



March 2024

VETERANS HEALTH CARE

Improvements Needed in Patient Tracking for Non-Biological Implantable Medical Devices

Accessible Version

Why GAO Did This Study

VHA provided health care to over 6 million veterans in fiscal year 2022. Such care can include receiving an implantable medical device. The approximately 226,000 implants provided each year by VHA include biological implants made from body tissues, such as skin grafts, or non-biological implants made from materials such as plastic or metal. Examples of the latter include pacemakers and hip replacements.

The James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 includes a provision for GAO to study VHA's oversight of implantable medical devices. This report (1) describes VHA offices that oversee implantable medical devices; (2) describes VHA's monitoring of implant safety issues; and (3) examines how VHA ensures tracking of non-biological implants to individual patients.

GAO reviewed policies, data, safety reports, and other information on non-biological implants with a focus on certain cardiology and orthopedic implants. GAO interviewed officials from VHA and four VA medical centers (and their regional management), selected based on factors such as the volume of cardiology and orthopedic implants, facility size, and location.

What GAO Recommends

GAO recommends VHA (1) add a policy requirement that non-biological orthopedic devices be effectively tracked and (2) assess, across all clinical specialties, its ability to track non-biological implantable devices to individual patients and take actions to address any identified gaps. VHA agreed with GAO's recommendations.

View [GAO-24-106621](#). For more information, contact Sharon M. Silas at (202) 512-7114 or silass@gao.gov.

VETERANS HEALTH CARE

Improvements Needed in Patient Tracking for Non-Biological Implantable Medical Devices

What GAO Found

Multiple Veterans Health Administration (VHA) offices are involved in overseeing implantable medical devices received by veterans. VHA's National Center for Patient Safety, the lead office for patient safety issues, is responsible for monitoring device safety issues. This office evaluates patient risk when safety issues are identified and collaborates with VHA's clinical program offices to develop VHA's response. National program offices for clinical specialties such as the National Cardiac Device Surveillance Program and the National Surgery Office are also responsible for overseeing cardiac electronic and orthopedic devices, respectively.

GAO found that VHA is unable to ensure that all non-biological implantable medical devices are tracked to individual patients. Such tracking is important so that when a safety issue occurs VHA can ensure patients are notified and receive appropriate care. For the two clinical specialties reviewed, the National Cardiac Surveillance Program was able to effectively track cardiac electronic devices to individual patients, but the National Surgery Office was not able to effectively do so for orthopedic devices. VHA policy requires tracking outside the medical record for cardiac devices but does not require it for orthopedic devices. Accordingly, this gap adversely affects VHA's ability to ensure such tracking is occurring.

Example of Knee and Hip Replacement Implantable Medical Devices



Source: Monstar Studio/stock.adobe.com (photo). | GAO-24-106621

Accessible Text for Example of Knee and Hip Replacement Implantable Medical Devices

Close-up of non-biological implantable medical devices for knee and hip.

Source: Monstar Studio/stock.adobe.com (photo). | GAO-24-106621

GAO also found VHA has not fully assessed, across all specialties, its ability to ensure that non-biological implantable medical devices can be effectively tracked to individual patients. Officials with the National Center for Patient Safety and others have recognized the need to develop better tracking capabilities across VHA. An assessment of VHA's ability to track all non-biological implantable medical devices across all clinical specialties could help the agency target and

prioritize the most critical devices. This would help ensure these patients receive appropriate care in the event of safety issues.

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Abbreviations

FDA	Food and Drug Administration
NCPS	National Center for Patient Safety
VA	Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Networks

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March 27, 2024

The Honorable Jon Tester
Chairman
The Honorable Jerry Moran
Ranking Member
Committee on Veterans' Affairs
United States Senate

The Honorable Mike Bost
Chairman
The Honorable Mark Takano
Ranking Member
Committee on Veterans' Affairs
House of Representatives

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) provided implantable medical devices to approximately 165,000 patients in fiscal year 2023.¹ Implantable medical devices replace, support, or substitute for deformed or weakened anatomical body parts. Some implantable devices are "biological," that is, made from skin, bone, or other body tissues. Other implantable medical devices are non-biological—made from metal, plastic, ceramic, or other materials—such as pacemakers and hip replacements.²

Implantable medical devices can improve a patient's health and, in some cases, save a patient's life. However, there are safety issues that can arise with implantable medical devices that may pose a significant risk to a patient's health. Some of the most serious safety issues can result in a device being recalled, which results in removal from the market or in a correction to the device. In recent years there have been numerous examples of implantable medical devices being recalled for safety

¹This is according to data provided by VHA from its National Prosthetics Patient Database. The 165,000 patients received a total of around 231,000 implantable devices. VHA provided care to an average 6.3 million veterans from fiscal years 2018 through 2022.

²In this report we use the term "implantable medical device" to refer to both biological and non-biological implants.

issues.³ For example, some implantable cardiac devices were recalled in 2021 due to issues such as premature battery depletion for pacemakers or reduced shock energy for defibrillators.⁴ There have also been recalls initiated for orthopedic hip joints—specifically the metal-on-metal joints pulled from use in 2010.⁵ The National Center for Patient Safety (NCPS) is the lead VHA office for patient safety issues, including those involving implantable medical devices.

In 2021, the VA Office of Inspector General issued a report on VHA's purchasing, inventory management, and tracking procedures for biological implantable medical devices and found deficiencies in multiple areas.⁶ For example, the VA Office of the Inspector General found that (1) poor inventory management practices resulted in inaccurate inventories of biologic implantable devices, and (2) VHA was not always able to identify which patients had received specific biologic implantable medical devices.

The James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 includes a provision for GAO to study VA's surveillance of implantable medical devices.⁷ In this report, we:

1. describe the VHA offices involved in the oversight of implantable medical devices;
2. describe how VHA monitors implantable medical device safety issues; and

³The Food and Drug Administration (FDA) defines a recall as a manufacturer's removal or correction of a marketed product that the agency considers to be in violation of the laws it administers and against which the agency would initiate legal action. Most medical device recalls are initiated voluntarily by manufacturers.

⁴There have also been safety issues with certain pacemakers due to cybersecurity vulnerabilities. GAO recently reviewed and reported on cybersecurity issues for medical devices. See GAO, *Medical Device Cybersecurity: Agencies Need to Update Agreement to Ensure Effective Coordination*. [GAO-24-106683](#) (Washington, D.C.: Dec. 21, 2023).

⁵In 2010, a widely used metal-on-metal hip implant design was voluntarily recalled worldwide by the manufacturer because of higher than anticipated failure rates at 5 years.

⁶VA Office of Inspector General Office of Audits and Evaluations, *Veterans Health Administration: Biologic Implant Purchasing, Inventory Management, and Tracking Need Improvement* [19-07053-51](#), (Washington, D.C.: Feb. 25, 2021).

⁷Pub. L. No. 117-263, div. E, tit. LI, § 5112, 136 Stat. 2395, 3208 (2022). We have ongoing work examining FDA's post market surveillance of medical devices.

3. examine VHA's efforts to ensure it is tracking non-biological implantable medical devices so that individual patients can be identified and notified when needed.

