DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Biologic Implant Purchasing, Inventory Management, and Tracking Need Improvement

AUDIT | REPORT #19-07053-51 | FEBRUARY 25, 2021

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Executive Summary

The Veterans Health Administration (VHA) uses a significant number of biologic implants such as skin substitutes, tendons, and corneal implants to treat patients for a wide range of conditions. VHA classifies biologic implants as a subset of items used within the prosthetic program, but the logistics program manages the inventories. In fiscal year 2019, VHA reported spending about $86 million in prosthetic funding on almost 60,300 biologic implants.

The VA Office of Inspector General (OIG) conducted this audit to determine if VHA had effective procedures for managing biologic implants in three areas:

1. **Purchasing.** VHA policy requires facilities to purchase biologic implants using certain types of funds:
    - **Logistics** funds are used to purchase *initial* inventory paid for from a pool of facilities' general-purpose monies.
    - **Prosthetic** funds are used for *replacement* inventory and *just-in-time* purchases.[1] Both are paid for from a national pool used only for prosthetic items.[2]

    VHA policy requires staff to record prosthetic purchases in the National Prosthetics Patient Database (NPPD), which allows VHA to monitor prosthetic purchases nationwide and inform budget and allocation decisions.[3]
2. **Inventory management.** Inventory management helps facilities ensure implants are available when needed. VHA policy requires facilities to record initial and replacement inventory purchases. While there is no national policy requiring facilities to record just-in-time purchases, local policies may require facility staff to record such purchases.[4] Inventory must align with what facilities have on hand.

[1] Just-in-time purchases involve biologic implants that have short shelf lives. VHA must order and receive them immediately prior to the scheduled procedure.

[2] VHA Directive 1761(2), *Supply Chain Inventory Management*, October 24, 2016; VHA Directive 1081.01(1), *Procurement of Surgical Implants under 38 U.S.C. 8123*, October 29, 2018, made effective December 1, 2018, by the VHA Memorandum, "Replacement of Implant Pre-Authorization Process by VHA Directive 1081.01, Procurement of Implants under 38 United States Code (U.S.C.) Section 8123 Effective December 1, (VIEWS 134659)," November 30, 2018. Directive 1761(2) instructs logistics staff to use funds for total supply support, which would include initial inventories. Directive 1081.01(1) allows facilities to use prosthetic funds for replacement inventory or just-in-time purchases, but not for initial inventory.

[3] VHA Directive 1081.01(1). The directive requires prosthetic staff to complete documentation. Officials from VHA's Prosthetic and Sensory Aids Service agreed to the audit team's interpretation that documentation includes completing entries for the NPPD.

[4] Just-in-time purchasing allows medical providers to order and use an item before the item is paid for or becomes part of a facility's inventory.

3. **Tracking.** Tracking is important for ensuring patient safety because if an implant is recalled by its manufacturer, VHA needs to be able to contact the recipient and take appropriate remedial steps. Facilities are required to track each biologic implant and its recipient so that VHA can maintain its required accreditation with the Joint Commission, an independent, nonprofit organization that sets healthcare standards.[5]

The OIG examined policies and practices in these three areas because of the complexity of the purchasing process, the importance of a well-managed inventory to the effective functioning of VA facilities, and the necessity of tracking implant recipients in the event of a recall. The audit team assessed four VA medical facilities with biologic implant activities—including their associated community-based outpatient clinics—that provide services such as surgery, podiatry, dentistry, and wound care.[6]

What the Audit Found

The audit team identified deficiencies in all three focus areas; that is, implants were not always properly purchased, accurately inventoried, or traceable to the recipients. However, a number of issues impeded the team's evaluation of the purchasing, inventorying, and tracking of biologic implants at the four facilities visited. Medical documentation did not always allow the team to determine the reason for purchasing an implant and therefore whether facilities used the correct type of funds. Vague implant descriptions meant that the team could not always estimate the amount of inappropriate funding spent on certain implants. Further, since VHA policy did not require staff to designate purchases as biologic implants, the team could not determine whether facility staff recorded all biologic implants. Lastly, some facilities' clinics did not keep inventory or tracking records at all. Despite these deficiencies, the evidence from examining purchases, the NPPD, facility logs, other documentation, and interviews with VHA, facility, and clinic staff supports the team's findings. The amount of funding used inappropriately, the number of items missing from inventory, and the number of untracked items may, however, be understated.

[5] VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017; Joint Commission, *Transplant Safety,* TS.03.01.01, January 1, 2020. The directive requires compliance with the Joint Commission and states that the Joint Commission provides an "internationally accepted external validation that an organization has systems and processes in place to provide safe and quality-oriented health care." The Joint Commission requires tracking of implanted biologic implants.

[6] The four medical facilities and associated clinics the team assessed were the Atlanta VA Health Care System in Decatur, Georgia; the Edward Hines Jr. VA Hospital in Hines, Illinois; the John L. McClellan Memorial Veterans' Hospital in Little Rock, Arkansas; and the Eastern Colorado Health Care System in Aurora, Colorado.

VHA Needs to Improve Biologic Implant Purchasing Processes and Oversight

The audit team found that VHA's purchasing agents at the four facilities reviewed did not properly record all biologic implant purchases or use the appropriate funding sources. The purchasing agents did not record 2,931 of 10,305 purchased biologic implants (28 percent) in the NPPD. Instead, agents documented the implants in tissue logs—spreadsheets, databases, and third-party systems used to track biologic implants—which varied by facility and clinic. The team also found that purchasing agents sometimes improperly used logistics funds instead of prosthetic funds.

The audit team found that for the items recorded in the NPPD, purchasing agents at times improperly used prosthetic funds to purchase initial inventory for the following reasons:

- Clinic staff sent requests to purchasing agents that mixed inventory types.
- Purchasing agents mishandled the purchase requests they received, did not ensure requests for implants met funding requirements, and may have selected the incorrect funds.
- Prosthetic purchasing agents did not ensure they received consult notifications from clinic staff with the information necessary to complete NPPD entries.[7]

When purchasing agents use the incorrect funding category or fail to record implants in the NPPD, it affects what funds are available for other needs and makes budgeting more difficult.

VHA Needs to Improve Inventory Management of Biologic Implants

VHA's poor inventory management practices resulted in inaccurate inventories of biologic implants. At the four facilities visited, staff could not locate 714 biologic implants, valued at almost $1.1 million, that were listed in their inventories. Facility staff listed the 714 items in the facility tissue logs, but the audit team did not find the items in their storage locations. The team also found 288 additional items, valued at almost $433,000, in storage locations that staff had not recorded in their logs.

These inventory inaccuracies were caused by nonstandard record-keeping methods associated with facilities' use of tissue logs. Having established these tissue logs, facility staff did not review the information they contained to ensure the inventory listed was accurate. These poor inventory management practices increased the risk for delays in care, as medical providers stated

[7] Consult notifications are consults sent from clinic staff to prosthetic agents that include the necessary information for prosthetic agents to complete entries in the NPPD.

they delayed scheduling, canceled, or came close to canceling procedures due to concerns that implants were not available in the inventory.

At the national level, VHA lacked a consistent inventory management policy for biologic implants. VHA program office staff communicated to the audit team that they were unaware facilities were not using the approved inventory system, the Generic Inventory Package, to inventory biologic implants. Staff were not using that system because it did not allow them to enter serial numbers and other critical information needed for tracking.

VHA Needs to Track All Implanted Biologics

Despite the Joint Commission requirement that VHA track biologic implants, a standard in effect since 2009, VHA lacked the fundamental processes, controls, and systems needed to accurately track biologic implants. Without these, patients could be at risk in the event of a recall. Further, the lack of documentation related to implants limits VHA's ability to identify vendors if complications develop.

Because VHA did not have a national system that met facility needs for compliance with Joint Commission requirements and lacked a policy that prescribed how to track biologic implants, the four medical facilities created, used, and reviewed tissue logs. However, these tissue logs were not being effectively used to track patients who received implants. At the four facilities visited, staff did not track 4,611 of the 10,305 biologic implants inserted from October 1, 2017, through March 31, 2019. Staff at three of the four facilities were unaware of the issues with tracking documented in this report; staff at the fourth facility said they created a tracking work group in January 2020.

The OIG emphasizes that the number of untracked implants was very likely higher than 4,611. That total does not include implants the audit team determined the facility used without updating the inventory or recording in the NPPD. Further, local policies did not always require reviews of facilities' tissue logs for completeness or accuracy. Even though reviews were required at two of the four facilities the audit team visited, supervisors did not consistently or adequately perform them.

