Advisory Committee on Immunization Practices (ACIP) recommendations/ eligibility, and CDC's clinical guidelines [5–8].

Beginning in May 2021, awardees were required to conduct site visits with COVID-19 vaccination providers who store and administer vaccine (i.e., "store and administer" provider locations) and depot locations (i.e., any location used to routinely store or redistribute COVID-19 vaccine to multiple locations) for as long as the federal government provided COVID-19 vaccines [9]. The number of annual site visits required of each awardee was determined by the CDC and based on a jurisdiction's population size. The four primary goals of CVPO program site visits were to 1) assess adherence to program requirements, ACIP recommendations, and CDC guidelines, 2) identify and address provider strengths and challenges, 3) identify and address educational needs, and 4) ensure proper storage and management of vaccines administered [9]. Guidance documents and reviewer resources were developed to support awardee staff in conducting CVPO program site visits. Ongoing

awardee and healthcare provider training opportunities as well as technical assistance were provided by the federal government.

We summarize healthcare provider adherence to CVPO program compliance requirements overall and by compliance area from approximately 17,000 awardee-led site visits conducted as part of the CDC COVID-19 Vaccination Provider Oversight program.

2. Methods

The present study assessed CVPO site visit data collected between May 14, 2021, and May 1, 2023. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[1]

2.1. Instrument development

A centralized database was developed by CDC's Immunization Services Division (ISD) in REDCap, an online survey and management database tool [10,11]. The database comprised seven unique instruments that aligned with corresponding CVPO program guidance requirements [7], including 1) Provider Details, 2) Billing, Documentation, Vaccine Recipient Communication, and Reporting, 3) Storage and Handling per Unit, 4) Storage and Handling Sitewide, 5) Vaccination Procedures, 6) Ancillary Supply Kits, and 7) Future Follow-up Checklist.

2.2. Healthcare provider sites

Minimum CVPO program annual site visit targets were set by the CDC and based on 2019 U.S. Census population estimates. Awardees selected which participating CVPO program provider locations received site visits and were asked to prioritize providers with greater patient throughput. All providers were required to have COVID-19 vaccine inventory on-site at the time of the site visit. In addition, at least 10 % of provider site visits had to be conducted at federal-channel provider locations (i.e., Health Resources and Services Administration [HRSA] and Indian Health Service [IHS] locations). Awardees were also directed to visit all depot locations that stored or redistributed COVID-19 vaccine. Awardees were advised not to revisit sites unless there were unresolved issues pertaining to vaccine storage and handling, fraud, abuse, or other severe compliance concerns.

2.3. Data collection

Each site visit was conducted by awardee-appointed staff. Site visit reviewers were responsible for scheduling, completing, and documenting site visit data in REDCap as well as conducting provider follow-up, as necessary. Reviewers assessed healthcare provider compliance using all seven instruments and recorded data in REDCap within 10 days from the date of the visit.

If a healthcare provider was determined to be non-compliant with CDC and/or vaccine manufacturer requirements, immediate actions (i. e., REDCap-prompted actions taken at the

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[1]See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

time of the site visits), or future follow-ups were required. Reviewers discussed any findings requiring follow-up for or with the provider location using the Future Follow-up Checklist. Follow-up plans and timelines were developed to address any issues with adherence to requirements or opportunities for improvement; completion of corrective actions for addressing observed non-compliance was verified and documented by the site visit reviewer using the Future Follow-up Checklist.

2.4. Measures

Overall site visit completion status was confirmed by reviewing each data instrument's completion status. If all instruments—including the Future Follow-up Checklist—were marked as "complete" by the reviewer within REDCap, the site visit was included in the analysis.

Healthcare provider compliance for all store and administer locations was evaluated using CDC and/or vaccine manufacturer requirements and grouped into the following compliance areas: 1) vaccine storage and monitoring, 2) vaccine preparation, 3) vaccine administration-process, 4) vaccine administration-correct vial, 5) vaccine administration-correct interval, 6) vaccine administration-error reporting, and 7) reporting (i.e., immunization registry reporting, inventory reporting, temperature excursion, and vaccine wastage reporting). Site visit performance was assessed using instrument responses to all questions within a compliance area. Healthcare providers were considered "compliant" if all site visit question responses indicated compliance with CDC and/or vaccine manufacturer requirements. A healthcare provider was categorized as "non-compliant" if at least one non-compliant action was indicated or if a required question was not answered. For healthcare provider locations with more than one vaccine storage unit recorded, compliance was assessed separately for each unit; healthcare providers were considered compliant with vaccine storage and monitoring compliance if all units associated with the visit were found to be compliant. Non-compliance was further assessed by the sub-category where the concern(s) occurred. Overall healthcare provider compliance was calculated by determining the proportion of site visits compliant across all seven compliance areas.

