

U.S. Department of Health and Human Services
Office of Inspector General



Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19

Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections
January 2023, OEI-05-22-00010





Why OIG Did This Review

Successful national vaccination campaigns and routine vaccination efforts depend on complete and timely vaccination data being available to State and local immunization programs. The Centers for Disease Control and Prevention (CDC) relies on State and local immunization programs to monitor vaccination coverage and to plan strategies to increase uptake among communities with low coverage. To fulfill this important role, immunization programs need complete and accurate individual-level vaccination data from all providers.

Comprehensive data are important for State and local immunization programs; however, two key types of providers are not required to submit individual-level data to immunization programs' databases: Federal agencies and retail pharmacies that partner with the Federal government. Combined, these two types of providers have already administered over 250 million COVID-19 vaccine doses.

How OIG Did This Review

In December 2021, we administered a survey to 56 State and local immunization programs that have immunization databases. We asked immunization programs whether they receive COVID-19 vaccination data from Federal agencies and retail pharmacy partners; whether they experience challenges in obtaining complete and accurate data; and how these challenges impact their vaccination campaigns, if at all.

Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19

Key Takeaway

Many State and local immunization programs reported having incomplete individual level data for the more than 250 million COVID 19 vaccine doses administered by Federal agencies and retail pharmacies that receive vaccines directly from CDC. These programs rely on individual level data in their immunization databases to manage vaccination campaigns.

What OIG Found

State and local immunization programs reported experiencing challenges in obtaining data for their immunization databases both from Federal agencies that provide vaccinations and from retail pharmacies that receive vaccines from CDC (to which we refer as retail pharmacy partners). As of December 2021, nearly all State and local immunization programs reported that they were not receiving individual-level data on vaccinations from at least one of the three Federal agencies with the largest vaccination programs: the Department of Veterans Affairs (VA), the Department of Defense (DoD), and/or the Indian Health Service (IHS). Most programs reported that they received data from retail pharmacy partners, but the data were often incomplete, inaccurate, or delayed. Federal agencies and retail pharmacy partners are not required to submit vaccination data to immunization programs.

Immunization programs said that without complete individual-level vaccination data, they struggled to accurately measure vaccination coverage and to target outreach to unvaccinated and vulnerable populations. Because State and local immunization databases contain data on all types of vaccinations, if left unresolved, these challenges will likely hinder the ongoing COVID-19 vaccination campaign, responses to future public health emergencies, and routine vaccination campaigns (e.g., flu shots).

State and local immunization programs said that they need help from CDC to obtain comprehensive vaccination data. Immunization databases are operated by 64 separate States, cities, and territories, with varying policies and technological capabilities. Federal agencies and retail pharmacy partners agreed to submit COVID-19 vaccination data either to State and local immunization databases or directly to CDC. CDC reported that it was determined that Federal agencies would transmit data directly to CDC only, rather than to immunization databases, because of policy and technical challenges that could not be resolved in the necessary timeframe. Retail pharmacy partners often do not share these challenges, and CDC reported encouraging them to submit data directly to immunization databases. The Federal government set up systems outside of State and local immunization databases to help share data that CDC receives with immunization programs, but the data it shares are aggregated, and programs reported that these aggregate data were not sufficient to comprehensively monitor their vaccination campaigns. To meet this need in the long term, CDC established and is working to set up the Immunization Gateway (IZ Gateway)—a data-exchange system intended to connect Federal agencies with immunization programs—but programs reported that it has been delayed. Given the complexity of collecting and sharing data across the many different stakeholders that make up the Nation's public health system, CDC has publicly called for updated data authority to better address public health concerns. However, there are steps CDC can take in the interim to help address immunization program needs.

What OIG Recommends and How the Agency Responded

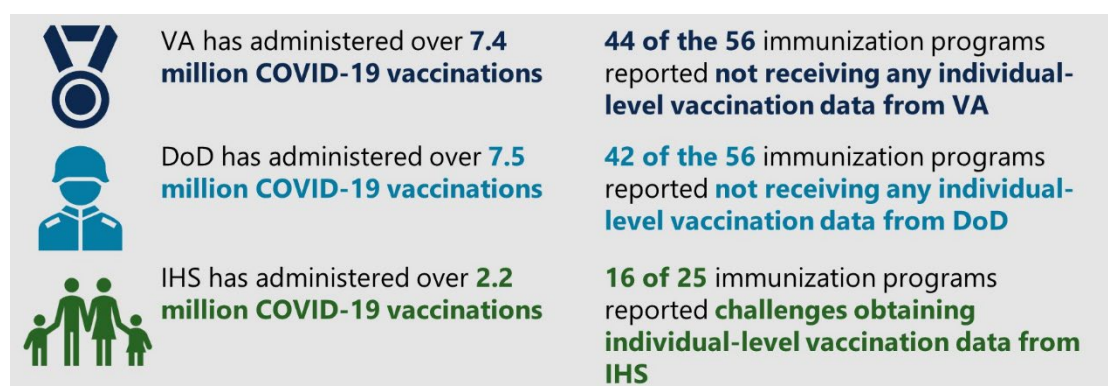
We recommend that CDC (1) work with State and local immunization programs, and retail pharmacy partners, to mitigate reported data gaps and timeliness challenges and (2) provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address vaccination campaign needs. CDC nonconcurred with our first recommendation and concurred with our second recommendation.

KEY FINDINGS

Challenges with data on vaccines administered by Federal vaccination providers hindered State and local immunization programs' efforts to comprehensively monitor COVID-19 vaccination coverage.

State and local immunization programs reported that they did not receive individual-level data on vaccines administered by Federal agencies.

Federal agencies may submit data either to State and local immunization databases or to CDC. However, CDC reported to OIG that it was determined that Federal agencies should submit data to CDC for efficiency related to policy and technical challenges in establishing connections to immunization databases. CDC shares aggregated Federal agency data with State and local immunization programs, but some programs reported that these aggregate data were not sufficient for individual-level monitoring.



Source: CDC COVID-19 Data Tracker, OIG analysis of survey results, 2022.¹

State and local immunization programs reported challenges with data on individual-level vaccine administration received from pharmacies that partner with the Federal government.

While Federal retail pharmacy providers may submit data either to immunization databases or to CDC, CDC reported to OIG that pharmacies were encouraged to submit vaccination data to immunization databases because many pharmacies already have connections established.



Source: CDC Federal Retail Pharmacy Program, OIG analysis of survey results, 2022.²

TABLE OF CONTENTS

| | |
|--|-----------|
| BACKGROUND..... | 1 |
| FINDINGS..... | 8 |
| Most State and local immunization programs did not receive individual-level data on vaccinations administered by at least one Federal agency, and programs reported challenges with the limited data received..... | 8 |
| Although most immunization programs received individual-level data on vaccines administered by retail pharmacy partners, many reported challenges with the data..... | 11 |
| With insufficient vaccination data, some immunization programs reported struggling to monitor vaccination campaigns, despite Federal efforts | 12 |
| CONCLUSION AND RECOMMENDATIONS..... | 17 |
| Work with State and local immunization programs and retail pharmacy partners to mitigate reported data gaps and timeliness challenges..... | 18 |
| Provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address vaccination campaign needs..... | 18 |
| AGENCY COMMENTS AND OIG RESPONSE | 19 |
| DETAILED METHODOLOGY | 20 |
| APPENDIX..... | 22 |
| Agency Comments | 22 |
| ACKNOWLEDGMENTS AND CONTACT | 25 |
| Acknowledgments..... | 25 |
| Contact..... | 25 |
| ABOUT THE OFFICE OF INSPECTOR GENERAL..... | 26 |
| ENDNOTES | 27 |

BACKGROUND

OBJECTIVE

Identify the extent to which the immunization databases of States and local immunization programs receive COVID-19 vaccination data from Federal agencies and retail pharmacy partners.