To address all three objectives, we reviewed VHA documentation related to implantable medical devices, with a focus on non-biological implantable medical devices.⁸ We reviewed VHA's policies and procedures related to implantable medical devices. We interviewed VHA national-level officials with responsibilities related to implantable medical devices and patient safety. We selected two clinical specialties—cardiology and orthopedics—to help us understand how oversight, monitoring, and tracking played out for two specific clinical areas responsible for a high volume of non-biological implantable medical devices at VHA. (See app. II for information on implantable medical devices commonly used by VHA.) These clinical specialties are responsible for non-biological implantable medical devices including pacemakers, defibrillators, and joint replacements for hips, knees, and shoulders.⁹

We also selected four VA medical centers (VAMC) based on variation in factors such as the volume of cardiology and orthopedic implants used by their facility, facility size, and location: Houston, TX; Lebanon, PA; Loma Linda, CA; and Minneapolis, MN. We reviewed documents and interviewed officials from each of these VAMCs with responsibilities for implantable medical devices, with a focus on non-biological cardiac and orthopedic implants, and their associated Veterans Integrated Services Networks (VISN). The information we obtained from these VAMCs cannot be generalized to other VAMCs. We also contacted Veterans Service

⁸We focus on non-biological implantable medical devices since they make up the majority of devices used at VHA. The recent work conducted by the VA Office of Inspector General focused on biological implantable medical devices.

⁹Within the cardiology specialty, we focused on those non-biological implantable devices tracked through the National Cardiac Device Surveillance Program. Other clinical specialty areas that use implantable medical devices include, for example, gynecology, ophthalmology, plastic surgery, podiatry, and dental.

Organizations to determine if they had any particular concerns among their members pertaining to implantable medical devices.¹⁰

To describe the national-level VHA offices responsible for oversight of implantable medical devices, we reviewed documents and interviewed officials from the relevant national offices involved, including the NCPS, the Procurement and Logistics Office, and the Prosthetic and Sensory Aids Service. We also reviewed documents and interviewed officials from the national program offices with (1) responsibility for cardiac implants such as pacemakers and defibrillators—the National Cardiac Device Surveillance Program, and (2) responsibility for surgical specialties including orthopedics and orthopedic implants—the National Surgery Office.

To describe how VHA monitors implantable medical device safety issues, we reviewed documents and interviewed officials from NCPS, VHA's primary patient safety office. For example, we analyzed documentation from NCPS on safety issues from approximately the past 10 years (January 2012 to June 2023) that had affected VHA and thus been communicated across the department, including to VISNs and VAMCs. We also analyzed documentation and interviewed officials from the four VAMCs we selected and their associated VISNs, regarding their experiences with monitoring for safety issues. For each of these levels of VHA, we reviewed information on eight selected implantable medical devices—four cardiac and four orthopedic—that had publicly reported safety issues (primarily recalls).¹¹

To examine VHA's efforts to ensure it is tracking non-biological implantable medical devices so that individual patients can be identified and notified when needed, we reviewed documents and interviewed

¹⁰We contacted seven Veterans Service Organizations: (1) American Legion, (2) Disabled American Veterans, (3) Paralyzed Veterans of America, (4) Veterans of Foreign Wars, (5) Blinded Veterans Association, (6) Vietnam Veterans of America, and (7) Wounded Warrior Project. To select organizations that represented a variety of veterans, we focused our search on larger congressionally chartered organizations that had work activities (e.g., advocacy, legislative action, or programs) relevant to the topic of medical devices, prosthetics, or surgical implants. We also looked for organizations that represented the interests of a specific veteran population with disabilities.

¹¹We selected two recalls for which we knew VHA took action. In addition, we selected six recalls that 1) affected a large number of medical devices, 2) were associated with the orthopedic and cardiology specialties, 3) were manufactured by major medical device manufacturers in each specialty, and 4) were recently recalled between January 1, 2021, and June 16, 2023. For more information on our selection process, see appendix III.

officials from the aforementioned VHA national-level offices, including NCPS, the National Cardiac Device Surveillance Program, and the National Surgery Office. We also analyzed documentation and interviewed selected VAMC and VISN staff regarding their experiences tracking implants so that they can identify and notify patients of safety issues. As in the previous objective, for each of these levels, we asked officials to provide us with specific information on the eight selected implantable medical devices. We evaluated VHA's tracking efforts against VHA's policies on patient safety and quality management, as well as federal internal controls related to monitoring activities and remediating deficiencies on a timely basis.¹²

We conducted this performance audit from January 2023 to March 2024, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Implantable Medical Devices

Implantable medical devices are designed to replace, support, or substitute for deformed or weakened anatomical body parts. Some implants are "biologic," that is, made from skin, bone or other body tissues. Examples include skin and bone grafts. Non-biological devices—made from materials such as plastic or metal—include knee and hip replacements, pacemakers, and defibrillators. According to data from VHA, in fiscal year 2023, non-biological implantable devices accounted for 89 percent of all implantable devices ordered by VHA providers.

The Federal Drug Administration (FDA), manufacturers, and VHA all have responsibilities for ensuring the safety of implantable medical devices prior to implantation. FDA is responsible for ensuring that all medical devices sold in the United States provide reasonable assurance of safety

¹²Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014).

and effectiveness and do not pose a threat to public health.¹³ Manufacturers must obtain premarket review of their implantable medical devices.¹⁴ In addition, FDA, medical device manufacturers, and the facilities that use the devices have certain responsibilities for ensuring device safety once on the market, including reporting certain adverse events to FDA.¹⁵ VHA has various policies and procedures in place to ensure that implantable medical devices are procured, stored, and utilized consistent with federal law and prevailing medical standards.¹⁶ Furthermore, VAMCs are required to comply with regulatory standards established by The Joint Commission—a hospital accreditation organization—for implantable medical devices (see text box).

The Joint Commission’s Requirements for Implantable Medical Devices

It is VHA policy that its medical facilities must maintain health care accreditation for ongoing compliance with regulatory standards through The Joint Commission. The Joint Commission, a hospital accreditation organization, requires accredited hospitals to trace all biological implantable medical devices to individual patients. The Joint Commission does not specify the same for non-biological implantable medical devices, although its standards state that non-biological implantable medical devices may also require tracking to support patient notification in the event of a recall or investigation for safety issues. VHA’s 2020 policy, “Management of Biological and Non-Biological Implants,” requires this tracing for biological but not non-biological implantable medical devices.

Source: GAO analysis of The Joint Commission and Veterans Health Administration (VHA) information. | GAO-24-106621

VHA Organization

VHA is the nation’s largest integrated health care system, serving over 6 million veterans in fiscal year 2022. At the national level, VHA has national program offices that perform a range of administrative or clinical functions. For example, NCPS is responsible for all aspects of patient

¹³FDA classifies each medical device type into one of three classes based on the level of risk it poses to the patient or the user and the controls necessary to reasonably ensure its safety and effectiveness, with class I being the lowest risk and class III being the highest.

¹⁴Class III devices require FDA’s premarket approval, the most stringent type of premarket review, and must submit an application that includes full reports of investigations, including clinical data. Class I and class II devices require premarket notification, although most class I and some class II devices are exempt from the process.

¹⁵These requirements may also apply to importers and distributors of medical devices. See generally 21 C.F.R. part 803.

¹⁶For example, VHA requires review of medical device specifications prior to responding to requests from the prescribing physician.

safety. Other national offices monitor the provision of health care services within their specific clinical areas, such as cardiology or orthopedics.

At the regional level, there are 18 VISNs that are responsible for overseeing VAMCs within a defined geographic area.¹⁷ VISN offices often have staff that work with or report to a national office in order to implement and oversee policies at the medical centers. At the local level, there are 172 VAMCs throughout the United States. Veterans receive implantable medical devices at some, but not all, VHA facilities, depending on the nature and complexity of the procedure.