Throughout the COVID-19 response, CDC's vaccination guidance was updated each time vaccine manufacturer requirements or vaccine recommendations changed. For each CDC and/or ACIP recommendation and/or new or amended EUA, the CVPO site visit reviewer guide and associated REDCap database were updated to be concordant. REDCap survey instrument question modifications were compiled and placed on a timeline; conditional data statements were used to ensure only site visit questions applicable to the time when the site visit occurred were assessed.

2.5. Statistical analysis

Using enrollment data from the midpoint of the study period (May 1, 2022), the proportion of enrolled providers receiving a site visit was determined for each U.S. Department of Health and Human Services (HHS) region[2] by dividing the number of site visits by the number of enrolled providers per region. ArcGIS software was used to visualize CVPO site visit proportions by HHS region. Chi-square statistical testing was used to assess variability

in healthcare provider compliance with CVPO program requirements by provider type. All statistical analysis was conducted using SAS 9.4 software (SAS Institute, Cary NC).

2.6. Role of funding source

3. Results

A total of 18,697 site visits were recorded in REDCap; 1,243 site visit records were excluded due to data incompleteness (i.e., site visit not in "complete" status), missing site visit date information, or because the site visit occurred outside of the study period. Of the 17,454 site visits included in the analysis, healthcare provider compliance was evaluated on the subset of store and administer provider locations; 378 site visits conducted at depot locations or missing a provider function assignment were excluded from the compliance analysis, resulting in 17,076 site visits remaining for this study.

3.1. Site visit characteristics

Of the healthcare provider types enrolled in the CVPO program, medical practices (e.g., family medicine, pediatric, internal medicine, and OB/GYN specialties) and public health providers (e.g., public health clinics, Federally Qualified Health Centers (FQHC), and Rural Health Clinics) represented the largest proportion of healthcare provider sites receiving CVPO program site visits (33.8 % and 21.3 %, respectively). Alternatively, home health (0.5 %), long-term care (0.5 %), and Indian Health Service/Tribal providers (0.7 %) comprised the smallest share of awardee-led site visits. Most CVPO healthcare providers stored and administered vaccines (97.8 %), with only 359 (2.1 %) visited providers indicated as vaccine depot locations (Table 1). The proportion of site visits conducted with store and administer locations by HHS region ranged from 7.9 % (Region 6) to 37.2 % (Region 10) (Fig. 1).

3.2. CVPO program compliance overall and by category

Healthcare provider compliance was greater than 90 % in five out of seven compliance areas [vaccine preparation (95.2 %), vaccine admin-process (94.8 %), vaccine admin-correct vial (97.5 %), vaccine admin—correct interval (92.1 %), and vaccine admin—error reporting (96.4 %)] (Fig. 2). Overall, 63.3 % of healthcare providers were compliant with all CVPO program compliance requirements, including all CDC and/or vaccine manufacturer recommendations.

Healthcare provider compliance was lowest for vaccine storage and monitoring (79.9 %) and reporting (82.6 %); non-compliance in both areas also varied by compliance sub-category (Fig. 2). Of the 1,472 (8.6 %) site visits reporting a temperature excursion within the past

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[2]Health and Human Services regions refer to the ten administrative divisions within the United States Department of Health and Human Services (HHS), each covering specific geographic areas within the United States and its territories. Additional information available at: https://www.hhs.gov/about/agencies/iea/regional-offices/index.html

30 days (data not shown), 39.1 % were non-compliant with CDC-required temperature excursion processes (e.g., quarantining impacted vaccine, storing vaccine in a backup unit, reporting the temperature excursion to the immunization program, and contacting the vaccine manufacturer for usability documentation). Non-compliance with vaccine transport processes and documentation requirements (including having a digital data logger [DDL] available to monitor and record temperatures during transport) was 9.8 %. For the reporting compliance area, 17.4 % of all sites were non-compliant with one or more reporting requirements; non-compliance by sub-category ranged from 4.6 % (temperature excursion reporting) to 8.6 % (vaccine inventory reporting) (Fig. 2).