State and Local Immunization Databases

State and local health departments rely on Immunization Information Systems (IIS)—confidential, population-based, computerized databases that record information on immunization doses and are maintained by State and local immunization programs (hereinafter referred to as immunization databases).³ These immunization databases can help vaccination providers determine patient needs and assist in surveillance and program operations to guide public health.⁴ Immunization databases should combine immunization information from participating providers into a single record for each person residing or receiving vaccines in a given jurisdiction.⁵ Relying primarily on CDC funding, all 50 States, the District of Columbia, 5 other cities, and 8 territories each operate an immunization database.⁶ These databases collectively are the backbone for monitoring vaccinations during a national mass-vaccination campaign, such as the COVID-19 vaccination effort.^{7, 8}

According to the Centers for Disease Control and Prevention (CDC), these immunization databases play a critical role in monitoring COVID-19 vaccination administration and coverage estimates.⁹ As outlined in the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (the *Playbook*), CDC instructed State and local immunization programs to use their immunization databases to collect required data on vaccine administration and report those data to CDC.¹⁰ Required data include elements such as administration date, dose number, and recipient ethnicity.¹¹

CDC established functional standards and guidance for State and local immunization programs to improve immunization databases so that the databases are capable of achieving the vision of easily accessible real-time, consolidated immunization data.¹² For example, one standard states that databases should support public health response during disease outbreaks.¹³ Another standard states that databases should support immunization program activities during a public health emergency according to the jurisdiction's public health emergency plan.¹⁴ CDC conducts an annual survey of immunization programs about their databases,

using these functional standards to measure progress, identify areas for improvement, set program priorities, and influence policy-level decision making.¹⁵ Although jurisdictions rely primarily on CDC grants for IIS maintenance, operation, and enhancement, CDC does not require grantees to satisfy all standards as a condition of funding.¹⁶ Adherence to the functional standards is encouraged, but remains with each IIS program.¹⁷

The 64 immunization databases are operated by State and local immunization programs, and vary as to local reporting requirements, data-sharing policies, and system capabilities. For example:

- Some immunization programs operate under State laws or policies that prohibit sharing personally identifiable information about residents with the Federal government.¹⁸
- Some immunization databases do not have bidirectional data exchange capabilities, which limits the ability to share immunization data with providers and other immunization database users who need it.^{19, 20}
- Some immunization programs do not require vaccine providers to report data for individuals over the age of 19.²¹
- Some immunization programs do not require all pharmacists to report vaccinations administered to their immunization database.²²

CDC and others have highlighted the need for increased investment and authority related to public health data. CDC called for increased data modernization and authority to address data gaps created by receiving data from a variety of sources in inconsistent ways.²³ Specifically, CDC noted that updated data authority could improve CDC's legal ability to access secure public health data in a timely and coordinated way. Additionally, in March 2022 former CDC directors called attention to the lack of funding and legal authority needed for CDC to achieve accurate, timely, and comprehensive data.²⁴

Federal Agencies and Retail Pharmacy Partners

COVID-19 vaccine providers may receive their vaccine supply directly from CDC, from their respective local health departments, or from a combination thereof.²⁵ Two types of vaccination providers who receive some portion of their vaccine supply directly from CDC are (1) Federal agencies that provide vaccines and (2) retail pharmacies that partner with the Federal government as members of the Federal retail pharmacy partner program.^{26, 27}

Federal agencies and pharmacies that receive vaccines directly from CDC signed agreements which specified the conditions for receiving COVID-19 vaccines. These agreements state that Federal retail pharmacy partners and Federal agency providers should transmit data on vaccine administration either (1) to State and

local immunization databases or (2) to another system, as designated or agreed to by CDC. CDC told OIG that it was determined that Federal agencies would transmit data directly to CDC only, to allow efficient resolution of policy and technical requirements that could not have been achieved in the necessary timeframe at the individual immunization program level. However, many retail pharmacies were connected to State and local immunization databases prior to the COVID-19 vaccination campaign and CDC stated to OIG that it encouraged retail pharmacy partners to directly transmit vaccination data to State and local immunization databases. The signed agreements also outline timeliness expectations for transmitting vaccination data, stating that transmission should occur as soon as practicable, or within 72 hours, depending on the type of vaccination provider and jurisdictions' immunization database capabilities.

The number of these Federal agency and pharmacy partners providing vaccinations varies amongst immunization programs' jurisdictions, but they are widespread and represent a substantial portion of the data that immunization programs need. For example, while all jurisdictions may not have DoD facilities, VA is present in all States. Combined, these two agencies have administered over 14 million doses to veterans, active military, and other beneficiaries. All State and local immunization programs utilize the Federal retail pharmacy program to help administer vaccinations in their areas.²⁸ There are 21 pharmacy partners, representing 41,000 locations.²⁹ In addition to including large chain pharmacies (e.g., Walgreens, CVS) the program includes partners with a small number of stores and those which serve rural areas. As of March 2022, pharmacy partners receiving vaccines directly from CDC were responsible for 40 percent of all administered doses of COVID-19 vaccines.^{30, 31}

Federal agencies and pharmacy partners have administered over 250 million COVID-19 vaccinations nationally.

Of the five **Federal agencies that provide vaccinations**, these three have administered the most doses: the Department of Veterans Affairs (VA), the Department of Defense (DoD), and the Indian Health Service (IHS).



**VA has administered
7.4 million**

COVID-19 vaccinations to veterans, their spouses, and caregivers



**DoD has administered
7.5 million**

COVID-19 vaccinations to service members and eligible civilians



**IHS has administered
2.2 million**

COVID-19 vaccinations to American Indians and Alaska Natives

There are over 41,000 **retail pharmacy partners** that receive COVID-19 vaccines directly from CDC.



**Retail pharmacy partners have administered over
234.9 million**

COVID-19 vaccinations

Sources: CDC COVID-19 Data Tracker, CDC Federal Retail Pharmacy Program.^{32, 33}

Immunization Gateway (IZ Gateway)

The Immunization Gateway (IZ Gateway) development began prior to the pandemic as a Health and Human Services (HHS) pilot project with the focus of facilitating interstate vaccine administration data exchange.^{34, 35} In the *Playbook*, CDC described the IZ Gateway as a tool for (1) Federal agencies to share immunization data with State and local immunization programs, and (2) sharing among different State and local immunization databases.³⁶ CDC told OIG that it is not currently planning to use the IZ Gateway to share data between immunization programs and retail pharmacies because most pharmacies can already exchange data with State and local immunization databases. CDC identified connecting immunization databases to the IZ Gateway as an immediate priority in the *Playbook*.³⁷ However, connecting these systems has been a complex process that encountered setbacks during the campaign.^{38, 39}

Once a jurisdiction or Federal agency provider is connected, the IZ Gateway can provide access to patient-identifiable vaccination records, which is important for immunization programs. For example, once a Federal agency is connected to the IZ Gateway, the agency can report and query any vaccination data with multiple State and local immunization programs.⁴⁰ Additionally, multijurisdictional providers and immunization programs can query the IZ Gateway to obtain an individual's full

immunization history across States and localities.⁴¹ Immunization programs need identifiable records to link with existing data in their immunization databases and perform functions such as facilitating authorized access to vaccination records by individuals and their providers.

Tiberius

Tiberius is a platform created specifically for the COVID-19 pandemic that pulls data from various sources to display aggregated, deidentified information related to manufacturing; supply chain; allocation; and delivery and administration of vaccines. Tiberius was developed for Operation Warp Speed (later renamed Countermeasures Acceleration Group (CAG)), the collaboration of the Department of Defense (DoD) and HHS. When CAG was dissolved in December 2021, management of Tiberius was transitioned to CDC.⁴² Tiberius provides a zip code view of priority populations and provides tools to assist State and local immunization campaigns in decision making.⁴³ Tiberius integrates COVID-19 vaccination data from several systems, such as data that Federal agencies and retail pharmacy partners submit to CDC.