VHA's Implantable Medical Device Lifecycle

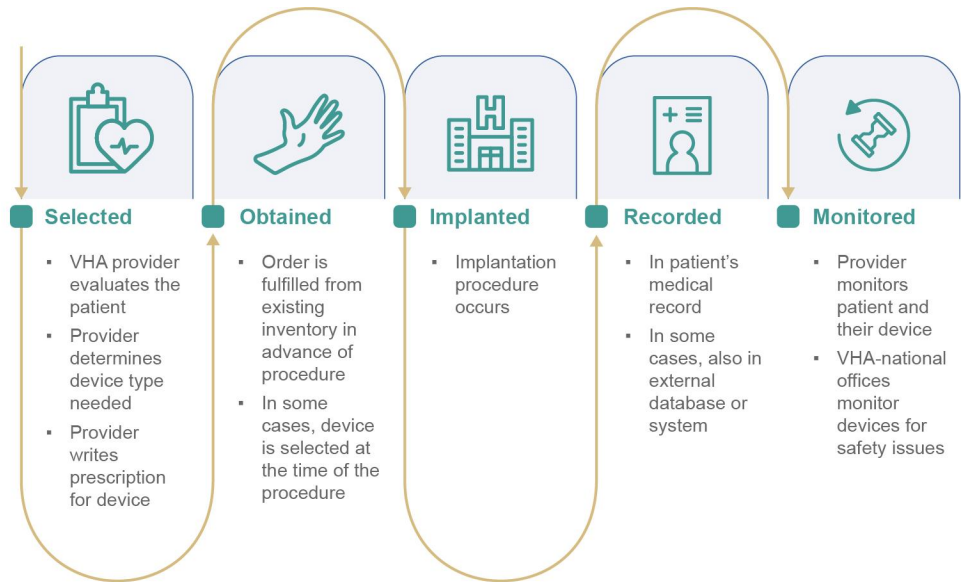
As shown in figure 1, the implant process begins when a VHA provider has determined an implantable medical device would benefit the patient. The provider evaluates the patient and decides which device (brand, model, etc.) would be best, and then writes a prescription for the device. In some cases, the specific device is not determined until the time of the implantation procedure.¹⁸ After the procedure, clinicians document the implantable medical device in the patient's electronic health record, and, in some cases, in an outside registry or system.¹⁹ After implantation, VHA providers monitor patients' health and device performance, as part of their care.

¹⁷VHA previously realigned some of its VISN boundaries in 2002 and 2015, decreasing the number of VISNs from 23 to the current 18.

¹⁸For example, according to a VHA orthopedic surgeon, in orthopedic procedures such as knee replacements, surgeons will work with manufacturer representatives to identify a set of components that they believe would best meet the patient's needs. This selection of implantable medical devices is placed in the operating room. Then, once the procedure has begun, the surgeon selects the best option, based on an assessment of the body cavity (surrounding tendons, bones, etc.) where the implantable device will go.

¹⁹Specifically, within 2 days, the following is required to be documented in the patient record: the date of the procedure, and a complete description of the device, including reference, model, and catalog numbers, if available.

Figure 1: Steps Involved in Implanting a Medical Device at the Veterans Health Administration (VHA)



Source: GAO analysis of VHA information; RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

Accessible Text for Figure 1: Steps Involved in Implanting a Medical Device at the Veterans Health Administration (VHA)

1. Selected:
 - a. VHA provider evaluates the patient
 - b. Provider determines device type needed
 - c. Provider writes prescription for device
2. Obtained:
 - a. Order is fulfilled from existing inventory in advance of procedure
 - b. In some cases, device is selected at the time of the procedure
3. Implanted:
 - a. Implantation procedure occurs
4. Recorded:
 - a. In patient's medical record
 - b. In some cases, also in external database or system
5. Monitored:
 - a. Provider monitors patient and their device
 - b. VHA-national offices monitor devices for safety issues

Source: GAO analysis of VHA information; RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

Multiple VHA Offices Are Involved in Overseeing Implantable Medical Devices

Multiple VHA offices are involved in overseeing implantable medical devices. These national-level offices are responsible for overseeing key aspects of implantable medical devices, including managing inventory, documenting information on the implants, and monitoring and communicating safety issues. VHA oversight is also shared to some extent with the VHA-level office of the clinical specialty implanting the device. Further, VISNs and VAMC officials also have some oversight responsibilities for implantable medical devices.

VHA-level responsibilities. Multiple VHA national-level offices are responsible for key aspects of implantable medical device oversight as outlined in a variety of VHA policies. For example, NCPS is the lead office for patient safety and the Procurement and Logistics Office is the lead office for VHA’s 2020 policy on implant management.²⁰ See table 1.

Table 1: Veterans Health Administration (VHA) Offices Involved in Overseeing Implantable Medical Devices

VHA office	Role(s)
National Center for Patient Safety	<ul style="list-style-type: none"> Lead office on patient safety at VHA, including providing policy guidance and leadership on operational management for all aspects of patient safety.^a Responsible for the oversight and management of patient safety programs within VHA. Monitors external and internal sources for safety issues, including recalls. Lead office for the policy on oversight and management for the removal of recalled products, including notifying VA staff to remove recalled products.^b
Procurement and Logistics Office	<ul style="list-style-type: none"> Lead office for VHA’s policy on implant management.^c Responsible for supply management, including inventory and purchase of medical devices.
Prosthetic and Sensory Aids Service	<ul style="list-style-type: none"> Lead office (along with Procurement and Logistics) for VHA’s policy for the purchase of implantable medical devices.^d Responsible for fulfilling prosthetic implant orders from clinicians such as pacemakers and hip replacement components. Responsible for maintaining records on the requests and payment of implantable medical devices.

Source: GAO analysis of VHA documents. | GAO-24-106621

^aDepartment of Veterans Affairs, Veterans Health Administration, *VHA Directive 1050.01: VHA Quality and Patient Safety Programs* (Washington, D.C.: Mar. 24, 2023).

²⁰Department of Veterans Affairs, Veterans Health Administration, *VHA Directive 1081.02: Management of Biological and Non-Biological Implants* (Washington, D.C.: Oct. 29, 2020).

^bDepartment of Veterans Affairs, Veterans Health Administration, *VHA Directive 1068: Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities* (Washington, D.C.: June 19, 2020).

^cDepartment of Veterans Affairs, Veterans Health Administration, *VHA Directive 1081.02: Management of Biological and Non-Biological Implants* (Washington, D.C.: Oct. 29, 2020).

^dDepartment of Veterans Affairs, Veterans Health Administration, *VHA Directive 1081.01: Procurement of Surgical Implants Under 38 U.S.C. 8123* (Washington, D.C.: Nov. 23, 2018).

In addition, other VHA national-level offices with clinical specialty expertise have responsibilities for implantable medical device oversight. VHA takes steps to ensure that clinicians in specialty areas, such as cardiology and orthopedics—the two specialties we focused on in our review—have the necessary knowledge of the device to make clinical decisions about its use and safety concerns. For example, cardiologists with the National Cardiac Device Surveillance Program monitor the safety of pacemakers and other cardiovascular implantable electronic devices as outlined in policy. Similarly, surgeons within the National Surgery Office execute clinical oversight and provide guidance for all VHA surgical programs, including orthopedics as outlined in policy. See table 2.

Table 2: Veterans Health Administration (VHA) Offices Involved with Cardiac and Orthopedic Implantable Medical Devices

VHA office	Clinical specialty area	Key role(s)
National Cardiac Device Surveillance Program	Cardiology: cardiovascular implantable electronic devices	<ul style="list-style-type: none"> Ensures VHA patients with cardiovascular implantable electronic devices are registered by VA medical center staff in the National Cardiac Device Surveillance Program.^a Monitors the safety of the approximately 50,000 cardiovascular implantable electronic devices implanted in VHA patients. Provides clinical support to providers: informing them about issues discovered in monitoring. Provides information to VA medical center clinicians on potentially affected patients in the event of safety issues affecting cardiovascular implantable electronic devices.
National Surgery Office	Orthopedics	<ul style="list-style-type: none"> Executes clinical oversight, and provides guidance for all VHA surgical programs, including, but not limited to, orthopedics.^b Maintains clinical oversight of the established VHA surgical programs, surgical outcomes and surgical outcomes, data analyzed for research purposes. Ensures that VA medical centers with a surgery program have a surgical work group that meets to discuss patient safety concerns, including those involving implantable medical devices.