3.3. CVPO program compliance by healthcare provider type

Compliance with all CVPO program requirements varied by healthcare provider type, ranging from 45.7 % for state or local corrections/detention providers to 72.7 % for public health providers (Table 2). Using public health providers as the reference group, observed overall compliance was significantly different across all healthcare provider types (p-value < 0.05). For storage and monitoring, compliance was the lowest for state or local corrections/ detention (64.0 %), urgent care (66.2 %), and pharmacy-independent providers (69.7 %) (p-value < 0.0001). Medical practice compliance with CVPO program requirements was significantly lower as compared to public health providers for all compliance areas excluding vaccine preparation (p-value = 0.22) and vaccine administration—correct vial (p-value = 0.15).

No relationship between the timing of ACIP recommendation and/or EUA guidance changes on healthcare provider compliance was observed. Healthcare provider compliance overall and by individual compliance area remained relatively consistent across the study period (data not shown).

4. Discussion

This study found that most healthcare providers that received a COVID-19 Vaccination Provider Oversight program site visit were compliant with program requirements overall and by compliance area. More than 90 % of healthcare providers were compliant with COVID-19 vaccine preparation, administration, and error reporting processes. Non-compliance was higher for vaccine storage and handling and vaccine reporting. Immunization program awardees demonstrated immense capacity to support large-scale monitoring and evaluation of COVID-19 efforts to support oversight of proper vaccine management, administration, and safety.

As part of the Vaccines for Children program (VFC) [12], awardees are required to conduct quality assurance site visits with VFC providers to ensure proper storage, handling, and administration of VFC-purchased vaccines. Modeled after systems used to support the VFC program, healthcare provider adherence to COVID-19 vaccine administration, documentation, accountability, and vaccine management requirements were evaluated over the length of the CVPO program. The present study observed similar areas for non-compliance as has historically been observed for VFC providers (internal data report); vaccine storage and handling and documentation concerns continue to demonstrate the

greatest areas of healthcare provider non-compliance. To address these challenges, CDC implements annual training requirements and routinely develops program guidance to support awardee and provider education on proper vaccine management and administration, including vaccine storage and monitoring. Although time and resource intensive, these efforts respond to healthcare provider challenges (e.g., staff turnover, changes in reporting guidance) to ensure the quality of vaccines administered and long-term program integrity.

Over the past decade, the CDC has implemented several measures to improve vaccine management practices. These included stricter temperature monitoring device requirements (e.g., digital data logger requirements) along with enhanced documentation practices for temperature excursions. The CDC's Storage and Handling toolkit [13] is routinely updated to provide the latest guidance and recommendations for maintaining vaccine integrity and efficacy. Additionally, unannounced site visits focused on assessing provider storage and handling practices were introduced to the VFC program in 2016. While these spot checks were not a component of the CVPO program, they contribute to enhanced oversight of federally-purchased vaccines and could be considered for future federal vaccine programs.

Similar to the VFC program, immediate actions and follow-up activities were integrated into the site visit protocol to ensure compliance concerns were promptly addressed. This approach also supported the standardization of corrective actions across immunization programs. Furthermore, the reinforcement of provider education through the review of CDC requirements and recommendations during all site visits—irrespective of compliance status—fostered long-term compliance by equipping providers with the tools necessary to safely administer viable vaccines beyond the immediate post-visit period. Continued utilization of similar resources will be critical to the achievement of long-term compliance and the successful implementation of future vaccination programs.

Frequent changes in COVID-19 vaccine recommendations, including by age group, vaccine history, immunocompromised status, and new vaccine formulation approvals introduced additional complexity and challenges to adhering to CVPO program compliance requirements. Nonetheless, participating healthcare providers demonstrated generally high program compliance for vaccine administration processes (94.8 %), use of correct vials (97.5 %) and dose intervals (92.1 %), and reporting vaccine administration errors (96.4 %). Further, compliance across these areas remained consistent throughout the length of the CVPO program, irrespective of changes to vaccine recommendations or formulations. Although responsible for managing competing immunization priorities and navigating pandemic-related healthcare service disruptions, awardee oversight helped to ensure the continued viability and safety of COVID-19 vaccine products administered at these provider sites. As such, continued coordination between awardees and healthcare providers was essential in sustaining the high implementation of CVPO program safety requirements and ensuring the safe administration of the COVID-19 vaccine.