The Federal government offered technical assistance and other opportunities to State and local immunization programs to help them use Tiberius for their vaccination campaigns.⁴⁴ CDC reported to OIG that regular trainings in addition to office hours were offered to State and local immunization programs. If an immunization program reported challenges reconciling data between its immunization database and Tiberius, CDC offered support and, in some cases, a contractor. Additionally, in June 2022, following immunization programs' feedback asking for increased information about vaccinations provided by retail pharmacy partners, CDC informed jurisdictions that efforts to improve Tiberius and create a more efficient and unified presentation of retail pharmacy partner activity were beginning.

However, media outlets reported that State and local immunization programs struggled to leverage Tiberius for their COVID-19 vaccination campaigns. One program noted that the platform was complex and required multiple staff members to undergo training.⁴⁵ A second program reported that it was unable to use Tiberius to locate and map all critical populations.⁴⁶ Unlike the IZ Gateway, Tiberius does not provide access to patient-identifiable records.⁴⁷

CDC COVID-19 Data Tracker

CDC publishes a public online data dashboard, the COVID-19 Data Tracker, which includes aggregate information about vaccinations administered (e.g., vaccination coverage; vaccines administered by race/ethnicity, age, and sex; and vaccinations by county).⁴⁸ The information currently is updated weekly.⁴⁹ The tracker includes information submitted through State and local immunization databases, the Vaccine Administration Management System (VAMS), and direct data submissions.⁵⁰ VAMS is an online tool to manage vaccine administration available to enrolled

jurisdictions, Federal agencies, and organizations that do not have existing systems to report data on COVID-19 vaccine administration.⁵¹ CDC does not share any personally identifiable information.⁵²

Related Work

In conjunction with this work, OIG issued *Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs* (OEI-04-21-00190), which provides a broader review of challenges faced by State and local immunization programs in the early stages of the COVID-19 vaccination including (1) achieving logistical efficiency, (2) obtaining complete vaccine data from all providers, (3) combating vaccine hesitancy with public health messaging, and (4) overseeing vaccine providers.

OIG recommended that CDC (1) update mass vaccination program plans with strategies that address awardee-reported logistical challenges; (2) strengthen reporting of vaccine allocation and administration data; (3) clarify roles and responsibilities within HHS for vaccine public health messaging during a pandemic; and (4) work with State and local immunization programs to enhance current and future capabilities for provider training and oversight.

Methodology

To understand how many State and local immunization programs were receiving data, in December 2021 we administered an online survey to 56 State and local immunization programs that have immunization databases. These included all 50 States and the 6 cities (Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio) that operate an immunization database. We did not survey the eight territories with an immunization database. We asked immunization programs whether they receive COVID-19 vaccination data from Federal agencies that provide vaccinations and retail pharmacies partnered with CDC, and whether they experience challenges obtaining complete and accurate data. We also asked programs how missing or inaccurate data affects local vaccination campaigns, if at all. We did not ask State and local immunization programs about their immunization database technical capabilities or reporting requirements. We did not survey Federal agencies or retail pharmacy partners.

Limitations

Our analysis relied only on self-reported data from State and local immunization programs. We did not independently verify information received from immunization programs. We followed up with programs to clarify responses only when their survey results were unclear.

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

Most State and local immunization programs did not receive individual-level data on vaccinations administered by at least one Federal agency, and programs reported challenges with the limited data received

As of December 2021, 52 out of 56 State and local immunization programs reported not receiving any individual-level vaccination data from at least one of the following Federal agencies that provide vaccinations: VA, DoD, and/or IHS.⁵³ Further, immunization programs reported that when they did receive vaccination data from these Federal agencies, the data were often untimely or incomplete.

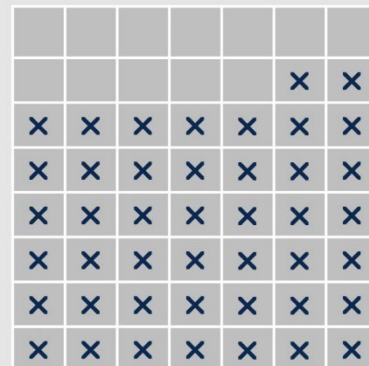
CDC does not require Federal agencies to submit individual-level vaccination data directly to State and local immunization databases. Federal agencies' signed agreements with CDC state that vaccination data must be transmitted either to State and local immunization databases or to another system as agreed upon. CDC told OIG that it was determined that Federal agencies would report directly to CDC only, due to policy and technical limitations. State and local immunization databases are designed for individual-level data about vaccine doses and the residents who received them. CDC provides aggregated (i.e., zip-code-level) summaries of COVID-19 vaccine doses administered by the Federal agencies, but this information cannot be integrated directly into State and local immunization databases.⁵⁴

Most immunization programs reported not receiving individual-level data on vaccinations administered by Veterans Affairs or Department of Defense providers

Forty-four State and local immunization programs reported not receiving any individual-level data on COVID-19 vaccinations administered by VA, and 42 reported not receiving this data from DoD.

Pre-existing data-sharing policies may limit an agency's ability to share data on vaccine administration with a State or local immunization program. For example, one immunization program reported that VA maintained that its patients must consent before their data can go to the immunization database. In one State, the governor enacted an executive order requiring VA to transmit data to the State's immunization database.⁵⁵ An additional immunization program reported being told that VA's current privacy policy does not allow the sharing of health data unless there is a State mandate.

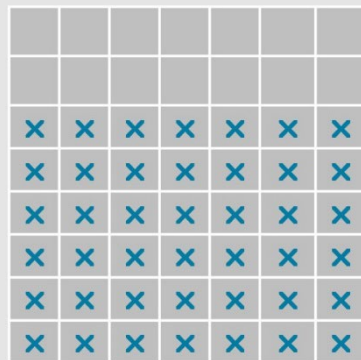
44 of the 56 immunization programs reported **not receiving any data** from VA providers



Source: OIG analysis of survey data, 2022.

Immunization programs reported similar challenges with DoD, citing DoD confidentiality and privacy concerns. For example, one immunization program reported that DoD clinics are hesitant to share data on vaccine administration without expressed approval from leadership although DoD has released COVID-19 case data to comply with the State's law. Further, one program specifically stated that there is no requirement for DoD to share data with its local immunization database, and any data obtained is due to local entities building relationships with organizations in their jurisdiction.

42 of the 56 immunization programs reported **not receiving any data** from DoD providers



Source: OIG analysis of survey data, 2022.

Of the smaller group of State and local immunization programs that reported receiving some data from VA or DoD, most reported that their immunization databases do not receive timely transmissions on a regular basis. Instead, these programs sometimes reported that VA and DoD occasionally submitted files for batch upload or that providers manually entered data directly into the immunization database. For example, one immunization program reported that VA only manually uploads a file upon request of the immunization program. Similarly, one program reported relying on data being manually entered into the local database by DoD providers.

VA and DoD data may be of special importance for those State and local immunization programs with large veteran and military populations. Veterans comprise more than 10 percent of the adult population in Alaska, Virginia, and Montana.⁵⁶ Additionally, North Carolina is home to the largest military base in the world and has an estimated 113,000 active duty and reserve personnel.^{57, 58} One immunization program that reported having a

large veteran population stated that not having data directly from VA created serious quality issues when the immunization program tried to create a complete picture of vaccination coverage.

Most immunization programs reported receiving individual-level data on vaccines administered by IHS providers, but many reported challenges

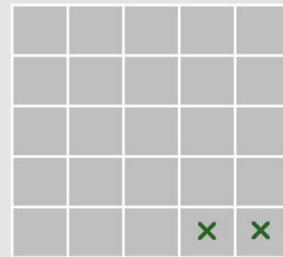
In contrast to VA and DoD, most immunization programs reported receiving some vaccination data from IHS, but many programs also reported that IHS data received were incomplete. Of the 25 State and local immunization programs with documented IHS facilities, 2 reported not receiving any data at all, and 14 reported challenges, such as with obtaining data from all IHS providers.^{59, 60} Only nine of these immunization programs reported receiving data from IHS and did not report challenges in obtaining all the data needed.

Some of the 14 State and local immunization programs that received data but reported challenges attributed these challenges to IHS facilities' differing technological capabilities.