What the OIG Recommended

The OIG made 11 recommendations to VHA to improve how it purchases, inventories, and tracks biologic implants.[8] These included clarifying guidance for clinic staff and purchasing agents on determining the correct funding category and sending notifications to prosthetic agents

[8] Recommendations directed to the under secretary for health were submitted to the executive in charge, who had the authority to perform the under secretary's functions and duties. Effective January 20, 2021, he was appointed to acting under secretary for health with the continued authority to perform the functions and duties of the under secretary.

to improve the accuracy of medical and administrative records. The OIG also recommended creating a cost code for recording biologic implant purchases, clarifying inventory responsibilities, and providing national oversight of inventory management and more effective systems to help ensure records' completeness and accuracy. The OIG called on VHA to establish a structure of responsibility, which would create policy and guidance that would help ensure tracking is effective and complete.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with all recommendations and provided corrective action plans that are responsive to the intent of the recommendations. Appendix D includes the full text of the executive in charge's comments. The OIG made a few changes to terminology at VHA's suggestion to make it more reader-friendly regarding consult notifications. The OIG will monitor the implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

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Abbreviations

GAO	Government Accountability Office
GIP	Generic Inventory Package
NPPD	National Prosthetics Patient Database
OIG	Office of Inspector General
VHA	Veterans Health Administration

Introduction

The VA Office of Inspector General (OIG) conducted this audit to determine if the Veterans Health Administration (VHA) had effective procedures for purchasing, inventorying, and tracking the biologic implants it uses to treat patients. VHA uses a significant number of biologic implants such as skin substitutes, tendons, and corneal implants. In fiscal year 2019, VHA reported spending about $86 million in prosthetic funding on almost 60,300 biologic implants. The audit team assessed four VA medical facilities with biologic implant activities—including their associated community-based outpatient clinics—that provide services such as surgery, podiatry, dentistry, and wound care.[9]

Purchasing Biologic Implants

To acquire biologic implants, VHA employs procurement methods that differ from standard VHA practices, particularly in how the agency orders and pays for implants. In December 2018, VHA changed its policy, allowing medical providers to verbally request delivery directly from the vendor and use the implant even before payment.[10] This process is typically referred to as "just-in-time" purchasing. Unlike the standard process, this process does not require that an item be entered into inventory when received; instead, it relies on providers to report the use of the implant to purchasing agents, who in turn pay vendors.

VHA divides funds into two categories—general- and specific-purpose funds. General-purpose funds represent about 66 percent of all funding. At the facility level, the medical center director has discretion on how to best spend general-purpose funds to meet the needs of veterans. In contrast, specific-purpose funds represent about 34 percent of all funding and can only be used for their designated purpose. VHA provided logistics purchases with general-purpose funds and prosthetic with specific-purpose funds. While facilities can use logistics funds for any general facility need, they can only use prosthetic funds for prosthetic needs.

VHA allocates monies between logistics/general-purpose and prosthetic funds differently. While general-purpose funds are allocated using a complex model that accounts for facilities' number of patients, regional variances, high-cost patients, education support, research support, and equipment, prosthetic funds are allocated based on prior-year spending found in the National Prosthetics Patient Database (NPPD). VHA did not track the spending of general-purpose funds

[9] The four medical facilities and associated clinics the team assessed were the Atlanta VA Health Care System in Decatur, Georgia; the Edward Hines Jr. VA Hospital in Hines, Illinois; the John L. McClellan Memorial Veterans' Hospital in Little Rock, Arkansas; and the Eastern Colorado Health Care System in Aurora, Colorado.

[10] VHA Directive 1081.01(1), *Procurement of Surgical Implants under 38 U.S.C. 8123*, October 29, 2018, made effective December 1, 2018, by the VHA Memorandum, "Replacement of Implant Pre-Authorization Process by VHA Directive 1081.01, Procurement of Implants under 38 United States Code (U.S.C.) Section 8123 Effective December 1, 2018 (VIEWS 134659)," November 30, 2018.

used to purchase biologic implants, but tracked prosthetic funds used to purchase $86 million in biologic implants for fiscal year 2019.

For biologic implants, VHA policy states different funds should be used depending on whether the product ordered was for initial inventory, replacement inventory, or just-in-time use. Staff should use logistics, or general-purpose, funds controlled by the facility director for initial inventory. Just-in-time orders and inventory replacements should use prosthetic funds controlled by the national prosthetic program.[11]

Inventorying Biologic Implants

VHA requires facilities to enter all biologic implants, except just-in-time purchases, into VHA's inventory management system—the Generic Inventory Package (GIP)—or to request a waiver to use a different inventory management system. VHA did allow an exception for facilities that were still transitioning to GIP from the outdated Prosthetic Inventory Package that had been used to track items purchased with prosthetic funding.[12] This exception allowed facilities to keep biologic implant inventories in the Prosthetic Inventory Package instead of GIP.

VHA requires facilities to review their inventories either monthly or yearly, depending on the type of inventory point or location. VHA defines inventory points as primary, secondary, or stand-alone. A primary inventory point is generally a storage area that contains all items for an inventory account and is replenished by placing orders outside of the facility. A secondary inventory is a point of distribution from the primary inventory replenished by the primary inventory and maintained in the end-user area, such as a clinic. A stand-alone inventory is a primary inventory that is both storage and point-of-use and does not have distribution points. This type of inventory is typically utilized in areas like the operating room when specialty items are purchased. Both secondary and stand-alone inventories must be reviewed at least monthly. For purposes of this review of biologic implants, the audit team reviewed stand-alone inventories that required monthly reviews.

Tracking Biologic Implants

VHA's policy requires healthcare facilities to comply with Joint Commission standards, which include tracking biologic implants.[13] The commission standards are an internationally recognized

[11] Appendix C provides more details on biologic implant purchasing.

[12] VHA Memo, "Transition from Prosthetic Inventory Package to Generic Inventory Package," August 15, 2018; VHA Memo, "Transition from Prosthetic Inventory Package to Generic Inventory Package (VIEWS 01262031)," September 16, 2019. The first memo required the transition to GIP by December 31, 2018; the second required the transition to GIP by December 31, 2019.

[13] The Joint Commission, *Standards Manual*, TS.03.02.01, January 2020; VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017. The Joint Commission manual states, "The hospital traces all tissues bi-directionally."

way to externally validate that an organization has systems and processes for safe, quality health care. The Joint Commission standard for tracking biologic implants requires hospital records to be linked from the biologic implant supplier to the recipient, and from the recipient back to the biologic implant supplier.

This commission standard has been in effect since 2009, but at that time VHA did not have a national system to track biologic implants. Therefore, staff at VHA facilities responded by developing their own tracking systems, or tissue logs, to comply with the standard. These logs varied from staff-developed spreadsheets to off-the-shelf software systems.

Results and Recommendations

Finding 1: VHA Needs to Improve the Biologic Implant Purchasing Process and Oversight

Purchasing agents are responsible for paying for biologic implants at VHA facilities, but the audit team found that the agents at the four facilities visited did not properly record the purchase of 2,931 biologic implants in the NPPD. Facilities' purchasing agents also improperly used prosthetic funds to purchase some of the 7,374 biologic implants listed in VHA's NPPD, since some of these implants were initial inventory and should have been purchased with general-purpose funds. Improper use of funds occurred because clinic staff sent requests to purchasing agents that mixed inventory types, purchasing agents mishandled the purchase requests they received, and prosthetic purchasing agents did not ensure that they received consult notifications from clinic staff. Additionally, VHA did not require staff to purchase implants with a specific code when using general-purpose funds. Without an improved purchasing process, VHA cannot fully account for funds spent on biologic implants, or prosthetic items in general. VHA may also have difficulty budgeting and allocating funds effectively.

What the OIG Did

The audit team conducted site visits to four facilities and reviewed clinics at all campuses, including community-based outpatient clinics. While clinic structure varied at different facilities, the clinics all included services such as surgery, podiatry, dentistry, and wound care. For the four facilities visited, the team compared VHA's list of purchased biologic implants to the implanted items identified on facility tissue logs from October 1, 2017, through March 31, 2019. When records did not match, the team and facility representatives discussed the reasons for the discrepancies.

To understand the processes followed by clinics and purchasing agents, the audit team conducted interviews and reviewed national and local policies. The team interviewed clinic staff, logistics purchasing agents, and prosthetic purchasing agents at the four facilities, as well as officials from VHA's Prosthetic and Sensory Aids Service and Procurement and Logistics Office. Appendix A provides more information about the team's methodology.

Finding 1 discusses issues with VHA's procedures for purchasing biologic implants:

- Purchasing agents did not properly document biologic implant purchases in the NPPD.
- Clinic staff sent purchasing agents biologic implant requests that mixed inventory types.
- Purchasing agents mishandled purchase requests.
- Clinic staff did not routinely provide consult notifications.

- VHA did not require identification of biologic implants purchased with general-purpose funds.

Purchasing Agents Did Not Properly Document Biologic Implant Purchases in the NPPD

VHA policy requires staff to record all prosthetic purchases, including biologic implants, in the NPPD. Of the 10,305 biologic implant purchases at the four facilities, the audit team found purchasing agents did not enter 2,931 (28 percent) into the NPPD. Without NPPD entries, it is difficult to determine whether purchasing agents used prosthetic funds for these implants as required. In order to identify the funding source of the items not entered into the NPPD, facilities had to manually review documentation of the purchases. For the 2,931 biologic implant purchases, the team found some instances when purchasing agents improperly used logistics funds. Using the national average cost of a biologic implant, the team estimated these biologic implants were worth over $4.4 million.[14]

For the remaining 7,374 biologic implants (72 percent) that purchasing agents paid for with prosthetic funds and entered into the NPPD, the audit team found multiple medical providers requested that purchasing agents use prosthetic funds to pay for initial inventory, even though VHA policy states that initial inventory should be purchased with general-purpose funds. Because the team could not definitively determine which biologic implants were purchased for initial inventory, the team concluded that an unknown portion of the 7,374 biologic implants were improperly purchased with prosthetic funds. Table 1 shows the number of prosthetic implants purchased at the four facilities during the period audited and how many were entered into the NPPD.