Source: GAO analysis of VHA documents. | GAO-24-106621

^aDepartment of Veterans Affairs, Veterans Health Administration, *VHA Directive 1189: National Cardiac Device Surveillance Program* (Washington, D.C.: Jan. 13, 2020).

^bThe National Surgery Office has operational oversight of VHA surgical programs, including the transplant program, and selected specialty programs. Exceptions are dental, ophthalmology, and podiatrist surgery services that are managed by separate offices, according to the Director of the National Surgery Office. Department of Veterans Affairs, *Veterans Health Administration, VHA*

Directive 1102.01 (2): National Surgery Office (Washington, D.C.: April 24, 2019, amended on April 19, 2022.)

While not an established program office, in 2021 VHA convened a VHA national-level “Biological Implant Tracking Integrated Project Team” in response to the 2021 VA Office of Inspector General report on VHA’s handling of biological implantable medical devices. One of the report’s recommendations called for VHA to establish a structure for oversight responsibility that can provide guidance for tracking biological implanted devices.

VISN- and VAMC-level responsibilities. VISN and VAMC offices and officials also have oversight responsibilities for implantable medical devices.

- VISN directors are required by policy to ensure that patient safety recommendations from NCPS are completed by VAMCs, and to report to NCPS safety events that may affect multiple VAMCs.²¹ VISN Chief Supply Chain officers are responsible for coordinating the removal of recalled products in their VISN.²²
- VAMC directors are ultimately responsible for implantable medical device activities within their VAMC.²³ As part of this, they are required to designate Implant Coordinators at the medical center level who are responsible for ensuring that implant information is recorded in a patient’s medical record.²⁴ VAMC chiefs of staff, who report to VAMC directors, are responsible for ensuring that clinical staff follow implantable medical device policies. Further, clinicians in specialty areas such as cardiology and orthopedics have additional responsibilities, including notifying patients of a safety issue with an implantable medical device.

²¹VHA Directive 1050.01: VHA Quality and Patient Safety Programs.

²²VHA Directive 1068: Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities.

²³VHA Directive 1081.02: Management of Biological and Non-Biological Implants.

²⁴Implant coordinators may or may not be clinical staff. The implant coordinators may be part of any number of VAMC service lines, such as nursing, surgery, or logistics, among others. Per VHA policy, regardless of organizational alignment, the implant coordinators are considered specialty service personnel since they support specialty clinicians and perform certain administrative functions of an implanting specialty service.

VHA's National Center for Patient Safety Identifies Potential Safety Issues and Determines VHA's Response

NCPS is the lead office for monitoring and responding to all patient safety issues at VHA, including those related to implantable medical devices. NCPS monitors both external and internal sources to identify these issues. It then evaluates any risks an issue poses for patients in coordination with VHA program offices and subject matter experts to determine VHA's response.

Monitoring for Safety Issues

NCPS is required by policy to conduct both external and internal monitoring for patient safety issues—including safety issues with implantable medical devices.²⁵

- **External monitoring.** According to NCPS documents and officials, NCPS's external monitoring for safety issues includes reviewing information received from federal agencies, manufacturers, and other sources such as news outlets. Specifically, NCPS reviews the notifications it receives in a centralized email account from multiple sources. Federal agency sources include FDA, the Centers for Disease Control and Prevention, and the Department of Defense, among others. Manufacturer notifications typically are sent by individual manufacturers to NCPS when the manufacturer or supplier determines that their product has been sold to a VHA facility. In our review of the eight selected safety issues, NCPS provided documentation indicating that for those specific safety issues it had received notifications from multiple external sources including the FDA and manufacturers.
- **Internal monitoring.** According to NCPS documents and officials, NCPS's internal monitoring for safety issues includes reviewing information received from internal VHA sources such as national program offices for clinical specialties—e.g., the National Cardiac Device Surveillance Program. Other sources include health care

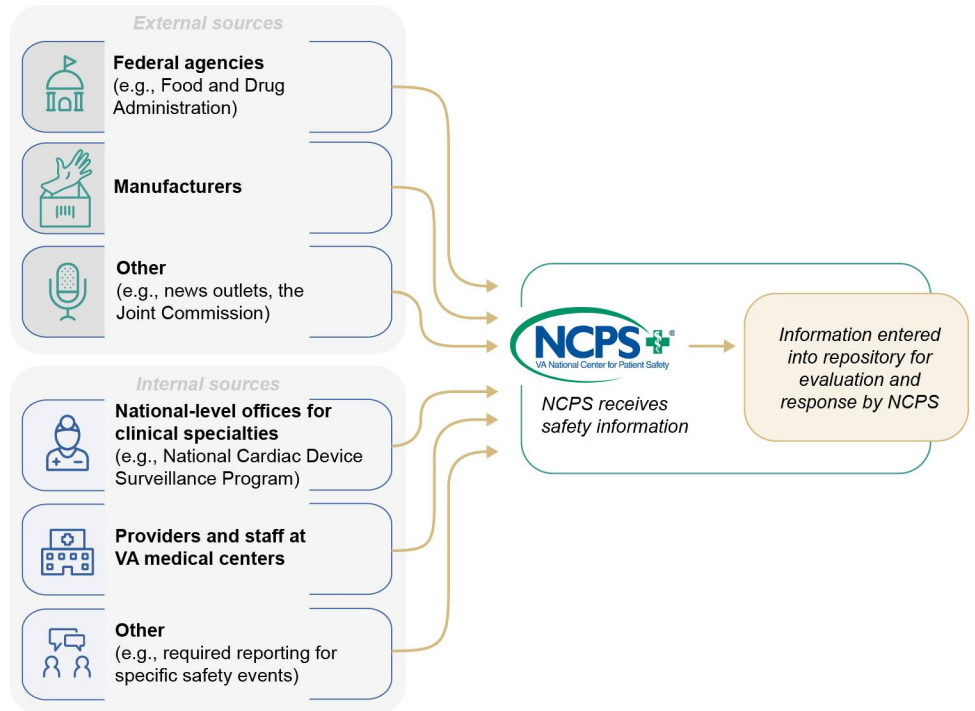
²⁵According to the VHA Directive on Patient Safety, NCPS is to establish and provide operational oversight of VHA patient safety programs, including the monitoring of patient safety data and related process improvement activities at the national, regional, and local levels. *VHA Directive 1050.01: VHA Quality and Patient Safety Programs.*

providers and staff at the local VAMC levels. For example, VAMC staff may receive a letter about a safety issue from a device manufacturer and then forward this letter to NCPS. In addition, VHA staff are required to report certain safety issues—such as unexplained patient deaths—to VHA’s Joint Patient Safety Reporting system.²⁶ In our review of the eight selected safety issues, NCPS provided documentation that showed that in some cases it received information from both external and internal VHA sources. For example, some of the internal VHA sources included the National Cardiac Device Surveillance Program and a VAMC patient safety official.

After information from external and internal sources is received, NCPS staff are responsible for entering this information into its Safety Triage and Assessment Repository system (referred to hereafter as the Repository), as appropriate. According to NCPS documents, safety issue information entered in this system generally includes the source of the information, implantable medical device manufacturer, implant model (if applicable), and a description of the issue. This information is then available to the NCPS staff for evaluation and response. See figure 2.

²⁶The Joint Patient Safety Reporting system is a mandated web-based system used by VHA employees to report patient safety events. *VHA Directive 1050.01: VHA Quality and Patient Safety Programs*.