Some facilities may have an electronic health record (EHR) that can more easily be connected into an immunization database for automatic submission. One program suggested that this technological difference was dependent on whether a facility is IHS- or Tribally operated, noting that Tribal facilities were not always supported by compatible data-exchange systems and may have faced greater challenges establishing connection with the immunization database. Additionally, immunization programs reported that connecting IHS facilities to their database was challenging because each location must connect to the database individually, requiring testing and troubleshooting unique to each facility.

Although not all jurisdictions have IHS facilities, their immunization programs may need data from IHS facilities outside of their area. American Indians and Alaska Natives (AI/ANs) may receive care at any hospital or clinic.⁶¹ For example, one immunization program noted that Tribal lands sometimes span multiple States and therefore the program worked with out-of-State IHS facilities to ensure full coverage. Complete IHS data may be particularly important for certain jurisdictions with high concentrations of AI/AN populations or where a single Tribal land may cover multiple jurisdictions. For example, the Navajo administrative unit alone serves 224,000 individuals and has facilities in Arizona, New Mexico, and Utah.⁶²

2 of the 25 immunization programs reported **not receiving any data** from IHS providers



14 programs reported **challenges obtaining data**

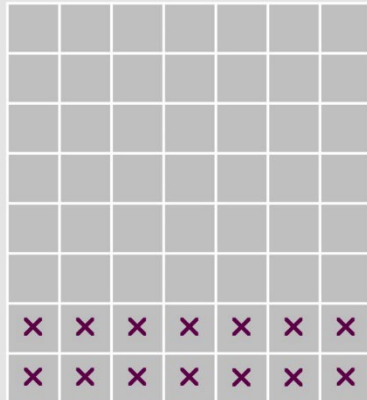
Source: OIG analysis of survey data, 2022.

Although most immunization programs received individual-level data on vaccines administered by retail pharmacy partners, many reported challenges with the data

As of December 2021, 42 State and local immunization programs reported that they received at least some patient-level data directly from all of the pharmacy partners offering vaccinations in their jurisdiction. However, 14 State and local immunization programs reported not receiving any individual-level data from at least one retail pharmacy partner active in their area. One immunization program estimated that its immunization database was missing information on 400,000 doses from retail pharmacy partners at the time of our survey. Moreover, many immunization programs reported quality or timeliness challenges with the data they did receive. Retail pharmacy partners signed agreements with CDC that state that vaccination data must be transmitted either to State and local immunization databases or to another system determined by CDC, and CDC reported to OIG that it encouraged retail pharmacy partners to report to local immunization databases.

Many immunization programs reported challenges with vaccination data from pharmacies, such as with timeliness, accuracy, and completeness

14 of the 56 immunization programs reported **not receiving any data** from at least one retail pharmacy partner



 **30 programs** received **untimely, inaccurate, or incomplete data**

Source: OIG analysis of survey data, 2022.

Thirty immunization programs reported challenges with vaccination data received from pharmacy partners, including receiving untimely, inaccurate, or duplicate data, or not receiving all vaccination records from a pharmacy that was otherwise submitting data.

Some immunization programs noted that retail pharmacy partners sometimes simply failed to submit data in a timely fashion. One program reported that some doses were not reported until months after the actual administration date.

State and local immunization programs also sometimes reported various concerns about the accuracy and completeness of data received. For example, immunization programs reported that they discovered patterns of deleted doses, missing data elements, and duplicate reporting. One immunization program reported that even after working with the pharmacy partners in an effort to resolve these challenges, the program may still be left with inaccurate data.

Additionally, some State and local immunization programs reported that retail pharmacy partners sometimes experienced interruptions with their data transmissions. Some immunization programs attributed missing records to delayed or interrupted data transmissions. One immunization program stated that when data transmissions were interrupted, it was unable to recover all data reported during the interruption. Without being able to recover this data, immunization programs are left with records missing. Further, resolving the interruption may require that immunization program staff provide technical assistance to pharmacies, where pharmacy staff often did not know why the transmission was interrupted.

Some immunization programs reported that missing or untimely pharmacy vaccination data may be related to third-party data-sharing vendors

Retail pharmacies sometimes partner with third-party vendors to manage data-sharing systems for reporting to State and local immunization programs, and immunization programs noted that these vendors might have caused some data challenges. For example, one immunization program reported that a vendor is responsible for data transmissions but the vendor's system sometimes went down for days at a time. After the connection issue was resolved, the immunization program said that it struggled to obtain the records missing because of the downtime. Another immunization program noted that if a patient scheduled an appointment but then canceled and rescheduled, the vendor might transmit both a record for the canceled appointment and a record for the rescheduled appointment that occurred, resulting in more records for vaccine administration than a patient received. Finally, one program attributed inaccurate dates of administration to a vendor that used the billing date instead of the administration date.

Fourteen State and local immunization programs reported that many of the data challenges experienced were associated with one common third-party vendor. Immunization programs reported that this vendor works with some of the country's largest pharmacy chains. Given that this vendor works with these large chains, this single vendor is likely responsible for transmitting a great deal of retail pharmacy data.

With insufficient vaccination data, some immunization programs reported struggling to monitor vaccination campaigns, despite Federal efforts

Without complete and reliable individual-level data from all Federal agencies and pharmacy partners, many immunization programs reported facing challenges managing effective vaccination campaigns. While Federal agencies and retail pharmacy partners are not required to submit data directly to immunization databases, State and local immunization programs reported that incomplete data

hindered their efforts to estimate vaccination coverage rates, effectively plan strategic targeted interventions, and provide vaccination records to individuals and providers.

Difficulty estimating coverage rates



Nearly half of all Americans age 75 or older are veterans.⁶³

Many of these older veterans are eligible for VA health care services, including vaccinations.

Without VA data, one immunization program said, it could not accurately estimate vaccination rates for its older populations.

Some immunization programs reported being unable to accurately estimate vaccination coverage rates without complete and timely vaccination data from all providers. Vaccination coverage is the estimated percentage of people in a community who have received vaccines.⁶⁴ Monitoring vaccination coverage, through data on vaccine administration, allows immunization programs to track and measure the success of their efforts.

When data are missing or inaccurate, immunization programs cannot confidently determine these estimates. For example, one immunization program reported that data missing from retail pharmacies affected its total vaccination count and the vaccination numbers it reported to the public. Another immunization program reported that without data from Federal agencies that provide

vaccinations, it had difficulty accurately estimating vaccination coverage for counties with large military populations.

Although CDC makes Federal agency and pharmacy partner data available at the aggregate level through Tiberius and the public COVID-19 Data Tracker, some immunization programs noted differences in the aggregate data and the programs' databases. Some immunization programs reported that the vaccination coverage estimates in their databases were smaller than CDC's estimates. One immunization program added that CDC's publicly reported estimates may also have been larger because a person who received their first dose from a Federal provider and their second from a non-Federal provider could have been counted as two different individuals who received their first doses, not as a single fully vaccinated person. CDC commented that a number of factors may contribute to such discrepancies and some of them are not solely under Federal control, such as incomplete or inaccurate data maintained by State and local immunization programs.

Challenges in targeting outreach to unvaccinated and vulnerable populations



Most Americans live within 5 miles of a pharmacy.

CDC partnered with 21 retail pharmacies and their 41,000 retail locations across the country because pharmacies can reach people who cannot access other providers easily, such as rural Americans.^{65, 66}

Rural Americans are at higher risk of death from COVID-19, so increasing vaccination rates in remote areas is key.⁶⁷ Without complete and accurate data from retail pharmacies, **State and local immunization databases are potentially missing vaccination records for some Americans disproportionately affected by COVID-19.**

Some immunization programs reported using data to systematically identify communities with low vaccination coverage to plan local pop-up vaccination clinics, target vaccination marketing campaigns, or conduct other outreach aimed at increasing vaccination rates. However, without the data needed, some State and local immunization programs reported struggling to plan and enact strategic targeted interventions.