[14] The average unit cost data contained 4,720 different price points, with unit costs ranging from $0 to $75,000 and an average unit cost of $1,502.48. The average unit cost was selected because it allowed for the broadest interpretation of a single unit cost from all known transactions but reduced the impact of outlier transactions where facilities purchased higher quantities of individual items.

Table 1. Prosthetic Biologic Implants Purchased from October 1, 2017, through March 31, 2019

Facility	Total biologic implants purchased*	Biologic implants entered into the NPPD	Biologic implants not entered into the NPPD
Atlanta	1,149	181	968
Little Rock	905	123	782
Hines	4,463	3,607	856
Denver	3,788	3,463	325
Total	**10,305**	**7,374**	**2,931**

Source: VA OIG analysis of facility tissue logs and VHA's NPPD.
**The total was developed from the total implanted biologics on the facility tissue logs and VHA's NPPD.*

Clinic Staff Sent Purchasing Agents Biologic Implant Requests That Mixed Inventory Types

Many of the purchasing agents' errors occurred because clinic staff requests mixed inventory types. Given VHA's distinction between using prosthetic funds for just-in-time or replacement purchases and general-purpose funds for initial inventory purchases, clinic staff should not mix these types of requests. In other words, biologic implants using general-purpose funds should be sent to logistics purchasing agents, while those using prosthetic funds should be sent to prosthetic purchasing agents. However, clinic staff sometimes included both types of purchases in a single request. Purchasing agents receiving such a request could improperly pay for the implant if they used just one type of fund.

For example, if a dentist performing a procedure for a veteran wanted to also increase inventory, he or she might request multiple implants. Some would be "just-in-time" for the procedure (and thus purchasable with prosthetic funds), whereas the other implants would be initial inventory (and thus purchasable with general-purpose funds). The purchasing agent who received this request might not notice the distinction and would purchase all the implants from the same fund, some of them improperly. Instead, this order should have been sent in two parts: one as a prosthetic purchase for the veteran and the rest as a logistics purchase from general-purpose funds for initial inventory.

While evaluating the 2,931 purchases not entered into the NPPD, the audit team found clinic staff followed informal procedures for making purchases. They thus improperly sent purchase requests to logistics to be paid for from general-purpose funds when the requests should have been sent to prosthetic agents. Since clinic staff sent the requests to logistics, the logistics purchasing agent did not create consult notifications.

Clinic staff told the audit team there is no written policy for determining whether to send a purchase request to logistics or prosthetic purchasing agents. Further, many staff members stated they were not trained on how to make the determinations and generally relied on experience or verbal guidance.

The audit team found VHA's guidance lacked both the clarity and the detail needed to ensure clinic staff knew when to send purchase requests to prosthetic agents and when to send to logistics. Clinic staff did not always know if an item was a biologic implant because they did not have a list that defined biologic implants. Staff at some facilities stated that one product was a biologic implant, while staff at another facility stated it was not.

Recommendation 1 addresses the need for VHA to implement specific controls and guidance for facilities to determine when to send purchase requests to prosthetic purchasing agents and when to send requests to logistics purchasing agents.

Purchasing Agents Mishandled Purchase Requests

The audit team concluded prosthetic and logistics purchasing agents sometimes mishandled requests from clinic staff because they did not identify whether the biologic implant was for a just-in-time purchase or inventory replacement (prosthetic funding) or whether it was for initial inventory (logistics or general-purpose funding). As a result, they did not ensure they selected the correct funds for biologic implant purchase requests. While evaluating the 2,931 purchases, the team found prosthetic purchasing agents paid for biologic implants without assurance the purchase request was for a just-in-time purchase or inventory replacement of a biologic implant. Similarly, logistics purchasing agents paid for biologic implants from general-purpose funds without assurance the request was for initial inventory.

When the audit team spoke to purchasing agents involved, they stated that there was not a written policy for formal reviews of purchases to determine if the requests were for initial inventory, inventory replacement, or just-in-time purchases. Purchasing agents could not readily tell if items on a request were biologic implants, nor did they have processes to review requests for the type of purchase. In general, purchasing agents were either not aware of the prosthetic funding requirement or relied on their experience to determine if the item was a biologic implant. Further, when the clinic staff submitted purchase requests, they did not clearly designate if the item was initial inventory, replacement inventory, or just-in-time.

The audit team found that VHA lacked effective guidance to ensure prosthetic and logistics purchasing agents formally reviewed purchase requests for biologic implants to determine which funding type was appropriate. Recommendation 2 stresses the importance of guidance for purchasing agents on how to ensure they select the correct funds for biologic implant purchase requests.

Clinic Staff Did Not Routinely Provide Consult Notifications

The audit team determined that prosthetic purchasing agents did not always ensure that clinic staff provided the proper consult notifications. When clinic staff perform a medical procedure that involves an implant, they must initiate a consult notification. This notification provides information about the patient and implant that is needed for prosthetic funding and ensures a record of the implant in the patient's prosthetic file. Although prosthetic and logistics staff indicated that the majority of the 2,931 biologic implant purchases without NPPD entries were made using prosthetic funds, they did not provide the team with copies of those determinations. Prosthetic and logistics staff stated clinic staff failed to enter the proper data into the electronic health record that would provide the necessary purchase information.

The audit team found that VHA should issue additional guidance to ensure that all prosthetic agents receive the proper consult notification for all purchases. Recommendation 3 is for clinic staff to provide required notifications.

VHA Did Not Require Identification of Biologic Implants Purchased with General-Purpose Funds

VHA could estimate the value of biologic implants purchased with prosthetic funds because its policy required prosthetic agents to enter purchases of biologic implants into the NPPD. However, VHA did not track the biologic implants that logistics purchasing agents paid for from general-purpose funds. While VHA policy requires agents to enter purchases into VHA's financial management system, the system does not have specific cost codes that differentiate between general-purpose and prosthetic funds. Therefore, the audit team could not identify biologic implants that were paid for with general-purpose funds in either VHA's financial management system or the NPPD.

Recommendation 4 suggests that VHA require facilities to place all biologic implant purchases made with general-purpose funds under the same cost category. In addition to improving funding accountability, facilities could use this cost category to more effectively track use and inventory.

Finding 1 Conclusion

VHA staff did not always select the proper funds for biologic implant purchases or create required notifications to purchasing staff. This could affect VHA's budgeting decisions, as facilities did not enter 2,931 of 10,305 biologic implant purchases valued at an estimated $4.4 million into the NPPD. Further, incorrect fund selection could reduce facilities' available funds for other needs. VHA needs to improve guidance to purchasing agents and clinic staff, require clinic staff to create consult notifications, and improve how it tracks biologic implants in its financial management system.

Recommendations 1–4

The OIG made the following recommendations to the under secretary for health:[15]

1. Provide clarifying guidance and controls to clinic staff on making determinations to send purchase requests and consult notifications to the appropriate purchasing agents.
2. Provide clarifying guidance to purchasing agents on how to effectively evaluate biologic implant purchase requests for the correct funding source.
3. Provide clarifying guidance to prosthetic agents to ensure they receive clinic staff consult notifications on all prosthetic purchases of biologic implants.
4. Create a biologic implant cost code for general-purpose funds to improve funding accountability and potentially assist in ensuring all biologic implant use is tracked.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with recommendations 1 through 4. To address recommendations 1 and 2, the executive in charge reported the Prosthetic and Sensory Aids Service will reeducate prosthetic and clinical staff on the updated VHA Directive 1081.02, *Management of Biological and Non-Biological Implants*, dated October 29, 2020. For recommendation 2, he stated that VHA will reeducate prosthetic and logistics staff assigned to procure surgical implants. For recommendation 3, the executive in charge reported that the Prosthetic and Sensory Aids Service will partner with clinical access coordinators, its Data Management Council, and Veterans Integrated Service Network and facility Prosthetic and Sensory Aids Service leaders to identify opportunities for improvement. For recommendation 4, he reported that the Procurement and Logistics Office is working with relevant financial points of contact to establish a biologic implant cost code for general-purpose funds. VHA comments may be found in full in appendix D.

OIG Response

The executive in charge's corrective action plans are responsive to the intent of the recommendations. The OIG replaced "NPPD notifications" throughout the report with "consult notifications" as this more closely aligned to the terminology used by VHA in the actual process of entering information into the NPPD. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

[15] Recommendations directed to the under secretary for health were submitted to the executive in charge, who had the authority to perform the under secretary's functions and duties. Effective January 20, 2021, he was appointed to acting under secretary for health with the continued authority to perform the functions and duties of the under secretary.