Figure 2: The National Center for Patient Safety (NCPS) Monitors Safety Issues Received from External and Internal Sources



Source: GAO analysis of information provided by NCPS officials; Department of Veterans Affairs (VA) (logo), RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

Accessible Text for Figure 2: The National Center for Patient Safety (NCPS) Monitors Safety Issues Received from External and Internal Sources

1. External sources:
 - a. Federal agencies (e.g., Food and Drug Administration)
 - b. Manufacturer
 - c. Other (e.g., news, outlets, the Joint Commission)
2. Internal sources:
 - a. National-level offices for clinical specialties (e.g., National Cardiac Device Surveillance Program)
 - b. Providers and staff at VA medical centers
 - c. Other (e.g., required reporting for specific safety events)
3. NCPS receives safety information.
4. Information entered into repository for evaluation and response by NCPS.

Source: GAO analysis of information provided by NCPS officials; Department of Veterans Affairs (VA) (logo), RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

Evaluating and Responding to Safety Issues

NCPS is required by policy to evaluate and respond to safety issues.²⁷ According to NCPS officials, they do this by evaluating the safety issue information that has been collected in the Repository and determining an appropriate response. During the course of the evaluation and response discussions, additional information, such as the planned response, and the rationale behind the evaluation and the planned response decisions, is collected and recorded in the Repository. According to NCPS officials, the relevant NCPS staff meets as frequently as needed and at a minimum each week.

- **Evaluating safety issues.** According to NCPS officials—an interdisciplinary team—including subject matter experts in areas such as statistics, informatics, clinical care, and biomedical engineering—evaluates the information about each safety issue that has been recorded in the Repository. In its evaluation, this team considers factors such as how many patients are, or potentially could be affected by the safety issue and the severity or degree of harm the safety issue may pose to patient health. For example, the team would evaluate the adverse effects that might occur, how quickly these might occur, and how likely it is that patients will be injured by the product.

In our review of the eight selected safety issues, we found that NCPS generally used the Repository to detail the evaluation considerations. For example, in one case, evaluation notes from the Repository showed that NCPS received a manufacturer's letter via VAMC staff detailing a product quality issue with a hip replacement part. The manufacturer stated in the letter that if a certain part of the hip replacement system was used incorrectly, it would not fit correctly with another part. However, the manufacturer stated that correct use of the product should avoid any issues. The NCPS team's evaluation found that, based on the information provided by manufacturers, VHA did not need to notify patients, since there was no recall involved. Instead, NCPS officials notified the National Surgery Office, and collaborated

²⁷As previously described, while multiple VHA-level offices have oversight responsibilities related to implantable medical devices, according to policy, NCPS is the lead office on patient safety including the policy on oversight and management of the removal of recalled products. See *VHA Directive 1050.01: VHA Quality and Patient Safety Programs* and *VHA Directive 1068: Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities*.

with that office to communicate the issue to orthopedic providers and staff at the VAMCs.

- **Responding to safety issues.** According to NCPS officials, after evaluating a safety issue the NCPS team makes decisions about the appropriate response for VHA to take to address the safety issue. Specifically, the NCPS team decides whether VHA needs to take action to address the safety issue, what that action is, and who it should be communicated to—e.g., clinical specialty program offices, VISNs, VAMCs, and patients. According to NCPS officials and our review of the eight selected safety issues, while NCPS policies do not outline the specific actions that need to be taken, their responses can include taking no action, increased patient monitoring, or removing the implant from inventory.

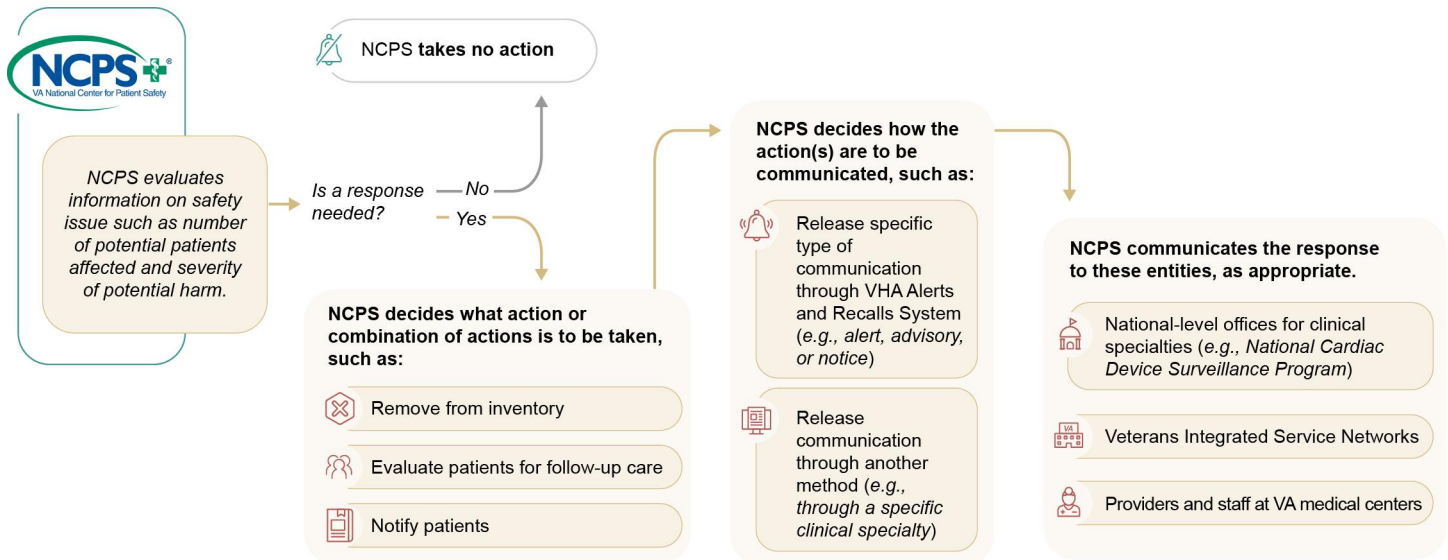
According to NCPS, VISN, and VAMC officials we spoke with regarding this issue, when additional follow up or a replacement device is needed the patient's VAMC clinician is responsible for patient outreach.²⁸ For example, if a pacemaker battery was experiencing early battery failure, the cardiologist at the VAMC would contact the patient. If the NCPS staff determines that a communication should be released across VHA it typically utilizes the VHA Alerts and Recalls System to do so. The system requires the responsible VAMC staff to acknowledge receipt of the required actions and affirm completion, if applicable.²⁹ However, the NCPS team could also utilize another communication method. For example, in two cardiac device safety issues included in our review, NCPS collaborated with the National Cardiac Device Surveillance Program to communicate the response plans to VISNs and VAMCs. VAMC

²⁸According to NCPS officials, VHA patient notifications are governed by *VHA Directive 1004.08: Disclosure of Adverse Events to Patients*, which states that VAMCs have responsibilities for clinical and institutional disclosures. VHA officials also told us that in some cases manufacturers will also send notification letters to patients with non-biological implantable medical devices that have safety issues. Department of Veterans Affairs, Veterans Health Administration, *VHA Directive 1004.08: Disclosure of Adverse Events to Patients* (Washington, D.C.: Oct. 31, 2018.)

²⁹The VHA Alerts and Recalls System is an electronic workflow management system which allows NCPS to assign specific actions related to safety events to specific users at the VISN and VAMC level. In a product recall, for example, NCPS could assign a logistics officer to remove items from the facility. We reviewed the alerts, advisories, and notices released through the VHA Alerts and Recalls System between January 2012 and June 8, 2023. For this period there were 89 communications released, ranging between two and fourteen per year, and six were related to implantable medical devices. See appendix III for more information.

clinicians are then responsible for taking the appropriate action, including notifying patients. See figure 3.