Some immunization programs reported that incomplete data limited their ability to promote health equity because the programs could not accurately identify vaccination disparities between demographic groups. For example, one immunization program reported that without data from VA, DoD, and IHS, it could not accurately calculate vaccine rates or provide vaccination records for special populations, such as Tribal members and their families; rural communities; and veterans experiencing homelessness. Immunization programs specifically described the importance of IHS data to monitor vaccination coverage of American Indians and Alaska Natives (AI/ANs), a demographic group at high risk for the

negative impacts of COVID-19. AI/ANs have historically experienced a lower life expectancy and disproportionate disease burden compared to other Americans, and AI/ANs are nearly twice as likely to die from COVID-19 as are White Americans.^{68, 69}

Some immunization programs also conducted outreach to individual residents, but incomplete vaccination records made it difficult to efficiently and correctly identify unvaccinated or partially vaccinated residents who would benefit from reminders. For instance, one immunization program said that it sent out reminder letters to all unvaccinated older residents using data in its immunization database, but then it received many calls from individuals who informed the program that they had already been vaccinated by Federal agencies. Similarly, another immunization program noted that incomplete data limit its ability to conduct any outreach about booster needs.

Inability to provide up-to-date records to individuals and providers

Some immunization programs reported not being able to provide records to residents when requested because these residents had been vaccinated by Federal agency or retail pharmacy providers that did not report to immunization databases. Without complete vaccination data, immunization programs cannot always provide

accurate individual vaccination records when requested by residents and health care providers. For example, one immunization program said that it received reports of residents who requested a second or third COVID-19 vaccine dose but faced challenges when vaccination providers could not find evidence of earlier doses in the immunization databases. One purpose of State and local immunization databases is to offer up-to-date vaccination records for individual residents and health care providers, and residents sometimes inquire about obtaining proof of their vaccination status.

Lack of comprehensive information on vaccination providers

Some immunization programs reported not knowing that lists of all Federal agency providers providing vaccinations in the programs' jurisdiction were available. Without comprehensive information about all providers operating in their jurisdiction, State and local immunization programs do not know the extent to which the program is missing vaccination data. CDC indicated that it would notify programs of any Federal providers that enroll directly with CDC to receive and dispense vaccinations.⁷⁰ Additionally, CDC stated that immunization programs can access lists of enrolled providers in Tiberius.

The Federal government is making efforts to share vaccination data from Federal providers, but immunization programs reported that these efforts had not yet met program needs

CDC and other parts of the Federal government have taken steps to provide immunization programs with data from Federal agencies. However, these efforts did not yet offer all the data that immunization programs needed.

The Federal government made aggregate data available, but immunization programs reported that those data did not provide sufficient individual-level details to fully meet immunization programs' needs

The Tiberius data system provides State and local immunization programs with the Federal government's aggregate, deidentified counts of the total number of vaccines administered by Federal agencies and pharmacy partners.⁷¹ Tiberius also offers aggregate equity and social vulnerability metrics at the zip-code level. However, some programs reported still being unable to confidently estimate vaccination coverage because they could not compare this deidentified data against their own individual-level data records to resolve data discrepancies such as doses that were accidentally recorded twice. Aggregate data also did not provide the type of detail that immunization programs needed to support all vaccination-campaign efforts. For example, one immunization program said that the available aggregate Federal agency data did not allow a sufficiently granular breakdown for use in small-scale health equity promotions. And because aggregate data cannot be used to update records for individual residents, it does not help State and local immunization programs

ensure that they provide residents and health care providers with accurate vaccination records.

The current Federal immunization data exchange solution will likely solve many issues with Federal agency data, but this solution was delayed and may have outstanding challenges

Immunization programs acknowledged that CDC is actively working on setting up the IZ Gateway as a solution to support the exchange of vaccination data between Federal agencies and State and local immunization databases. Some immunization programs anticipated that the IZ Gateway will help them obtain some or all of the data needed from Federal agencies.

At the time of our survey in December 2021, the IZ Gateway was not yet operational for the exchange of immunization data between Federal agencies and all State and local immunization databases, but the process has since progressed. Some of these immunization programs reported being in the process of setting up agreements with VA and CDC to share data through the IZ Gateway in the future. In May 2022, CDC reported that 1 immunization program was actively exchanging data with VA, and CDC reported that as of November 2022, 23 immunization programs were doing so.

In addition, other immunization programs expressed concerns that they will not be able to connect to the IZ Gateway system when it is ready because of potential technical limitations of their immunization databases. For example, some immunization programs said that the software company contracted to build and maintain their immunization database systems had indicated that it may opt out of participating in the IZ Gateway. Twelve immunization programs reported using this software company for their immunization database systems. If this company opts out of the IZ Gateway, these immunization programs may not be able to exchange immunization data via the IZ Gateway.

CONCLUSION AND RECOMMENDATIONS

High-quality, comprehensive data on vaccine administration are essential for State and local immunization programs to protect the health and well-being of the populations they serve. The COVID-19 pandemic highlighted the public health need for this data. Immunization programs need individual-level vaccination data to estimate coverage rates, identify populations in need of vaccines, and protect those at higher risk of negative health outcomes. However, nearly all programs reported challenges in obtaining individual-level data on COVID-19 vaccinations administered by Federal agencies and retail pharmacy partners, with many receiving no individual-level data at all on vaccinations administered by Federal agencies.

Vaccine data sharing is complex, as it involves many stakeholders with different policies and technical capabilities. Prior to the pandemic, CDC recognized the need for a long-term solution to facilitate comprehensive sharing of individual-level vaccine data, but that solution was not in place when the public health emergency began. Federal agencies and retail pharmacy partners were not required to submit individual-level COVID-19 vaccination data directly to immunization databases, given existing policy and technical limitations. To help meet the immediate need for immunization program oversight of COVID-19 vaccinations, CDC made available aggregate data, which can be helpful but are not entirely sufficient for vaccination monitoring.

CDC is actively working to set up the IZ Gateway as a long-term solution to connect Federal agencies with State and local immunization databases, and to connect different State and local immunization databases with one another. Congress and CDC are also considering changes to immunization databases and the authorities that govern how public health data are collected and shared.^{72, 73} These efforts to facilitate data sharing on vaccination administration, for the COVID-19 vaccination campaign as well as for other emerging infectious diseases and routine vaccinations (e.g., flu vaccines), may address challenges described by State and local immunization programs. Recent concerns about the threat of mpox—another infectious disease with available vaccines—underscore the urgency of improving vaccination data sharing. There are additional steps CDC can take to help meet immunization programs' needs, beyond prioritizing the completion of the IZ Gateway. We recommend that CDC:

Work with State and local immunization programs and retail pharmacy partners to mitigate reported data gaps and timeliness challenges

CDC should take action to improve the data immunization programs receive from retail pharmacy partners. CDC should, at minimum, facilitate solutions to sizable gaps in reporting from retail pharmacy partners to State and local immunization programs. For example, CDC could prioritize the 14 immunization programs that reported not receiving any data from at least one retail pharmacy partner present in their jurisdiction. CDC could clarify expectations and facilitate better data reporting for the COVID-19 vaccination campaign and future vaccination efforts. To further improve data quality and transmission timeliness, CDC could also work with the third-party vendors that contract with major national pharmacy chains to identify improvements.

OIG's companion work, *Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs* (OEI-04-21-00190), also recommends that CDC develop strategies to improve vaccine administration data. Specifically, that recommendation states that CDC should define and communicate data quality standards for providers and require that immunization programs develop an approach to provide routine data quality feedback to all providers of IIS reporting. Further, that recommendation states that CDC should continue to work with immunization programs on the collection of complete and accurate race and ethnicity data. This report's findings also support that recommendation.

Provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address vaccination campaign needs

CDC should offer updated educational opportunities to ensure that immunization programs understand how existing tools can assist in their COVID-19 vaccination campaigns. These opportunities could include webinars or publication of a frequently-asked-questions document about how to leverage data sources outside of immunization databases, such as Tiberius and the COVID-19 Data Tracker, to address gaps reported to OIG. For instance, CDC could instruct immunization programs on how to access complete lists of Federal agency and retail pharmacy providers through Tiberius.

