DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Systems and Tools Implemented to Track COVID-19 Vaccine Data

REVIEW | REPORT #21-00913-267 | DECEMBER 7, 2021

MISSION

The mission of the Office of Inspector General is to serve veterans and the public by conducting meaningful independent oversight of the Department of Veterans Affairs.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244

Executive Summary

As a federal agency administering COVID-19 vaccines, VA is required to report directly to the Centers for Disease Control and Prevention (CDC) on its COVID-19 vaccine supply and on all administered doses.[1] The VA Office of Inspector General (OIG) conducted this review to determine if the Veterans Health Administration (VHA) implemented the data collection and reporting systems needed to fulfill this role—specifically, to report on the supply of vaccines to VA medical facilities and clinics, and doses administered to veterans enrolled in VA's healthcare system and to VA employees.

Developing systems to track and report on the supply and administration of the COVID-19 vaccines presented distinct challenges for VHA. One challenge was that VHA does not have a centralized pharmacy inventory management system to track vaccine supply at facilities.[2] Another was the scale of the effort: the two populations that were the immediate focus—veterans enrolled in VA's healthcare system and VHA employees—numbered some 9.5 million. To vaccinate these populations, VA had to quickly modify separate tracking systems. VA also had to be able to track vaccinations for unenrolled veterans (around 10 million as of June 2021), veterans' spouses and caregivers, and other federal agency employees to prepare for providing vaccinations to these or others as needed.[3]

What the Review Found

VHA has done an admirable job setting up systems and tools to collect data and report on COVID-19 vaccines to the CDC under short time frames. VHA began receiving the COVID-19 vaccine the week of December 14, 2020. As of April 7, 2021, VHA reported it had administered almost 5.4 million doses of the vaccine.[4] Although VHA staff swiftly developed the necessary data collection systems, the review team determined the reliability of COVID-19 vaccine data could be improved in several areas. VHA could monitor system checks it added to minimize data

[1] CDC, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*, ver. 2.0, October 29, 2020.
[2] Government Accountability Office (GAO), *VA Health Care: Pharmacy Inventory Management Could Benefit from System-Wide Oversight,* GAO-18-658, September 2018.
[3] Strengthening and Amplifying Vaccination Efforts to Locally Immunize All Veterans and Every Spouse Act (SAVE LIVES Act), Pub. L. No. 117-4 (2021); Economy Act, 31 U.S.C.§ 1535; "VA Fourth Mission Summary," accessed May 25, 2021, https://www.va.gov/health/coronavirus/statesupport.asp. Although the Economy Act authorized VA and the Department of Homeland Security to execute an interagency agreement providing vaccinations for certain Department of Homeland Security personnel, this activity was part of VHA's Fourth Mission.
[4] This included vaccinations for almost 27,000 Department of Homeland Security employees. The sources of this information reported to the OIG were the national dashboard VHA developed for data reporting for veterans and employees, and VHA's Corporate Data Warehouse for Department of Homeland Security employees.

entry errors and add controls for verifying facility-level data and processes for validating summary data to their sources.

Inaccurate and inconsistent data could impede managers' efforts to schedule and prioritize COVID-19 vaccinations. Furthermore, VHA cannot be assured of the accuracy of national immunization data reported to the CDC on the percentages of veterans and employees vaccinated. Finally, without being able to determine what happens to all vaccine doses that enter its healthcare system, VHA increases the risks of COVID-19 vaccine theft.[5]

The team determined that problems with data reliability existed in the following areas:

- Pharmacy Benefits Management Services (PBM) staff do not have procedures in place to verify data they collect from facilities' manually entered vaccine supply data, which are prone to error.[6]
- Vaccination data in key systems were inconsistent and contained inaccuracies due to inadequate validation and user error.
- VHA staff at some VA medical facilities initially lacked system access to enter employee vaccination data.
- The dashboard VHA developed to consolidate vaccine data contained unvalidated data.

VHA Put the Necessary Systems in Place for Data Capture and Reporting

The review team found that VHA developed a new data system to capture information on vaccine supply and expanded the use of two existing systems to record doses administered. (This effort is described in appendix A.) In addition, VHA updated an existing tool to transmit required information to the CDC and developed another tool to consolidate data on vaccine supply and doses administered for internal and external reporting. Specifically, VHA created a SharePoint website to track vaccine supply and modified its Computerized Patient Record System (CPRS)

[5] See VHA technical comment 1 on page 52 conceding that there were errors, but there was no evidence they actually impeded efforts. VHA stated that the same inventory procedures are used for controlled substances, so the same level of risk of theft applies. The OIG updated the language here to reflect the fact that data errors and inconsistencies could impact managers' efforts to schedule and prioritize vaccinations, even though no instances of this impact were observed. However, the OIG maintains that while VHA did set up responsive systems within a short time frame, the tighter controls and processes recommended would reduce risks and provide greater assurance of appropriate vaccine distribution in the areas identified.

[6] See VHA technical comment 2 on page 52. VHA contends that it is the lack of tools and perpetual inventory management system (which the OIG noted in the report), rather than negligence or inattention, at issue. VA also notes that verification of vaccine supply data is not a PBM responsibility. The OIG updated the report to reflect that PBM *does* not (rather than *cannot*) verify the data that facilities report. However, the OIG disagrees with VA's suggested changes asserting PBM is not responsible for verifying the accuracy of facility-reported vaccine data (see OIG response on page 36). PBM's responsibilities are outlined in VHA's COVID-19 vaccination plan (see page 35 of this report).

and its Occupational Health Record-keeping System 2.0 (OHRS) to capture doses administered to veterans and employees.[7] VHA also updated the Veterans Data Integration and Federation Platform for reporting data on vaccine supply and doses administered to the CDC.[8] Finally, VHA created a Power Business Intelligence (BI) dashboard to consolidate vaccine data from all COVID-19 vaccine-related data sources for internal decision-making and national reporting.

PBM Staff Do Not Have Procedures in Place to Verify Data They Collect from Facilities' Manually Entered Vaccine Supply Data, Which Are Prone to Errors

Every day, VA medical facilities' pharmacy staff manually record COVID-19 vaccine supply data on PBM's SharePoint website, including quantity of vaccine doses received, quantity on hand (those remaining at the end of each day), doses wasted (those that spoiled, expired, or were otherwise insufficient for use and had to be discarded), doses redistributed (sent to another VA pharmacy), and extra doses.[9] Extra doses are any that are administered over the standard number per vial; they began to be counted after administrators realized that, with certain needles, more could be extracted from each vial.[10]

PBM staff conduct basic checks of the SharePoint data reported by medical facilities, but the OIG determined staff do not fully validate the data they collect from facilities. PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supply or data collection processes and rely on facility staff to enter the correct data. The OIG acknowledges that it would be resource-intensive for PBM officials to verify all facility-

[7] VA, Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version (REDACTED),* November 20, 2020. CPRS is a Veterans Health Information Systems and Technology Architecture (VistA) application that enables electronic management of all information connected with any patient. CPRS supports clinical decision-making and enables users to review and analyze patient data. "Occupational Health Record-keeping System (OHRS)," VA Datasets, accessed December 15, 2020, https://www.data.va.gov/dataset/Occupational-Health-Record-keeping-System-OHRS-/j3ss-2phg. OHRS 2.0 is a web-based application that enables employee occupational health staff to create, maintain, and monitor medical records for VA employees.

[8] The Veterans Data Integration and Federation Platform extracts and prepares COVID-19 vaccine data to transmit three data files to the CDC daily.

[9] See VHA technical comment 3 on page 53. For the heading of this section, VHA contends that PBM is not responsible for verifying facility vaccine supply data, and that this responsibility rests with the local facility. However, the OIG finds this inconsistent with VHA's own vaccination plan.

[10] CDC Vaccine Task Force, Distribution, and Pharmacy, *Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage,* updated May 18, 2021, accessed July 1, 2021, https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf. Each vaccine has a standard number of doses that is expected to be pulled from each vial: initially five for Pfizer and 10 for Moderna. As of February 2021, Pfizer began counting six doses as the standard per vial.

reported data and the team discussed with VHA officials alternatives at the facility or Veterans Integrated Service Network level.[11]

The OIG's analysis of PBM's COVID-19 vaccine supply data identified errors in VA medical facilities' documentation of vaccine on hand, doses wasted, doses redistributed, and extra doses administered. (The review scope and methodology are detailed in appendix B.) These differences may be due to manual data entry and the lack of verification. Facilities' data entry errors may also have been exacerbated by changing guidance that was responsive to vaccine manufacturers' updates and other information. According to PBM officials, PBM was only reporting vaccine waste to the CDC at the time of this review.[12] However, without a way to verify facility-entered data, PBM cannot account for all vaccine that enters VHA's healthcare system.

Vaccination Data in CPRS and OHRS Were Inconsistent and Inaccurate Due to Inadequate Validation and User Error

VHA initially tracked COVID-19 vaccinations for veterans and employees and validated some of the data. However, the review team identified instances of documentation that called into question the accuracy of veteran and employee vaccination data (such as second shots dated before or the same day as first shots).

The challenges in entering data in CPRS and OHRS that the team identified included inconsistent documentation of vaccine refusals in CPRS and OHRS and inconsistent second-dose notifications for employees in OHRS. According to VHA officials, they have taken steps to address the identified issues, including issuing data entry guidance and building in system checks, and creating two reports to help facilities identify errors in veteran vaccination records.

VHA Staff at Some VA Medical Facilities Initially Lacked System Access to Enter Employee Vaccination Data

In addition to inconsistent data entry and user errors, some individuals lacked system access needed to record employee vaccinations, creating OHRS implementation challenges. To gain OHRS access for vaccine administrators, facility staff were to submit the names of those who needed access and had completed two required training courses. Office of Information and

[11] See VHA technical comment 4 on page 53. To address this comment, the OIG added information acknowledging that it would be resource-intensive for PBM to visit all facilities to verify vaccine supply data. However, the OIG contends that there are many options for validating this data, including facility pharmacy staff conducting on-site validation.

[12] See VHA technical comment 5 on page 53 contending that PBM was not responsible for verifying facility data (which the OIG finds inconsistent with VHA's own vaccination plan), and that the CDC agreement with VA on only reporting waste was not a PBM decision. According to a PBM official, at the time of this review CDC did not have the capability to accept data on vaccine supply and extra doses dispensed; however, vaccine waste was reported each week to CDC.

Technology staff said that after they received the list of names, they typically granted access within 24 to 48 hours. However, some employees from five of the 13 facilities the OIG reviewed said they lacked access to OHRS 2.0 during the vaccine rollout for staff. One employee waited more than 10 days for access; in the interim, this employee used a spreadsheet to record shot information. OHRS staff were aware of delays, but said the issues generally came from staff not completing the required training or from vaccine coordinators not putting users' names forward to obtain access. So that access issues do not hamper future vaccination documentation efforts, VHA should make sure all necessary users have access to any additional systems that might be developed for vaccination documentation in a timely and ongoing manner.

The Dashboard That VHA Developed to Consolidate Vaccine Data Contained Unvalidated Data

In addition to expanding on or developing systems to collect data on vaccines, VHA developed a dashboard to consolidate all data for reporting on vaccine supply and doses administered. While the documentation VHA provided to the review team for the dashboard outlines the data sources of each variable and notes that "data in the dashboard is validated back to the original sources," the team found that VHA did not adequately validate the data. When reviewing the data sources (PBM, CPRS, and OHRS), the OIG identified a lack of validation within PBM's SharePoint website, and data entry errors within CPRS and OHRS 2.0. Also, the OIG identified potential issues with the dashboard related to redistributed or relocated vaccines, labeling of the data source on the Power BI dashboard, time lags leading to differences between Power BI and facility data, and the aggregation of data for medical facilities in the same healthcare system.

What the OIG Recommended

The OIG made three recommendations to the under secretary for health, including developing processes for verifying medical facility vaccine supply data and for monitoring the use of tools that have been fielded to minimize data entry errors, and ensuring the consolidated dashboard data are reliable, accurate, and complete.

Management Comments

The acting under secretary for health concurred with recommendations 1 and 2 and concurred in principle with recommendation 3. The acting under secretary provided an action plan to address all three recommendations and asked the OIG to close recommendation 3. VHA also provided 24 technical comments for this report. The full text of the acting under secretary for health's comments, the action plan, and the technical comments appears in appendix C.

OIG Response

The acting under secretary's planned corrective actions are responsive to recommendations 1 and 2 and address the issues identified in the report. The corrective actions for recommendation 3 partially address the issues identified in the report. VHA's response states that while the goal of the VHA Support Service Center (VSSC) is to provide accurate and reliable information to leadership and the field, VSSC is not privy to or responsible for the reliability testing done on the data sources for the Power BI dashboard. If it is not possible for VSSC to verify dashboard data for reliability, accuracy, or completeness, the OIG believes that steps should be taken to disclose known data limitations to dashboard users. In addition, VHA's actions do not address other identified limitations with the inaccurate labeling of data sources in Power BI source documentation or time lags in the data. The OIG will close all recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

In response to the acting under secretary for health's 24 general and technical comments, the OIG made language changes as appropriate when additional support was provided. For other comments, the OIG either did not have support for the requested change, or the OIG disagreed with the accuracy of the proposed change. The OIG's responses to the technical comments are on pages 34 through 37.

LARRY M. REINKEMEYER
Assistant Inspector General
for Audits and Evaluations

Contents

Executive Summary i

Abbreviations viii

Introduction 1

Results and Recommendations 9

Finding: VHA Quickly Implemented Vaccine Data Systems and Tools, but Faced Challenges Verifying Facility Data Due to Manual Processes, User Error, Lack of System Access, and Validation Deficiencies 9

Recommendations 1–3 32

Appendix A: Background 38

Appendix B: Scope and Methodology 43

Appendix C: Veterans Health Administration Management Comments 47

OIG Contact and Staff Acknowledgments 60

Report Distribution 61

Abbreviations

BI	Business Intelligence
CDC	Centers for Disease Control and Prevention
CPRS	Computerized Patient Record System
GAO	Government Accountability Office
OHRS	Occupational Health Record-keeping System
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VSSC	VHA Support Service Center

Introduction

As a federal agency administering the COVID-19 vaccines, VA is required to report directly to the Centers for Disease Control and Prevention (CDC) on its vaccine supply and on all administered doses.[13] VA tracks the vaccines from the point of receipt at facilities through the point of administration to veterans and employees. According to the Veterans Health Administration's (VHA) COVID-19 vaccination plan, tracking the receipt and distribution of vaccines is a key aspect of a successful immunization program. It is also intended to facilitate transmitting required data to the CDC, scheduling second injections, and reporting any adverse reactions. The VA Office of Inspector General (OIG) conducted this review to determine if the VHA implemented data collection and reporting systems needed to track and report on the COVID-19 vaccine. Specifically, this review focused on the supply of vaccines to VA medical facilities and clinics, and doses administered to veterans enrolled in VA's healthcare system and VA employees. In conducting its work, the team became aware of challenges VHA faced affecting the accuracy and completeness of data collected and reported through these systems.

VHA's Guidance on COVID-19 Vaccinations

VHA developed a vaccination plan that included sections focused on data collection and reporting. The plan included information about developing and modifying systems to capture data on vaccine supply and on doses administered to veterans and VA employees. VHA also developed guidance for using the systems and tools it implemented to track vaccine supply and doses administered.

VHA's Vaccination Plan

At the beginning of September 2020, VHA assembled a team to plan for the availability of the COVID-19 vaccines for veterans enrolled in VA's healthcare system and for VA employees.[14] VHA's vaccination plan was developed in partnership with other federal agencies, including the CDC, and focused on "planning that is ethical, evidence-based, equitable, transparent, and aimed at maximizing benefits of COVID-19 vaccination."[15] One of the main goals of the plan was to track and report on the supply and administration of the vaccine for internal and external stakeholders.

Guidance included in the plan focused on identifying and providing vaccinations to populations at highest risk, monitoring vaccine safety, and reporting required information to the CDC. To target populations at highest risk, VHA's plan recommended VHA facilities prioritize veterans

[13] CDC, *COVID-19 Vaccination Program Interim Playbook, for Jurisdiction Operations*, ver. 2.0, October 29, 2020.
[14] VA, *COVID-19 Vaccination Plan for the Veterans Health Administration,* ver. 2.0, December 14, 2020.
[15] VA, *COVID-19 Vaccination Plan for the Veterans Health Administration.*

and employees for vaccinations based on guidance from the CDC's Advisory Committee on Immunization Practices. VHA also developed a tool to help VHA facilities and pharmacies (e.g., clinics) prioritize the veterans they serve for vaccinations.[16] See appendix A for additional information on this tool.

The vaccination plan also included information about vaccinations for veterans' caregivers, people residing in state veteran homes, and other federal partners (such as Department of Homeland Security employees) in case VA was asked to administer vaccines to these groups. This aspect of the plan became even more important after President Biden signed the Strengthening and Amplifying Vaccination Efforts to Locally Immunize All Veterans and Every Spouse Act, or the SAVE LIVES Act on March 24, 2021.[17] According to a VA press release, this act expanded VA's legal authority to provide COVID-19 vaccines to all veterans, regardless of their VA healthcare enrollment status, and to provide vaccines to veteran spouses and caregivers.[18]

Among other federal partners, at the time of this review, VA had administered vaccinations to Department of Homeland Security employees and frontline workers. This support fell under the authority of the Economy Act, which authorizes federal agencies to provide services or supplies to other federal agencies on a reimbursable basis, and was initiated in response to a declaration of the COVID-19 public health emergency.[19] In addition, as of April 2021, VA had partnered with the National Archives and Records Administration to start administering vaccinations to archives staff who support VA claims processing, and had also started to provide vaccination support to the Food and Drug Administration and the federal court system.[20] This review focuses on doses administered to veterans enrolled in VA's healthcare system and VA employees. However, the data collection and reporting systems VHA used to track and report on the

[16] "About VHA: Useful Terms, Community-Based Outpatient Clinics," accessed June 16, 2021, www.va.gov/health/aboutvha.asp. "To make access to health care easier, VHA utilizes Community -Based Outpatient Clinics across the country. These clinics provide the most common outpatient services, including health and wellness visits."

[17] Strengthening and Amplifying Vaccination Efforts to Locally Immunize All Veterans and Every Spouse Act (SAVE LIVES Act), Pub. L. No. 117-4 (2021).