Figure 3: The National Center for Patient Safety (NCPS) Approach for Evaluating and Responding to Safety Issues on Implantable Medical Devices



Source: GAO analysis of information provided by NCPS officials; Department of Veterans Affairs (VA) (logo), RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

Accessible Text for Figure 3: The National Center for Patient Safety (NCPS) Approach for Evaluating and Responding to Safety Issues on Implantable Medical Devices

1. NCPS evaluates information on safety issue such as number of potential patients affected and severity of potential harm.
2. Is a response needed?
 - a. No: NCPS takes no action.
 - b. Yes: NCPS decides what action or combination of actions is to be taken, such as: remove from inventory, evaluate patients for follow-up care, and notify patients.
 - i. NCPS decides how the action(s) are to be communicated, such as:
 1. Release specific type of communication through VHA Alerts and Recalls System (e.g., alert, advisory, or notice)
 2. Release communication through another method (e.g., through a specific clinical specialty)

- ii. NCPS communicates the response to these entities, as appropriate.
 - 1. National-level offices for clinical specialties (e.g., National Cardiac Device Surveillance Program)
 - 2. Veterans Integrated Service Networks
 - 3. Providers and staff at VA medical centers

Source: GAO analysis of information provided by NCPS officials; Department of Veterans Affairs (VA) (logo), RaulAlmu/stock.adobe.com (illustrations). | GAO-24-106621

VHA Is Not Able to Ensure All Non-Biological Implantable Medical Devices Are Tracked Back to Individual Patients

We found that VHA is not able to ensure that all non-biological medical devices are effectively tracked to individual patients. Specifically, for the two clinical specialties we reviewed, while VHA was able to effectively track cardiac electronic devices to individual patients, it was unable to effectively do so for orthopedic devices. We also found VHA has not fully assessed its ability across all specialties to ensure that non-biological implantable medical devices can be effectively tracked back to individual patients.

VHA Is Not Able to Ensure All Orthopedic Devices Are Tracked Back to Individual Patients

We found the National Cardiac Device Surveillance Program was able to track cardiac electronic devices to individual patients, but the National Surgery Office was unable to do so for non-biological orthopedic implantable devices.³⁰ Similarly, the VAMCs in our review were generally able to track cardiac electronic devices to individual patients but not orthopedic devices. We also found that policy gaps—specifically, a lack of tracking requirements—contributed to VHA’s inability to ensure that all non-biological medical can be effectively traced back to individual patients. These policy gaps created additional gaps in data collection for orthopedic implantable medical devices.

³⁰As discussed earlier, the National Surgery Office also has oversight for several other surgical specialties, including, for example, cardiothoracic surgery, neurological surgery, obstetrics and gynecological surgery, and plastic surgery.

Furthermore, for the two clinical specialties we reviewed, we found that there is a policy requirement to track cardiac electronic implantable devices but not orthopedic implantable devices.

- The National Cardiac Device Surveillance Program has a policy requiring VAMC staff to record in its tracking system all patients who receive cardiac electronic implantable devices. Therefore, the Program and VAMCs were able to use its database to identify patients. When we asked the VAMCs about the selected electronic cardiology devices with safety issues, the VAMCs were generally able to effectively track the devices to individual patients.
- In contrast, there is no policy requirement that VAMC staff record all patients who receive orthopedic—or other non-biological implantable medical devices—in a tracking system separate from the patient’s medical record. When we asked the VAMCs about the selected orthopedic devices with safety issues, the VAMCs were not able to effectively track the devices to individual patients.

The policy gaps for orthopedic implantable devices adversely affect VHA’s ability to conduct necessary oversight. However, these gaps did not exist for cardiac implantable electronic devices. Specifically, the National Cardiac Device Surveillance Program, through its data system, has the information necessary to help it conduct oversight to ensure non-biological implantable medical devices can be tracked to individual patients. According to the director, the Program regularly reviews the data VAMCs have recorded in the system to ensure it is complete for all patients and follows up when their oversight identifies issues. However, the National Surgery Office does not have its own data system nor access to patient data through another mechanism to help it conduct oversight for the tracking of orthopedic devices to individual patients. As previously mentioned, both the National Surgery Office and the VAMCs were not able to identify individual patients with the selected orthopedic devices with safety issues. Some VAMC officials said that, if they needed to identify patients affected by a safety issue with an orthopedic

implantable device, it would require a time-consuming search of the medical records (see text box).³¹

³¹We also found that NCPS, VHA’s principal patient safety office, did not have the capability to track orthopedic, or any type of implantable medical devices to individual patients.

“...all the relevant medical files for the type of procedure within the timeframe would have to be pulled and reviewed individually. The process would be very labor- and time-intensive.”

Source: GAO interview with a VAMC orthopedic clinician. Clinician responded with the above when asked how they would track patients, if needed, in the event of an implant safety issue. | GAO-24-106621

Having the ability to ensure orthopedic implantable medical devices can be tracked to individual patients would be consistent with VHA’s policy on quality and patient safety that affirms the agency’s commitment to quality health care and patient safety.³² It would also be consistent with federal standards for internal control, which call for establishing monitoring activities and remediating internal control deficiencies on a timely basis—such as easily identifying and contacting patients if there are safety issues with their devices.³³ Until VHA remedies the policy and data collection gaps in the agency’s ability to track orthopedic implantable medical devices back to individual patients, VHA cannot ensure these patients can receive appropriate care in the event of safety issues, nor that it can meet its commitment to quality health care and patient safety.

VHA Has Not Fully Assessed Its Ability to Track Non-Biological Implantable Medical Devices Across All Specialties

VHA’s inability to effectively track non-biological implantable medical devices is not limited to orthopedic devices—we found that the agency has not fully assessed its ability across all specialties to track these devices. NCPS (VHA’s principal patient safety office) officials told us they cannot track any implantable medical devices to the individual patient level. They cited a lack of access to patient-specific data and the lack of a national tracking system as the reasons why they cannot do this. NCPS officials have recognized the need to develop better tracking capabilities for implantable medical devices across VHA, including non-biological implantable medical devices (see text box). For example, from 2017 to 2020, NCPS submitted internal funding requests for an Implant Tracking Registry and Alert System for both biologic and non-biologic implants, so that VHA could identify and locate patients quickly in the event of a safety issue. According to NCPS officials, requests for this type of system have not been submitted since 2020 because of other priorities. Further, NCPS officials also said that NCPS started but did not complete an assessment

³²VHA Directive 1050.01: VHA Quality and Patient Safety Programs.

³³[GAO-14-704G](#).

of gaps in tracking capabilities in 2018 and used some of the incomplete information to help inform its subsequent funding request.³⁴

“Currently, there is no effective way for VHA to ensure that patients impacted by an implant recall or safety issue can be tracked and notified.”

Source: Internal information technology funding request for an implant tracking registry and alert system, submitted by the National Center for Patient Safety (2020). | GAO-24-106621

Further, in 2021, VA’s Office of Inspector General found that VHA lacked oversight of biological implantable medical devices.³⁵ VHA convened a Biological Implant Tracking Integrated Project Team to address the Inspector General’s recommendations. This team began reviewing tracking capabilities for biological implantable medical devices in 2021. VHA’s 2020 policy related to implant management specifies that biological implantable medical devices are to be tracked to individual patients outside of a patient’s medical record, but the policy does not include the same requirement for non-biological implantable medical devices.³⁶ An official who is part of the Biological Implant Tracking Integrated Project Team said that, at their VAMC, they used the biological implantable medical device tracking systems to track non-biological devices outside of the medical record.³⁷ This official said they did this because of clinical best practices for handling similar devices using a single process, even though VHA policy does not require the data system be used for tracking non-biologicals. The Integrated Project Team completed an assessment of the systems used by VAMCs to track biological devices, and, in December 2023, drafted a guidebook summarizing implant tracking, with intent to support VAMCs’ processes

³⁴According to the preliminary information from the incomplete assessment in 2018, there was the need for more analysis on issues such as the ability to track and responsibilities for tracking, among others.