Finding 2: VHA Needs to Improve Inventory Management of Biologic Implants

Due to poor inventory management practices, VHA's inventory of biologic implants at the four facilities the audit team visited was inaccurate and incomplete. These facilities did not use a standardized inventory system for biologic implants and did not conduct reviews of inventory on hand. These problems occurred because VHA national policy did not provide effective guidance to the facilities regarding how best to inventory biologic implants, nor did the available guidance clarify facility staff's responsibilities for inventorying these implants. As a result, the audit team could not locate 714 biologic implants valued at almost $1.1 million. Facility staff also did not record an additional 288 biologic implants valued at almost $433,000 in inventory or tissue logs. Poor inventory management jeopardized prompt care, as medical providers stated they delayed scheduling, canceled, or came close to canceling procedures due to inventory issues.

What the OIG Did

While on-site at the four facilities, the audit team used each facility's tissue log to conduct physical inventory reviews. Any item listed on the tissue log that had not been implanted or disposed of should have been available and on hand. In conducting this review, the team used a judgmental sample to randomly select items from tissue logs and off the shelf to compare them for inconsistencies.

To understand VHA's guidelines for inventory management, the audit team reviewed VHA's inventory policy and conducted extensive interviews with staff and officials from the Prosthetic and Sensory Aids Service, the Procurement and Logistics Office, and the four facilities. Appendix A provides more information about the team's overall methodology.

Finding 2 discusses issues with VHA's procedures for inventorying biologic implants:

- Facilities used poor inventory management practices. Specifically, facilities did not have a standardized inventory management system that met their needs, and facilities did not perform inventory reviews.
- Biologic implants on hand and tissue logs of available implants were inconsistent.
- Lack of inventory management increased the risk of delays for medical procedures.
- VHA did not provide effective guidance to facilities regarding biologic implant inventory roles and responsibilities.

Facilities Used Poor Inventory Management Practices

VHA facilities did not use effective inventory management tools for biologic implants, such as a standardized inventory management system with uniform access, data entry, and supervision.

Instead, facilities used tissue logs, which amounted to spreadsheets, databases, and third-party systems that varied by facility and clinic. The team found facility managers did not perform reviews of inventory to ensure tissue logs accurately reflected the available inventory. In addition, two of the four facilities had clinics that did not use tissue logs or record their inventory in any way.

Facilities Did Not Have a Standardized Inventory Management System That Met Their Needs

Although VHA policy requires facilities to inventory biologic implants in GIP, staff at the four facilities explained that GIP did not support tracking specific products by serial and lot numbers.[16] For example, GIP would indicate that the facility had eight items of a certain type in the operating room, but would not provide the serial or lot numbers for each item to track the implants. Facility staff thus implemented tissue logs to address this deficiency.

These tissue logs lacked many of GIP's useful inventory management features, such as standardized access, data entry, and reporting. While staff could access GIP through VA software to enter items at receiving areas such as the warehouse, they had only limited access to the tissue logs. Only specific staff with special permission had access to the logs, which were not always located at receiving areas. GIP also required standardized data entry that ensured staff entered information consistently. In contrast, staff using the tissue logs to record the receipt, movement, and use of biologic implants did so inconsistently. In some instances, staff did not provide enough detail for other facility staff to identify the type of implant. For example, one entry described an item only as an "implant." Finally, while information in GIP could easily be included in national data reports, information in the nonstandard tissue logs could not be readily consolidated and compiled.

The OIG concluded that although GIP did not enable the tracking of biologic implants, it offered several useful features as an inventory management system that were missing in the tissue logs. Recommendations 5 and 6 call on VHA to ensure facilities use an approved inventory management system that allows them to perform effective oversight of biologic implants by providing clear guidance and monitoring compliance.

Facilities Did Not Perform Inventory Reviews

Although VHA policy requires that stand-alone storage locations (like the biologic implant storage locations at these four facilities) be reviewed monthly, the audit team found that the

[16] VHA Directive 1761(2), *Supply Chain Inventory Management*, October 24, 2016, amended on October 26, 2018. This directive states that facilities will enter all expendable supplies, including biologic implants, into GIP. The Veterans Integrated Service Network or medical facility may submit a memorandum to request a waiver from the requirement to use GIP. None of the four facilities had requested a waiver.

tissue logs were not being reviewed that frequently. In fact, facility staff disagreed about who should be conducting inventory reviews. VHA policy states that the Procurement and Logistics Office is responsible for Prosthetic and Sensory Aids Service performance measures, regardless of the inventory management system used, and logistics staff are responsible for performing inventory reviews.[17] However, logistics staff in charge of inventory did not believe they were responsible for reviewing biologic implant inventories. They instead assumed the responsibility belonged to prosthetic staff. Because most biologic implants were never entered into GIP, logistics staff drew the incorrect conclusion that others were responsible for reviewing the biologic implant inventory.

When the audit team spoke to officials with the Procurement and Logistics Office about this issue, the officials were unaware that facilities were not using GIP to inventory biologic implants. Further, the officials stated that not all biologic implant purchases qualified as inventory because clinic staff ordered many biologic implants as just-in-time items. While the audit team agreed with this statement, most implants on hand fell in the other categories and could be kept in inventory for up to five years. Clinic staff requested these implants as inventory and not for a specific patient. By policy, logistics staff should have considered all these items as inventory, recorded them in GIP, and performed required monthly reviews.

Recommendations 7 and 8 direct VHA's Procurement and Logistics Office to ensure logistics staff perform inventory reviews as required and suggest VHA monitor medical facility compliance with on-site inventories.

Biologic Implants On Hand and Tissue Logs of Available Implants Were Inconsistent

Due to the poor inventory management practices detailed above (pages 11 and 12), VHA's inventory of biologic implants at the four facilities the audit team visited was inaccurate and incomplete. The team searched for 1,510 of 2,498 biologic implants listed in inventories and determined that 714 of the 1,510 implants (47 percent) were missing from their designated locations. Auditors found an additional 288 implants on hand that staff failed to record in tissue logs. Based on the estimated average cost of a biologic implant, VHA potentially lost track of about $1.1 million in biologic implant inventory. Table 2 shows the results of inventory searches by facility.

[17] VHA Directive 1761(2). This directive states that the logistics program is responsible for all clinical items, with the exception of pharmacy and research items. It further details the requirements for reviews of inventory. For primary inventories, facilities must complete a review once per fiscal year. For secondary and stand-alone inventories, facilities must review inventory at least once a month. At all facilities the audit team visited, the biologic implant inventory locations were stand-alone.

Table 2. Audit Team Biologic Inventory Results

Facility	Number of implant items for which the audit team searched	Missing items	Additional items the audit team found that were not listed in inventory
Atlanta	803	370	133
Little Rock	210	124	0
Hines	235	133	123
Denver	262	87	32
Total	**1,510**	**714**	**288**

Source: VA OIG comparisons of facility tissue logs and physical inventory.

When the audit team spoke to facility staff about these missing biologic implants, staff stated that they thought most of the missing items were used in procedures and they simply failed to update the tissue logs. The team found several instances supporting this assertion based on a limited review of medical procedures. However, these instances illustrate VHA's need to implement a standardized inventory management system for biologics. It is unclear how many others were missing due to being expired, discarded, or misplaced.

In some cases, clinics ordered unnecessary inventory that went unused due to poor inventory management. For example, clinic staff at one facility ordered 197 biologic implants but ultimately returned 99 unused. As of May 2019, the remaining 98 items had been on the shelf for an average of over 400 days, with an average expiration in 232 days. In another clinic, because staff members had failed to record the product in inventory at the facility, staff unnecessarily ordered more of it.

Lack of Inventory Management Increased the Risk of Delays for Medical Procedures

Poor inventory management increases the risk of delays for medical procedures if the required implants are not available. The audit team heard from medical providers and staff at multiple facilities that they delayed, canceled, or came close to canceling procedures because biologic implants were not available in the inventory. Selected accounts follow:

- An oral surgeon discussed not offering implant restoration due to the difficulty of the ordering process.
- A dentist at a different facility stated he often had problems getting items needed for procedures and had to cancel or reschedule because of the lack of products. He further stated he was considering leaving VA over his frustrations with inventory.
- Clinic staff almost canceled a clinical procedure because the tissue logs incorrectly listed items as available when they were not. Fortunately, clinic staff followed up with the

purchasing agent who was able to order and receive the implant just prior to the procedure.

VHA Did Not Provide Effective Guidance to Facilities Regarding Biologic Implant Inventory Roles and Responsibilities

VHA national policy did not provide effective guidance to VHA facility staff on their roles and responsibilities in implementing processes to effectively inventory biologic implants. VHA policy clearly states that the chief supply chain officers for Veterans Integrated Service Networks are responsible for conducting annual reviews of their facility logistics programs.[18] VHA policy also states that VHA's Procurement and Logistics Office is to provide oversight of Prosthetic and Sensory Aids Service supply inventories, regardless of the inventory system used or the program office assigned supply management responsibilities.

However, staff at the four facilities the audit team visited were unclear regarding their responsibilities for managing the biologic implant inventory. Staff at all four facilities did not understand that biologic implants are clinical supplies defined in VHA's inventory policy and that reviewing these inventories is the facility logistics staff's responsibility. Many logistics staff stated incorrectly that they never purchased biologic implants and that inventory reviews of biologic implants were not their responsibility. They mistakenly believed all biologic implant purchases and subsequent inventory reviews were made by the facility's prosthetic staff. Since prosthetic agents normally ordered only one item at a time, most logistics staff—including officials from the Procurement and Logistics Office—believed these purchases were just-in-time purchases that did not fit VHA's definition of inventory. However, many prosthetic purchases were for inventory or inventory replacement.