Prior to the commercialization of COVID-19 vaccines into the traditional healthcare market, pharmacies interested in administering the COVID-19 vaccine could enroll in the awardee-managed CVPO program, the Federal Retail Pharmacy Program (FRPP), or dually enroll in both. The FRPP was a collaborative initiative involving federal and state public health

agencies, 21 national pharmacy partners, and independent pharmacy networks, with the aim of increasing access to COVID-19 vaccination [14]. In the present study, independent and chain pharmacy providers enrolled in the CVPO program demonstrated moderate overall compliance (57.9 % and 66.9 %, respectively); similar non-compliance as compared to other healthcare provider types was also observed for storage and handling and reporting (Table 2). Pharmacies enrolled by awardees were required to participate in COVID-19 vaccine site visits upon request; however, there was no similar requirement for pharmacies only receiving vaccines as part of the FRPP. Although such pharmacies may have internal processes to assess their vaccine management practices, these were not evaluated in this study. Research suggests pharmacy involvement as immunizers significantly increases vaccine uptake [15]; however, additional efforts may be required to better understand approaches needed to evaluate vaccine storage, handling, and administration practices in pharmacies outside of those directly receiving vaccine from awardees.

This study has several limitations. First, awardees were not required to conduct site visits with all enrolled CVPO program providers; therefore, site visit data may not be representative of all COVID-19 vaccination providers. Next, the completion status for each data collection form was self-selected by awardee-appointed site reviewers; no formal validation of submitted site visit data was performed. The authors were unable to determine whether an incomplete "Future Follow-up Checklist" instrument reflected site visit reviewer non-compliance or if no follow-up actions were necessary. Therefore, site visits that did not identify compliance issues may have been excluded, leading to lower observed compliance scores. The CVPO program site visit data dashboard was created to support programmatic activities; additional data recoding efforts were necessary to prepare data for use in research. Updates to the REDCap database were resource intensive which caused delays in aligning database content with new CDC and/or ACIP recommendations and/or the addition of new vaccine formulations. Although the authors were unable to associate observed negative changes in provider compliance with CVPO program changes, compliance remained relatively constant over the length of the program. Finally, some jurisdictions elected to complete more CVPO program site visits than others which may have affected the direction of overall findings. The proportion of site visits conducted relative to enrolled providers ranged from 7.9 % (Region 6) to 37.2 % (Region 10) across HHS regions; however, this study did not account for the fact that certain jurisdictions enrolled a greater number of providers into the CDC COVID-19 Vaccination Program than others. Furthermore, proportions were calculated using point-in-time data for enrolled providers as of the study mid-point, which may not have been fully representative of all providers with inventory and actively vaccinating throughout the study period.

This report presents an overview of healthcare provider adherence to COVID-19 Vaccination Provider Oversight program compliance requirements, including CDC and/or vaccine manufacturer recommendations. The high number and variety of healthcare providers participating in CDC's CVPO program demonstrate both the interest and capacity of vaccination providers to participate in nationwide efforts to vaccinate both adult and pediatric populations. Further, high healthcare provider compliance, coupled with thorough follow-up efforts by awardees to address any non-compliance concerns, highlights the success of jurisdictions supporting healthcare providers with proper vaccine management

(e.g., vaccine storage and handling), administration, and safety procedures. Additional research—including investigating factors contributing to statistically relevant variations in compliance among different provider types—can further strengthen vaccine storage, handling, and administration support to ensure effective and safe vaccination and to maintain vaccine confidence. Lessons learned from this program will be important for future vaccine response activities and for building a broader U.S. Government routine vaccine program for adults.

Acknowledgments

6. Data Statement

The data that support the findings of this study are available from the corresponding author, T.C.S., upon reasonable request.

Data will be made available on request.

References

[1]. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020. Accessed March 15, 2023. https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020.

[2]. National Institute of Health. Decades in the Making: mRNA COVID-19 Vaccines. Accessed March 15, 2023. https://covid19.nih.gov/nih-strategic-response-covid-19/decades-making-mrna-covid-19-vaccines.

[3]. Centers for Disease Control and Prevention. COVID Data Tracker: COVID-19 Vaccinations in the United States. Accessed August 8, 2023. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-count-total.

[4]. Centers for Disease Control and Prevention. How to Enroll as a COVID-19 Vaccination Provider. Accessed March 15, 2023. https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

[5]. Centers for Disease Control and Prevention. COVID-19 ACIP Vaccine Recommendations. Accessed March 16, 2023. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

[6]. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Accessed April 4, 2023. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

[7]. Centers for Disease Control and Prevention. CDC COVID-19 Vaccination Program Operational Guidance. Accessed April 4, 2023. https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html.