AGENCY COMMENTS AND OIG RESPONSE

CDC nonconcurred with our first recommendation and concurred with our second recommendation.

In nonconcurring with our first recommendation—that CDC should work with State and local immunization programs and retail pharmacy partners to mitigate reported data gaps and timeliness challenges—CDC indicated that it does not have the legal authority to standardize reporting across all jurisdictions. CDC stated that in the absence of a Federal mandate for all vaccination events to be reported to IISs, IIS data will continue to be inconsistent. Specifically, CDC noted that some jurisdictions lack legal authority to collect and share pharmacy vaccination data, and that jurisdictions may not prioritize pharmacy connections to IISs because some pharmacies may have lower immunization volume than do other providers.

While OIG recognizes that limits on legal authority impact CDC's ability to ensure comprehensive vaccination data sharing across all jurisdictions, we continue to believe that CDC has opportunities to improve the data immunization programs receive from retail pharmacy partners. Indeed, CDC agreed that additional work with pharmacies is needed to ensure robust immunization data and stated that it continues to work with partners to address technological issues within IISs and pharmacy systems. OIG supports these efforts, and we encourage CDC to focus on immunization programs that reported the greatest gaps in data from Federal retail pharmacy partners.

In concurring with our second recommendation—that CDC should provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address vaccination campaign needs—CDC stated that it provides immunization programs with technical assistance; educational outreach; and information on where and how to find data. For example, CDC described conducting individual outreach to jurisdictions, holding regular office hours to solicit feedback on jurisdictions' needs, hosting webinars on its data systems, and issuing weekly reports on data quality. OIG believes that CDC could take additional steps to help immunization programs leverage data sources outside of immunization databases, such as providing instructions on how to access complete lists of Federal agency and retail pharmacy providers through Tiberius.

In technical comments, CDC also stated that concerns raised in our report regarding an immunization database software company potentially choosing not to participate in the IZ Gateway had been resolved.

For full text of CDC's comments, see the Agency Comments appendix at the end of the report.

DETAILED METHODOLOGY

For this data brief, we conducted a survey among State and local immunization programs and analyzed their responses.

Scope

We included 56 State and local immunization programs in our review. This includes all 50 States and the 6 cities (i.e., Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio) that operate an immunization database. We included all States and cities to ensure that we could provide comprehensive information about immunization data received by State and local programs from Federal agencies and retail pharmacy partners. We did not include the eight U.S. territories with immunization databases in this review.

Data Sources and Collection

In December 2021, OIG sent an online survey to State and local staff who manage immunization programs and immunization databases. All 56 States and localities responded to our survey. In February 2022, OIG followed up via email with seven immunization programs to request more in-depth information regarding unclear responses.

Survey questions

We used the survey to ask State and local immunization programs about data received from Federal COVID-19 vaccination providers. First, we asked whether programs receive data from (1) Federal agencies that provide vaccinations (VA, DoD, IHS, the Bureau of Prisons (BoP), and the Department of State) and (2) retail pharmacies participating in the Federal retail pharmacy partner program (e.g., Walgreens, CVS, Walmart), and how programs use this data in immunization campaigns.^{74, 75} We asked immunization programs to describe how data are received, either through (1) automated means (e.g., an electronic health exchange, or an HL7 system interface) or (2) other methods such as manual entry by providers or program staff, and any challenges with receiving data through either method. Additionally, we asked how State and local immunization campaigns are limited by incomplete data. Finally, we asked State and local immunization programs about how CDC or others could assist with these issues.

Data analysis

We analyzed surveys and followup emails to understand the data State and local immunization programs are receiving from Federal agencies and retail pharmacy

partners. First, we reviewed survey responses to understand whether State and local immunization programs received any data from Federal agency providers or retail pharmacy partners.

After determining whether State and local immunization programs received any data, we reviewed surveys to gain greater insight into how the data were received and any challenges with completeness, accuracy, and timeliness of the data.

We analyzed the surveys to identify how immunization programs use this data to administer their vaccination campaigns or any limitations their campaigns experience because of incomplete, inaccurate, or untimely data.

APPENDIX

Agency Comments



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

DATE: December 6, 2022

TO: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections

FROM: Rochelle P. Walensky, MD, MPH
Director, CDC Centers for Disease Control and Prevention (CDC)

SUBJECT: INFORMATION ONLY – CDC’s response to the Office of the Inspector General’s (OIG) draft report, “Challenges With Data From Federal Vaccination Partners Hinder Efforts by State and Local Immunization Programs To Combat COVID-19, OEI-05-22-00010” (the Report)

KEY INFORMATION

This memorandum is to inform you that CDC has responded to the Report by detailing the agency’s planned actions (TAB A). CDC appreciates the opportunity to review and comment on this report prior to the final release.

A handwritten signature in black ink, appearing to read "Rochelle P. Walensky", written over a horizontal line.

Rochelle P. Walensky, MD, MPH

Attachment

TAB A: CDC’s planned actions regarding recommendations

Centers for Disease Control and Prevention (CDC)’s planned actions in response to the Office of the Inspector General’s (OIG) draft report, “Challenges With Data From Federal Vaccination Partners Hinder Efforts by State and Local Immunization Programs To Combat COVID-19, OEI-05-22-00010” (the Report)

CDC appreciates OIG’s ongoing work on the Report and strongly supports state and local immunization program efforts to increase vaccination rates and reduce vaccine-preventable disease through ongoing data collection and monitoring using jurisdiction immunization information systems (IIS). As described in the OIG report, complete and timely vaccination data is important for immunization programs to successfully identify populations at high risk for vaccine-preventable diseases and target interventions and resources efficiently. IIS comprise the information systems, programs, people, and process associated with the system and is directly related to increasing vaccination rates and reducing vaccine-preventable disease. IIS uses confidential, population-based, computerized databases that record immunization doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, IIS provides consolidated immunization histories for use by a vaccination provider in determining appropriate patient vaccinations. IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goal of improving vaccination rates and reducing vaccine-preventable diseases. CDC plans to continue progress in IIS performance, standards, and sustainability; and in strengthening connections to and within the public health information technology environment.

OIG Recommendation (1)

OIG recommends CDC take action to improve the data immunization programs receive from retail pharmacy partners by:

- Facilitating solutions where there are sizeable gaps in reporting from retail pharmacy partners to state and local immunization programs. For example, CDC could prioritize the 14 immunization programs that reported not receiving any data from at least one retail pharmacy partner present in their jurisdiction.
- Clarifying expectations and facilitating data reporting for the coronavirus disease 2019 (COVID-19) vaccination campaign and future vaccination efforts.
- Working with third-party vendors that contract with major national pharmacy chains to identify improvements.

CDC Response: CDC nonconcur with OIG’s recommendation.

CDC agrees that additional work with pharmacies is needed to ensure robust reporting of immunization data to IIS. CDC continues to work with IIS partners to address technological issues within the IIS and/or pharmacy systems. However, the ecosystem in which IIS operate is complicated by the web of policies and regulations that govern IIS reporting. IIS policies and regulations are enacted at the state and local levels, and CDC does not have the legal authority to standardize reporting across the nation. IIS policies govern the reporting entities (i.e. who reports to the jurisdiction IIS), what data may be collected, what type of consent is required to collect data, and what data may be shared. Currently, some jurisdictions are limited in their ability to collect and share data from pharmacies because they do not have the legal authority to do so, per

state and local regulations. In other cases, jurisdictions may prioritize pharmacies lower in their onboarding queues to focus on high-volume providers of routine immunizations. Ensuring sustainable and diverse mechanisms of financial support, a trained workforce, and adequate reporting authorities would enhance pharmacy data collection and reporting to the IIS. In the absence of a federal mandate for all vaccination events to be reported to the IIS for population health monitoring, IIS data will continue to be inconsistent across the nation.