Recommendation 5 is that VHA's national guidance should more clearly establish the roles and responsibilities for managing the biologic implant inventory.

Finding 2 Conclusion

Due to poor inventory management practices, VHA's biologic implant inventory lacked fundamental controls to prevent waste and ensure that the implants were available for medical procedures. As a result, the four VHA facilities reviewed could not account for about $1.1 million in implants missing from inventories. VHA needs to provide clarifying guidance for staff in charge of biologic implant inventories and ensure the national program offices oversee facility compliance with VHA's inventory policy.

[18] Veterans Integrated Service Networks are 18 regional groupings of medical centers, community-based outpatient clinics, and other medical facilities through which VHA delivers health care.

Recommendations 5–8

The OIG made the following recommendations to the under secretary for health:[19]

5. Direct the Procurement and Logistics Office to clarify guidance on the use of an approved inventory management system specific to biologic implants and the related VHA network, office, and facility staff responsibilities.
6. Monitor facility compliance with the use of an approved inventory management system for completeness and accuracy.
7. Direct the Procurement and Logistics Office to ensure logistics staff perform inventory reviews of biologic implants, as required.
8. Monitor medical facility compliance with required reviews of on-site inventory.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with recommendations 5 through 8. To address recommendation 5, the executive in charge reported the Procurement and Logistics Office collaborated with the Prosthetic and Sensory Aids Service to draft the recently published VHA Directive 1081.02, *Management of Biological and Non-Biological Implants*, dated October 29, 2020. The national prosthetic and logistics program offices are developing lunch and learn ongoing trainings regarding the requirements and implementation of the directive. The executive in charge reported that VHA Directive 1761, *Supply Chain Management Operations*, is being updated and will contain clarifying language on inventory management of the Prosthetic and Sensory Aids Service's clinical inventory items. Further, he stated the quality control review conducted by the Veterans Integrated Service Network's chief logistics officer at each medical facility was revised to ask if all VA-owned inventories of biologic and nonbiological implantable devices are managed in approved systems.

To address recommendation 6, the executive in charge repeated that the quality control review was revised to allow the Veterans Integrated Service Network to determine if an approved inventory management system was used and included information on additional checks and random audits. He further stated that VHA is in the process of correcting the supply chain common operation picture dashboard, which VHA uses to monitor supply chain activity. The executive in charge stated VHA will correct problems with the dashboard caused by migration issues and include data pertaining to biological and nonbiological inventory points.

[19] Recommendations directed to the under secretary for health were submitted to the executive in charge, who had the authority to perform the under secretary's functions and duties. Effective January 20, 2021, he was appointed to acting under secretary for health with the continued authority to perform the functions and duties of the under secretary.

For recommendation 7, the executive in charge reported that the quality control review performed by the Veterans Integrated Service Network once per fiscal year will include determining if biologic and nonbiologic implant inventories were recorded and scanned in accordance with VHA Directive 1761, and whether biologic and nonbiologic implant inventories are being reviewed weekly.

To address recommendation 8, the executive in charge reported that the Veterans Integrated Service Network chief logistics officer will complete and submit the results of the revised quality control review checklist to the Procurement and Logistics Office to address deficiencies. VHA's comments may be found in full in appendix D.

OIG Response

The executive in charge's corrective action plans are responsive to the intent of the recommendations. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

Finding 3: VHA Needs to Track All Implanted Biologics

Despite the Joint Commission requirement that VHA track implanted biologics—a standard in effect since 2009—VHA lacked the fundamental processes and controls needed to effectively track these implants. VHA did not designate the responsibility for overseeing tracking, did not develop a national policy describing how facilities should track these implants, and did not have a standard tracking system for facilities to use that meets requirements.[20] As previously described, the four facilities the audit team visited established spreadsheets for tracking biologic implants—tissue logs—because of the lack of a standardized tracking system. However, the tissue logs at these four facilities were incomplete, with facilities failing to track at least 4,611 of the 10,305 biologic implants (45 percent) that were reported to have been used from October 1, 2017, through March 31, 2019. Staff at three of the four facilities were unaware of issues with tracking; staff at the fourth facility stated they had created a tracking work group in January 2020. Because two facilities had clinics that failed to track biologic implant use entirely, the audit team concluded that the number of untracked biologic implants is likely higher than 4,611.[21] Without a better system for tracking biologic implants, facilities cannot notify veterans if their implants are recalled so that appropriate medical follow-up and treatment can be administered.

The OIG observed that this problem has been noted by Joint Commission reviews of VHA facilities. From 2017 to 2019, the Joint Commission reviewed 138 VHA facilities on a range of standards. These reviews cited five facilities for lack of compliance with the standard that requires biologic implant tracking.[22] For more on these reviews, see appendix B.

What the OIG Did

The audit team analyzed biologic implant entries in four facilities' tissue logs and the NPPD from October 1, 2017, to March 31, 2019.[23] The tissue logs covered biologic implants at all facility campuses, including community-based outpatient clinics. The team attempted to locate other biologic implants that were not recorded in the NPPD (such as those purchased with

[20] VHA Directive 1100.16. The directive requires that VA medical facilities comply with Joint Commission standards. The standards require hospitals to track tissue, including biologic implants, from the supplier to the recipient and from the recipient to the supplier.

[21] This number is further understated by facilities failing to properly track use of the implants not found in inventory searches, as discussed in finding 2.

[22] Because the Joint Commission focused on a specific subset of standards within facilities, it is unknown how many of the remaining 133 facilities were examined for tissue-tracking compliance.

[23] Tracked implants included implanted, returned, wasted, and discarded implants. The NPPD is a central database of prosthetics data recorded at each VHA facility and posted to the individual veterans' prosthetic records. An item with a completed entry in NPPD has been purchased by prosthetics.

general-purpose funds), but facility documentation did not allow for meaningful analysis of biologic implants outside of the NPPD.

To gain an understanding of VHA's guidelines for tracking biologic implants and its oversight of tissue logs, the audit team conducted site visits to four facilities and interviewed officials from the Prosthetic and Sensory Aids Service and the Procurement and Logistics Office in VHA, the VA National Center for Patient Safety, and VA medical facilities. Appendix A provides more information about the audit team's methodology.

Finding 3 discusses issues related to the audit team's determination that VHA did not effectively track implanted biologic items:

- VHA needs to provide program oversight for tracking biologic implants.
- VHA needs to develop policies and procedures for tracking implanted biologics.
- VHA needs to establish a standardized tracking system for implanted biologics.
- The four facilities visited failed to track at least 45 percent of implanted biologics.

VHA Needs to Provide Program Oversight for Tracking Biologic Implants

VHA did not designate a national program office or other entity to oversee the tracking of biologic implants even though the administration requires that its facilities comply with Joint Commission accreditation standards, which include tracking implanted biologics. The commission's biologic implant standard has been in place since 2009, yet all the facilities visited by the audit team had problems with tracking.

The OIG determined that VHA should implement internal controls consistent with the third principle of the Government Accountability Office's (GAO) *Standards for Internal Control in the Federal Government*, which requires entities to establish the structure, responsibility, and authority necessary to achieve the entity's objectives.[24] Recommendation 9 calls on VHA to establish a structure for oversight responsibility that can provide guidance and instruction to facilities and clinics on tracking implanted biologics.

VHA Needs to Develop Policies and Procedures for Tracking Implanted Biologics

Without a national program office, VHA did not develop policies and procedures to guide its facilities as they attempted to comply with the Joint Commission requirement that they track biologic implants. The four facilities visited attempted to respond to the Joint Commission

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

requirement by establishing tissue logs, but there was no national or regional review of the information in the tissue logs to ensure accuracy or completeness.

At the local level, the four facilities did establish tissue log policies, but those policies did not always prescribe methods for reviewing entries to ensure clinic staff accurately recorded all biologic implant use. Staff at two of the four facilities visited by the audit team reported they performed reviews; however, one of those facilities could not provide documentation of the reviews, and the other showed significant deficiencies. The other two facilities did not require reviews and did not monitor tissue logs for accuracy or completeness. Overall, the OIG found that three of the four facilities were unaware of the issues with tracking biologic implants documented in this report. The fourth facility, whose reviews found significant deficiencies, initiated a tracking work group in January 2020.

Recommendation 10 is for VHA to develop policies and procedures for facilities to follow in implementing controls for tracking biologic implants.

VHA Needs to Establish a Standardized Tracking System for Implanted Biologics

While VHA used GIP as its inventory management system, facility staff could not use GIP for tracking biologic implants because that system did not allow staff to record serial or lot numbers that are necessary to identify a specific implant.

The tissue logs established to address this gap varied by facility and clinic. They consisted of staff-created spreadsheets, facility-created electronic spreadsheets, and third-party software systems. Each approach required clinic staff to take an extra step to enter information on implanted items for tracking in the facility's tissue log. Some clinics gave tissue log access to only a limited number of staff, who did not always record the use of biologic implants.