[8]. Hall E, Odafe S, Madden J, Schillie S. Qualitative Conceptual Content Analysis of COVID-19 Vaccine Administration Error Inquiries. Vaccines 2023;11(2):254. [PubMed: 36851132]

[9]. Centers for Disease Control and Prevention. CDC COVID-19 Vaccination Program Provider Requirements and Support. Accessed April 4, 2023. https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.

[10]. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208.

[11]. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377–81. [PubMed: 18929686]

[12]. Centers for Disease Control and Prevention. The Vaccines for Children Operations Guide. Accessed May 31, 2023.

[13]. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. Updated 2021. Accessed July 20, 2023. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

[14]. Centers for Disease Control and Prevention. Pharmacies Participating in the Federal Retail Pharmacy Program. Accessed June 8, 2023. https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/participating-pharmacies.html.

[15]. Lan LM, Veettil SK, Donaldson D, et al. The impact of pharmacist involvement on immunization uptake and other outcomes: An updated systematic review and meta-analysis. J Am Pharm Assoc 2022.

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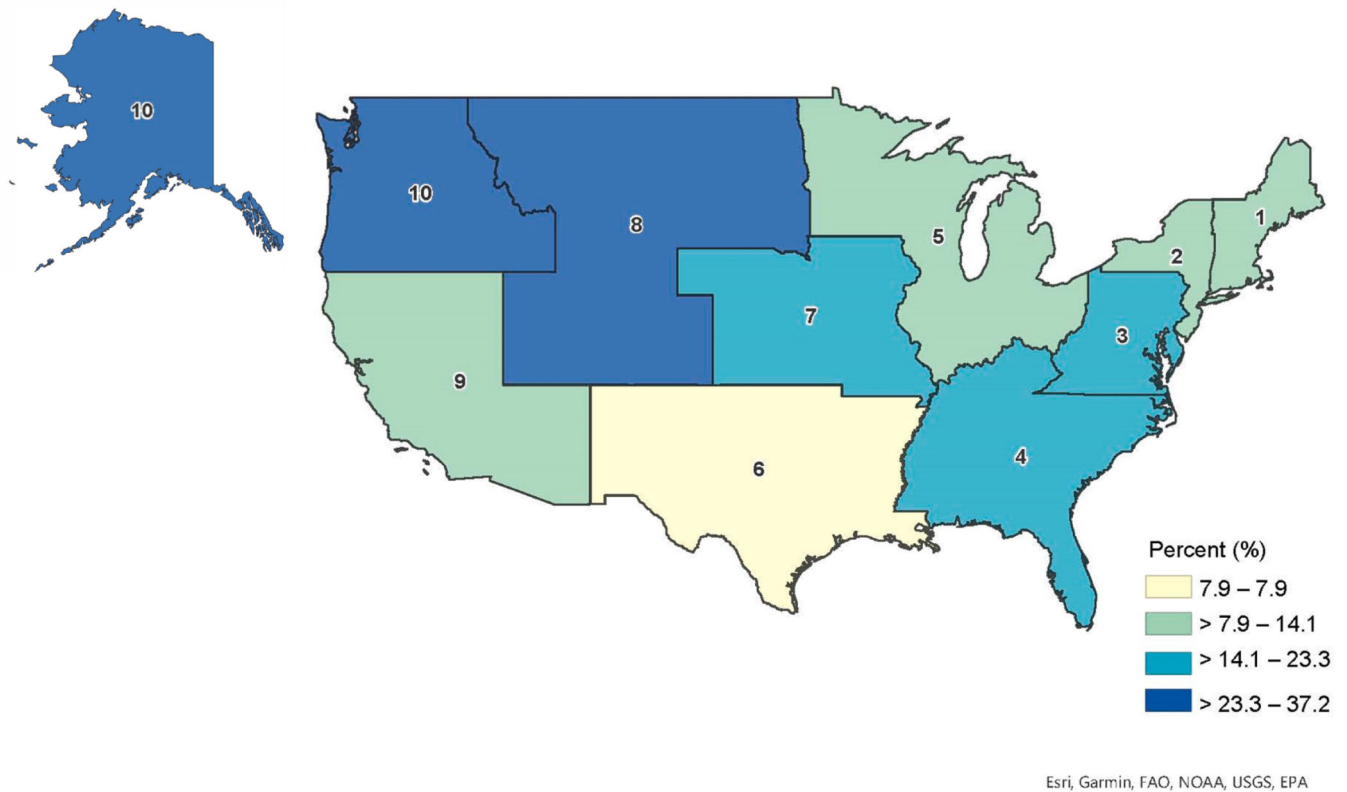
Not Pictured: Region 2: (Puerto Rico, the Virgin Islands), Region 9: (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Hawaii, Marshall Islands, Republic of Palau).