[18] VA, Office of Public Affairs Media Relations, "SAVE LIVES Act allows VA to soon provide COVID-19 vaccinations to all Veterans, their spouses and caregivers," news release, March 24, 2021.

[19] Economy Act, 31 U.S.C.§ 1535; "VA Fourth Mission Summary," VHA, accessed May 25, 2021, https://www.va.gov/health/coronavirus/statesupport.asp#:~:text=The%20state%20and%20community%20support,%2C%20testing%2C%20education%20and%20training. Although the Economy Act authorized VA and the Department of Homeland Security to execute an interagency agreement providing vaccinations for certain Department of Homeland Security personnel, this activity was part of VHA's Fourth Mission "to improve the nation's preparedness for response to war, terrorism, national emergencies, and natural disasters by developing plans and taking actions to ensure continued service to Veterans [and to] support national, state, and local emergency management, public health, safety and homeland security efforts."

[20] The Department of Health and Human Services provided a separate supply of vaccines to the National Archives to vaccinate its staff members.

COVID-19 vaccines given to these populations were relevant for the other populations VHA went on to vaccinate. For example, as of August 2021, VA required nearly every healthcare worker and contractor in its healthcare system to be vaccinated against COVID-19.[21] In addition, the OIG determined that lessons from this review will also be relevant for COVID-19 booster shots and for future events that require mass vaccinations. Appendix A provides additional information on VHA's prioritization plans for COVID-19 vaccinations.

Guidance Related to Using Systems and Tools for Tracking Vaccine Supply and Doses Administered

VHA developed or modified data systems and tools to track and report on the COVID-19 vaccine and issued guidance on their use. First, for vaccine supply to VA medical facilities and pharmacies, VHA's Pharmacy Benefits Management Services (PBM) built a SharePoint website that facilities were to use to track doses received, doses on hand (those remaining at the end of each day), doses wasted (those that spoiled, expired, or were otherwise insufficient for use and had to be discarded), and extra doses. Extra doses are any administered over the standard number per vial; with certain needles, additional doses could be extracted from each vial.[22] VHA staff began counting extra doses on December 17, 2020, once they received guidance on how to do so from the CDC and Food and Drug Administration. The SharePoint site contained instructions for how to report on these data elements, was updated continually, and included links to related memorandums and documents.[23] PBM also provided guidance on storage and redistribution requirements for the vaccines.[24]

VHA developed guidance for vaccine administration as well. In April 2020, VHA issued a memorandum notifying Veterans Integrated Service Networks (VISNs) to use a national template developed in the Computerized Patient Record System (CPRS)—used to track veteran vaccinations—to ensure consistent documentation and optimal monitoring of COVID-19

[21] VA, "Veterans Affairs Media Summary and News Clips," August 13, 2021.

[22] CDC Vaccine Task Force, Distribution, and Pharmacy, *Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage,* updated May 18, 2021, accessed July 1, 2021, https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf. Each vaccine has a standard number of doses that is expected to be pulled from each vial: initially five for Pfizer and 10 for Moderna. As of February 2021, Pfizer began counting six doses as the standard per vial.

[23] "COVID-19 Vaccines," VA MedSAFE Applications, accessed April 16, 2021, https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx. (This VA website is not publicly accessible.)

[24] VA, *Ultra-Cold (-70˚C) COVID Vaccine Distribution Plan*, ver. 3.0, December 23, 2020; VA, *Frozen COVID Vaccine Distribution Plan*, ver. 2.0, December 23, 2020; Pfizer *Ultra-Cold COVID Vaccine Redistribution Plan*, December 28, 2020; and Moderna *Frozen COVID Vaccine Redistribution Plan*, December 28, 2020.

vaccinations administered to veterans.[25] Written guidance included PowerPoint slides with instructions.[26] According to VHA officials, VHA hosted weekly meetings from November 2020 to March 2021 focused on data tracking and documentation, to provide guidance that was designed to assist facilities and clinics with documenting and tracking vaccines administered. For vaccines administered to employees, in November 2020 VHA issued a memorandum on documentation requirements.[27] In addition, new users of the Occupational Health Record-keeping System 2.0 (OHRS)—used to track employee vaccinations—were to complete two training courses before accessing the system.[28] VHA also developed step-by-step instructions to expedite vaccination documentation and mitigate documentation errors.[29]

Required Data Reporting

The CDC required vaccination providers to report certain data elements within 24 hours of administering the vaccine.[30] Required data elements include location, type of vaccine, and recipient name. Appendix A provides additional details on required and optional data reporting elements related to vaccine administration. CDC further required that vaccination providers report daily on COVID-19 vaccine supply on hand and doses wasted.[31] CDC guidance also explained that an immediate priority for the reporting of an immunization program's data is to assess and improve data quality by ensuring data are available, secure, complete, timely, valid, accurate, consistent, and unique.

[25] VA, Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version (REDACTED),* November 2020. CPRS is a Veterans Health Information Systems and Technology Architecture (VistA) application that enables electronic management of all information connected with any patient. CPRS supports clinical decision-making and enables users to review and analyze patient data. VHA memo, "Mandated Implementation of Coronavirus Disease 2019 (COVID-19) CPRS Tools," April 22, 2020. VHA's 18 VISNs are regional networks for healthcare delivery. They work together to meet local healthcare needs and provide care to veterans at medical facilities in the network.

[26] VA, "COVID-19 Immunization Clinical Reminder Clinician Education," December 30, 2020, PowerPoint slide presentation.

[27] VHA memo, "Coronavirus Disease 2019 (COVID-19) Vaccine Documentation Requirement for Veterans Health Administration (VHA) Employees and Health Care Personnel in the Occupational Health Record-keeping System 2.0," November 16, 2020.

[28] "Occupational Health Record-keeping System (OHRS)," VA Datasets, accessed December 15, 2020, https://www.data.va.gov/dataset/Occupational-Health-Record-keeping-System-OHRS-/j3ss-2phg. OHRS 2.0 is a web-based application that enables employee occupational health staff to create, maintain, and monitor medical records for VA employees.

[29] VA, *COVID-19 VAX Guided Entry,* January 25, 2021. The guide offers step-by-step instructions to expedite COVID-19 documentation and mitigate errors.

[30] CDC, *COVID-19 Vaccination Program Interim Playbook, for Jurisdiction Operations*.

[31] According to a PBM official, CDC did not have the capability to accept data on vaccine supply; however, vaccine waste has been reported to CDC weekly.

Unique Challenges VHA Faced Establishing Systems to Track Vaccine Supply and Doses Administered

Developing systems to track and report on the supply and administration of COVID-19 vaccine presented distinct challenges for VHA. One challenge was that VHA does not have a centralized pharmacy inventory management system, according to VHA officials. Prior reporting by the Government Accountability Office indicates that this has been a long-standing problem.[32] Lack of a centralized, national pharmacy inventory management system complicates and limits VHA's ability to track vaccine supply at facilities and pharmacies.

Another impediment was the scale of the effort. VHA initially focused on vaccinating two populations—approximately nine million veterans enrolled in VA's healthcare system and approximately 400,000 VHA employees. It planned to serve those at higher risk first, according to VHA's plan. Some veterans that VHA serves reside in rural locations or are transient, increasing the complexity of the task. To be prepared to vaccinate all enrolled veterans and personnel, VA had to modify separate tracking systems to record vaccinations for both groups.

VHA also had to be prepared to provide vaccinations to unenrolled veterans (around 10 million as of June 2021), their spouses and caregivers, and other federal agency employees, which exponentially increased the number and types of populations for which VHA would need to track vaccination-related data. When initially modifying the systems, VHA added a clinical reminder to the system tracking vaccinations for enrolled veterans. VHA expanded use of this clinical reminder for these other populations. The ability to track vaccinations for each of these populations could prove useful for COVID-19 boosters, if needed, and for future mass vaccination events.

Supply of Vaccines to VHA

VHA first received COVID-19 vaccine doses the week of December 14, 2020.[33] VHA's initial supply of the Pfizer vaccine went to 37 medical facilities with the capacity to meet the cold storage requirements and the ability to vaccinate large numbers of people.[34]

Table 1 provides details from when VHA initially received the vaccines. While each vaccine initially had a standard number of doses that was expected to be pulled from each vial, the Food

[32] Government Accountability Office (GAO), *VA Health Care: Pharmacy Inventory Management Could Benefit from System-Wide Oversight*, GAO-18-658, September 2018.

[33] VHA, National Center for Health Promotion and Disease Prevention, Patient Care Services, *COVID-19 Vaccine Planning,* December 18, 2020, Pharmacy Benefits Management Services data.

[34] VA, Office of Public and Intergovernmental Affairs, "VA announces initial plans for COVID-19 vaccine distribution," news release, December 10, 2020.

and Drug Administration provided a fact sheet for the range in the number of doses some vials were expected to hold.[35]

Table 1. VHA's Receipt of Supply and Vaccine Characteristics

Vaccine	Emergency use authorization date	Date VHA received first supply	Temperature range for freezer storage (degrees Celsius)	Vaccine doses in each vial	Days between doses to be considered fully vaccinated
Pfizer-BioNtech*	Dec. 11, 2020	Dec. 14, 2020	-70	5	21
Moderna †	Dec. 18, 2020	Dec. 21, 2020	-20	10	28
Janssen (Johnson & Johnson)††	Feb. 27, 2021	March 3, 2021	2 to 8	5	Single dose

Source: VA OIG analysis of Federal Drug Administration Emergency Use Authorizations; VHA COVID-19 Vaccine Planning presentation, December 18, 2020; PBM COVID-19 Vaccine Tracker data; Janssen COVID-19 Vaccine Fact Sheet, April 19, 2021; and VA Office of Public and Intergovernmental Affairs, "VA receives Janssen COVID-19 vaccine," press release, March 4, 2021, https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5632.

** The Pfizer vaccine was transported in temperature-controlled thermal shipping containers that provide safe storage up to 10 days if unopened. The vaccine can be stored in an ultra-low-temperature freezer for up to six months, in the shipping units with refilled dry ice for up to 30 days, or in refrigeration units at between 2 and 8°C for five days. The vials can be transferred to storage at between 2 and 8°C for an additional five days, for a total of up to 35 days. Once thawed and stored at between 2 and 8°C, the vials cannot be refrozen.*

† Once moved to a refrigerator, Moderna vials can be stored unpunctured at between 2° and 8°C for up to 30 days.

†† The Janssen vaccine was transported in a portable refrigerator unit or a container that maintains a temperature between 2 and 8°C. Unopened vials may be stored at between 9° and 25°C for up to 12 hours.

As of March 5, 2021, according to VHA officials, 246 VA medical facilities or associated clinics had received doses of the vaccine. According to VHA officials, as of April 7, 2021, VHA had

[35] See VHA technical comment 6 on page 53. VHA contends that information in table 1 was not accurate for the time frame of the review and could affect the OIG error calculation. The OIG updated the text to state that table 1 provides details from when VHA *initially* received the vaccines. Furthermore, the review team noted that while each vaccine initially had a standard number of doses that was expected to be pulled from each vial, the Food and Drug Administration provided fact sheets for the range in the number of doses some vials were expected to hold. In addition, since facilities were to report the actual number of doses administered, wasted, and extra doses, the expected number of doses is not relevant (table 2, page 17).

received more than 5.5 million doses of vaccine and administered almost 5.4 million of them, including over 4.8 million doses to veterans and over 560,000 doses to VA employees.[36]

Oversight of COVID-19 Vaccine

To prepare to receive and administer the COVID-19 vaccines, many VA and VHA offices had to work collaboratively. VHA's vaccination plan outlined the roles and responsibilities of VA and VHA program offices in overseeing data collection and reporting activities for the COVID-19 vaccine. Additionally, VHA officials provided the OIG with information about the duties of some of the offices with responsibilities for data tracking and reporting. Some of the main offices with responsibilities for data tracking and reporting can be seen in figure 1.

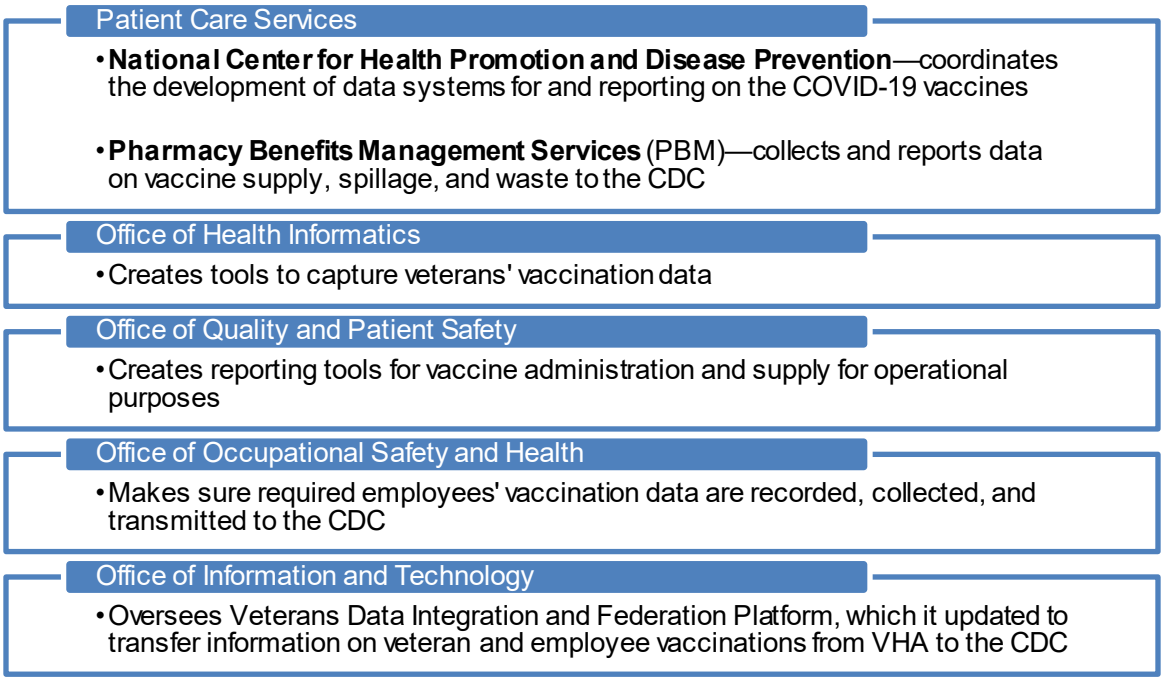

Figure 1. *Responsibilities of key VA and VHA program offices involved in tracking the receipt and distribution of the COVID-19 vaccine.*

Source: VA OIG analysis of information provided through interviews with, and documents from, VA and VHA officials.

[36] This included almost 27,000 vaccinations for Department of Homeland Security employees. VHA officials reported that the data source for doses received was PBM's SharePoint site, and the sources for doses administered were the dashboard developed for national reporting and VHA's Corporate Data Warehouse. Please see the section "VHA Quickly Implemented Vaccine Data Systems and Tools, but Faced Challenges Verifying Facility Data Due to Manual Processes, User Error, Lack of System Access, and Validation Deficiencies" for additional information.

Facility Vaccine Coordinators

According to a VHA memo, each medical facility should designate a COVID-19 vaccine coordinator and backup coordinator. The coordinator is responsible for

- serving as a point of contact between the facility and the VHA COVID-19 vaccine planning team;
- assisting the facility with triaging issues related to vaccine distribution, administration, and waste;
- ensuring that staff receive information and required training on vaccination administration and data collection; and
- organizing vaccine distribution within the facility, in collaboration with the VISN vaccine coordinator.[37]

VISN Vaccine Coordinators

VISN vaccine coordinators oversee and organize vaccination activities for the VISNs and VA medical facilities. VISN coordinators work with the various groups outlined in VHA's plan to facilitate information sharing and guidance about the vaccine.

[37] VHA memo, "Designating a COVID-19 Vaccine Team and Vaccine Coordinators," November 3, 2020.

Results and Recommendations

Finding: VHA Quickly Implemented Vaccine Data Systems and Tools, but Faced Challenges Verifying Facility Data Due to Manual Processes, User Error, Lack of System Access, and Validation Deficiencies

VHA has done an admirable job setting up systems and tools to collect data and report on the COVID-19 vaccines in a short time while dealing with the COVID-19 pandemic. VHA staff developed a new data collection system to capture information on the COVID-19 vaccine supply and expanded the use of two existing systems to record doses administered. VHA also updated one existing tool to facilitate the transmission of required data to the CDC and developed another to consolidate information on vaccine supply allocation and doses administered for internal and external reporting. However, the OIG found some data were unreliable (including information on vaccination refusals), and that staff at some VA facilities initially did not have access to the database used to track employee vaccinations. The OIG determined that reliability was impaired because VHA had not implemented sufficient processes to verify data it collects from facilities' manually entered vaccine data or to validate the data being used for national reporting. Reliability could be increased if VHA monitored the use of the tools and system checks it added to eliminate or minimize data entry errors and added processes making sure summary data are reliable, accurate, and complete.

Inaccurate and inconsistent data could undermine managers' decision-making efforts related to COVID-19 vaccinations, such as appointment scheduling and prioritization. Furthermore, VHA cannot be assured of the accuracy of national immunization data reported to the CDC on the percentages of veterans and employees vaccinated. Finally, without being able to determine what happens to all vaccine doses that enter its healthcare system, VHA increases the risks of COVID-19 vaccine theft.

For example, information provided by VHA to the review team indicated that as of April 7, 2021, VHA had received more than 5.5 million doses of vaccine and administered almost 5.4 million of them, including over 4.8 million doses to veterans and over 560,000 doses to VA employees. VHA also reported having over 1.4 million doses left on hand as of April 7, 2021.[38] The reported number of doses administered (about 5.4 million) plus doses on hand (over 1.4 million) equal more than the reported number of doses received (6.9 million compared with

[38] This included almost 27,000 vaccinations for Department of Homeland Security employees. VHA officials reported that the data source for doses received and doses on hand was PBM's SharePoint site , and the sources for doses administered were the dashboard developed for national data reporting and VHA's Corporate Data Warehouse.