According to GAO, VA has attempted to establish a standardized system that would enable the tracking of biologic implants.[25] In 2008, VA's Office of Information and Technology began to develop a system to track and retrieve identifying information that included the serial and lot number of surgical implants placed in patients. In 2012, VA suspended system development due to data reliability challenges and interoperability issues. In 2013, VHA abandoned another unsuccessful attempt to develop tracking software, the Veteran Implant Tracking and Alert System. While VHA did not require facilities to do so, it has allowed facilities to contract for at least two third-party systems intended to track implants.

[25] GAO, *Testimony Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives on VA Surgical Implants: Shortcomings in Implant Purchasing and Tracking*, GAO-14-271T, January 15, 2014.

Without guidance from the national office, facilities will continue to develop their own tracking procedures, which may not be complete or accurate despite facilities' best efforts. Recommendation 11 is for VHA to establish standardized systems for facilities to record biologic implant information that allows recipients to be readily tracked.

The Four Facilities Visited Failed to Track at Least 45 Percent of Implanted Biologics

Based on the audit team's review, the four facilities visited did not track at least 4,611 of 10,305 implanted biologics (45 percent). Further, two of the four facilities had clinics that did not track biologic implants at all. As a result, the team concluded that 45 percent was likely an understatement of items not tracked. In addition to issues discussed in findings 1 and 2, tracking issues were compounded because local policies did not prescribe reviews of tissue logs for completeness and accuracy. Without complete and accurate logs, the team could not confirm whether more items were missing from tracking. Further, the lack of reliable logs puts VHA at risk of not being able to notify veterans if their implants are recalled and limits the agency's ability to identify vendors if complications develop.

Because prosthetic agents record biologic implant purchases and their implantation in VHA's NPPD, the audit team compared the tracked biologic implants on each facility's tissue log to implanted biologics that facilities reported in VHA's NPPD. For the four facilities visited, the team used the NPPD and tissue logs to identify 10,305 implants. Table 3 shows each facility's documented implantations and the number of implants clinic staff did not record in their tissue logs.

Table 3. Implantations Documented but Not Recorded in Facility Tissue Logs from October 1, 2017, through March 31, 2019

Facility	Total implantations documented*	Total implantations recorded in tissue logs	Implantations not recorded in tissue logs	Percent of implantations not recorded in tissue logs
Atlanta	1,149	983	166	14
Little Rock	905	827	78	9
Hines	4,463	1,058	3,405	76
Denver	3,788	2,826	962	25
Total	**10,305**	**5,694**	**4,611**	**45**

Source: VA OIG analysis of facility tissue logs and VHA's NPPD.
**Counts an implant once if found in both VHA's NPPD and facility tissue logs.*

The team noted that this information is very likely incomplete and understated. Because local policies did not prescribe methods for reviewing tissue logs for accuracy and some clinics within

the main campuses or community-based outpatient clinics did not keep tissue logs, additional implants may not have been tracked. For example, Hines staff stated the facility initiated the use of tissue logs in its surgical unit on February 5, 2018, but as of June 2019 it had yet to expand tracking to several other clinics that routinely implanted biologics.

Finding 3 Conclusion

VHA did not consistently meet required Joint Commission standards for tracking biologic implant use, which puts VHA at risk of not being able to notify veterans if their implants are recalled. As the recommendations that follow reflect, VHA needs to delegate oversight responsibilities for tracking biologic implants. Further, VHA should establish policies and procedures that will enable the facilities to effectively track these implants. For the four facilities reviewed, clinic staff did not track at least 45 percent of implanted biologics, with some clinics not tracking their use at all.

Recommendations 9–11

The OIG made the following recommendations to the under secretary for health:[26]

9. Establish a structure for oversight responsibility that can provide guidance for tracking implanted biologics.
10. Create policies and procedures for facilities to follow as they implement effective controls for tracking biologic implants.
11. Establish standardized systems and requirements for facility staff to appropriately record necessary biologic implant attributes for accurate and accessible tracking of recipients to advance patient safety.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with recommendations 9 through 11. To address these three recommendations, the executive in charge reported the assistant under secretary for health for clinical services will charter a formal interdisciplinary workgroup to review and provide future recommendations to VHA on establishing a structure for oversight responsibility that can provide guidance for tracking implanted biologics with a target completion date of December 2021. VHA's comments may be found in full in appendix D.

[26] Recommendations directed to the under secretary for health were submitted to the executive in charge, who had the authority to perform the under secretary's functions and duties. Effective January 20, 2021, he was appointed to acting under secretary for health with the continued authority to perform the functions and duties of the under secretary.

OIG Response

The executive in charge's corrective action plans are responsive to the intent of the recommendations. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

Appendix A: Scope and Methodology

Scope

The audit team performed work from March 2019 through November 2020. During this audit, the team provided interim briefings to officials with the Prosthetic and Sensory Aids Service, Procurement and Logistics Office, and Surgical Services. The audit scope was nationwide and covered activities and decisions for

- tracking and purchasing implanted biologics from October 1, 2017, through March 31, 2019, and
- inventorying implanted biologics as of the dates of the site visits, which occurred from May 20 through September 25, 2019.

Methodology

To address the audit objective, the audit team reviewed applicable laws, regulations, policies, procedures, and guidelines regarding purchasing, inventorying, and tracking biologic implants. The team interviewed officials from VHA's Procurement and Logistics Office; Prosthetic and Sensory Aids Service; National Center for Patient Safety; External Accreditation Services and Programs Office of Quality, Safety, and Value; and National Surgical Services.

In addition, the audit team conducted site visits to four VA medical centers: the Atlanta VA Health Care System in Decatur, Georgia; the Edward Hines Jr. VA Hospital in Hines, Illinois; the John L. McClellan Memorial Veterans' Hospital in Little Rock, Arkansas; and the Eastern Colorado Health Care System in Aurora, Colorado. Site visits included reviews at clinics on all campuses and community-based outpatient clinics with biologic implant use. Two sites were selected based on having the highest biologic implant use for level 1a complexity facilities, and the last two sites were selected based on having the lowest biologic implant use for level 1a complexity facilities from October 1, 2017, through March 31, 2019.[27] The audit team selected level 1a facilities for review because they reported higher use of biologic implants.

The audit team also analyzed information from the four sites and reviewed facility tissue logs; compared facility tissue log entries to NPPD entries; performed nonstatistical random searches for inventory; interviewed 45 medical staff with direct knowledge of medical practices with biologic implant use; and interviewed prosthetic and logistics staff with direct knowledge of facility operations for purchasing, inventorying, and tracking biologic implants.

[27] VHA classifies facilities according to a complexity model that assigns one of the following five levels, listed in order of most complex to least: 1a, 1b, 1c, 2, and 3. The complexity model includes factors such as number of patients, number of high-risk patients, size of research programs, and size of teaching programs.

Fraud Assessment

The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The audit team exercised due diligence in staying alert to any fraud indicators by

- soliciting the OIG's Office of Investigations for information about any ongoing cases involving biologic implant purchases and
- performing analytics on biologic implant purchase histories by medical providers.

The OIG did not identify any instances of fraud or potential fraud during this audit.

Data Reliability

The audit team used computer-processed data from the NPPD and tissue logs from each medical center. To test for reliability, the team determined whether any data were missing from key fields, included any calculation errors, or were outside the time frame requested. The team also assessed whether the data contained obvious duplication of records, alphabetic or numeric characters in incorrect fields, or illogical relationships of data elements. In addition, the team compared biologic implant documentation from VHA's NPPD with facility tissue logs and with documentation in VHA's electronic health record system.

The audit team found many errors in the tissue logs, including missing key fields and alphabetic or numeric characters in incorrect fields. These errors affected the team's ability to perform a cost analysis of the specific missing items, but the team was able to use an average unit cost. The data were sufficient for the team's analysis related to determining what items staff properly entered. For entries missing key fields or with inaccurate character types, the team's analysis technique identified these items as not tracked. The team considered results of the analysis accurate because an incomplete or inaccurate entry of key fields would prevent users from effectively using the data to identify either the implant or the recipient. The team concluded that the data obtained were sufficiently reliable for the purposes of the audit.

Data Limitations

Beyond computer-processed data, the audit team experienced two data limitations. Due to ambiguous medical documentation of the funding source used for individual implants, the team could not perform an analysis quantifying the percentage of funds that were inappropriately used. Even without being able to quantify the funds, the team was able to support that funding was questionable and not always appropriate. By reviewing purchasing procedures, comparing the NPPD to tissue logs, and discovering several instances of inappropriate use, the team obtained enough evidence to question the use of funding.

The audit team also experienced limitations in determining the total number of biologic implant purchases at each facility. Neither national databases nor facility staff could provide a complete list of all biologic implant purchases. Without that information, the team could not assess whether facility staff completely and accurately recorded all biologic implants in their tissue logs. Concerns about the quality of this information also impeded the team's reviews of inventory and tracking. However, the team obtained sufficient evidence for its conclusions by comparing facility tissue logs and NPPD entries to assess completeness and accuracy. The OIG acknowledges that its findings might be understated because staff might not have recorded additional purchases in the tissue logs or the NPPD.

Neither the inability to quantify inappropriate use of funds nor the possibility of understated results reduced the OIG's belief that the deficiencies observed were sufficient to support the conclusions about funding, inventory, and tracking.