Fig. 1.

Proportion of enrolled providers receiving a COVID-19 Vaccination Provider Oversight program site visit[a] by Health and Human Services region[b], May 14, 2021 – May 1, 2023. ([a]Depicts completed site visits conducted at store and administer provider locations. [b]Health and Human Services regions refer to the ten administrative divisions within the United States Department of Health and Human Services (HHS), each covering specific geographic areas within the United States and its territories: *Region 1* (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont); *Region 2* (New Jersey, New York, Puerto Rico, and the Virgin Islands); *Region 3* (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia); *Region 4* (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee); *Region 5* (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin); *Region 6* (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas); *Region 7* (Iowa, Kansas, Missouri, and Nebraska); *Region 8* (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming); *Region 9* (Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and the Republic of Palau); *Region 10* (Alaska, Idaho, Oregon, and Washington). Additional information available at: https://www.hhs.gov/about/agencies/iea/regional-offices/index.html).
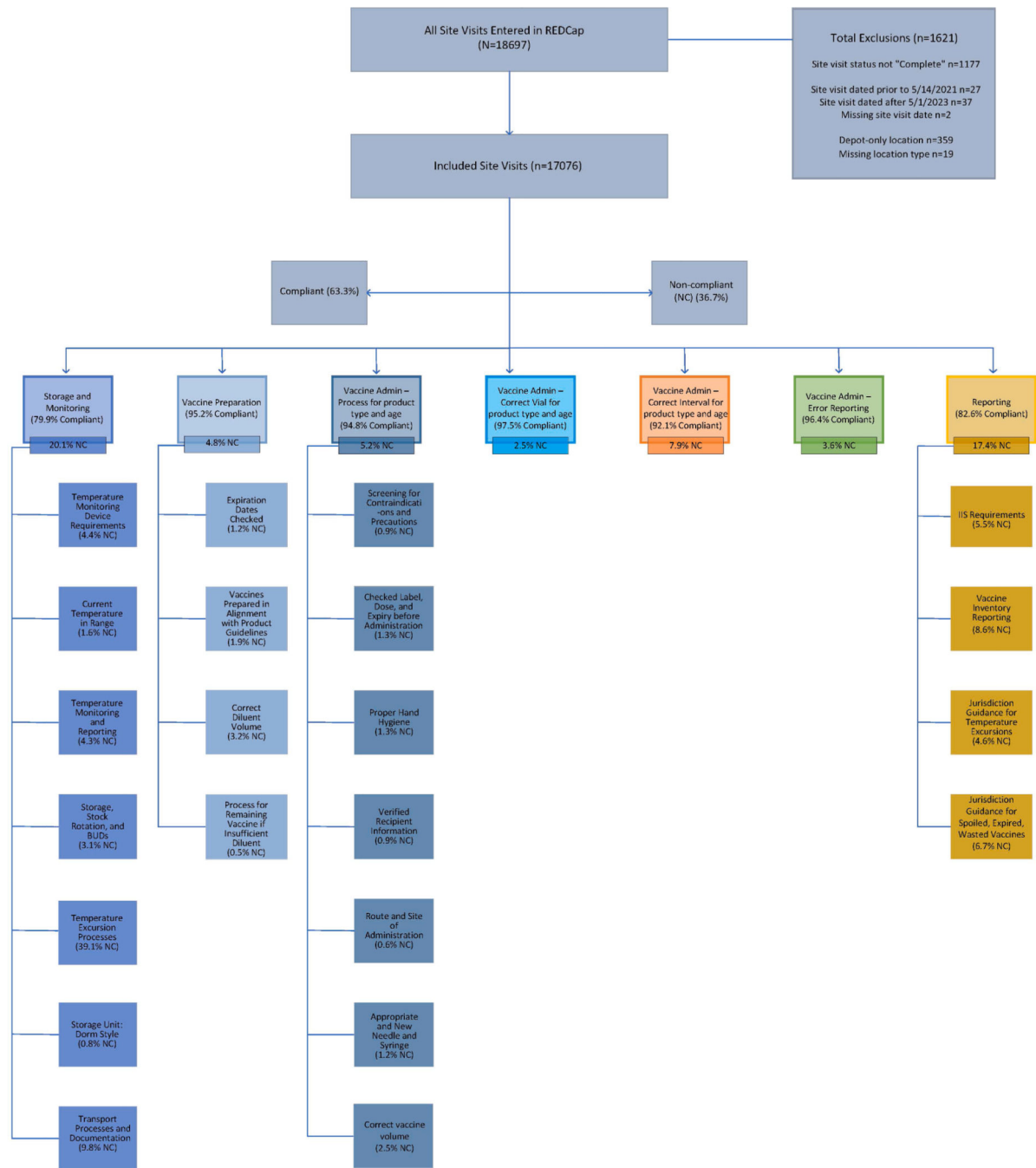
Fig. 2.