5.5 million).[39] In addition, information provided to the OIG on April 8, 2021, through VA's COVID-19 weekly update indicated that about 4.5 million doses had been administered by VA as of April 7, 2021—a difference of about 800,000 doses administered. Potential reasons for these differences include extra doses, waste, and data entry errors, and are outlined further in this report.

Federal internal control standards require managers to obtain relevant data from reliable internal sources that are reasonably free from error and represent what they purport to represent. Managers should use the data to provide information that is complete and accurate.[40] VHA met the immediate need to modify and develop systems to document the receipt and administration of the COVID-19 vaccines in an unprecedented situation, focusing on making sure veterans and employees received vaccinations. However, to confirm that reported vaccine data are accurate and complete and that vaccines are accounted for, the OIG determined that the department should take steps to address the data reliability issues this report discusses. These findings can also serve as lessons for future mass vaccination events.

The OIG's review finding is based on the following observations:

1. VHA put the necessary systems and tools in place for data capture and reporting.
2. PBM staff do not have procedures in place to verify data they collect from facilities' manually entered vaccine supply data, which are prone to error.
3. Vaccination data in CPRS and OHRS were inconsistent and inaccurate due to inadequate validation and user error.
4. VHA staff at some VA medical facilities initially lacked system access to enter data on employee vaccinations.
5. The dashboard that VHA developed to consolidate vaccine data contained unvalidated data.[41]

[39] See VHA technical comment 7 on page 54. VHA contends the likely cause of the discrepancies between doses administered and doses received is the 10 to 20 percent overfill of both the Pfizer and Moderna product and the timing of when inventories are done versus when doses are administered. The OIG did not make the suggested changes because VHA did not provide documentation that the discrepancies were due to overfills or timing.

[40] GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

[41] See VHA technical comment 8 on page 54. VHA contends that the data are validated against sources. However, VHA also concedes erroneous or incomplete data are beyond the reach of VSSC and only inconsistencies can be reported to the data owner. Further, in its action plan, VHA states that "VSSC does not own those sources and is not privy to the reliability tests those programs conduct on their data, methodologies, or processes. Each is responsible for ensuring they are sharing accurate data with others in the system, including VSSC. VSSC is not a data governance body." The OIG maintains that federal internal control standards require managers to obtain data that are reasonably free from error and evaluate both internal and external sources for data for reliability.

What the OIG Did

From the CDC and VHA's vaccination plans, the review team obtained data elements required for vaccine supply and administration.[42] The team also reviewed documentation, guidance, and other materials for data collection systems and tools used by VHA to collect and report on the COVID-19 vaccines in order to determine if they are functioning at vaccination locations. For the systems assessment, the team reviewed their available data or excerpts to determine if the data collected appeared accurate and complete, and if different data sources capturing the same data produced the same results. The team's data review period was from December 2020 through June 2021, and the scope included vaccine supplies to VA medical facilities' pharmacies, and doses administered to veterans enrolled in VA's healthcare system and VA employees.

To gain a better understanding of VHA's vaccination plan, the team interviewed VHA officials and asked about their oversight responsibilities and the data systems VHA personnel are using to collect and report on the COVID-19 vaccines. The team did not conduct in-person site visits due to COVID-19 precautions. Instead, the team conducted virtual site visits to a judgmental sample of 13 VA medical facilities with varied vaccination rates between January 19 and January 25, 2021. During interviews, the team spoke with those responsible for documenting the receipt and administration of the COVID-19 vaccines to learn how data collection tools and systems were being implemented at the local level. In addition, the team interviewed four randomly selected VISN vaccine coordinators who authorized redistribution of vaccines. Appendix B provides additional information on the review's scope and methodology.

VHA Put the Necessary Systems and Tools in Place for Data Capture and Reporting

VHA created a SharePoint website to track vaccine supply, and modified CPRS and OHRS to capture doses administered to veterans and employees. VHA also updated the Veterans Data Integration and Federation Platform, a tool for reporting data on vaccines to the CDC. The following information describes what each data system does (at the time of this review) and the group responsible for it.

- **SharePoint website.** VA medical facility pharmacy staff manually collect and enter vaccine supply data into the website daily. The website captures quantities of doses received, on hand (those remaining at the end of each day), wasted (those that spoiled, expired, or were otherwise insufficient for use and had to be discarded), and

[42] CDC, *COVID-19 Vaccination Program Interim Playbook, for Jurisdiction Operations*; VA, *COVID-19 Vaccination Plan for the Veterans Health Administration*.

redistributed between locations, as well as extra doses.[43] PBM staff are responsible for documenting and tracking the number of vaccine doses ordered and shipped to each facility or pharmacy, along with transferring the SharePoint supply data to a database. PBM staff also follow up daily with sites that do not report.

- **CPRS.** VHA staff enter vaccine details into a CPRS template in veterans' medical records when administering the vaccine. Staff use a national COVID-19 clinical reminder developed for CPRS by VHA's Metrics and Informatics Workgroup to record details such as date of first and second doses, and vaccine lot number. Staff also use designated CPRS fields to enter vaccine refusals or reasons for deferment, set reminder notifications for scheduling second doses on time, and document prior COVID-19 vaccinations.[44] The clinical reminder was developed to provide standardized documentation of and data on veteran vaccinations.[45]
- **OHRS 2.0.** According to VHA officials, VHA deployed OHRS 2.0 on December 2020 as an employee medical record and rapidly expanded it to track employees' COVID-19 vaccinations. Staff pull up the employee's record, note the date the vaccine was administered, the type of vaccine, and when a second dose is due, if applicable. The Office of Occupational Safety and Health is the business owner of OHRS, which was modified to document employees' COVID-19 vaccinations.
- **Veterans Data Integration and Federation Platform.** The Veterans Data Integration and Federation Platform is a tool that extracts and prepares COVID-19 vaccine data to transmit three vaccination data files to the CDC daily, including (1) veteran, caregiver, and other federal partner vaccination data from facilities using CPRS; (2) veteran patient data from facilities using the Cerner new electronic health record; and (3) employee data from OHRS (includes all VA employees vaccinated).[46] The Veterans Data Integration and Federation operations team is responsible for the autogenerated COVID-19 vaccine data sent to the CDC through daily file transfers.

[43] CDC Vaccine Task Force, *Distribution, and Pharmacy, Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage,* updated May 18, 2021, accessed July 1, 2021, https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf.

[44] According to VHA officials, CPRS was also later used to capture vaccinations for unenrolled veterans, their spouses and caregivers, and other, non-VA federal partners.

[45] "Frequently Asked Questions," VA website on EHR Modernization, accessed April 27, 2021, https://www.ehrm.va.gov/resources/faqs. According to VHA officials, veteran data are pulled from the new electronic health record for facilities and clinics that have begun using the new Cerner Millennium system—those at the Mann-Grandstaff facility in Spokane, Washington, and its associated clinics.

[46] According to VHA officials, VA was provided an application programming interface to begin automated daily transmissions.

Appendix A provides additional information on data transfer from VHA to CDC and on VHA's efforts to set up or modify these systems and tools. VA tracks the vaccine from CDC shipping orders to the point of receipt at facilities through to the point at which doses are administered to veterans or employees.

Any wasted or unused vaccines are returned to the facility's pharmacy at the end of the day, and pharmacy staff conduct a manual inventory count and record the on-hand doses on PBM's SharePoint site. Data are then extracted from PBM's SharePoint website, CPRS, and OHRS, and transmitted to the CDC. Figure 2 depicts the flow of vaccine data into the VA and to the CDC.

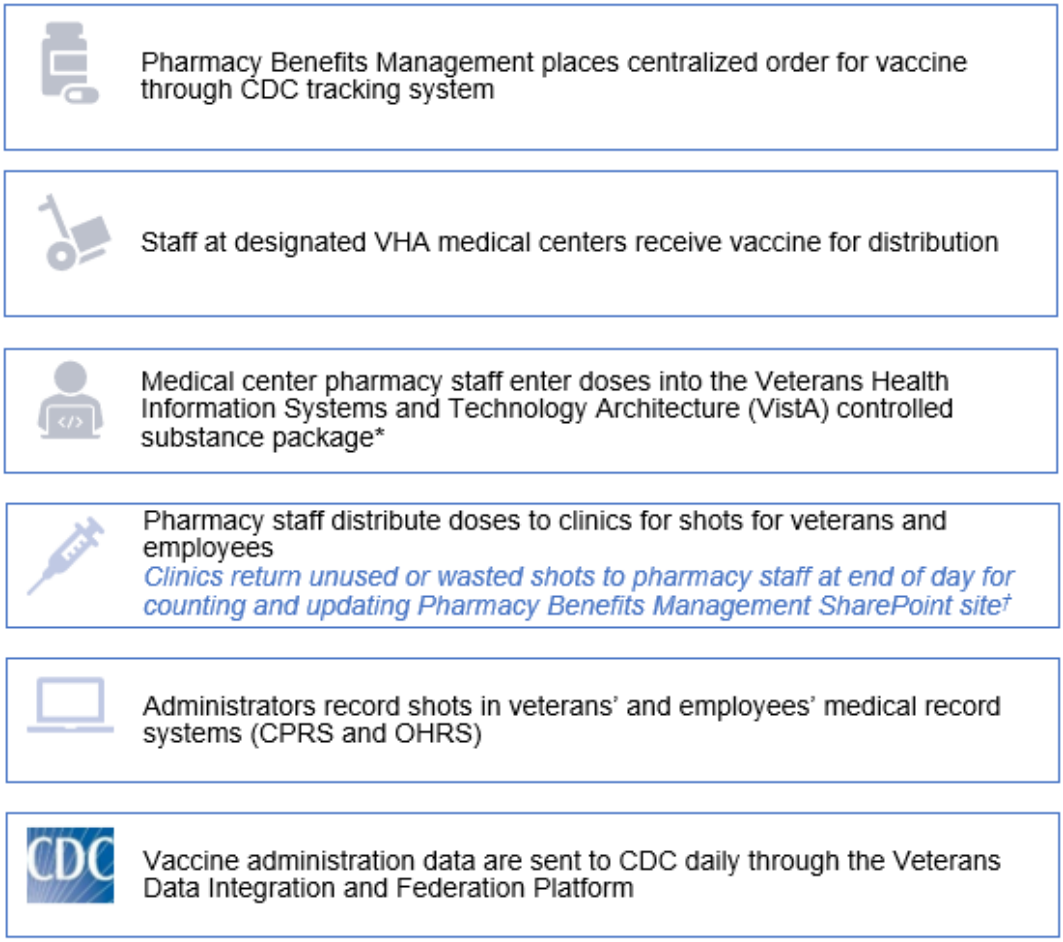

Figure 2. *Movement of vaccine data into and through VA for veterans enrolled in VA's healthcare system and VA employees.*

Source: VA OIG analysis of VHA documentation and interviews with agency officials.

** Veterans Health Information Systems and Technology Architecture (VistA) Controlled Substances Release Notes, version 3.0, March 1997. The VistA controlled substance software package is installed at VA medical facilities to monitor and track the receipt, inventory, and dispensing of all controlled substances.*

† *Wasted doses that spoiled, expired, or were otherwise insufficient for use are destroyed and recorded as waste. A PBM official indicated the only vaccine supply data PBM sends to the CDC pertains to wasted doses, on a weekly basis. (VHA indicated in its technical comment 9 on page 55 that the waste data are sent to the CDC weekly and that VA was not required to report daily on-hand inventory data to CDC. The OIG did not verify these assertions.)*

PBM Staff Do Not Have Procedures in Place to Verify Data They Collect from Facilities' Manually Entered Vaccine Supply Data, Which Are Prone to Error

PBM does not have a process in place to verify vaccine supply data that are manually entered by facilities into its SharePoint site.[47] According to PBM officials, PBM was only reporting vaccine waste to the CDC at the time of this review. However, for effective monitoring managers should use data reasonably free of error to provide information that is complete and accurate.[48] Specifically for COVID-19 vaccines, PBM is responsible for "ensuring purchased COVID-19 vaccines from the manufacturer are received by VHA facility pharmacies" and "ensuring that the number of doses from each multi-dose vial is accounted for and tracking is set up for purchased vaccines and distribution throughout the facility."[49] Since manual entry is subject to error, without a process in place to verify facility-entered data, PBM lacks assurance that the data its staff collect from facilities are accurate or complete, or if all vaccine supply distributed to each facility is accounted for.[50]

PBM program officials told the team what data they verify. They check the number of doses received by the facilities by comparing shipping orders from the CDC with what the facilities enter into SharePoint. In addition, PBM officials said they verify the number of doses that primary sites redistribute to secondary sites (such as a VA medical facility redistributing doses to another facility or a community-based outpatient clinic), but they did not capture information on which secondary locations received the vaccines.

In contrast, PBM officials said they do not verify facility-reported data on the PBM SharePoint site; they rely on facility staff to enter correct data on doses in inventory, doses wasted, and extra doses.[51] PBM officials told the team that their data verification processes are limited to checking for outliers and basic errors or omissions, such as incorrect labeling of data field entries. These

[47] See VHA technical comment 10 on page 55. VHA contends that PBM is not responsible for verifying facility vaccine supply data. However, the OIG finds this inconsistent with VHA's own vaccination plan. The OIG maintains that this is a PBM responsibility, and it is insufficient to state that facility staff must be relied on to enter the correct data.

[48] GAO, *Standards for Internal Control in the Federal Government*.

[49] VA, COVID-19 Vaccination Plan for the Veterans Health Administration.

[50] See VHA technical comment 11 on page 55. VHA contends that PBM is not responsible for verifying facility vaccine supply data. However, the OIG finds this inconsistent with VHA's own vaccination plan.

[51] "COVID-19 Vaccines," VA MedSAFE Applications.

checks included reaching out to sites that did not enter data, checking that quantities entered were whole numbers, and verifying that reported doses wasted matched what was reported to the CDC. The OIG concluded that these checks will not detect whether the data entered by the facilities were accurate—for example, whether a facility that reported having 10 doses on hand actually had 10 doses on-site. PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supplies or data collection processes. The OIG acknowledges that completing on-site spot checks of all facilities' vaccine supply would be resource-intensive for PBM and discussed alternative options with VA to periodically spot-check the supply inventory against the data reported to the SharePoint site. For example, VISN pharmacist executives could conduct this check during periodic facility site visits, which would not use additional PBM resources but would provide VHA some assurance that the reported data are accurate.[52]

Further, at the time of the team's review, PBM staff did not verify data maintained at facilities on vaccines redistributed to secondary sites. According to VHA's vaccine redistribution plan, the VISN pharmacist executives and facility vaccine coordinators were responsible for tracking all secondary redistributions.[53] Four VISN vaccine coordinators the team spoke with provided evidence that they track doses leaving primary locations to the secondary distribution location and said they did not see any value in capturing the same data on PBM's SharePoint site. Yet without identifying the secondary locations that the vaccines are redistributed to, VA staff at the national level do not know if the PBM data accurately reflect the vaccine supply.[54] Beginning May 12, 2021, VA leaders determined no new COVID-19 vaccine orders should be placed with the CDC. Instead, to reduce waste, VISNs should redistribute unexpired vaccines across VA facilities and VISNs before ordering new inventory. Information on these redistributions was to be reported to PBM's SharePoint site and to PBM via email.

[52] See VHA technical comment 12 on page 55. The OIG added language to acknowledge how resource-intensive verifying on-site facility-level supply data would be for PBM staff and summarized alternative options that were discussed with PBM officials. However, the OIG maintains that implementing a process to verify the accuracy of the data being reported to the SharePoint on vaccine supply is a PBM responsibility, and it is insufficient to state that facility staff must be relied on to enter the correct data.

[53] The OIG adjusted its language to address VHA technical comment 13 on page 56 regarding VISN and facility responsibility for tracking data on secondary distribution sites. However, the OIG maintains that overall responsibility for vaccine supply data is PBM's.

[54] The OIG adjusted its language to address VHA technical comment 14 on page 56 regarding VA at a national level not knowing about secondary redistributions unless these data are tracked, and that the VISN and facilities were responsible for tracking data on secondary distribution sites. However, the data are collected by PBM, and the OIG maintains that overall responsibility for vaccine supply data is PBM's.

Facilities Used Some Local Inventory-Tracking Processes, Which Were Manual and Vulnerable to Errors and Manipulation

VA medical facilities are required to document the supply of the vaccine through the VistA controlled substance package, in addition to reporting it on PBM's SharePoint site. Employees the team spoke with from 13 VA medical facilities were either using tracking sheets associated with the VistA controlled substance package to record the use of the vaccine or had created spreadsheets of their own for tracking inventory. However, OIG determined that transferring information from these tracking sheets or spreadsheets into the SharePoint website could be subject to error. In addition, the VistA information is stored locally, and it cannot be used by PBM to see what is occurring nationally or across all facilities with vaccine supply.[55]

Facility pharmacy staff at 11 locations indicated they either complete physical inventory checks or verify the VistA controlled substance package inventory counts daily. To verify VistA data, staff check them against spreadsheet records of the number of vaccine doses the pharmacy filled and delivered, along with the number returned as waste based on how many syringes the pharmacy created, delivered, and recovered each day.

Staff at the other two of the 13 VA facilities the team visited virtually said they generally review the VistA controlled substance package inventory report to make sure it matches what was entered manually into the PBM SharePoint supply tracker. All these manual processes are subject to error, increasing the likelihood of miscounts.

The review team's analysis of PBM's COVID-19 vaccine supply data identified potential errors in VA medical facilities' documentation of vaccine on hand, doses wasted, doses redistributed, and extra doses administered. The team compared facility-reported data from PBM's database with data on doses administered from the dashboard VHA uses for national vaccine data reporting, which draws from CPRS and OHRS records. The dashboard number of vaccination doses administered to veterans, employees, and Department of Homeland Security employees did not match the number from PBM on vaccine doses used. PBM's number of "total vaccinations" was calculated based on doses received, doses remaining on hand, doses wasted,

[55] As noted previously, VHA has had, and continues to experience, challenges with vaccine and pharmacy inventory because it does not have a centralized pharmacy inventory system that allows tracking of inventory at local facilities and pharmacies at a national level.

doses redistributed from one location to another inside VHA, and extra doses administered.[56] Figure 3 illustrates the calculation.

Figure 3. *VA OIG calculation of PBM data to determine total vaccinations administered.*
Source: VA OIG analysis of PBM data.