³⁵VHA: *Biologic Implant Tracking Needs Improvement* [19-07053-51](#).

³⁶VHA Directive 1081.02: *Management of Biological and Non-Biological Implants*. Further, as previously mentioned, The Joint Commission, a hospital accreditation organization, requires accredited hospitals to trace all biological implantable medical devices to individual patients. The Joint Commission does not specify the same for non-biological implantable medical devices, although its standards state that non-biological implantable medical devices may also require tracking to support patient notification in the event of a recall or investigation for safety issues.

³⁷This official was not from one of our four selected VAMCs.

for biological implant tracking.³⁸ However, there is no mention of plans to extend these efforts to non-biological implantable medical devices.

Recognizing that tracking all devices could be a resource-intensive undertaking, an assessment of VHA's ability to track all non-biological implantable medical devices to individual patients across all clinical specialties could help the agency determine the scope of the devices that should be tracked outside of the patient medical record. Such an assessment could also help the agency to target and prioritize the most critical non-biological implantable medical devices for tracking to the individual patient. For example, in 2015, FDA's Center for Devices and Radiologic Health Medical Device Registries Task Force noted examples of devices that could be reviewed to determine whether they should be prioritized for tracking such as implantable rhythm and heart failure devices, hip and knee replacement devices, and spine surgery devices, among other devices.³⁹

Conducting an assessment of device tracking across all specialties and subsequently taking steps to address any identified gaps, such as those we identified in our review, would help VHA ensure the most critical non-biological implantable medical devices can be tracked to individual patients. It also would be consistent with VHA's policy on quality and patient safety that affirms the agency's commitment to quality health care and patient safety.⁴⁰ In addition, having this assurance would also be consistent with federal standards for internal control, specifically those which call for establishing monitoring activities and remediating internal control deficiencies on a timely basis—such as ensuring VHA has the ability to effectively identify and notify patients if there was a safety issue

³⁸According to the National Surgery Office, as of January 2024, formal approval of the guidebook was pending.

³⁹Medical Device Registry Task Force & the Medical Devices Epidemiology Network, *Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research, Draft for Public Comment* (Silver Spring, MD: Aug. 20, 2015). Similarly, according to a 2012 article, Kaiser Permanente—a large integrated health care system—determined that the monitoring of medical devices was so critical to patient safety and quality care that they prioritized the establishment of patient registries. These included registries for cardiac devices including pacemakers and for orthopedic devices including hip and knee replacement devices, among others. See Elizabeth W. Paxton, Maria C.S. Inacio, and Mary-Lou Kiley, "The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities." *The Permanente Journal*, vol. 16, no. 2 (2012): 36-44.

⁴⁰VHA Directive 1050.01: VHA Quality and Patient Safety Programs.

involving their device.⁴¹ Until VHA assesses and remedies gaps contributing to the agency's inability to track non-biological implantable medical devices back to individual patients, it cannot ensure these patients receive appropriate care in the event of safety issues, nor that it can meet its commitment to quality health care and patient safety.

Conclusions

VHA provided health care services to over 6 million veterans in fiscal year 2022—services that include implanting over 200,000 medical devices annually to improve patient independence, quality of life, and longevity. When an implantable medical device fails, the patient with that device can face serious health risks if the failure is not addressed. Because of this, monitoring and tracking implantable medical devices back to individual patients is critical so that VHA can, in the instance of a safety issue, easily contact affected patients to take appropriate steps. However, clear gaps exist in the agency's ability to track orthopedic implantable medical devices back to individual patients. Until VHA remedies these policy gaps, VHA cannot ensure it is meeting its commitment to quality health care and patient safety.

Similarly, we found that the agency has not fully assessed its ability across all specialties to track implantable medical devices to individual patients across all specialties. Such an assessment would help identify the highest risk devices and ensure VHA is able to target its policies and resources effectively to identify and notify patients in a timely manner when needed.

Recommendations for Executive Action

The Under Secretary of Health should ensure VHA includes requirements in its policies that non-biological orthopedic implantable medical devices be effectively tracked to the patient level and ensure that VHA national-level offices have access to the information from the tracking systems for oversight. (Recommendation 1)

The Under Secretary of Health should undertake an assessment across all clinical specialties to identify where other gaps exist in its ability to effectively track non-biological implantable medical devices to individual

⁴¹[GAO-14-704G](#).

patients and take actions to address any identified gaps. Such actions should include ensuring appropriate policies are in place, requiring the use of data systems for tracking, and ensuring that VHA national-level officials have access to the information from the tracking systems for oversight. Actions may also include identifying one program office with ultimate responsibility for implantable medical device oversight at the national level, which could be one of the national offices such as NCPS or an interdisciplinary team such as VHA's Biological Implant Tracking Integrated Project Team. (Recommendation 2)

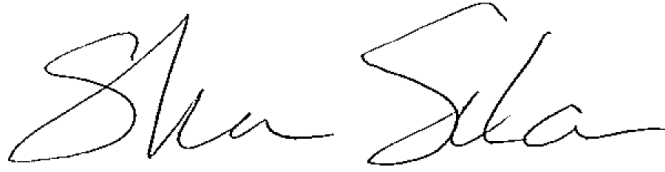
Agency Comments

We provided a draft of this report to VA for review and comment. In its written comments, reproduced in appendix IV, VA reported that VHA concurred with our recommendations and identified actions VHA will take to address them. To address our first recommendation regarding ensuring non-biological orthopedic devices can be effectively tracked to patients VHA will “coordinate policy review, and as needed, policy development.” Further, VHA will “develop and recommend options for VHA national-level offices to have access to the tracking information for oversight.” To address our second recommendation to undertake an assessment across all clinical specialties to identify where other gaps exist in its ability to effectively track non-biological implantable medical devices to individual patients, the department said this is an area in VHA's oversight “that has not previously been evaluated” and will require research and resources to complete, including involving multiple stakeholders and a consideration of information technology systems. VHA also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and the Secretary of Veterans Affairs. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or silass@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

Letter

A handwritten signature in black ink, appearing to read "Sharon Silas". The signature is fluid and cursive, with the first name "Sharon" and the last name "Silas" written in a similar style.

Sharon M. Silas
Director, Health Care

Appendix I: Implantable Medical Devices Commonly Prescribed by Veterans Health Administration (VHA) Providers, Fiscal Years 2019-2023

Implantable medical devices are used to treat, or otherwise improve, a wide variety of medical conditions among the VHA patient population. The VHA provider evaluates the patient’s condition, and then orders—via a prescription—the type and number of implantable devices needed. Table 3 below lists the number of implantable medical devices prescribed by VHA providers from fiscal year 2019 to fiscal year 2023. This data was provided from VHA’s National Prosthetics Patient Database and determined to be sufficiently reliable for these purposes.