OIG Recommendation (2)

OIG recommends CDC offer updated educational opportunities to ensure immunization programs understand how existing tools can assist in their COVID-19 vaccination campaigns. These could include webinars or the publication of a frequently asked questions document about leveraging data sources outside of immunization databases, such as Tiberius and the COVID-19 Data Tracker, to address gaps reported to OIG. For example, CDC could instruct immunization programs to access complete lists of federal agency and retail pharmacy providers through Tiberius.

CDC Response: CDC concurs with OIG's recommendation.

CDC agrees that ongoing outreach to ensure awareness of existing tools and data is helpful to jurisdictions. CDC provides technical assistance, educational outreach, and information on data systems (e.g. where and how to find data). This includes individual outreach to jurisdictions by assigned project officers and subject matter experts to provide customized technical assistance, regular webinars on data systems (e.g., HHS-CAG webinars on Tiberius, CDC webinars on the Immunization Data Lake, Data Clearinghouse, Immunization Gateway, etc.), available reports (e.g., provider data, partner administration data), resources and guidance, weekly data quality reports to highlight areas of concern and suggested steps for improvement, and regular office hours to answer questions and solicit feedback on jurisdiction needs. CDC does not own jurisdiction, participating partners, or other federal agency systems and must rely on system owners to determine the training needs of their users but does provide communications and access to training materials, when feasible.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Jonathan Jones, Samantha Handel-Meyer, and Kayla Phelps served as the team leaders for this study. Others in the Office of Evaluation and Inspections who conducted the study include Danielle Noriega and Alexandra Roehll. Office of Evaluation and Inspections headquarters staff who provided support include Kalliane Davidson, Althea Hosein, Christine Moritz, and Sara Swisher.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Lauren Buss, Evan Godfrey, Dwayne Grant, and Rebekah Schwartz.

This report was prepared under the direction of Laura Kordish, Regional Inspector General for Evaluation and Inspections in the Chicago regional office; Adam Freeman, Deputy Regional Inspector General; and Hilary Slover, Assistant Regional Inspector General.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

ENDNOTES

¹ CDC, *Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities*, as of May 4, 2022. Accessed at [CDC COVID Data Tracker: Vaccinations in the US](#) on May 4, 2022.

² CDC, *Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities*, as of May 4, 2022. Accessed at [CDC COVID Data Tracker: Vaccinations in the US](#) on May 4, 2022.

³ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, Section 11: COVID-19 Requirements for Immunization Information Systems of Other External Systems, page 38. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on May 14, 2021.

⁴ CDC, *About Immunization Information Systems*. Accessed at [About Immunization Information System \(IIS\) | CDC](#) on June 9, 2022.

⁵ CDC, *Immunization Information Systems Functional Standards (IIS)*, v4.1. See Essential Infrastructure Functional Standards 1, 1.1, 1.3, and 1.4. Accessed at [IIS Functional Standards v4.1 | CDC](#) on October 1, 2021.

⁶ CDC, *Immunization Information Systems Annual Report (IISAR) Data Overview*. Accessed at [IISAR Annual Report Data Overview | CDC](#) on May 11, 2021.

⁷ During the 2009 H1N1 pandemic, IISs were leveraged extensively to support mass vaccination efforts. See American Immunization Registry Association (AIRA), *Mass Vaccination Capabilities Summary*, page 5. Accessed at [Mass Vaccination Capabilities Summary \(memberclicks.net\)](#) on September 30, 2021.

⁸ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems, page 38. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on May 14, 2021.

⁹ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, page 63, Appendix D. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on April 27, 2021.

¹⁰ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, page 39. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on April 27, 2021.

¹¹ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, pages 63-64. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on April 27, 2021.

¹² CDC, *Immunization Information System (IIS) Strategic Plan*. The 2018-2020 Strategic Plan builds on the prior plan from 2014-2017. In addition to population-level goals, the plan supports goals for the point of clinical care that support use by vaccination providers in determining appropriate patient vaccinations. Accessed at [IIS 2018-2020 Strategy Initiative and Plan Introduction | CDC](#) on June 9, 2022.

¹³ CDC, *Immunization Information Systems (IIS) Functional Standards, v4.1*. See Essential Infrastructure Functional Standard 14. Accessed at [IIS Functional Standards v4.1 | CDC](#) on September 13, 2022.

¹⁴ CDC, *Immunization Information Systems (IIS) Functional Standards, v4.1*. See Essential Infrastructure Functional Standard 17. Accessed at [IIS Functional Standards v4.1 | CDC](#) on September 13, 2022.

¹⁵ CDC, *Immunization Information Systems Annual Report (IISAR) Data Overview*. IISAR data from 2012-2019 are currently publicly available. Accessed at [IISAR Annual Report Data Overview | CDC](#) on June 9, 2022.

¹⁶ Congressional Research Service, *Immunization Information Systems: Overview and Current Issues*, February 1, 2022. Accessed at [R47024 \(congress.gov\)](#) on September 12, 2022.

-
- ³¹ As of April, 7, 2022, 563.4 million total doses had been administered. CDC, *COVID-19 Vaccinations in the United States*. Accessed at [CDC COVID Data Tracker: Vaccinations in the US](#) on April 7, 2022.
- ³² CDC, *Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities*, as of May 4, 2022. Accessed at [CDC COVID Data Tracker: Vaccinations in the US](#) on May 4, 2022.
- ³³ CDC, *The Federal Retail Pharmacy Program for COVID-19 Vaccination*. Accessed at [COVID-19 Vaccination Federal Retail Pharmacy Partnership Program | CDC](#) on May 10, 2022.
- ³⁴ Record of IZ Gateway development appears as early as April 2019. See CDC, *The Immunization Information System (IIS) Landscape*. Accessed at [The Immunization Information System \(IIS\) Landscape \(healthit.gov\)](#) on June 22, 2022.
- ³⁵ CDC identifies the COVID-19 pandemic as beginning in December 2019. CDC, *CDC Museum COVID-19 Timeline*. Accessed at [CDC Museum COVID-19 Timeline | David J. Sencer CDC Museum | CDC](#) on June 22, 2022.
- ³⁶ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, page 35, footnote 7. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on July 23, 2021.
- ³⁷ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, page 38. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on July 23, 2021.
- ³⁸ In June 2020, an AIRA representative reported that there were still IZ Gateway policy and technical issues that needed to be resolved before the Gateway could be leveraged on a national scale. See [Coronavirus vaccine: State immunization databases hold key to success \(usatoday.com\)](#) from June 12, 2020. Accessed on July 17, 2021.
- ³⁹ As of late 2019, the IZ Gateway was only in a proof-of-concept stage and some programs noted not intending to sign the memorandum that allowed for cross-jurisdiction querying of registries. National Governors Association, *Supporting an Equitable Distribution of COVID-19 Vaccines: Key Themes, Strategies, and Challenges Across State and Territorial COVID-19 Vaccination Plans*, page 19, December 2020. Accessed at [Supporting-an-Equitable-Distribution-of-COVID-19-Vaccine.pdf \(nga.org\)](#) on April 6, 2022.
- ⁴⁰ HHS, *Immunization (IZ) Gateway Portfolio Overview*, see page 2. Accessed at [Immunization \(IZ\) Gateway Portfolio Overview \(hhs.gov\)](#) on June 15, 2022.
- ⁴¹ CDC, *Immunization Gateway Information Sheet*. See Connect: National Provider Organizations to Multiple IISs. Accessed at [IZ Gateway Information for COVID-19 Vaccination Reporting | CDC](#) on June 15, 2022.
- ⁴² Government Accountability Office (GAO), *HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues*, see page 17. Accessed at [GAO-22-104453, COVID-19: HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues](#) on September 13, 2022.
- ⁴³ U.S. Department of Defense, *Tiberius Platform Aids COVID-19 Logistics, Delivery*. Accessed at [Tiberius Platform Aids COVID-19 Logistics, Delivery > U.S. Department of Defense > Defense Department News](#) on June 11, 2022.
- ⁴⁴ Politico, *States Complain Feds' Data System Is Holding Up Vaccination Effort*. Accessed at [States complain feds' data system is holding up vaccination effort - POLITICO](#) on June 11, 2022.
- ⁴⁵ Politico, *States Complain Feds' Data System Is Holding Up Vaccination Effort*. Accessed at [States complain feds' data system is holding up vaccination effort - POLITICO](#) on June 11, 2022.
- ⁴⁶ USA Today, *A National System to Prioritize COVID-19 Vaccines Has Largely Failed As Our States Rely On Their Own Systems*. Accessed at [COVID-19 vaccine: Distribution system fails to live up to promise \(usatoday.com\)](#) on June 11, 2022.
- ⁴⁷ GovConWire, *Palantir Helps HHS Develop "Tiberius" System to Track COVID-19 Vaccine Production, Distribution*. Accessed at [Palantir Helps HHS Develop 'Tiberius' System to Track COVID-19 Vaccine Production, Distribution - GovCon Wire](#) on June 17, 2022.
- ⁴⁸ CDC, *COVID-19 Data Tracker – Vaccine Distribution & Coverage*. Accessed at [CDC COVID Data Tracker](#) on June 23, 2022.