Table 2 shows examples of data not matching at 10 facilities the team selected. Facilities are ordered based on the magnitude of the percent difference between PBM's records and the dashboard. The team found the largest positive percent difference (23 percent) at the Kansas City VA Medical Center and the largest negative percent difference (-64 percent) at the VA Finger Lakes Healthcare System.[57]

Table 2. Comparison of PBM Data on Vaccine Doses Used with Data on Doses Administered from the Dashboard Used by VHA for National Reporting

VA medical facility/Healthcare system	PBM vaccine doses used	Dashboard vaccination doses administered	Difference*	Percent difference
Kansas City VA Medical Center, MO†	26,784	21,802	4,982	23

[56] In response to VHA technical comment 15 on page 56, the review team took steps to ensure the daily update times for different data systems were aligned; to make sure that the most recent reported on-hand doses for each site were not erroneously zeroed out; and to match three-digit VA facility station codes across data sources and combine data for facilities sharing the same three-digit station code when the data were reported differently by different data systems (e.g., at the five-digit versus three-digit level). While the data variations in reports extracted from multiple electronic data systems could be due to timing, erroneous zeroes in on-hand doses, or the merger of related VA facility data when necessary, in the absence of documentation from PBM on how to review the data for accuracy or reliability, the review team used professional judgment while conducting these analyses, intended to determine the accuracy and reliability of PBM's vaccine supply data. In addition, while VHA notes in its technical comments that "these tools were designed to function independently of one another, so comparing sources isn't appropriate," the dashboard that VHA uses to report on COVID-19 vaccine compiles data across these same sources.

[57] Footnote 56 is responsive to VHA technical comment 16 on page 57.

VA medical facility/Healthcare system	PBM vaccine doses used	Dashboard vaccination doses administered	Difference*	Percent difference
Mann-Grandstaff VA Medical Center, Spokane, WA	6,782	5,652	1,130	20
VA Western New York Healthcare System †	25,887	21,671	4,216	19
VA Nebraska-Western Iowa Health Care System †	44,808	37,725	7,083	19
Northport New York Health Care System	13,926	11,795	2,131	18
New Mexico Health Care System	16,598	19,067	-2,469	-13
Oklahoma City Health Care System †	15,378	17,797	-2,419	-14
VA Northern Indiana Health Care System †	10,202	12,366	-2,164	-17
VA Eastern Kansas Health Care System (Topeka campus) †	6,280	11,675	-5,395	-46
VA Finger Lakes Healthcare System (Bath campus) †	3,889	10,773	-6,884	-64

Source: OIG analysis of PBM's COVID-19 vaccination supply data and VHA Power Business Intelligence (BI) reports for employee, veteran, and Department of Homeland Security vaccinations, retrieved on February 25, 2021.

** A positive difference means fewer shots were given than the PBM system recorded, based on the immunization record. A negative difference means more shots were given than the PBM system recorded, based on the immunization records.*

† For these locations the review team combined PBM's supply data from subsites with the same three-digit station code to match the way data were reported on the Power BI dashboard, where data are only reported at the three-digit station code instead of at the five-digit level. For further details of station code identification concerns, see section titled "Power BI Data Were Not Validated to Their Sources."

In addition to potential data entry errors and miscounts, local data entry processes also put VA facilities and pharmacies at risk of data manipulation, as shown in the following example.

Example

One VA facility chief of pharmacy explained that the PBM vaccine data as reported on the SharePoint site are entered based on an "honor system," and no supporting evidence is required when reporting. The pharmacy chief said the

> *facility recently held a mass vaccination event and miscalculated vaccine doses needed, leading to many doses expiring. Initially, the pharmacy chief was told 155 doses had been wasted that day, but only 28 wasted doses were documented on the SharePoint site. The pharmacy chief told the review team that excess vaccine doses from COVID-19 vaccine vials for vaccine administered later that day from different vials were used to offset the wasted doses so as not to report the actual number of wasted doses.*[58]

When the review team followed up about the possibility of using excess doses to offset wasted doses, the VISN vaccine coordinator was not aware of any instance of this occurring. However, the coordinator said it was possible because of the numerous changes in VA guidance on how to document or track waste and excess doses for the vaccine.[59]

Changing Guidance May Have Compounded Problems with Data Entry

While medical facilities have always been required by the VA COVID-19 vaccine guidance to report on vaccine waste, for more than a month after VHA first received COVID-19 vaccinations, VHA had changing requirements for collecting data on extra doses administered and on doses wasted, as illustrated in figure 4.[60] The OIG recognizes that updated guidance is symptomatic of working in changing conditions. In addition, PBM officials said that guidance changes were made in response to updated information from external sources—like the CDC—as it became available. Updates were often responsive to developments released about the various vaccine doses, handling, and reporting. However, it is important to note that these midcourse corrections can have an impact on data accuracy and oversight.

[58] The review team forwarded the allegations made by the facility chief pharmacist to the OIG Office of Investigations for further review. The Office of Investigations declined to review the matter further due to lack of evidence provided by the complainant.

[59] See VHA technical comment 17 on page 57, with VHA contending that "VA only changes guidance when necessary to meet the CDC's changing requirements."

[60] VA, *Ultra-Cold (-70°C) COVID Vaccine Distribution Plan*; VA, *Frozen COVID Vaccine Distribution Plan*.

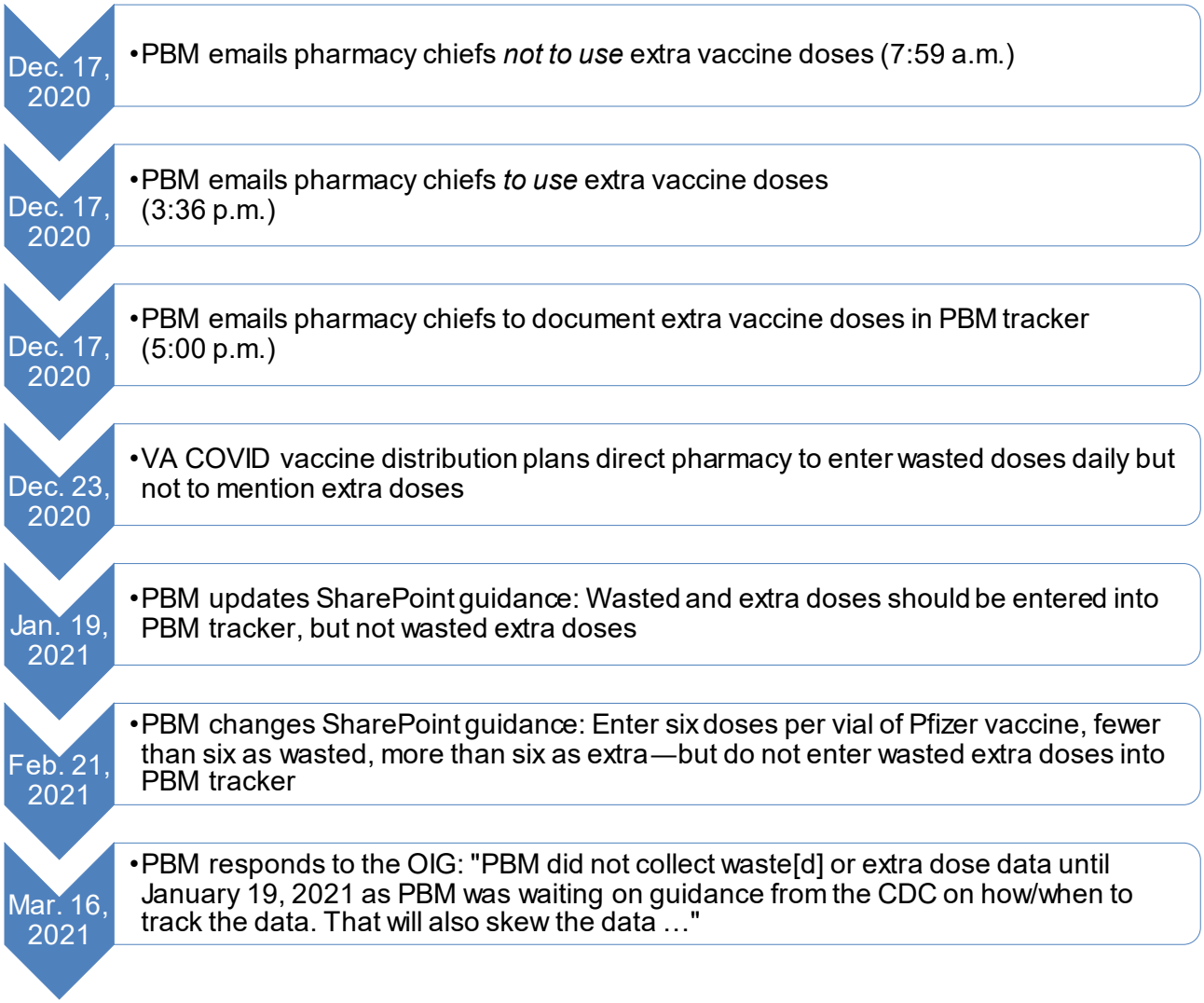

Figure 4. *Timeline of PBM Changing Guidance.*

Source: VA OIG analysis of PBM Guidance.

Initially, vials of Pfizer and Moderna vaccines carried five and 10 doses, respectively. The vaccine manufacturers and the Food and Drug Administration then indicated that vials could include extra doses. VA first decided not to use the extra doses but changed course the same day the Food and Drug Administration provided guidance on using them.[61]

As of February 21, 2021, Pfizer changed guidance to indicate that each vial of vaccine would contain six doses instead of five, and inventories should be documented accordingly. From this date on, PBM provided guidance to the facilities that more than six doses pulled from a Pfizer

[61] See VHA technical comment 18 on page 57, which indicates VA clarified that the change in using extra doses was made after additional guidance was confirmed by CDC, the Food and Drug Administration, and VA leaders.

vial would be documented as extra doses administered, and fewer than six would be documented as waste.

In addition to the review team's analysis presented in table 2, a VISN vaccine coordinator provided the team with a daily COVID-19 vaccination report for facilities in that regional network showing vaccine supply data did not match the vaccination records for the number of vaccination doses administered to veterans and employees. The VISN coordinator believed the discrepancies were due to changing guidance on documentation requirements for entering vaccines wasted and extra doses on PBM's SharePoint site, as well as to potential underreporting of employee vaccinations from OHRS used to populate the dashboard that VHA developed to consolidate vaccine data.[62]

As VHA moves forward with data collection and tracking for the COVID-19 vaccine, it should seek to maintain documentation that is as accurate and complete as possible. To do so, VHA should consider implementing processes to help verify facility-entered data.

Vaccination Data in CPRS and OHRS Were Inconsistent and Inaccurate Due to Inadequate Validation and User Error

VHA took steps to track COVID-19 vaccinations for veterans and employees and does validate some data. However, the review team identified instances of questionable documentation of vaccinations, some caused by facilities entering data in an inconsistent manner, and others caused by data entry errors. As a result, veteran and employee vaccination data may not be accurate.

VHA checks information in CPRS and OHRS. As CPRS veteran vaccination information is submitted to the CDC, VHA uses the CDC Clearinghouse Validator to check for errors in the required data elements, especially in demographic data. According to managers in the Offices of Population Health and Health Solutions, demographic information (such as gender, date of birth, race/ethnicity, and address components) is extracted directly from VistA. This information is already in the system for veterans enrolled in VA's healthcare system. Unless the information contains irregularities—a zip code plus three digits instead of zip plus four, or a date of birth missing the month or day—it is sent to the CDC exactly as it is recorded in VistA. The Veterans Data Integration and Federation team has developed programming code to identify and reformat identified errors, removing the last three digits of a zip plus three and assigning 01 for a missing day or month. This process, however, does not identify data entry errors that do not have to do with format, such as an inaccurate date of birth or an incorrect lot number. As information from employee vaccination records is submitted to the CDC, OHRS 2.0 automatically checks

[62] VHA technical comment 19 on page 58 proposes that the guidance referred to was "CDC" guidance, but that was not attributed in the actual statements made by the VISN coordinator.

particular fields and provides feedback if the data are incorrect. For additional information on data validation efforts, see appendix A.

Despite these efforts, the team identified seven types of inconsistencies and errors across medical facilities in entering vaccination data into CPRS and OHRS for doses administered from December 2020 to April 2021, and documented in these systems as of April 15, 2021:

1. Inconsistent documentation of refusals in CPRS and OHRS
2. Inconsistent second-dose notifications for employees in OHRS
3. Inaccurate second-dose documentation in CPRS and OHRS
4. Erroneous vaccination records from before December 14, 2020, in CPRS and OHRS
5. Erroneous multiples of doses and vaccine types in CPRS and OHRS
6. Potential duplication of veteran and employee vaccination counts
7. Veterans and employees who received vaccinations at more than one facility

These inconsistencies and errors were not prevented by the validation processes in place during the time of the team's review. VHA has since taken steps to address these errors. For example, for veteran vaccinations, VHA staff said they have developed two reports to help identify COVID immunization documentation errors, so that facilities can then correct them. First, the COVID Immunization Extract Report (VistA) is a proactive solution to facilitate medical center monitoring of the quality of vaccine documentation prior to its transmission to the CDC. Second, the COVID-19 Veteran Vaccination Corrections Report (VHA Support Service Center (VSSC) web-based report) identifies four types of errors, such as administration date prior to December 1, 2020 (one of the issues the review team identified below). It provides a list of errors from records that were sent to and rejected by the CDC, which can then be corrected. According to a VHA official, use of these reports started in January 2021, with VHA's Office of Health Informatics accessing the reports, sharing the information with the facilities and clinics, and assisting with corrections as needed. This official said that by March 2021 many sites were routinely utilizing the reports and that their use became mandatory in April 2021. VHA staff also stated that in April 2021, training was provided to local and VISN staff to disseminate information about these reports. However, some data inconsistencies and errors continue to occur.

Inconsistent Documentation of Refusals in CPRS and OHRS

Refusals of vaccines by veterans are tracked on the VHA dashboard used for national reporting when documented using the CPRS clinical reminder.[63] Through interviews with facility staff, the review team determined some veteran vaccination refusals were not consistently recorded using the clinical reminder.[64] Employees the review team spoke with at 11 of the 13 VA medical facilities selected for virtual site visits indicated they were recording veteran refusals at some point in various locations, such as in the clinical reminder template, administrative notes, or patient records. Employees at the two remaining facilities did not track veterans' vaccination refusals. Refusals are not captured nationwide in the VSSC report for any facilities not recording this information in the standardized clinical reminder. Therefore, failure to use the clinical reminder can lead to incomplete data on refusals, or other vaccination outcomes that could be captured by the reminder, including contraindications and deferrals. To address this issue, VHA officials released a memo in May 2021 stating, "Facilities should make a minimum of 2 attempts to contact Veterans whose COVID-19 vaccination status is not documented in the electronic health record" and that "vaccine refusals … should be documented in the national CPRS COVID-19 vaccine clinical reminder."[65]

The team determined this problem also affected employee vaccination refusals. A November 16, 2020, memo to VISN and medical facility directors stated that all COVID-19 vaccination events, including vaccination refusals by VHA employees, must be documented in OHRS 2.0.[66] According to a VHA official, there is currently a separate avenue for documenting COVID-19 vaccine refusals in OHRS 2.0 within the COVID-19 VAX Guided Entry.[67] During interviews at 13 facilities from January 19 to January 25, 2021, staff from six facilities said they were not entering employee refusals into OHRS, while a staff member from another facility said the facility was reporting employee refusals in OHRS. At three other facilities staff were using the Light Electronic Action Framework system or SharePoint to track employee refusals. At the three remaining facilities, staff were using a survey to gauge interest in receiving the vaccine. According to VHA, the CDC does not require documentation of veteran and employee refusals

[63] VHA's Metrics and Informatics Group developed the COVID Surveillance Dashboard (Power BI dashboard) to consolidate and report internally and externally on all VHA COVID-19 vaccine data.

[64] See also VA OIG, *Inconsistent Documentation and Management of COVID-19 Vaccinations for Community Living Center Residents,* Memo No. 21-00913-91, April 14, 2021. The OIG conducted additional work specific to vaccine refusals, contraindications, and deferrals for VHA's community living center residents, which identified inconsistent tracking of these vaccination outcomes.

[65] VHA memo, "COVID-19: Outreach and Documentation of COVID-19 Vaccination Status," May 19, 2021.

[66] VHA memo, "Coronavirus Disease 2019 (COVID-19) Vaccine Documentation Requirement for Veterans Health Administration (VHA) Employees and Health Care Personnel in the Occupational Health Record-keeping System 2.0." However, according to VHA officials, employee vaccination refusal is not among the elements required for reporting to the CDC at this time.

[67] VA, *COVID-19 VAX Guided Entry*. The guide offers step-by-step instructions to expedite COVID-19 documentation and mitigate errors.

but doing so may be helpful for scheduling vaccinations. However, officials expressed reservations concerning employee personally identifiable information when documenting refusals for all employees.

Without documenting refusals in a consistent way, such as through use of the clinical reminder in CPRS, or in OHRS, VHA cannot track refusals at the national level. This information could help VHA better manage its vaccine supply by documenting how many veterans and employees do not want to be vaccinated and so do not need the vaccine.

Inconsistent Second-Dose Notifications for Employees in OHRS

The review team determined the process for second-dose notifications for employee vaccinations was inconsistent and was left up to facilities' discretion. OHRS 2.0 provides the date the second dose is due to assist vaccinators in their notification processes. Sites have been encouraged to use the same method or platform to schedule the second dose that they did for the first dose (such as Microsoft SharePoint, Microsoft Bookings, and the Light Electronic Action Framework system). A VHA official stated that while the facilities used different systems, the system used by each facility was selected based on the facility's needs and familiarity with the systems. The OIG determined that leaving this notification process up to facilities creates the risk that employees will not be notified in a timely manner and may not receive a second dose unless they follow up themselves.

Inaccurate Second-Dose Documentation in CPRS and OHRS

The OIG found records in which veterans had second vaccination doses documented in CPRS without a first dose. In other records first and second doses appeared on the same day. An official said that when both a first dose and a second dose have the same date, she counts that record as indicating the veteran received only the first dose. The official also uses the time stamp and date to determine how many doses were administered. In addition, the official said the inaccurate second-dose documentation occurred when a staff member began logging a vaccination into the system but closed the program before finishing. When staff returned to the program to edit that record, the system automatically populated the information from the edit as a second dose.