Government Standards

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

Appendix B: Joint Commission Results, 2017–2019

The Joint Commission cited five VHA medical facilities for biologic implant tracking issues in calendar years 2017 through 2019, according to VHA's director of external accreditation services and programs. During that time, the Joint Commission reviewed 138 facilities; however, the commission did not include all applicable standards during each survey. Therefore, VHA does not know whether the Joint Commission reviewed how the 133 facilities without a citation were tracking implanted biologics and, if so, found them compliant.

The Joint Commission has seven performance elements related to its transplant safety accreditation requirement, TS.03.02.01. Table B.1 shows that 31 of the 138 facilities were cited for one or more performance elements.

Table B.1. The Joint Commission Citations for Tissue Tracking at VHA Facilities from 2017–2019 by Performance

Performance element	Citations
1. The hospital's records allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier.	5
2. The hospital identifies, in writing, the materials and related instructions used to prepare or process tissues.	11
3. The hospital documents the dates, times, and staff involved when tissue is accepted, prepared, and issued.	11
5. The hospital retains tissue records on storage temperatures, outdated procedures, manuals, and publications for a minimum of 10 years.	10
6. The hospital retains tissue records for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest). If required by state and/or federal laws, hospitals may have to retain tissue records longer than 10 years. Records are kept on all of the following: - The tissue supplier - The original numeric or alphanumeric donor and lot identification - The name(s) of the recipient(s) or the final disposition of each tissue - The expiration dates of all tissues	4

Source: VHA director of external accreditation services and programs.
Note: VHA did not report any citations for performance element four.

Appendix C: Background

VHA Implant Procurement Process

The implant procurement process begins when a VHA prescribing specialty clinician identifies a need for an implant, which VHA Directive 1081.01(1) defines as "any biological or non-biological material which is manufactured or processed to be placed into a surgically or naturally formed cavity on the human body; is covered with tissue, has the potential to be covered with tissue, or is permanently embedded in tissue."

Once the medical provider identifies a need, he or she would determine the type of implant required for the procedure. Based on product selection and accessibility, one of the following actions occurs:

- **Initial Inventory Request.** The clinician, specialty service, or implant coordinator submits a purchase request to logistics personnel to establish an initial inventory of the product. Logistics purchasing agents evaluate the purchase request for initial inventory to ensure the request was for an implant. Logistics personnel also verify that the request was not for a just-in-time or inventory replacement implant. This step ensures that staff use the appropriate funding. Logistics purchasing agents pay for the item(s) upon receipt at the facility.
- **Inventory Replacement.** The clinician determines that the facility has the required implant in inventory at the facility and obtains it. Prosthetic purchasing agents then replace the item using prosthetic funds.
- **Just-in-Time Purchases.** The clinician, specialty service, or implant coordinator contacts a vendor to order an implant or implants for use. The clinician performs the scheduled procedure using the implant(s). The use of a just-in-time implant obligates the government to pay the vendor for the product(s). The use of an implant in inventory results in ordering and paying for a replacement. The clinician documents use in the veteran's electronic health record and completes a consult in the Computerized Patient Record System within two days of the surgery.

Purchasing agents for the Prosthetic and Sensory Aid Service receive the consult from clinicians and an invoice from the vendor for the implant(s). The purchasing agents verify that the vendor did not include any implant expendables on the invoice. Implant expendables are items that staff use one time in procedures that are not implants, and that staff purchase with logistics funds. If the vendor included expendables, the purchasing agent returns the invoice and asks the vendor to submit separate invoices for implant(s) to the Prosthetic and Sensory Aids Service and for any associated implant expendables to logistics personnel.

A purchasing agent reviews the consult and determines if the implant met prosthetic funding requirements. To meet prosthetic funding requirements, the item(s) must be an implant that a clinician used during a procedure. The purchasing agent then compares the consult to the vendor invoice and reviews the documents for completeness and accuracy.

The purchasing agent processes the purchase order if the document was complete and accurate and the cost for the item(s) was below the authorized micro-purchase threshold. Otherwise, the purchasing agent submits a request for payment to the Network Contracting Office. For expendables, a logistics purchasing agent would process the purchase order as above.

Appendix D: Management Comments

Department of Veterans Affairs Memorandum

Date: January 4, 2021

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Biologic Implant Purchasing, Inventory Management and, and Tracking Need Improvement (Project Number 2019-07053-R5-0001) (VIEWS 03992534)

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

1. Thank you for the opportunity to review the draft report on the Veterans Health Administration (VHA) Biologic Implant Purchasing, Inventory Management, and Tracking Need Improvement. I concur with the findings and provide the attached action plan to address the recommendations.

2. The Office of Prosthetics and Sensory Aids Service has taken several steps to improve oversight of biologic implants. In partnership with VHA's Office of Procurement and Logistics they have expanded education and training on the importance of procurement, inventory and tracking of biological and non-biological implants.

3. The Office of Prosthetics and Sensory Aids and the Office of Procurement and Logistics have expanded authorities for implant procurements which lessens the administrative burden on clinicians. It also removes cumbersome administration requirements for timeliness of implant ordering which strengthens vendor relations and improves care coordination for surgical procedures and fiscal timeliness for procurements.

4. For purposes of accuracy and clarity, VHA asks OIG to replace the term "NPPD Notifications" throughout the report with either "consult notifications" or "VistA notifications" or "prosthetic consult service requests." These three terms are easier for the general reader to understand and are more appropriate to the process itself.

The OIG removed point of contact information prior to publication.

(Original signed by)

Richard A. Stone, M.D.

Attachments

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report: Audit of Biologic Implant Purchasing Inventory Management, and Tracking Need Improvement (Project Number: 2019-07053-R5-0001)

Date of Draft Report: November 20, 2020

Recommendations/Actions	**Completion Date**
Status	

The OIG made the following recommendations to VHA's Executive In Charge, Office of the Under Secretary for Health

Recommendation 1. Provide clarifying guidance and controls to clinic staff on making determinations to send purchase requests and NPPD notifications to appropriate purchasing agents.

VHA Comments: Concur. The Office of Prosthetic and Sensory Aids Service (PSAS) agrees that clarifying guidance and enhanced controls on consult submissions to PSAS will improve the procurement process of biological implants. To accomplish this, PSAS will re-educate PSAS and clinical Staff on the updated VHA Directive, 1081.02, Management of Biological and Non-Biological Implants, dated October 29, 2020. Directive 1081.02 identifies responsible agents and compliance with the accountably and procurement of surgical implants. Education will re-enforce the importance for clinical staff to ensure Prosthetic Consult Service Requests are submitted appropriately and timely to PSAS to ensure procurement accountability.

To demonstrate full implementation, VHA will provide the following documentation:

- Updated VHA Directive, 1081.02.
- Communication documents provided to the field which outline the updated processes.

Status: In progress **Target Completion Date:** September 2021

Recommendation 2. Providing clarifying guidance to purchasing agents on how to effectively evaluate biologic implant purchase requests for the correct funding source.

VHA Comments: Concur. The Office of Prosthetic and Sensory Aids Service (PSAS) agrees that clarifying guidance to purchasing staff on effective evaluations of biologic implant requests and ensuring the proper funding source is critical in the procurement process. The PSAS Program Office will re-educate PSAS staff on the updated VHA Directive, 1081.02, Management of Biological and Non-Biological Implants, dated October 29, 2020. The PSAS Program Office in partnership with VHA's Procurement and Logistics Service will jointly re-educate PSAS and logistic staff assigned to procure surgical implants. To demonstrate full implementation, VHA will provide OIG with communication documents provided to relevant employees that outline updated processes.

Status: In Progress **Target Completion Date:** September 2021

Recommendation 3. Provide clarifying guidance to prosthetics agents to ensure they receive clinic staff NPPD notifications on all prosthetics purchases of biologic implants.

VHA Comments: Concur. The office of Prosthetic and Sensory Aids Service (PSAS) agrees that enhancement of business practice guidelines will provide greater clarity on consult service requests to PSAS. To accomplish this, PSAS will partner with Clinical Access Coordinators, PSAS Data Management Council, and Veterans Integrated Service Network and facility PSAS leadership to identify opportunities for improvement on prosthetic consult service requests to support biological implant ordering and inventory accountability. To demonstrate full implementation, VHA will provide OIG with its updated Business Practice Guidelines which include opportunities to consider a potential inclusion of inventory clarification deemed appropriate for that facility.

Status: In Progress **Target Completion Date:** September 2021

Recommendation 4. Create a biologic implant cost code for general purpose funds to improve funding accountability and potentially assist in ensuring all biologic implant use is tracked.

VHA Comments: Concur. The Procurement and Logistics Office is working relevant financial points of contact to establish a biologic implant cost code for general purpose funds.

Status: In Progress **Target Completion Date:** March 2021

Recommendation 5. Direct the Procurement and Logistics Office to clarify guidance on the use of an approved inventory management system specific to biologic implants and related VHA network, office and facility staff responsibilities.