-
- ⁴⁹ CDC, *Frequently Asked Questions about COVID-19 Vaccination Data*. See How Often Are COVID-19 Vaccination Data Updated? Accessed at [Frequently Asked Questions about COVID-19 Vaccination Data | CDC](#) on June 23, 2022.
- ⁵⁰ CDC, *Frequently Asked Questions about COVID-19 Vaccination Data*. See How Are Vaccine Administration Data Reported to CDC? Accessed at [Frequently Asked Questions about COVID-19 Vaccination Data | CDC](#) on June 23, 2022.
- ⁵¹ CDC, *Vaccine Administration Management System (VAMS)*. Accessed at [VAMS COVID-19 Vaccination Reporting | CDC](#) on October 19, 2022.
- ⁵² CDC, *Data Definitions for COVID-19 Vaccinations in the United States*. Accessed at [Data Definitions for COVID-19 Vaccinations in the United States \(cdc.gov\)](#) on June 23, 2022.
- ⁵³ All Federal agencies are not present in all jurisdictions. Fifty-two out of 56 jurisdictions are not receiving data from VA, DoD, and/or IHS where it is expected or wanted.
- ⁵⁴ CDC stated that availability of DoD vaccine administration data may be more limited due to security concerns.
- ⁵⁵ New York State, Governor Kathy Hochul, *Executive Order No. 8: Directing the Department of Veterans Affairs to Transmit Immunization Records*. Accessed at [No. 8: Directing the Department of Veterans Affairs to Transmit Immunization Records | Governor Kathy Hochul \(ny.gov\)](#) on March 3, 2022.
- ⁵⁶ Newsweek, *Which U.S. States Have the Highest Concentration of Veterans?*, November 17, 2018. Accessed at [Which U.S. States Have the Highest Concentration of Veterans? \(newsweek.com\)](#) on March 3, 2022.
- ⁵⁷ The Soldiers Project, *Top 5 Largest Military Bases in the World by Population and Area*, March 1, 2022. Accessed at [Top 5 Largest Military Bases in the World by Population & Area \(thesoldiersproject.org\)](#) on March 3, 2022.
- ⁵⁸ Governing, *Military Active-Duty Personnel, Civilians by State*. Accessed at [Military Active-Duty Personnel, Civilians by State \(governing.com\)](#) on May 4, 2022.
- ⁵⁹ Not all State and local immunization programs have IHS facilities. 25 States have facilities. IHS, *Find Health Care*. Accessed at [Find Health Care | Indian Health Service \(IHS\)](#) on March 21, 2022.
- ⁶⁰ IHS may not cover all AI/ANs in a jurisdiction. The *Playbook* instructed jurisdictions to incorporate a variety of AI/AN organizations in their planning process (e.g., State-recognized tribes, unrecognized tribes, Urban Indian Health Centers (UIHCs)). CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*, October 29, 2020, version 2.0, page 9. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on March 3, 2022.
- ⁶¹ IHS, *Frequently Asked Questions*. Accessed at [Frequently Asked Questions | for Patients \(ihs.gov\)](#) on March 3, 2022.
- ⁶² IHS, *Navajo Area*. Accessed at <https://www.ihs.gov/Navajo/> on March 3, 2022.
- ⁶³ Statista, *Percentage of U.S. Population Who Are Veterans in 2019, by Age and Gender*. Accessed at [Percentage of U.S. population who are veterans by age and gender 2019 | Statista](#) on May 10, 2011.
- ⁶⁴ CDC, *What is Vaccination Coverage and Why is it Important?* Accessed at [VaxView Vaccination Coverage | CDC](#) on March 3, 2022.
- ⁶⁵ CDC, *The Federal Retail Pharmacy Program for COVID-19 Vaccination*. Accessed at [COVID-19 Vaccination Federal Retail Pharmacy Partnership Program | CDC](#) on May 10, 2022.
- ⁶⁶ GAO, *COVID-19 Federal Efforts to Provide Vaccines to Racial and Ethnic Groups*, February 2022. Accessed at [GAO-22-105079, Accessible Version, covid-19: Federal Efforts to Provide Vaccines to Racial and Ethnic Groups](#) on May 10, 2022.
- ⁶⁷ Murthy Patel, Bhavini, Sterrett, Natalie, et al., *Disparities in COVID-19 Vaccination Coverage Between Urban and Rural Counties – United States, December 14, 2020 – April 10, 2021*, MMWR Morb Mortal Wkly Rep 2020;71:335340. Accessed at [MMWR, Disparities in COVID-19 Vaccination Coverage Between Urban and Rural Counties — United States, December 14, 2020–April 10, 2021 \(cdc.gov\)](#) on May 9, 2022.
- ⁶⁸ IHS, *Disparities*, October 2019. Accessed at [Disparities | Fact Sheets \(ihs.gov\)](#) on March 3, 2022.

⁶⁹ Arrazola, Jessica, Masiello, Matthew M., Joshi, Sujata, et al., *COVID-19 Mortality Among American Indian and Alaska Native Persons — 14 States, January–June 2020*, MMWR Morb Mortal Wkly Rep 2020;69:1853-1856. Accessed at [COVID-19 Mortality Among American Indian and Alaska Native Persons — 14 States, January–June 2020 | MMWR \(cdc.gov\)](#) on March 3, 2022.

⁷⁰ CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, Role of Commercial and Federal Partners, page 25. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on February 24, 2022.

⁷¹ Federal COVID-19 data platforms available to immunization programs include HHS' Tiberius dashboard for vaccine distribution and CDC's public COVID-19 Data Tracker. See CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, page 49, for description of Tiberius. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on March 3, 2022. Also see CDC's public COVID-19 data tracker accessed at [CDC COVID Data Tracker: Vaccinations in the US](#) and [CDC COVID Data Tracker: County View](#) on April 8, 2022.

⁷² The Immunization Infrastructure Modernization Act of 2021 directs HHS to improve data sharing and other aspects of IISs. Accessed at [H.R.550 - 117th Congress \(2021-2022\): Immunization Infrastructure Modernization Act of 2021 | Congress.gov | Library of Congress](#) on September 15, 2022.

⁷³ The PREVENT Pandemics Act considers revisions on authorities of HHS to support preparedness, including the collection of public health data. Accessed at [S.3799 - 117th Congress \(2021-2022\): PREVENT Pandemics Act | Congress.gov | Library of Congress](#) on September 15, 2022.

⁷⁴ Some multijurisdictional vaccination providers receive COVID-19 vaccine allocation directly from CDC. These providers include Federal agencies (i.e., BoP, DoD, DoS, VA, and IHS) and select pharmacy partners (e.g., Walgreens, CVS, Walmart, Rite Aid Corp). CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, October 29, 2020, version 2.0*, pages 25 and 74. Accessed at [COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](#) on February 14, 2022.

⁷⁵ We did not ask respondents to differentiate between data received from Federally run and Tribally run IHS facilities.