VHA issued guidance to try to address these errors and has also built an alert into CPRS. According to VA documentation, if the user sees a prior dose of vaccine in the dialog display or a warning that a second dose is being documented when it is really a first dose, the user should stop and notify the clinical applications coordinator or vaccine coordinator and not click "finish."[68] Additionally, if both doses had the same date, staff were to delete the second entry.

[68] VA, "COVID-19 Vaccine Education TIP Sheet," January 11, 2021.

A variation of this error also occurred in OHRS employee records, where second doses were dated before the first. A VHA official stated that this occurred due to an input error. The official also stated VHA added guided data entry to help prevent this error from occurring.[69]

Erroneous Vaccination Records from before December 14, 2020, in CPRS and OHRS

According to VHA officials, vaccination records dated earlier than December 14, 2020, are the result of user errors.[70] For example, in CPRS, if the vaccinator pulls up documentation from a prior visit instead of creating a new record for the vaccination, the vaccination date reverts to the visit date that was selected. As of April 2021, a VHA official said they have changed this format in OHRS so that a date administered must be less than or equal to today. For CPRS, officials are able to run error reports to catch these errors and make needed corrections. VHA officials also said they provided education to vaccine coordinators on how to create a new visit for the date vaccines were provided instead of adding an addendum to a prior note or visit. This type of error is tracked and submitted to the CDC. According to VHA-provided data, the error rate for all files submitted to the CDC (including for this type of error) was less than 1 percent as of March 3, 2021.

Erroneous Multiples of Doses and Vaccine Types in CPRS and OHRS

As of April 15, 2021, over 1,000 records in CPRS and about 560 records in OHRS showed more than two doses of the Pfizer and Moderna vaccines. According to a VHA official, these are likely due to data entry errors and are, or should be, marked for deletion in the system for OHRS.

As for type, VHA officials stated that when the team saw vaccines from both Pfizer and Moderna for the same location, these were likely to be data entry errors. At the time, according to a VA official, there should have been only one type of vaccine at each location where vaccinations were being provided.[71] As of April 15, 2021, about 170 veterans had vaccinations with more than one type of vaccine recorded in CPRS.

Potential Duplication of Veteran and Employee Vaccination Counts

Vaccinations received by veterans from outside the VHA—from public clinics or pharmacies—and by employees who are veterans can be documented in the CPRS clinical reminder using a

[69] VA, *COVID-19 VAX Guided Entry*. The guide offers step-by-step instructions to expedite COVID-19 documentation and mitigate errors.

[70] VHA began receiving COVID-19 vaccines the week of December 14, 2020.

[71] According to a VHA official, there were two exceptions to this statement, in Florida and North Carolina. These two sites received both Pfizer and Moderna vaccines.

"prior/historical" prompt. However, it is up to the person entering the vaccine information to use this prompt. A review of CPRS vaccination data found that most veteran records labeled "outside" as of April 15, 2021, were appropriately marked as historical (16 were not).

According to an OHRS official, if an employee who is also a veteran receives a vaccination outside VA, VHA depends on the employee to release the information to the Office of Occupational Safety and Health, whose staff then enter it into OHRS. Since CPRS and OHRS do not communicate, VHA officials have no way to verify employee information in CPRS and cannot identify or remove duplicates. As a result, OIG concluded employees who are veterans were counted twice. A review of CPRS vaccination data found that many of the records marked as "employees" in CPRS did not have the notations that VHA officials said they would if they had been appropriately labeled as "historical." As of May 11, 2021, around 2,027 individuals were marked as "employees" in CPRS—potential duplicate counts for employee vaccinations recorded in OHRS and also in CPRS.

Veterans and Employees Who Received Vaccinations at More Than One Facility

As of April 15, 2021, more than 1,500 records in CPRS showed vaccinations for one veteran at more than one location. VHA officials stated that vaccination records in CPRS at more than one facility for the same veteran could be for seasonal residents known as "snowbirds" registered at both facilities. There is one record per veteran, so these veterans would not be counted twice.

In OHRS, approximately 1,000 employees were listed as having had vaccinations at more than one facility as of April 15, 2021. An OHRS official stated that this could occur because some employees received doses at different facilities. Another possibility is that vaccinators might have recorded a vaccination in the wrong employee's record.

VHA has an opportunity to address the inconsistent data entry and data errors as it moves forward with documenting veteran and employee vaccinations. For example, additional guidance could help facilities consistently and correctly enter vaccination information, and built-in system checks and data on vaccinations should be monitored to minimize data entry errors. These types of improvements would provide VHA with more accurate and reliable vaccination data. As VHA continues to offer vaccinations to unenrolled veterans and their spouses and caregivers, these vaccinations will be tracked in CPRS, according to VHA, making it even more important for VHA to ensure the completeness and accuracy of its data. As previously mentioned, according to an official, VHA provided additional guidance and training sessions in April 2021 to try to address and minimize known data entry errors.

VHA Staff at Some VA Medical Facilities Initially Lacked System Access to Enter Data on Employee Vaccinations

In addition to inconsistent data entry and input errors, system access limitations resulted in OHRS implementation challenges. During interviews between January 19 and January 25, 2021, employees from five of the 13 facilities told the review team they lacked access to OHRS 2.0 during the rollout of the COVID-19 vaccinations for staff; staff at the remaining eight facilities did not have access problems. For those who did, staff at two facilities told the team that OHRS was not available to document vaccines at the point of administration; one staff member said access to OHRS was down for a span of 10 days. During this time, facility personnel at both sites said they used a secure spreadsheet to document employee vaccinations. Staff at the three remaining facilities mentioned having access issues and delays at the beginning, which were corroborated in April 2021 by a VISN vaccine coordinator not affiliated with the 13 sites.

To gain OHRS access, facility staff were to submit a list of new users who required it. New users must complete two training courses before being granted access to the system. The Office of Information and Technology said that access is generally granted within 24 to 48 hours. However, based on the team's facility staff interviews, this was not always the case. For example, staff at one facility said that the time between completion of training and being able to use the system was as long as five days.

During a call with OHRS staff, the team asked if they were aware of sites experiencing delays in receiving access. A staff member acknowledged the delays but said the issues generally came from new users not completing the required training or from vaccine coordinators not providing users' names so they could obtain access. The staff member also said Google Chrome is required to access OHRS 2.0, and some locations were using the wrong browser. To make sure access issues do not hamper future vaccination documentation efforts, VHA should make sure all necessary users have access to any additional systems that might be developed for vaccination documentation in a timely and ongoing manner.

The Dashboard That VHA Developed to Consolidate Vaccine Data Contained Unvalidated Data

In addition to expanding on or developing three systems and one tool to collect data on vaccines, VHA developed a dashboard to consolidate all data for reporting on the receipt and administration of the COVID-19 vaccines. Although the documentation VHA provided to the review team for the dashboard outlines its data sources and variables and notes that "data in the dashboard is validated back to the original sources," the team found that VHA did not adequately validate the data.

Power BI Dashboard Provides Information for Reporting

VHA's Metrics and Informatics Group developed the COVID Surveillance Dashboard (Power BI dashboard) to consolidate and report internally and externally on all VHA COVID-19 vaccine data. VHA uses the dashboard internally to coordinate and track vaccine distribution and make decisions about prioritization, logistics, and process effectiveness.[72] The dashboard is also used for national reporting on how many vaccinations VA has provided. According to the VSSC deputy director, staff in VHA's Office of Quality and Patient Safety are tasked with updating Power BI each weekday. A staff member explained the Power BI data come from different data systems—PBM's data, and from veteran and employee vaccination records—and were uploaded automatically for all but employee records.

Power BI Data Were Not Adequately Validated to Their Sources

The Power BI dashboard consolidates data from each of VHA's data collection systems for centralized monitoring and reporting. According to the VSSC deputy director, the data are considered validated if they are pulled from the original sources (PBM, CPRS, OHRS 2.0). She also said that VHA considers feedback received from facilities as part of its validation of the data. However, VSSC staff did not obtain data reliability tests from each program office to ensure data were accurate, complete, and free from errors. Each office is responsible for ensuring the data shared are accurate, according to the VSSC deputy director.

When reviewing these data sources, the OIG identified a lack of validation within PBM's SharePoint website, and data entry errors within CPRS and OHRS 2.0, as discussed previously. The OIG also identified additional potential issues with dashboard data, as discussed below. Federal internal control standards require managers to obtain data that are reasonably free from error and to evaluate both internal and external sources of data for reliability. Furthermore, managers should process obtained data and evaluate the processed data so that it is considered quality information. Quality information is considered appropriate, current, complete, and accurate.[73] Based on the errors below, the team concluded that VHA was not adequately validating the data in the dashboard. Inadequate validation of data prevents VHA leaders from accurately reporting on vaccination supply and administration.

[72] VHA's technical comment 20 on page 58 draws the distinction that the dashboard is used for vaccine administration, with some distribution information populated from the PBM SharePoint site. VHA further notes that sending data once daily for dynamic data is a problem, and PBM is currently working with the dashboard team to remove all distribution data from the dashboard and point users to the PBM SharePoint site. The OIG has not assessed any proposed actions to update the source of vaccine distribution data for the dashboard. At the time of the team's review, dashboard vaccine distribution data came from the PBM SharePoint site. (see VHA comment 21).

[73] GAO, Standards for Internal Control in the Federal Government.

The review team identified potential issues with the dashboard related to (1) ownership of redistributed or relocated vaccines, (2) labeling of the data source on the Power BI dashboard, (3) time lags leading to differences between Power BI and facility data, and (4) aggregation of data for medical facilities in the same, and across multiple, healthcare systems.[74]

- **Ownership of redistributed or relocated vaccines.** Vaccines considered on hand at one facility but stored at another were not accurately reflected in the dashboard. For example, staff at the Jesse Brown Medical Center stored 2,335 doses of Pfizer vaccine at the Hines Medical Center for appropriate cold storage. The staff at the Jesse Brown Medical Center considered these doses as sequestered for them and not for use at the Hines Medical Center. However, these doses were not reflected in the Power BI dashboard as supply for the Jesse Brown Medical Center.[75] The storage of these doses may have been appropriate, but the way the data were recorded did not accurately reflect supply levels for each facility.
- **Labeling of the data source.** The data definitions of the Power BI dashboard state, "Data in the dashboard is validated back to the original sources," which includes PBM's database and veteran and employee vaccination records.[76] However, the team's review of the Power BI dashboard revealed that data source information was inaccurate, as shown in table 3. PBM does not track vaccinations to veterans and employees and cannot be the source of data on total doses administered.

Table 3. Power BI Dashboard Data from Vaccine Supply Tab on Doses Administered: Inaccurate Source Data

Data point	Data definition	Data source
Total doses administered	Number of vaccine doses administered to veterans and employees	PBM

Source: Power BI dashboard and Power BI definitions document.

[74] A healthcare system typically includes a medical facility and numerous clinics and other facilities. VHA asserts in its technical comment 21 on page 58 that findings related to potential issues with ownership of redistributed or relocated vaccines should be removed from the report because PBM's SharePoint site is considered the official source for vaccine distribution data. However, at the time of the OIG's review, vaccine supply data, including inaccurate data on redistributions, were being reported on the COVID-19 dashboard.

[75] Vaccine supply data displayed on the Power BI dashboard during the time of the team's review (December 2020 through June 2021) came from PBM. See VHA technical comment 22 on page 59.

[76] VHA, COVID Vaccine Dashboard, January 5, 2021.

When asked, VSSC staff said the data on doses administered from the inventory tab of the Power BI dashboard come from CPRS and OHRS immunization records, not PBM.[77]

In another example, the Power BI report as of March 22, 2021, indicated the number of "VA employees" vaccinated was 283,979 of 372,113 (about 76 percent). On further review of the Power BI report, the team found that the source data for the overall employee count were misrepresented. The report definitions state that the data are pulled from OHRS, which is where employee vaccinations are recorded. However, Power BI staff told the team that the 372,113 includes only VHA employees who are in the VHA human resource system recorded under a "paid status," not all VA employees. OHRS 2.0 will include records for all VHA healthcare personnel vaccinated by VHA, including volunteers, students, trainees, and contractors. Because VHA officials confirmed that the 283,979 represents all VA employees who were vaccinated, the review team determined that not including all VA staff in the overall employee count (the denominator) resulted in an inflated percentage of vaccinated employees. OHRS officials agreed with this interpretation.

- **Time lags between Power BI and facility data.** From talking to the employees at the 13 facilities reviewed, the team identified instances in which the Power BI data did not match other sources of vaccination data. Facility staff said discrepancies were likely due to delays in updating the dashboard.
    - On January 31, the number of Kansas City VA Medical Center employees that OHRS showed as vaccinated did not align with the number in Power BI (2,613 versus 6,373), and the number of doses administered at the facility from veteran and employee vaccination records did not match that in Power BI (10,750 versus 13,700).
    - On January 26, the number of doses administered at the Orlando VA Medical Center from veteran and employee vaccination records did not align with veteran and employees counts in Power BI (22,578 versus 25, 277).
- **Aggregation of data for medical facilities in the same, and across, healthcare systems.** Power BI tags data from large healthcare systems using a three-digit identifier. The review team found the first three digits are shared by all the facilities in a healthcare system, and across some healthcare systems. In addition, some facilities also have a five-digit identifier, the last two digits unique to the facility. Aggregating data to the three-digit identifier does not allow for accurate reporting at the facility level. For example,

[77] See VHA technical comment 23 on page 59. VA believes that statement is inaccurate as the vaccine supply data on the dashboard at the time of the review were provided by PBM. Nevertheless, the OIG accurately reported the statements provided during interviews with VSSC officials.

data on doses administered at the Albany Stratton VA Medical Center were rolled up with those of other facilities sharing the same first three-digit identifier, instead of being attributed to the Albany facility.

According to the deputy director, the VSSC has not been directed to provide a full, detailed facility-level report through Power BI and doing so would result in the dashboard report being quite lengthy.[78] The VSSC deputy director also told the review team that VSSC relies on feedback from facilities about errors in Power BI. However, staff the team spoke with at six of the 13 facilities said that they did not review Power BI for accuracy. Moreover, the team determined facilities cannot review their individual data because numbers are aggregated to the healthcare system level.

Relying on facilities to inform the program office of data issues and errors and not being able to explain the data differences the team noted between different sources point to insufficient oversight of the Power BI data, which are used for national reporting on VHA vaccine supply and doses administered.

Conclusion

VHA made great strides in developing a SharePoint website and modifying two existing data systems and one tool in a short time for COVID-19 vaccine data collection and reporting. VHA also developed a second tool to consolidate all vaccine data for national reporting. Despite the large population it was responsible for administering vaccinations to and the lack of a comprehensive pharmacy inventory management system, VHA developed a process for tracking vaccine supply to facilities and pharmacies and implemented procedures to document the receipt and administration of doses for both veterans and employees to meet all CDC reporting requirements. VHA went beyond what was required and developed a dashboard for internal and external reporting, drawing on all data sources.

However, the OIG determined that VHA's COVID-19 vaccine data were not as reliable as they could be, and that some staff initially lacked access to OHRS. For vaccine supply data, weaknesses were caused by the inability of PBM to verify facility-entered vaccine supply data collected by PBM, and a lack of verification of the manual data entry at the facility level, which were subject to errors. For doses administered, limited data validation processes and inconsistent and inaccurate documentation in veteran and employee medical records affected data accuracy. Since the OIG started this review, VHA has taken steps to address identified data errors, such as developing data entry guidance and reports that facilities can use to identify errors.

[78] See VHA technical comment 24 on page 59. As noted by VSSC officials in this technical comment, the Power BI dashboard does contain facility-level information, but information for each VA medical facility at the three-digit station code is not always available. This is what the team was referring to when it reported the VSSC deputy director's comment—that she said the VSSC team had not been asked to provide a report this detailed.

Finally, VHA relied on a dashboard for comprehensive data reporting that was not adequately validated to source data and included other errors. Unreliable, inaccurate, and incomplete information may make it difficult for managers to make informed decisions, including decisions regarding prioritizing and scheduling COVID-19 vaccinations. Moreover, VHA cannot be assured of the accuracy of national immunization data reported to the CDC on the number of veterans and employees who were vaccinated and who refused vaccinations. In addition, without knowing what happens to all vaccine doses that enter its healthcare system, VHA runs the risk of undetected COVID-19 vaccine theft.

As VHA continues to offer vaccinations to its employees and veterans enrolled in VA's healthcare system—as well as to unenrolled veterans, veterans' spouses and caregivers, and employees of other federal agencies—effective tracking is even more important. Accurate and complete data tracking will help VHA ensure it appropriately accounts for allocated vaccines and knows who receives those doses. The data will also be important should VHA need to administer boosters for COVID-19, and the lessons learned about related processes and systems will be valuable for guiding any future mass vaccination events.

Recommendations 1–3

The OIG made the following recommendations to the under secretary for health:

1. Develop processes for verifying facility data entered on the Pharmacy Benefits Management Services' SharePoint website (or any subsequent data collection tool) for vaccine supply and usage.
2. Develop a process to monitor the use of tools that have been fielded to standardize data entry for vaccine doses administered by VA medical facilities and clinics to minimize data entry errors, including the Computerized Patient Record System's clinical reminder, the Occupational Health Record-keeping System 2.0's guided data entry guidance, and reports that can be used to identify data entry errors in these systems, or in any subsequent systems that VA uses to collect data on vaccinations.
3. Make sure that the Power BI dashboard data are reliable, accurate, and complete, and capture all vaccine data more accurately for VA medical facilities in the same healthcare system.

Management Comments

The acting under secretary for health concurred with recommendations 1 and 2 and concurred in principle with recommendation 3. The acting under secretary also stated that there is no evidence that VA's vaccine supply and usage data have impeded VA managers' efforts to schedule and prioritize vaccinations. He further noted that CDC officials have been complimentary of VA's data quality and responsiveness to vaccine receipt and distribution. The acting under secretary

reiterated the OIG's finding that VA was able to expand on existing systems, as well as develop and implement new systems, to capture and report COVID-19 vaccine data. This effort involved internal collaboration, as well as collaboration with other federal partners, enabling VA to build the systems needed to support a large-scale nationwide vaccination campaign. Specific to documentation of COVID-19 vaccinations for veterans and VHA employees, the acting under secretary highlighted the OIG's finding that VA implemented standardized national tools for the documentation of vaccines administered and has implemented local changes to identify and create solutions to address user entry errors. VA also provided a detailed accounting of other developments and progress related to the recommendations.