Overview of COVID-19 Vaccination Provider Oversight program site visits and compliance across compliance areas and sub-categories. Abbreviations: NC, Non-compliant; BUD, Beyond Use Date; IIS, Immunization Information System.

Table 1

Demographic characteristics of providers with completed COVID-19 Vaccination Provider Oversight program site visits.

Provider Type	Site Visit Method (n, %)[b]		Provider Function (n, %)[c]		Row Total (n, %)
	In-Person	Virtual	Store & Administer Provider Location	Depot Location	
Public Health Provider (includes FQHCs and RHCs)	3184 (20.5)	523 (27.1)	3630 (21.3)	77 (21.5)	3709 (21.3)
Commercial Vaccination Service Provider	126 (0.8)	7 (0.4)	127 (0.7)	6 (1.7)	133 (0.8)
State or Local Corrections/Detention	143 (0.9)	24 (1.3)	164 (1.0)	4 (1.1)	168 (1.0)
Health Center	1183 (7.6)	158 (8.2)	1322 (7.7)	19 (5.3)	1343 (7.7)
Home Health	82 (0.5)	8 (0.4)	89 (0.5)	1 (0.3)	90 (0.5)
Hospital	1522 (9.8)	248 (12.9)	1643 (9.6)	127 (35.4)	1770 (10.1)
IHS or Tribal	94 (0.6)	22 (1.1)	114 (0.7)	2 (0.6)	116 (0.7)
Long-Term Care	86 (0.6)	6 (0.3)	91 (0.5)	1 (0.3)	92 (0.5)
Medical Practice	5349 (34.5)	552 (28.7)	5876 (34.4)	20 (5.6)	5903 (33.8)
Pharmacy-Chain	591 (3.8)	19 (1.0)	598 (3.5)	11 (3.1)	610 (3.5)
Pharmacy-Independent	2127 (13.7)	200 (10.4)	2300 (13.5)	26 (7.2)	2328 (13.3)
Urgent Care	233 (1.5)	33 (1.7)	260 (1.5)	4 (1.1)	266 (1.5)
Other	680 (4.4)	109 (5.7)	728 (4.3)	60 (16.7)	789 (4.5)
Not assigned[a]	117 (0.8)	18 (0.9)	134 (0.8)	1 (0.3)	137 (0.8)
Column Total	15517 (88.9)	1927 (11.0)	17076 (97.8)	359 (2.1)	17454 (100.0)

Abbreviations: FQHC, Federally Qualified Health Center; RHC, Rural Health Clinic; IHS, Indian Health Service.

[a] Missing site visit provider type field.

[b] n = 10 missing.

[c] n = 19 missing.

Table 2

Provider compliance by provider type and compliance area among recipients of COVID-19 Vaccination Provider Oversight program site visits.[a]