VHA Comments: Concur. The current version of VHA Directive 1761(2), Supply Chain Management Operations, dated October 26, 2018, establishes the following responsibilities:

a. The VHA Procurement and Logistics Office (P&LO) provides oversight and sets policies, procedures, and performance measures for Prosthetics and Sensory Aids Service (PSAS) supply inventories. P&LO also monitors performance to ensure achievement of established goals, regardless of the inventory system utilized or the program office assigned management of these supplies.

b. The Veterans Integrated Service Network (VISN) Chief Logistics Officer (CLO) coordinates with the facility Chief Supply Chain Officer (CSCO) to assess inventory management programs, provide quality control review once per fiscal year, and manage supply chain data at VISN medical facilities.

c. The CSCO establishes a local supply chain management program that meets VHA policy and operational requirements.

d. The CSCO establishes a total supply support program at VA medical facilities and utilizes VHA-approved inventory management systems to maintain automated inventories.

e. The CSCO monitors establishes supply chain benchmarks ensuring local processes meet or exceed all measures.

f. The medical facility logistics program manages the inventory of PSAS clinical items.

VHA P&LO collaborated with the PSAS program office to draft the recently published VHA Directive 1081.02, Management of Biological and Non-Biological Implants, dated October 29, 2020. VHA Directive 1761, Supply Chain Management Operations is currently being updated and will contain clarifying language on inventory management of Prosthetics and Sensory Aids Service (PSAS) clinical inventory items. In addition, language regarding unused implants includes:

"If a patient-specific implant (biological or non-biological) is unused, the clinical service should coordinate and return the implant(s) to the vendor, if the clinical service arranged the delivery of the implant, or contact PSAS personnel to assist if a purchase order has already been provided to the vendor. All unused patient-specific implants must be returned to the vendor."

The VISN CLO conducts the annual Quality Control Review (QCR) at each medical facility and utilizes the QCR checklist. The QCR checklist was revised to include question #22, which reads: "Are all VA-owned inventories of biological and non-biological implantable devices managed in the generic inventory package (GIP) or other VHA P&LO Logistics Operations approved systems?"

The VHA P&LO and VHA PSAS program office are developing ongoing lunch and learn training regarding the requirements and implementation of VHA Directive 1081.02, Management of Biological and Non-Biological Implants.

Status: In Progress **Target Completion Date:** February 2021

Recommendation 6. Monitor facility compliance with the use of an approved inventory management system for completeness and accuracy.

VHA Comments: Concur. VHA Directive 1761(2) states the Veterans Integrated Service Network (VISN) Chief Logistics Officer (CLO) is responsible for "assessing programs at VISN medical facilities through a quality control review (QCR) once per fiscal year utilizing the QCR checklist and instructions." The current QCR checklist has been revised to include question #22, which reads: "Are all VA-owned inventories of biological and non-biological implantable devices managed in the generic inventory package (GIP) or other VHA Procurement and Logistics Office (P&LO) Logistics Operations approved system?"

The facility Chief Supply Chain Officer (CSCO), Medical Center Director, VISN Chief Supply Chain Officer, and Network Director review and sign completed QCR results prior to their submission to the P&LO. As part of the national QCR program, the VHA P&LO Policy, Compliance and Standardization Office performs random audits of completed QCRs.

VHA Directive 1761(2) states: "the facility Chief Supply Chain Officer (CSCO) is responsible for monitoring established supply chain monitors and benchmarks, and ensuring local processes are established to meet or exceed all measures. The VHA P&LO, Supply Chain Data Informatics Office (SCDIO) has established the supply chain common operating picture (SCCOP) dashboard to monitor supply chain activity and attainment of various performance measures. When the SCCOP dashboard recently migrated from Spotfire to PowerBI, P&LO found the "Items with Null and/or Blank Fields" report did not migrate correctly to include the biological and nonbiological implant inventory data or adequately monitor the inventory for completeness and accuracy. P&LO is in the process of correcting this report to include data pertaining to biological and nonbiological inventory points.

Status: In Progress **Target Completion Date:** February 2021

Recommendation 7. Direct the Procurement and Logistics Office to ensure logistics staff perform inventory reviews of biologic implants, as required.

VHA Comments: Concur. The recently published VHA Directive 1081.02, Management of Biological and Non-Biological Implants, dated October 29, 2020, states in the responsibilities section "the facility Chief Supply Chain Officer (CSCO) is responsible for ensuring all VA-owned implants and implant-related consumable inventories are purchased with facility funds and maintained in the VHA-approved inventory management system." The facility Chief Supply Chain Officer (CSCO) is also responsible for conducting VHA-owned inventory weekly reviews by supply chain management inventory management personnel or

supply technicians to ensure items are not past their expiration dates, there is no damage to product and product and storage areas are clean, in accordance with VHA Directive 1761(2).

VHA Directive 1761(2) requires generic inventory package (GIP) primary inventories with secondary inventories to be scanned as required, and stand-alone primaries to be scanned at least once per month. In addition, the directive states the VISN Chief Logistics Officer (CLO) is responsible for "assessing programs at VISN medical facilities through a quality control review (QCR) once per fiscal year utilizing the QCR checklist and instructions."

The current QCR checklist is being revised to include two additional questions:

1. Are biological and non-biological implant inventories recorded and scanned in accordance with VHA Directive 1761?
2. Are biological and non-biological implant inventories being reviewed weekly by supply chain management personnel to ensure items are not past their expiration dates, there is no damage to product and product and storage areas are clean, in accordance with VHA Directive 1761? Has this check been documented on a weekly sign-off sheet posted in the room including initial of the person who performed check and the date completed?"

Status: In Progress **Target Completion Date:** February 2021

Recommendation 8. Monitor medical facility compliance with required reviews of on-site inventory.

VHA Comments: Concur. The current quality control review (QCR) checklist revision includes two additional questions:

1. Are biological and non-biological implant inventories recorded and scanned in accordance with VHA Directive 1761?
2. Are biological and non-biological implant inventories being reviewed weekly by supply chain management personnel to ensure items are not past their expiration dates, there is no damage to products, and product and storage areas are clean, in accordance with VHA Directive 1761? Has this check been documented on a weekly sign-off sheet posted in the room (including the initials of the person who performed the check) and the date completed?

As the Veterans Integrated Service Network (VISN) Chief Logistics Officer (CLO) completes required QCRs of medical facilities in the VISN and submit the required checklists and action plans to the VHA Procurement and Logistics Office (P&LO), responses to identified biological and nonbiological implant inspection questions will be reviewed by P&LO as part of the QCR audit program and deficiencies addressed as needed.

Status: In Progress **Target Completion Date:** February 2021

Recommendation 9. Establish a structure for oversight responsibility that can provide guidance for tracking implanted biologics.

VHA Comments: Concur. The Assistant Under Secretary for Health for Clinical Services will charter a formal interdisciplinary workgroup comprised of members from: VHA's National Surgical Office, Office of Dentistry, and the National Programs for Podiatry and Ophthalmology in the Office of Specialty Care Services, as well as the National Center on Patient Safety, Procurement and Logistics Office, Office of Rehabilitation and Prosthetics, and the Office of Sterile Processing Services, to review and provide future

recommendations to VHA on establishing a structure for oversight responsibility that can provide guidance for tracking implanted biologics.

Currently, VA Dentistry has a fully functional tracking system within the dental electronic health record (Dental Record Manager Plus) to track implantable biologics. This system provides patient-level tracking of multiple biologic device attributes at both facility and national levels. Data include, but are not limited to, manufacturer, model number, lot number, and serial number.

Status: In Progress **Target Completion Date:** December 2021

Recommendation 10. Create policies and procedures for facilities to follow as they implement effective controls for tracking biologic implants.

VHA Comments: Concur. The Assistant Under Secretary for Health for Clinical Services will charter a formal interdisciplinary workgroup comprised of members from: VHA's National Surgical Office, Office of Dentistry, and the National Programs for Podiatry and Ophthalmology in the Office of Specialty Care Services, as well as the National Center on Patient Safety, Procurement and Logistics Office, Office of Rehabilitation and Prosthetics, and the Office of Sterile Processing Services, to review and provide future recommendations to VHA on establishing a structure for oversight responsibility that can provide guidance for tracking implanted biologics.

Status: In Progress **Target Completion Date:** December 2021

Recommendation 11. Establish standardized systems and requirements for facility staff to appropriately record necessary biologic implant attributes for accurate and accessible patient tracking to advance patient safety.

Comments: Concur. The Assistant Under Secretary for Health for Clinical Services will charter a formal interdisciplinary workgroup; comprised of members from VHA's National Surgical Office, Office of Dentistry, and the National Programs for Podiatry and Ophthalmology in the Office of Specialty Care Services, as well as the National Center on Patient Safety, Procurement and Logistics Office, Office of Rehabilitation and Prosthetics, and the Office of Sterile Processing Services, to review and provide future recommendations to VHA on establishing a structure for oversight responsibility that can provide guidance for tracking implanted biologics.

The current dental electronic health record (Dental Record Manager Plus) provides patient-level tracking of necessary biologic device attributes at both facility and national levels to advance patient safety. Recorded data include, but are not limited to, manufacturer, model number, lot number, and serial number.

Status: In Progress **Target Completion Date:** December 2021

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

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Bruce Nielsen passed away recently. Bruce was a trusted advisor and a dedicated and affable colleague; his keen intellect and good judgment were greatly valued. He will be missed.

Ken Myers passed away recently. Ken was a valued member of the Office of Audits and Evaluations who worked diligently to serve veterans and the public. He will be missed.

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