A summary of those developments and the actions proposed by the acting under secretary for health are detailed in appendix C. Key VA planned responses to the recommendations follow:

- **Recommendation 1.** PBM, in collaboration with the Office of the Assistant Under Secretary for Health for Operations, will develop and implement a quality assurance process to assess the accuracy of facility data on COVID-19 vaccine supply and usage. The planned actions are proposed to be completed by April 2022.
- **Recommendation 2.** Work related to data monitoring for CPRS and OHRS 2.0 is in progress, evolving, and developing. The target completion date for planned actions is December 2021.

  VA presented detailed information on its efforts in appendix C. For CPRS, VA stated that it "has had processes in place for daily monitoring of facility and VISN errors since the first days of administration and documentation," ensuring that documentation errors were corrected and that CDC transmission errors were remedied so data could be correctly sent the following day. In addition, VistA and VSSC tools have been developed to assist with vaccine documentation error corrections, and sites were provided direct access to line-item details on their vaccination errors and trained on these tools in April 2021. Finally, VA commented that VISN leaders have been briefed on vaccination documentation errors, and affirmed that they were responsible for error monitoring and correction, and for making sure local processes are in place to research and remedy vaccine documentation errors.

  For OHRS 2.0, submitting records to the CDC and monitoring and resolving errors is currently a manual workflow, and an automated process is being developed, according to VA's comments. In addition, a process to identify COVID-19 vaccine data entry errors in OHRS 2.0 has been implemented, which involves biweekly OHRS 2.0 team meetings and ad hoc reviews of errors and concerns. Reports have also been developed that capture missing doses and doses due within a specified time frame. For example, VA stated that as recently as August 2021, several tools

were developed for the OHRS 2.0 system to ensure data accuracy and improve vaccination documentation.

- **Recommendation 3.** VHA considered recommendation 3 fully implemented and asked OIG to consider closing it. VA commented that VSSC's goal is to provide accurate and reliable information to leaders and the field. While VSSC collects authoritative data on vaccine inventory from PBM, veteran vaccinations from the Corporate Data Warehouse, and employee vaccinations from OHRS, VSSC does not own those sources and is not privy to the reliability tests, methodologies, or processes that those programs use on their data. The acting under secretary for health also provided a list of checks that VSSC had completed to examine the accuracy of the data and noted that VSSC will be acquiring employee identifiable data from OHRS to allow a more thorough validation of station number and job series.

The acting under secretary for health also provided 24 technical comments, which the OIG addressed below and throughout the report. These VHA comments are also found in full in appendix C.

OIG Response

The corrective action plans for recommendations 1 and 2 are responsive to the intent of these recommendations.

The corrective action plan for recommendation 3 is partially responsive to the identified issues and intent of the recommendation. VHA's response states that while VSSC's goal is to provide accurate and reliable information to leadership and the field, VSSC is not privy to or responsible for the reliability testing done on the data sources for the Power BI dashboard. If it is not possible for VSSC to review the reliability, accuracy, and completeness of dashboard data, the OIG believes that steps should be taken to disclose data limitations to dashboard users. For example, PBM does not currently conduct any data reliability testing or validate the accuracy of data submitted to its SharePoint site by the facilities, although VSSC is in the process of acquiring additional employee data from OHRS to validate station numbers and job series. To the extent that PBM and OHRS 2.0 data are included in the dashboard, these limitations should be transparent to users of the dashboard.

Prior to closing recommendation 3, the OIG will seek evidence that documentation related to the dashboard accurately reflects data limitations identified by the OIG in this report. In addition, VHA's actions do not fully address other limitations the team identified with the inaccurate labeling of data sources in Power BI or acknowledge time lags in the data. For example, as of October 5, 2021, the data definitions of the Power BI dashboard still stated that, "Data in the dashboard is validated back to the original sources, provided by PBM, OHRS, and [the

Corporate Data Warehouse]," which contradicts VA's response to the OIG's recommendation, which states VSSC is not doing its own data validation.[79]

The OIG will monitor implementation of all the recommendations by VHA and will close the recommendations when it receives sufficient evidence demonstrating progress in addressing the recommendations and the specific risk areas identified in this report.

As to VHA's 24 general and technical comments, the OIG addressed them within the text or footnotes to the report narrative.

In some instances, the team made requested changes to the report, where additional support was provided. Specifically, the team clarified report language based on VHA's technical comments 6, 9, 13, 15, 16, 17, 18, 22, 23, and 24.

In other instances, the review team made some, but not all, of the suggested changes.

For example, for **comment 1** VHA's acting under secretary stated that there is no evidence that VA's vaccine supply and usage data have impeded VA managers' efforts to schedule and prioritize vaccinations. While the team acknowledged that it did not identify any specific instances of this and updated the language to reflect that impediments *could* result from not verifying vaccine supply data, the team did not remove the rest of the language as suggested. Moreover, adverse impact is not needed to redress identified deficiencies. The team maintains that VHA cannot be assured of the accuracy of the supply data reported to the CDC without verifying what facilities report to PBM's SharePoint site. In addition, the OIG disagrees with VHA that steps taken to validate vaccine supply data are sufficient and consistent with VHA's COVID-19 vaccination plan or with federal internal control standards, or that meeting CDC reporting requirements is the same as verifying the accuracy of reported data.

Specifically, the vaccination plan states that PBM is responsible for

- ensuring that the doses from each multi-dose vial [are] accounted for and tracking is set up for purchased vaccines and distribution throughout the facility,
- ensuring that a feedback loop is developed and followed by VHA facility pharmacy leadership to account for internal distribution of COVID-19 vaccines, and
- developing a finalized plan to track and monitor all COVID-19 vaccines at each facility.[80]

However, VHA has not implemented a process to make sure vaccine supply is accurately accounted for beyond the point at which it is first received at VA medical facilities and does not know if the tracking and monitoring of vaccines are accurate at the facility level.

[79] VHA, COVID Vaccine Dashboard, October 5, 2021.
[80] VA, COVID-19 Vaccination Plan for the Veterans Health Administration.

Additionally, VHA cites three components of federal internal controls:

- 13.01: Management should use quality information to achieve the entity's objectives.
- 13.02: Management designs a process that uses the entity's objectives and related risks to identify the information requirements needed to achieve the objectives and address the risks. Information requirements consider the expectations of both internal and external users. Management defines the identified information requirements at the relevant level and requisite specificity for appropriate personnel.
- 13.03: Management identifies information requirements in an iterative and ongoing process that occurs throughout an effective internal control system. As change in the entity and its objectives and risks occurs, management changes information requirements as needed to meet these modified objectives and address these modified risks.

Additional internal control standards, not cited by VHA but included in this report's findings on pages 10 and 28, require managers to evaluate both internal and external sources of data for reliability and process the obtained data into quality information that supports the internal control system. This involves processing data into information and then evaluating the processed information's quality. Quality information is appropriate, current, complete, accurate, accessible, and provided on a timely basis.[81] VHA has no assurance the vaccine supply data collected by PBM's SharePoint website is complete or accurate, absent a process for verifying what facilities are reporting.

The OIG also reviewed VHA's memorandum of agreement with the CDC and documentation from the CDC that was provided to the review team by VHA. Specific to vaccine supply, the memorandum focuses on vaccine ordering, storage, and monitoring requirements. It also notes that agencies must report on vaccine doses that were unused, spoiled, expired, or wasted, as well as on redistributed doses. However, PBM officials told the review team that CDC was only collecting data on vaccine waste during the time frame of this review. In addition, the CDC only reports on errors related to vaccine administration data if the data include erroneous information and formatting errors.

Similarly, for **comment 2**, the team updated the report language to reflect that PBM *does* not (rather than *cannot*) verify the data facilities report to its SharePoint site. However, the team did not make any additional changes because the report already addressed VHA's lack of a perpetual inventory management system and because the OIG continues to believe that VHA's COVID-19 vaccination plan tasks PBM with accounting for vaccine supply.

Likewise, for **comments 4 and 12**, the OIG made changes to acknowledge that PBM does not have the resources to send program-level staff to all VA medical facilities to conduct on-site

[81] GAO, *Standards for Internal Control in the Federal Government*.

verification on facilities' supply data but did not make any additional changes because the OIG continues to believe that VHA's COVID-19 vaccination plan tasks PBM with accounting for vaccine supply.

For **comment 14,** OIG updated the language to reflect that VA leaders will not know if vaccine supply data are accurate if secondary redistribution locations are not included, but did not make additional changes because the OIG continues to believe that VHA's COVID-19 vaccination plan tasks PBM with accounting for vaccine supply.

In other instances, the review team declined to make suggested changes related to PBM responsibility.

Comments 3, 5, 10, 11 all suggested changes to the report based on the statement that PBM is not responsible for verifying the accuracy of facility-reported vaccine data. The OIG did not make these changes based on PBM's responsibilities as outlined in VHA's COVID-19 vaccination plan and detailed on page 35 of this report. In addition, while VHA's vaccine distribution plans do require VA medical facility pharmacies to report on vaccine supply to PBM's SharePoint website daily, they do not assign overall responsibility for implementing processes to verify the accuracy of reported data on the facilities.

For **comments 7, 8, 19, 20, and 21**, the OIG made no changes, either because VHA did not provide support for the suggested changes, some of which were based on VHA's opinion, or because the team determined the information was not accurate. Explanations are included in the report as appropriate.

The information in the report was based on guidance applicable during the team's data collection period: December 2020 through June 2021.

Appendix A: Background

VHA's COVID-19 Vaccine Risk Stratification Plan

VHA's risk stratification plan for prioritizing the vaccine was intended to maximize the benefits of the COVID-19 vaccinations to veterans and staff when initial supply was limited and help guide outreach and scheduling when supply became more robust.[82] According to VHA officials, VISN medical facility directors were instructed to follow VHA's stratification plan to the extent possible, with local flexibility to maximize access and efficiency and limit potential waste.[83] VHA's first priority group included healthcare personnel and residents of inpatient community living centers (nursing homes). Because the supply of the vaccine was very limited during initial rollout, VISNs were tasked with determining which sites should receive the supply of vaccine product and how much was needed based on the number of employees and patients in the different approved risk stratification levels. PBM received notification of VHA's allocations each week from CDC and obtained input from the VISNs on where vaccines should be distributed.

Table A.1 provides a description of VHA's prioritization plan for COVID-19 vaccinations.

Table A.1. VHA Prioritization of Groups for COVID-19 Vaccines

Priority Group	Description
VHA: A-1a (CDC 1a)	Healthcare personnel working in, and veteran residents of, VHA's community living centers and in spinal cord injury and disorder centers
VHA: A-1b,c,d,e,f (CDC 1a)	Emergency Department, COVID-19 Intensive Care Unit, inpatient, and other staff providing face-to-face care and services for COVID-positive patients, and staff in other congregate living settings Veterans residing in other nursing facilities without access to vaccine; veterans residing in other VA residential/congregate settings

[82] VHA memo, "Updates to COVID-19 Risk Stratification in the Department of Veterans Affairs," February 18, 2021.

[83] VHA's 18 VISNs are regional networks for healthcare delivery. They work together to meet local healthcare needs and provide care to veterans at medical facilities in the network.

Priority Group	Description
VHA: A-2a, 2b, 2c, 3a, 3b, 4a, 4b, 4c, 4d (CDC 1a)	Core staff critical to the functioning of the hospital and the COVID response (e.g., logistics, facilities operations, police, food services, occupational health, environmental engineering, limited executive or leadership roles); inpatient staff, non-COVID units; staff performing high-risk procedures (non-COVID, prescreened); hemodialysis staff; oncology/chemotherapy unit staff; homeless outreach staff; staff with frequent contact with veterans who have not been prescreened for COVID symptoms (screeners, drivers, etc.); outpatient direct care/contact (prescreened, non-COVID) Other health-care personnel and staff (Front-line cemetery workers and veterans in care who are non-VA health-care Personnel may be offered vaccine during "A" as they are CDC 1a essential workers.)
VHA: B-1a, (CDC 1b)	All other staff Homeless veterans; hemodialysis patients; solid organ transplant patients or patients who are listed for transplant; and chemotherapy patients. Veterans aged 75 years and older because they are at higher risk of hospitalization, illness, and death from COVID-19
VHA: C-1a, C-1b, C-1c, D-1a, D-1b (CDC 1c)	Veterans aged 65–74 years because they are at high risk of hospitalization, illness, and death from COVID 19, and sequentially based on age, veterans 50 and older; veterans under 50

Source: VA, COVID-19 Vaccination Plan for the Veterans Health Administration.

Centers for Disease Control and Prevention Data Reporting Requirements

The CDC requires vaccination providers to report certain data elements within 24 hours of administering vaccinations.[84] Table A.2 provides the required and optional data reporting elements.

Table A.2. CDC's COVID-19 Vaccine Reporting Requirements

Required data elements	Optional data elements
Administered at location: facility name/ID	Comorbidity status (Y/N)
Administered at location: type	Recipient missed vaccination appointment (Y/N)
Administration address (including county)	Serology results (Y/N presence of positive results)
Administration date	Vaccination Refusal (Y/N)
CVX (Product)	
Dose number	
Recipient race	
Recipient ethnicity	

[84] CDC, *COVID-19 Vaccination Program Interim Playbook, for Jurisdiction Operations*.

Required data elements	Optional data elements
Immunization Information Systems Recipient Identification (ID)	
Immunization Information Systems vaccination event ID	
Lot Number: Unit of Use or Unit of Sale	
MVX (Manufacturer)	
Recipient address	
Recipient date of birth	
Recipient name	
Recipient sex	
Sending organization	
Vaccine administering provider suffix	
Vaccine administering site (on the body)	
Vaccine expiration date	
Vaccine route of administration	
Vaccination series complete	

Source: Centers for Disease Control and Prevention COVID-19 Vaccination Program.

Transmission of VHA Data to the CDC

VHA officials told the review team the CDC data submissions are systematically reviewed daily. Each file sent to the CDC is reviewed by two clinicians and a health science specialist for inaccuracies, including any missing or incorrect information or template formatting. A parallel report of prior day vaccinations is run in VHA's Corporate Data Warehouse and compared to the Veterans Data Integration and Federation report as a validation method. VHA officials stated if any inaccuracies are identified, the facility clinical applications coordinators and vaccination coordinators are contacted by email that day with a description of the problem and how to correct it. Also, sites are asked to respond when corrections have been made, and staff reported doing so.

VHA tracks the overall number and type of errors in vaccine data submitted to the CDC. VHA maintains a database of errors and corrections, according to Population Health and Health Solutions officials. According to VHA officials, errors identified early in the process were primarily related to formatting (for example, zip code not in xxxxx-xxxx format, or date not in MM/DD/YYYY format) and have been resolved. Errors identified more recently have been attributed to user input (such as the wrong two-letter state code), but training and direct contact with employees at sites where errors occurred have reduced the error rate. According to VHA provided data, the error rate for all files as of March 3, 2021, was less than one percent.

According to VHA officials, records that have been corrected are then retrieved automatically. Records that can be re-sent to the CDC (representing a unique veteran and vaccination event ID) are automatically extracted from VistA by the Veterans Data Integration and Federation or, if not a unique event ID, are flagged to be re-sent when the CDC is able to accept corrected/updated records. The CDC was not able to accept corrected records at the time of the team's review work, according to Population Health and Health Solutions officials. Each vaccination is associated with a unique vaccination event ID which is designated at the time of the vaccination. CDC only accepts a vaccination event ID once. Thus, corrected records (which will have the same vaccination event ID unique to the vaccination event) could not be resubmitted to the CDC. Until accepted, the CDC data may not match VHA's data because of errors VHA has fixed. According to a CDC official, CDC validates that records are properly formatted meaning they contain the right data elements in the correct format. Records that are improperly formatted will not be accepted into the Data Clearinghouse until they are reformatted and resubmitted (within 24 hours). However, according to the CDC, records with erroneous information, such as an inaccurate birth dates or vaccine types, are generally accepted and will not trigger a stop in the CDC's data validation process.

VHA Efforts to Develop or Modify Vaccine Reporting Systems

VHA started work to develop or upgrade the reporting systems before receipt of the vaccine, which started arriving at some sites the week of December 14, 2020. Table A.3 provides a timeline for VHA's work on five vaccine reporting systems.

Table A.3. Timeline of VHA's Work on Vaccine Reporting Systems

Reporting system	Description
PBM SharePoint site	**Week of October 26, 2020:** The initial version was built. **Week of December 7, 2020:** Enhancements for receipt of inventory were added.
CPRS	**August 2020:** Planning and building of the COVID-19 Clinical Reminder dialog began and continued through September 2020. **December 11-12, 2020:** Minor updates were made.
OHRS 2.0	**October 2020:** Began update to incorporate vaccination document development into application. **December 2020:** OHRS was deployed.
Veterans Data Integration and Federation	**September 2020:** The team submitted an initial request and began gathering requirements. **October 2020:** Received approval.
Power BI dashboard	**Around December 1, 2020:** Began building the skeleton for COVID-19 vaccine administration. **December 15, 2020:** Dashboard went live.

Source: Timeline documentation provided by VHA officials.

VHA worked in partnership with the Office of Information Technology to implement systems to nationally track the receipt and distribution of the vaccine across all VA facilities and clinics. For example, the national clinical reminder that VHA developed to document veteran vaccinations in CPRS provides a standardized way to capture this data nationally. This clinical reminder was programmed to include vaccination date, type, lot number and expiration date, location on body for shot administration (e.g., left deltoid), dose, deferral, refusal, or contraindication. Use of this clinical reminder provides a template with prepopulated vaccine information to ensure the required data elements are entered for each vaccination documented. According to a VHA official, in March 2020, subject matter experts started to develop different templates to assist facilities in documenting vaccines. The turnaround time for the templates averaged around three days and have been used over 30 million times by facilities and 5.6 million times by veterans.