Provider Type	Storage & Monitoring		Vaccine Preparation		Vaccine Administration-Process		Vaccine Administration-Correct Vial		Vaccine Administration-Correct Interval		Vaccine Administration-Error Reporting		Reporting[c]		Overall Compliance	
	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value
Public Health Provider (includes FQHCs and RHCs)	3198 (88.1)	(Ref.)	3452 (95.1)	(Ref.)	3465 (95.5)	(Ref.)	3545 (97.7)	(Ref.)	3407 (93.9)	(Ref.)	3518 (96.9)	(Ref.)	3164 (87.2)	(Ref.)	2639 (72.7)	(Ref.)
Commercial Vaccination Service Provider	94 (74.0)	<.0001	121 (95.3)	0.9267	115 (91.0)	0.0104	125 (98.4)	1.0000 *	122 (96.1)	0.3060	121 (95.3)	0.2930 *	92 (72.4)	<.0001	66 (51.9)	<.0001
State or Local Corrections/detention	105 (64.0)	<.0001	154 (93.9)	0.4907	153 (93.3)	0.1979	157 (95.7)	0.1174 *	145 (88.4)	0.0053	157 (95.7)	0.3953	119 (72.6)	<.0001	75 (45.7)	<.0001
Health Center	1105 (83.6)	<.0001	1253 (94.8)	0.6516	1258 (95.2)	0.6612	1294 (97.9)	0.6411	1227 (92.8)	0.1854	1272 (96.2)	0.2227	1107 (83.7)	<.0001	862 (65.2)	<.0001
Home Health	67 (75.3)	0.0003	86 (96.6)	0.8007 *	87 (97.8)	0.4370 *	89 (100)	0.2694 *	80 (89.9)	0.1261	85 (95.5)	0.3588 *	69 (77.5)	0.0077	52 (58.4)	0.0029
Hospital	1282 (78.0)	<.0001	1592 (96.9)	0.0030	1586 (96.5)	0.0715	1618 (98.5)	0.0537	1568 (95.4)	0.0215	1598 (97.3)	0.4929	1417 (86.2)	0.3606	1084 (65.9)	<.0001
IHS or Tribal	90 (78.9)	0.0033	107 (93.9)	0.5485	109 (95.6)	0.9358	110 (96.5)	0.3479 *	107 (93.9)	0.9990	109 (95.6)	0.4051 *	95 (83.3)	0.2306	71 (62.3)	0.0143
Long-term Care	64 (70.3)	<.0001	90 (98.9)	0.1303 *	89 (97.8)	0.4386 *	88 (96.7)	0.4756 *	78 (85.7)	0.0016	88 (96.7)	0.7593 *	84 (92.3)	0.1456	54 (59.3)	0.0049
Medical Practice	4737 (80.6)	<.0001	5554 (94.5)	0.2213	5512 (93.8)	0.0007	5710 (97.2)	0.1532	5270 (89.7)	<.0001	5595 (95.2)	<.0001	4646 (79.1)	<.0001	3531 (60.1)	<.0001
Pharmacy-Chain	478 (79.9)	<.0001	580 (97.0)	0.0413	577 (96.5)	0.2534	586 (98.0)	0.6123	557 (93.1)	0.5044	595 (99.5)	0.0003	533 (89.1)	0.1784	400 (66.9)	0.0034
Pharmacy-Independent	1605 (69.7)	<.0001	2205 (95.9)	0.1663	2178 (94.7)	0.1846	2244 (97.6)	0.8185	2117 (92.0)	0.0071	2246 (97.7)	0.0934	1868 (81.2)	<.0001	1333 (57.9)	<.0001
Urgent Care	172 (66.2)	<.0001	240 (92.3)	0.0481	240 (92.3)	0.0213	248 (95.4)	0.0231	228 (87.7)	0.0001	238 (91.5)	<.0001	191 (73.5)	<.0001	122 (46.9)	<.0001

Provider Compliance Area n (%) compliant, p-value[b] comparing compliant to non-compliant site visits

Provider Compliance Area n (%) compliant, *p*-value[b] comparing compliant to non-compliant site visits

Provider Type	Storage & Monitoring		Vaccine Preparation		Vaccine Administration-Process		Vaccine Administration-Correct Vial		Vaccine Administration-Correct Interval		Vaccine Administration-Error Reporting		Reporting c		Overall Compliance	
	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value	n (%)	*p*-value
Other	541 (74.3)	<.0001	706 (97.0)	0.0268	697 (95.7)	0.7329	718 (98.6)	0.1026	696 (95.6)	0.0667	713 (97.9)	0.1335	606 (83.2)	0.0047	459 (63.1)	<.0001
Not Assigned	104 (77.6)	0.0003	122 (91.0)	0.0354	122 (91.0)	0.0179	125 (93.3)	0.0057 [*]	118 (88.1)	0.0069	130 (97.0)	1.0000 [*]	110 (82.1)	0.0866	67 (50.0)	<.0001
Total	13642 (79.9)		16262 (95.2)		16188 (94.8)		16657 (97.5)		15720 (92.1)		16465 (96.4)		14101 (82.6)		10815 (63.3)	

Abbreviations: FQHC, Federally Qualified Health Center; RHC, Rural Health Clinic; IHS, Indian Health Service.

[a]Depicts completed site visits to store and administer provider locations.

[b]Chi-square test used unless otherwise noted.

[*]Fisher's exact test used.

[c]Includes immunization registry reporting, inventory reporting, temperature excursion, and vaccine wastage reporting.