In addition to developing the system upgrades, VHA officials told the review team that VHA hosted clinical office hours and calls to respond to questions from the field about data tracking and documentation, and to provide guidance and templates that would assist facilities and clinics to document and track vaccinations given. VHA officials reported that changing CDC guidance on what, and how, to document vaccination data elements resulted in numerous guidance and system changes and updates.

VSSC COVID-19 Vaccine Outreach Tool for Veterans

In addition to the tools discussed in the report, VHA also developed the VSSC COVID-19 Vaccine Outreach Tool to help individual facilities identify veterans in each of the selected risk stratification categories and to enable a targeted outreach process to notify veterans when the vaccine is available, and to schedule vaccination appointments. The tool includes veterans who have received care within the prior 365 days at any VHA medical facility or associated clinic.

To aid in contacting veterans to receive the vaccine based on VHA's prioritization plan, the tool contains the following fields: facility name, patient name, patient Integration Control Number, patient social security number, address, email, phone number, gender, race, and age. In addition, the tool includes information about whether veterans reside in inpatient specialty care or a Community Living Center, and about several health conditions such as whether the veteran has diabetes or is on dialysis. The tool also includes information about vaccine interest and refusal, if documented in CPRS.

This tool was designed to be used locally, and VHA officials told the review team that they do not track how or if facilities use it, or how veterans are prioritized for vaccinations at the local level. Six of 13 facilities interviewed reported using the tool. Three of the six facilities used the tool to track missed second dose appointments.

Appendix B: Scope and Methodology

Scope

The OIG team performed its work from December 2020 through August 2021. The scope of the review focused on VHA's approach to track and report on the supply and administration of the COVID-19 vaccines during December 2020 through June 2021.

Methodology

The OIG reviewed information from CDC and VHA's vaccination plans to determine data elements required by CDC for data collection and reporting. The OIG interviewed VA and VHA leaders from offices with responsibilities related to COVID-19 vaccine data collection and reporting regarding their oversight responsibilities and about the systems VHA is using to track and report on the COVID-19 vaccines. The OIG reviewed systems documentation, guidance, and other materials for the relevant data collection tools and systems, to determine if they were functioning and being used by locations administering the vaccines. The OIG also reviewed available data or excerpts from the systems to determine if the data collected appeared to be reliable and valid for the purposes of this review, and if different data sources capturing the same data produced the same output. The review team conducted virtual site visits to a judgmental sample of 13 VA medical facilities with varied vaccination rates between January 19 and January 25.

Table B.1. Facilities Where OIG Conducted Interviews, by City

Facility name
1. Samuel S. Stratton (Albany) VA Medical Center
2. VA Western New York Health Care System at Buffalo
3. Jesse Brown (Chicago) VA Medical Center
4. Chillicothe VA Medical Center
5. Dayton VA Medical Center
6. North Florida/South Georgia (Gainesville) Veterans Health System
7. Kansas City VA Medical Center (Missouri)
8. Clement J. Zablocki (Milwaukee) VA Medical Center
9. Orlando VA Medical Center
10. Puget Sound Health Care System
11. Aleda E. Lutz (Saginaw) VA Medical Center
12. VA St. Louis Health Care System
13. Central Texas (Temple) Veterans Health Care System

During these interviews, the team spoke with facility staff, including facility vaccine coordinators, geriatric extended care staff, health administration staff, nurses, and other leaders who were responsible for documenting the receipt and administration of the COVID-19 vaccine. In addition, the team interviewed four randomly selected VISN vaccine coordinators who authorized the redistribution of vaccines. The team did not conduct in-person site visits because of the COVID-19 pandemic.

Internal Controls

The review team determined internal controls were significant to the review objective. The team reviewed internal controls for VHA's COVID-19 vaccine data collection and reporting efforts from December 2020 through June 2021. The review work included an assessment of VHA's internal controls for validation testing of COVID-19 vaccine data sent to the CDC, controls for ensuring staff follow data collection and reporting requirements, oversight responsibilities for COVID-19 vaccine reporting and data collection, training efforts for staff using data collection systems for COVID-19 vaccines, and other data reliability testing for COVID-19 vaccine data. The internal control principles that were significant to this assessment included the following components and the underlying principles:

- Component 1—Control Environment; Principle numbers
    - 2. Exercises oversight responsibility
    - 3. Establishes structure, authority, and responsibility
    - 4. Demonstrates commitment to competence
- Component 3—Control Activities; Principle numbers
    - 10. Selects and develops control activities
    - 11. Selects and develops general controls over technology
    - 12. Deploys control activities through policies and procedures
- Component 4—Information and Communication; Principle number
    - 13. Uses quality information
- Component 5—Monitoring; Principle number
    - 16. Conducts ongoing or separate evaluations

The team determined internal control deficiencies significant to the review objective exist related to the COVID-19 vaccine data reliability and accuracy testing. The team identified VHA internal controls for testing and validating vaccine data, but determined those controls are lacking or ineffective. For example, PBM only verified the number of vaccines received at VA medical facilities and not how many vaccines were in supply, wasted, or extra doses were administered,

compared to source records. Also, VHA did not validate data results from the COVID-19 vaccine internal tracking and reporting Power BI dashboard to source data or provided inaccurate report sources. In addition, the team determined the control activities for ensuring staff followed data collection and reporting requirements were ineffective in some instances. For example, staff entered duplicate vaccination records for VA employees who are also veterans, inaccurate dates or series of vaccinations, inconsistent documentation of vaccine refusals, and vaccines received at multiple locations. OIG recommendations 1 through 3 address oversight controls for COVID-19 vaccine data quality controls.

Fraud Assessment

The review team assessed the risk that fraud and noncompliance with provisions of laws, regulations, contracts, and grant agreements, significant in the context of the review objectives, could occur during this review. The team exercised due diligence in staying alert to any fraud indicators. The OIG did not identify any instances of fraud or potential fraud during this review.

Data Reliability

The review team used computer-processed data from multiple information systems that collect and report VHA data for COVID-19 vaccine supply and vaccinations. The team obtained COVID-19 vaccine supply data from PBM's SQL data server and COVID-19 vaccination records from the Power BI dashboard, which reports summary vaccination data from other VHA data systems including CPRS, OHRS, and PBM's SQL data. The team also used veteran and employee vaccination data provided from the OIG's Data Modeling Group and the Data Services directorate, which they retrieved from VHA's Corporate Data Warehouse and OHRS.

To assess the reliability of the data, the team checked the PBM, Power BI, Corporate Data Warehouse, and OHRS data for obvious errors, such as missing data, data outside valid COVID-19 vaccination time frames, duplicate records, and inaccurate data fields such as numbers in alphabetic character fields. In addition, the data analyses provided by the OIG Data Modeling Group for VHA's Corporate Data Warehouse and OHRS vaccination records were independently verified for completeness by OIG's Data Services directorate to ensure inclusion of the entire population of veteran and employee COVID-19 immunization records. Samples of Corporate Data Warehouse and OHRS data were each compared to source records to ensure key data fields matched.

However, data reliability testing was limited because PBM and Power BI data could not be traced back to source documents. As a result, the review team compared PBM data to vaccination reports from the Power BI summary data and found inaccuracies in the reported PBM supply data for many VA medical facilities. The team also compared daily Power BI vaccination reports to similar extracts requested directly from VA medical facilities to match what was reported by Power BI back to the facilities' reported results. The team identified issues

with the reported data not matching the number of vaccinations given, as provided to the team by the VA facilities. The team also spoke with the managing officials responsible for each data system to assess any known weaknesses in the data systems and steps VA took to verify the reliability of the data systems.

The team concluded the data obtained to support the finding were sufficiently reliable for the purposes of the review.

Government Standards

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation, January 2012.*

Appendix C: Veterans Health Administration Management Comments

Department of Veterans Affairs Memorandum

Date: October 8, 2021

From: Acting Under Secretary for Health (10)

Subj: OIG Draft Report, Systems and Tools Implemented to Track COVID-19 Vaccine Data (2021-00913-AE-0033) (VIEWS 05733621)

To: Assistant Inspector General for Audits and Evaluations (52)

1. The Veterans Health Administration (VHA) thanks the Office of Inspector General (OIG) for the opportunity to review and comment on the draft report, Systems and Tools Implemented to Track COVID-19 Vaccine Data and for recognizing the tremendous work the Department of Veterans Affairs (VA) has done to make COVID vaccines available to VA employees and employees from other federal Agencies.

2. There is no evidence that VA's vaccine supply and usage data has impeded VA manager's efforts to schedule and prioritize vaccinations. The Centers for Disease Control (CDC) has been complimentary of VA's data quality and responsiveness to vaccine receipt and distribution.

3. VA expanded existing systems, as well as developed and implemented new systems to capture and report data for its COVID-19 vaccine campaign. This work was accomplished from September to December 2020, representing robust internal collaboration within VA, as well as with federal partners including CDC and the Department of Health and Human Services. This collaboration enabled the build and implementation of a data infrastructure to support a large-scale nationwide vaccination campaign.

4. VA implemented national systems and tools for documentation of COVID-19 vaccine administration to veteran patients and staff that provided standardized tools for data collection at the point of care. VA implemented local changes made at the national level to adjust for new vaccine products and guidance. This will identify and create solutions to address user entry errors such as data entry guidance with system checks and facility reports listing errors needing correction.

5. VHA concurs with recommendations 1 and 2; and concurs in principle with recommendation 3, recommending closure. VHA provides an action plan for recommendations 1 and 2 and technical comments.

The OIG removed point of contact information prior to publication.

Steven L. Lieberman, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report: Systems and Tools Implemented to Track

COVID-19 Vaccine Data

(2021-00913-AE-0033)

The OIG made the following recommendations to the under secretary for health:

Recommendation 1. Develop processes for verifying facility data entered on the Pharmacy Benefits Management Services' SharePoint website (or any subsequent data collection tool) for vaccine supply and usage.

VHA Comments: Concur. VHA's COVID-19 vaccine supply and usage data has been successfully used to ensure local supplies of vaccine are adequate to meet the immunization needs of Veterans, their caregivers, VA employees and fourth mission assignments. In addition, that data has supported vaccine redistribution efforts, and addressed other internal and external needs, including reporting to the Centers for Disease Control. VHA recognizes the importance of continually improving its processes and having internal quality controls so that data entry and reporting are as accurate as possible. Pharmacy Benefits Management, in collaboration with the Office of the Assistant Under Secretary for Health for Operations, will develop and implement a Quality Assurance process to assess the accuracy of facility data on COVID-19 vaccine supply and usage.

Status: In process Target Completion Date: April 2022

Recommendation 2. Develop a process to monitor the use of tools that have been fielded to standardize data entry for vaccine doses administered by VA medical facilities and clinics to minimize data entry errors, including the Computerized Patient Record System's clinical reminder, the Occupational Health Record-keeping System 2.0's guided data entry guidance, and reports that can be used to identify data entry errors in these systems, or in any subsequent data collection systems that VA uses to collect data on vaccinations.

VHA Comments: Concur. The work related to the Computerized Patient Record System (CPRS) and the Occupational Health Recordkeeping System (OHRS) 2.0 is actively in progress, evolving, and developing.

For CPRS, VA has had processes in place for daily monitoring of facility and Veterans Integrated Service Network (VISN) errors since the first days of administration and documentation. At that time, VHA's Office of Health Informatics Clinical Informatics and Data Management (CIDMO)/Field Informatics Stewardship (FIS) staff collated errors data and interacted directly with VA site staff to ensure that documentation errors were corrected, and where they also involved a CDC transmission error, to be sure those were remedied such that they correctly transmitted the following day.

The Veterans Health Information Systems and Technology Architecture (VistA) and VHA Support Services Center (VSSC) tools have been developed to assist with vaccine documentation errors correction. With their development, sites were provided direct access to line-item detail on their vaccination documentation errors. Over a two-week period in April 2021, CIDMO/FIS staff provided training to local and VISN staff on the VistA and VSSC reports functionalities. Training went into detail on how to run and interpret the reports. Several sites needed greater support through 1:1 interaction with

CIDMO/FIS staff, continuing for several weeks thereafter. Additionally, using Microsoft Teams, sites were encouraged to post questions such that these along with their solutions could be seen by all other sites. This process remains highly active today.

Messaging was sent more than once from CIDMO/FIS to VISN leadership briefing them on vaccination documentation errors. Ultimately, this resulted in each VISN affirming that they accepted responsibility for errors monitoring and correction, and that a local process was in place to research and remedy vaccine documentation errors. This did not absolve CIDMO/FIS from responsibility of oversight, and therefore its staff continue to monitor both aggregate, site and VISN documentation error counts, reaching out to sites when necessary. Again, this is a process that continues today. The Microsoft Teams chats remain well attended, and with site questions on vaccinations and documentation resolved often within minutes.

Occupational Health Record-keeping System (OHRS) 2.0, records submitted to the CDC for monitoring and identified record resolution is currently a daily manual workflow. An automated process for submitting records to the CDC is in production to remove the manual submission process and report missing data fields and values. To build on this functionality, OHRS 2.0 has added the ability to document additional doses administered to individuals that will be included in the reliable automation process.

A process to identify COVID-19 vaccine data entry errors in OHRS 2.0 has been implemented. There is a daily OHRS 2.0 Team dashboard that is released that identifies the number of errors in the CDC extract, any trends in errors, and reasons for such errors, a section on investigation that is informed by field concerns, requests, and needs for data improvement, a development section that is informed by the results of investigation and other critical releases, and a section for the Digital Transformation Center (DTC). The Digital Transformation Center informs on help desk cases opened, cases closed, user provisioning requests, help desk case trends, and license usage. The OHRS 2.0 Team, along with the business and the Office of Information and Technology, meets twice weekly and ad hoc to review the dashboard and concerns that arise.

Reports currently exist and capture missing doses. Reports have filter capabilities to identify various data elements such as doses due within a specified timeframe. The Office of Occupational Safety and Health is providing new reports and list views for users so they can quickly view immunization records waiting for verification review and have streamlined the user provisioning process for those needing immediate access to the OHRS 2.0 system. This standardized provisioning process will ensure users receive the proper role-based training for data they enter.

As recently as August 2021, several tools were developed and deployed to the OHRS 2.0 system to ensure data accuracy and improve vaccination documentation. The self-report and upload vaccine documentation feature ensures users verify vaccination data. The Quick Load Wizard ensures users can quickly document vaccinations at one time without having to enter information individually. This eliminates vaccination data entry errors seen with manual workflows. The new scribe functionality provides a guided vaccine documentation process that permits a second user to verify vaccine data entry, and the community page URL is changing to better reflect its future purpose as an all-encompassing vaccine self-reporting page.

Additional tools have been developed to streamline and assist with vaccine documentation accuracy. As of August 26, 2021, OHRS 2.0 can upload completed VA vaccination exemption forms, new easily recognizable dashboards to verify vaccine documentation and exemptions, and the ability to scribe immunization records at other facilities.

Users are encouraged to enter DTC help tickets when they encounter identified errors in the system and the development team continues to monitor these requests daily for trends and user needs. The

development team will continue to monitor and be flexible to changes. Quick Reference Guides and additional training on user needs continue as new OHRS 2.0 features are developed or enhanced.

A process to identify COVID-19 vaccine data entry errors in OHRS 2.0 has been implemented. There is a daily OHRS 2.0 Team dashboard that is released that identifies the number of errors in the CDC extract, any trends in errors, and reasons for such errors, a section on investigation that is informed by field concerns, requests, and needs for data improvement, a development section that is informed by the results of investigation and other critical releases, and a section for the DTC. The DTC informs on help desk cases opened, cases closed, user provisioning requests, help desk case trends, and license usage.

Status: In progress Target Completion Date: December 2021

Recommendation 3. Make sure that the Power BI Dashboard data is reliable, accurate, and complete, and capture all vaccine data more accurately for VA medical facilities in the same healthcare system.

VHA Comments: Concur in Principle. Our goal at the VHA Support Services Center (VSSC) is to always provide accurate and reliable information to leadership and the field. VSSC collected the authoritative data on vaccine inventory from Pharmacy Benefits Management (PBM), veteran vaccinations from the Corporate Data Warehouse (CDW), and employee vaccinations from OHRS. VSSC does not own those sources and is not privy to the reliability tests those programs conduct on their data, methodologies, or processes. Each is responsible for ensuring they are sharing accurate data with others in the system, including VSSC. VSSC is not a data governance body.

VSSC completed data reliability checks on each of the sources used for the Power Business Intelligence (BI) dashboard.

- PBM data – Our role is to collect the essential data elements from PBM, understand what they are providing, and join it to the other vaccine data by facility identification number (ID). We worked with their subject matter experts to understand each field and how it mapped to what we were asked to display in the PBI Dashboard. We did question data we received from them that appeared to be in error or we didn't fully understand. For example, one extract they sent contained 10 facility IDs that did not match our master facility list. We sent that information back to them for correction.
- CDW Immunization data – Veteran vaccination information comes from this file and was aggregated by facility. Any records from this file that were incomplete and did not have the essential data elements were excluded from the dashboard. Business rules for our methodology were established by the COVID Data integrated product team (IPT). Data with questionable information that could not be transmitted to CDC were output to a correction report for the field to review and update.
- OHRS 2.0 – This data proved to be the most difficult to use. We were not allowed to have employee identifiers due to privacy regulations, so we were unable to conduct the validation steps we would have preferred. The station numbers were inaccurate in some accounts. This was brought to our attention by some staff in the field when their local OHRS data did not match the dashboard. We verified that our reports matched what was displayed in OHRS. We would then report those findings back to the OHRS staff for remediation. A second station identifier was added to assist us, and we conducted some additional validation. We worked with staff in the field to review their OHRS inputs and compare with what we were seeing in our extracts. In some cases, the two station identifiers provided did not match within the same record. We again reported this back to the team, and we were told it could not be fixed because the data came from

inaccurate user accounts. The OHRS vaccine data was often dirty and did not pass our validation steps. Those records were output to the OHRS correction reports so the field could update them for proper inclusion in the dashboard.

The work on the Power BI dashboard continues to progress now that we are providing booster immunocompromised patients. These vaccinations will be identified in the data and reported in the dashboard. We will work closely with the members of the Data IPT to ensure we are capturing the information as it should be entered in the medical record and identify any outliers not following the set policy. We will also be acquiring employee identifiable data from OHRS 2.0 that will allow us to conduct more thorough validation of station numbers and job series. We will conduct all necessary validation prior to publishing the data on the Power BI dashboard. VHA considers this recommendation fully implemented and requests closure.

Status: Complete

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Attachment

VHA Technical Comments

OIG Draft Report: Systems and Tools Implemented to Track

COVID-19 Vaccine Data OIG 2021-00913-AE-0033)

NOTE: VHA's comments are specific to only one instance in the report, however, some of VHA's concerns appear multiple times in different sections of the report. VHA has not mentioned every occurrence of language that we are suggesting should be changed.

Comment 1

Draft location: Page ii, para 1, line 1

Current language: Inaccurate and inconsistent data impede managers' efforts to schedule and prioritize COVID-19 vaccinations. Furthermore, VHA cannot be assured of the accuracy of national immunization data reported to the CDC on the percentages of veterans and employees vaccinated. Finally, without being able to determine what happens to all vaccine doses that enter its healthcare system, VHA increases the risks of COVID-19 vaccine theft.

Suggested Language: Although some errors were observed in VA's data, there is no evidence that inaccurate or inconsistent data impeded managers' efforts to schedule and prioritize COVID-19 vaccinations. Furthermore, Pharmacy Benefits Management Staff told OIG that CDC has been very complimentary of the data quality provided by VA. VA implemented COVID vaccine inventory management procedures similar to those used in VA for controlled substances, therefore the risk of diversion of COVID vaccine withing the VA system is no greater than it is for controlled substances.

Justification: VA's COVID vaccine data quality met the internal operational and external reporting needs which is consistent with: 1) the VA COVID-19 Vaccination Plan for the Veterans Health Administration, December 14, 2020; 2) the GAO Standards for Internal Control in the Federal Government, September 2014, Paragraphs 13.01 through 13.03 (13.01-Management should use quality information to achieve the entity's objectives. 13.02-Management designs a process that uses the entity's objectives and related risks to identify the information requirements needed to achieve the objectives and address the risks. Information requirements consider the expectations of both internal and external users. Management defines the identified information requirements at the relevant level and requisite specificity for appropriate personnel. 13.03-Management identifies information requirements in an iterative and ongoing process that occurs throughout an effective internal control system. As change in the entity and its objectives and risks occurs, management changes information requirements as needed to meet these modified objectives and address these modified risks); and 3) the Memorandum of Understanding between VA and the CDC.

Comment 2

Draft location: Page ii, first bullet

Current language: Pharmacy Benefits Management Services (PBM) staff cannot verify facilities' manually entered vaccine supply data, which are prone to error.

Suggested language: VA does not have the tools to enable Pharmacy Benefits Management Services (PBM) staff to verify facilities' manually entered vaccine supply data, which are prone to error.

Justification: The lack of pharmacy inventory management system was identified as a significant system weakness early as the late 1990s but to date, VA has not prioritized the development of a system-wide perpetual inventory management system. The current language implies VA's inability to verify data is due to inattention or negligence, which is not accurate. Further, it implies facility data verification is a PBM responsibility, which it is not.

Comment 3

Draft location: Page iii, section title top of page

Current language: PBM Staff Cannot Verify Data They Collect From Facilities' Manually Entered Vaccine Supply Data, Which Are Prone to Errors

Suggested language: VA Cannot Verify Facilities' Manually Entered Vaccine Supply Data, Which Are Prone to Errors

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 4

Draft location: Page iii, para 2, line 1

Current language: PBM staff conduct basic checks of the SharePoint data reported by medical facilities, but the OIG determined the staff do not fully validate the data they collect from facilities. PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supply or data collection processes and rely on facility staff to enter the correct data.

Suggested language: PBM staff conduct basic checks of the SharePoint data reported by medical facilities, but the OIG determined the staff do not have the ability to validate facility level data because to do so require an on-site presence and can only be done by facility staff. PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supply or data collection processes and must therefore rely on facility staff to enter the correct data. In addition, verifying remains the responsibility of the facility and/or VISN vs PBM national office.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 5

Draft location: Page iii, para 3, line 1

Current language: According to PBM officials, PBM was only reporting vaccine waste to the CDC at the time of this review. However, without a way to verify facility-entered data, PBM cannot account for all vaccine that enters VHA's healthcare system.

Suggested language: According to PBM officials, VA was only reporting vaccine waste to the CDC at the time of the review at the direction of CDC. However, without a way to verify facility-entered data, VA cannot account for all vaccine that enters VHA's healthcare system.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility. The agreement to only report waste data was an agreement between VA and CDC and was not a PBM decision.

Comment 6:

Draft location: Page 5, Table 1

Current Language: Table 1. VHA's Receipt of Supply and Vaccine Characteristics

Comment and Justification: The accuracy of this table and the footnotes should be reviewed by the OIG team…by April of 2021, the storage considerations for Pfizer vaccine were updated to allow up to 2 weeks of storage in a freezer between -25C and -15C. The number of doses in the vial had also been updated to 6. For the Moderna vaccine, the number of doses per vial had been updated to "up to 11 doses" and a 15 dose NDC was added.

The information in the table, as written, isn't consistent with the EUA information for these products as of April 2021. Perhaps this is one of the sources of some of the data OIG has determined is in error.

Comment 7:

Draft location: Page 9, para 3, line 4

Current Language: VHA also reported having over 1.4 million doses left on-hand as of April 7, 2021. The reported number of doses administered (about 5.4 million) plus doses on hand (over 1.4 million), equal more than the reported number of doses received (6.9 million compared with 5.5 million).

Suggested Language: VHA also reported having over 1.4 million doses left on-hand as of April 7, 2021.[1] The reported number of doses administered (about 5.4 million) plus doses on hand (over 1.4 million), equal more than the reported number of doses received (6.9 million compared with 5.5 million). The likely cause of the discrepancy between doses administered and doses received is the overfill of both Pfizer and Moderna product that were realized with each product after facilities began to administer. So, while this might appear to be a data error, it in fact is more likely that it is accurate and is due to the 10 to 20% overfill noted with the vaccines (i.e., 5.5 million labeled doses vs. 6.6 actual doses) and the timing of when inventories are done vs. when doses are administered.

Justification: During the time of the review, the EUA changed for both the Pfizer and Moderna product information to reflect that extra doses may be contained in each vial. Although the Pfizer label was altered in January 2021 to have 6 doses per vial, several sites reported to PBM that in fact there may have been more than 6 doses in some vials depending on needle used. The Moderna label was changed in March 2021 to have "up to" 11 doses or 15 doses depending on the NDC used, but there was a note in the EUA that not all vials would have these "up to" amounts present. It took CDC several weeks to adjust inventory numbers for supply that was being allocated, and the VA guidance for documentation changed after sites were already using product due to changing guidance from the CDC.

Comment 8:

Draft location: Page 10, bullet 5

Current language: The dashboard that VHA developed to consolidate vaccine data contained unvalidated data.

Comment and Justification: This in an inaccurate statement. The data on the dashboard has been validated against the sources. Erroneous or incomplete data from the sources is beyond the reach of VSSC and only inconsistencies can be reported back to the data owner.

[1] This included almost 27,000 vaccinations for Department of Homeland Security employees. VHA officials reported that the data source for doses received and doses on hand was PBM's SharePoint site, and the sources for doses administered were the dashboard developed for national data reporting and VHA's Corporate Data Warehouse.

Comment 9:

Draft location: Page 13, last box of figure 2

Current Language: Vaccine administration data are sent to CDC daily through the Veterans Data Integration and Federation Platform.

Suggested Language: Vaccine administration data are sent to the CDC daily through the Veterans Data Integration and Federation Platform. Waste data is sent to the CDC weekly via upload to VTrcks. VA is not required to report daily on-hand inventory data to CDC at this time.

Justification: The rewritten statement more accurately reflects which data are sent to CDC and the cadence in which the data is sent.

Comment 10:

Draft Location: Page 13, section title at the bottom of the page and continuing to paragraph 1 line 1

Current Language: PBM Staff Cannot Verify Data They Collect from Facilities' Manually Entered Vaccine Supply Data, Which Are Prone to Error.

PBM does not have a process in place to verify vaccine supply data that is manually entered by facilities into its SharePoint site.

Suggested Language: VA Staff Cannot Verify Facilities' Manually Entered Vaccine Supply Data, Which Can be Prone to Error.

Not all VA facilities have a process in place to verify vaccine supply data that is manually entered by into the SharePoint site.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 11:

Draft Location: Page 14, line 5

Current Language: The OIG determined that without a process in place to verify facility-entered data, because manual entry is subject to error, PBM lacks assurance that the data they collect from facilities are accurate or complete, or if all vaccine supply distributed to each facility is accounted for.

Suggested Language: The OIG determined that without a process in place to verify facility-entered data, because manual entry is subject to error, VA lacks assurance that the data reported by facilities are accurate or complete, or if all vaccine supply distributed to each facility is accounted for.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 12:

Draft Location: Page 14, para 2, line 9

Current Language: PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supplies or data collection processes.

Suggested Language: PBM officials said they do not have the resources to complete on-site spot checks of VA medical facilities' COVID-19 vaccine supply or data collection processes and must therefore

rely on facility staff to enter the correct data. In addition, verifying local facility inventory is not a PBM responsibility.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 13:

Draft Location: Page 14, para 3, line 1

Current Language: Further, at the time of the team's review, PBM staff did not track or verify data maintained at facilities on vaccines redistributed to secondary sites.

Suggested Language: Further, at the time of the team's review, PBM staff did not track or verify data maintained at facilities on vaccines redistributed to secondary sites because it was determined that tracking this data was a VISN level responsibility per the guidance that was sent to the field by the COVID Vaccine Planning team.

Justification: The guidance at the time of the review was that it was the responsibility of the VISN to track.

Comment 14:

Draft Location: Page 14, para 3, line 5

Current Language: Yet without identifying the secondary locations that the vaccines are redistributed to, PBM staff at the national level do not know if the PBM data accurately reflect the vaccine supply.

Suggested Language: Yet without identifying the secondary locations that the vaccines are redistributed to, VA staff at the national level do not know if the VA data accurately reflect the vaccine supply.

Justification: Verification of facility level inventory data is not a responsibility of PBM. The inventory, and therefore the accuracy of the tracking data rests with the local facility.

Comment 15:

Draft Location: Page 15, para 4, line 5

Current Language: The dashboard number of vaccination doses administered to veterans, employees, and Department of Homeland Security employees did not match the number from PBM on vaccine doses used. PBM's number of "total vaccinations" was calculated based on doses received, doses remaining on hand, doses wasted, doses redistributed from one location to another inside VHA, and extra doses administered.

Suggested Language: The dashboard number of vaccination doses administered to veterans, employees, and Department of Homeland Security employees did not match the number from PBM on vaccine doses used. PBM's number of "total vaccinations" was calculated based on doses received, doses remaining on hand, doses wasted, doses redistributed from one location to another inside VHA, and extra doses administered. There are likely several different reasons for the data mismatch, including comparing data from different sources with different facility level breakdown, time of day (PBM data is required to be documented by no later than 11:59pm each day), etc. It is also important to note that both the vaccine inventory data and the administration data are considered dynamic numbers, so at any given point in time, there is potential for the numbers not to align.

Justification: Vaccine inventory data and vaccine administration data come from different sources. The tools use a different level of granularity for facility breakdown (STA3N vs STA6N), and there are different

timing requirements related to reporting, so at any given point in time, there is the potential for the numbers not to align. These tools were designed to function independently of one another, so comparing sources isn't appropriate.

Comment 16:

Draft Location: Page 16, para 2, line 3

Current Language: The team found the largest positive percent difference (23 percent) at the Kansas City VA Medical Center, while the largest negative percent difference (-64 percent) at the VA Finger Lakes Health Care System.

Suggested Language: The team found the largest positive percent difference (23 percent) at the Kansas City VA Medical Center, while the largest negative percent difference (-64 percent) at the VA Finger Lakes Health Care System. The difference in data sources is likely since both VISN 15 and VISN 2 are integrated networks, which means that from most data sources, all the facility level data rolls up under one number with several substations. The PBM data was separated by physical address of each location based on CDC requirements for ordering, and it is likely that the CPRS/OHRS data is not broken out in this manner, so attempting to match the data would be nearly impossible.

Justification: Vaccine inventory data and vaccine administration data come from different sources. The tools use a different level of granularity for facility breakdown (STA3N vs STA6N), and there are different timing requirements related to reporting, so at any given point in time, there is the potential for the numbers not to align. These tools were designed to function independently of one another, so comparing sources isn't appropriate.

Comment 17:

Draft Location: Page 18, para 1, line 2

Current Language: However, the coordinator said it was possible because of the numerous changes in VA guidance on how to document or track waste and excess doses for the vaccine.

Suggested Language: However, the coordinator said it was possible because of the numerous changes in VA guidance on how to document or track waste and excess doses for the vaccine secondary to change in CDC guidance.

Justification: VA only changes guidance when necessary to meet the CDC's changing requirements.

Comment 18:

Draft Location: Page 19, para 1, line 1

Current Language: Initially, vials of Pfizer and Moderna vaccines carried five and 10 doses, respectively. The vaccine manufacturers and the Food and Drug Administration then indicated that vials may include extra doses. VA first decided not to use the extra doses but changed course the same day the Food and Drug Administration provided guidance on using them.

Suggested Language: Initially, vials of Pfizer and Moderna vaccines were labelled, and it was listed in the Emergency Use Authorization approved by the FDA as carrying five and 10 doses, respectively. The vaccine manufacturers and the Food and Drug Administration then indicated that vials may include extra doses. VA first decided not to use the extra doses until additional guidance on allocations, documentation, and safety could be confirmed with both CDC and FDA. VA later changed guidance on use of these extra doses after additional information was received from CDC and FDA and VACO leadership discussion.

Justification: The suggested language more accurately reflects the reasoning why the VA guidance changed, as VACO leadership required confirmation from CDC/FDA outside of the Tweet that FDA had initially sent out on this topic.

Comment 19:

Draft Location: Page 20, para 1, line 4

Current Language: The VISN coordinator believed the discrepancies were due to changing guidance on documentation requirements for entering vaccines wasted and extra doses on PBM's SharePoint site, as well as to potential underreporting of employee vaccinations from OHRS used to populate the dashboard that VHA developed to consolidate vaccine data.

Suggested Language: The VISN coordinator believed the discrepancies were due to changing CDC guidance on documentation requirements for entering vaccines wasted and extra doses on PBM's SharePoint site, as well as to potential underreporting of employee vaccinations from OHRS used to populate the dashboard that VHA developed to consolidate vaccine data.

Justification: Changes in VA guidance were secondary to changes in CDC guidance for documentation waste and extra doses.

Comment 20:

Draft location: Page 26, para 4, line 3

Current Language: VHA uses the dashboard internally to coordinate and track vaccine distribution and coverage to make decisions about prioritization, logistics, and process effectiveness.

Suggested Language: VHA uses the dashboard internally to coordinate and track vaccine administration and coverage to make decisions about prioritization, logistics, and process effectiveness.

Justification: The PBM SharePoint site is considered the official source for vaccine distribution tracking, not the main COVID Vaccine dashboard. While there is some distribution data on the main dashboard, it is imported from the PBM SharePoint data once daily and was only put there for ease of use by VACO leadership request. It was realized soon after this data was provided to the dashboard team that sending data once daily at a given point in time, when this is truly a dynamic data source was a problem, and PBM is currently working with the dashboard team to remove all distribution data from the dashboard and point users to the PBM SharePoint site.

Comment 21:

Draft Location: Page 27, para 2, line 1

Current Language: The review team identified potential issues with the dashboard related to (1) ownership of redistributed or relocated vaccines…

Suggested Language: Recommend removing this part of the statement.

Justification: The PBM SharePoint site is considered the official source for vaccine distribution tracking, not the main COVID Vaccine dashboard. While there is some distribution data on the main dashboard, it is imported from the PBM SharePoint data once daily and was only put there for ease of use by VACO leadership request. It was realized soon after this data was provided to the dashboard team that sending data once daily at a given point in time, when this is truly a dynamic data source was a problem, and PBM is currently working with the dashboard team to remove all distribution data from the dashboard and point users to the PBM SharePoint site.

Comment 22:

Draft Location: Page 27, first bullet, line 6

Current Language: However, these doses were not recorded in the Power BI dashboard as supply for the Jesse Brown Medical Center.

Suggested Language: However, these doses were not recorded in the PBM SharePoint as supply for the Jesse Brown Medical Center due to the facility not following guidance on how to document inventory appropriately.

Justification: The example used was an issue caused by the facility not following guidance for how to document inventory. It is also noted that the Power BI dashboard is not the source for recording inventory data, the PBM SharePoint is.

Comment 23:

Draft location: Page 28, para 1

Current language: When asked, VSSC staff said the data come from CPRS and OHRS immunization records, not PBM.

Comment and Justification: This was an inaccurate capture of information. All inventory data on the dashboard have always been provided by PBM.

Comment 24:

Draft location: Page 29, para 2

Current Language: According to the VSSC deputy director, the center has not been directed to provide a detailed facility-level report through Power BI and doing so would result in the dashboard report being quite lengthy. The VSSC deputy director also told the review team that VSSC relies on feedback from facilities about errors in Power BI. However, staff the team spoke with at six of the 13 facilities said that they did not review Power BI for accuracy.

Comment and Justification: This is an inaccurate statement. The Power BI dashboard has always contained facility level information. VSSC always report using the STA6A when available. At one point there was a request that we report all vaccinations from the CDW immunization file without matching them to a visit record. This would allow us to report all vaccinations documented. Without a visit record there is only a 3-digit station code. This will result in information not being full reported at the individual station level for an integrated facility. All issues with the OHRS data were reported to us by the field because we had no other means to validate.

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Review Team	Jennifer L. McDonald, Director Christopher Bellin Kristin Nichols Carla Reid Douglas Rosales Brock Sittinger
Other Contributors	Darryl Joe Yu-fang Li Dharani Ranganathan Allison Tarmann Tiffany Woods

Report Distribution

VA Distribution

Office of the Secretary
Veterans Benefits Administration
Veterans Health Administration
National Cemetery Administration
Assistant Secretaries
Office of General Counsel
Office of Acquisition, Logistics, and Construction
Board of Veterans' Appeals

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

OIG reports are available at www.va.gov/oig.