Table 3: Implantable Medical Devices Prescribed by VHA Physicians, by Number of Unique Patients

Implantable medical device category	Implantable medical device category member	Fiscal year 2019	Fiscal year 2020	Fiscal year 2021	Fiscal year 2022	Fiscal year 2023
Head and neck	Intraocular lens	51,756	34,497	45,317	47,552	47,851
Head and neck	Head	576	439	507	629	842
Head and neck	Neck	497	418	367	367	366
Head and neck	Eyes all other	4,436	3,389	4,733	4,620	4,710
Head and neck	All other	1,600	1,131	1,364	1,442	1,779
Abdomen	Stent	5,728	4,975	4,745	3,937	4,003
Abdomen	Mesh	14,195	10,079	12,356	12,492	13,375
Abdomen	Catheter	2,656	2,483	2,579	2,543	2,420
Abdomen	Abdomen all other	3,574	2,504	3,261	3,383	3,387
Upper extremity	Arm	149	122	124	133	139
Upper extremity	Shoulder	1,766	1,207	1,542	1,527	1,920
Upper extremity	Hand	19	26	24	30	25
Upper extremity	All other	723	510	565	479	536
Lower extremity	Hip	9,231	6,125	7,844	7,408	7,755

**Appendix I: Implantable Medical Devices
Commonly Prescribed by Veterans Health
Administration (VHA) Providers, Fiscal Years
2019-2023**

Implantable medical device category	Implantable medical device member	Fiscal year 2019	Fiscal year 2020	Fiscal year 2021	Fiscal year 2022	Fiscal year 2023
Lower extremity	Knee	14,658	9,680	11,009	11,357	13,292
Lower extremity	Foot	78	53	183	227	209
Lower extremity	All other	6,935	5,519	6,008	6,116	6,080
Thoracic	Pacemaker/leads	8,069	7,294	8,309	7,862	7,691
Thoracic	Implantable cardiac defibrillators/leads	7,458	5,740	5,683	5,298	5,081
Thoracic	Stents	12,247	9,956	10,181	8,844	8,780
Thoracic	Valve	1,128	879	890	949	1,003
Thoracic	All other	7,532	6,123	7,018	7,314	7,625
Other categories	Dental implants	36,504	23,972	28,539	32,277	33,233
Other categories	All screws, plates, anchors, etc.	30,086	22,964	25,767	25,149	27,149
Other categories	Surgical implantables, all unknowns	8,146	6,959	7,154	6,536	6,105
Other categories	Biologic	31,413	22,413	26,298	24,692	26,256
	Total	261,160	189,457	222,367	223,163	231,612

Source: Veterans Health Administration (VHA) National Prosthetics Patient Database. | GAO-24-106621

Appendix II: Veterans Health Administration (VHA) Alerts and Recalls System Communications

The National Center for Patient Safety (NCPS) provided us with a list of all alerts, advisories, and notice communications from January 1, 2012, to June 8, 2023. These communications, which are developed in response to safety issues evaluated by NCPS, are sent to Veterans Administration Medical Centers (VAMC) and Veterans Integrated Service Networks (VISN) through the VHA Alerts and Recalls System. When the communication requires actions, such as removing products from inventory, VAMC staff are required to electronically acknowledge the action was completed in the VHA Alerts and Recalls System.

NCPS issued 89 communications through the VHA Alerts and Recalls System during the period, ranging between 2 and 14 per year. Among these, 56 were alerts (63 percent), 8 were advisories (9 percent), and 25 were notices (28 percent). Six of these were related to implantable medical devices. The six implantable medical device communications covered: cardiac devices (3), cybersecurity vulnerabilities in pacemakers and defibrillators (1), eye drainage stents (1), and use of incompatible drug formulations in an implantable infusion pump (1).

Following is additional information on alerts, advisories, and notices including the nature of those disseminated during the period we reviewed:

- **Patient Safety Alerts.** These are the most urgent of these safety communications, and generally require a specific action be taken to address actual or potential threats to life or health and often will require one or more clinical actions. For example, in 2017 VHA issued an alert to address cybersecurity vulnerabilities in pacemakers and implantable defibrillators. While the items did not need to be removed from use, these risks could allow hackers to program the devices, possibly harming patients. The alert instructed VAMC clinicians to ensure all their patients' devices receive a software update to fix the issue.

Safety issues addressed through alerts over the period include device malfunctions with IV drips, recalled cardiac defibrillator leads, voicemail greetings giving patients incomplete information, and

software issues. The required actions for these alerts are generally tailored to the specific problem, and have included ensuring software updates are implemented, identifying patients who are affected by a defective device, and re-recording voicemail information to be correct.

- **Patient Safety Advisories.** These are less urgent than alerts and generally require a specific action to address issues such as equipment design, product failure, and procedures or training, and they may recommend clinical action. For example, in 2022, VHA issued an advisory to highlight an institution-wide switch from one type of feeding tube connection to another. The advisory instructed VAMC providers to ensure staff and patients were trained to use the new connector.

Safety issues addressed through advisories over the period included patient ability to unlock doors with a plastic card, patient ability to disassemble wheelchairs, and software issues with the computerized patient record system. The recommended actions for these advisories are generally tailored to the specific problem and have included ensuring proper kinds of locks are used and ensuring wheelchairs in mental health units are equipped with tamper resistant hardware.

- **Patient Safety Notices.** These are generally the least urgent and provide awareness of patient safety vulnerabilities even where no solutions are immediately evident. Notices may or may not provide recommendations. For example, in 2022 a change in electronic health record software created interoperability issues between Department of Defense's data systems and VHA's data systems. These interoperability issues caused some clinically important patient information such as drug allergies to be lost in the transfer between the two systems. While no immediate solution to the issue was available, VHA recommended that facilities double check affected patients' information at the point of care to make the most clinically appropriate decisions.

Safety issues addressed through notices over the period include preventing vaccination extra dose events, guidance on use of personal protective equipment for patients with a suicide risk, a manufacturer's voluntary market withdrawal of a medical device, and software issues with the computerized patient record system. Although not all notices contain recommendations, some suggested solutions have included reminding staff to evaluate immunization needs and risks prior to vaccine administration and identifying and evaluating patients affected by a device that was withdrawn by the manufacturer.

Appendix III: Description of Selected Cardiology and Orthopedics Recalls for Non-Biologic Implantable Medical Devices

To examine how the National Center for Patient Safety (NCPS) monitors implantable medical device safety issues, we asked Veterans Health Administration (VHA) national program offices, VA Medical Centers (VAMC), and Veterans Integrated Service Networks (VISN) officials to provide us with information on eight selected non-biologic implantable medical devices—four cardiac and four orthopedic—that had publicly reported recalls. We selected two recalls for which we knew VHA took action. In addition, we selected six recalls that 1) affected a large number of medical devices, 2) were associated with the orthopedic and cardiology specialties, 3) were manufactured by major medical device manufacturers in each specialty, and 4) were recently removed from the market between January 1, 2021, and June 26, 2023.

Food and Drug Administration (FDA) data on these eight recalls found they affected 1,353,747 non-biologic implantable medical devices, some quantity of which may not have been implanted in patients due to being removed from use following a recall. The following table describes attributes of these four recalls. See Table 4.

Table 4: Description of Selected Cardiology and Orthopedics Recalls for Non-Biologic Implantable Medical Devices

Selected recall	Device description ^a	Number of devices affected ^b	Classification date ^c	FDA recall classification ^d
Cardiology 1	Defibrillator leads	256,000	12/15/2011	Class I
Cardiology 2	Cardiac resynchronization therapy leads	202,000	05/02/2012	Class II
Cardiology 3	Defibrillators and cardiac resynchronization therapy	528,479	03/26/2021	Class I
Cardiology 4	Pacemakers	337,987	05/07/2021	Class I
Orthopedics 1	Hip replacement cup	14,161	01/07/2021	Class II
Orthopedics 2	Tibial components	8,924	12/09/2022	Class II

**Appendix III: Description of Selected
Cardiology and Orthopedics Recalls for Non-
Biologic Implantable Medical Devices**

Selected recall	Device description^a	Number of devices affected^b	Classification date^c	FDA recall classification^d
Orthopedics 3	Hip ball	3,488	07/12/2022	Class II
Orthopedics 4	Shoulder stem	2,708	01/11/2022	Class II

Source: GAO analysis of Food and Drug Administration (FDA) recall data. | GAO-24-106621

^aFDA provided a brief description of the recalled medical device, which we shortened further for this column.

^bFDA reported this amount and it includes devices that were available worldwide, including in the United States.

^cOn this date, FDA classified these non-biologic recalls as class I, II, or III. This is typically later than the recall initiation date, which is the date that the firm first began notifying the public or consignees of the recall.

^dFDA assigns one of three recall classifications—class I, II, or III—to indicate the relative degree of health risk posed by the product being recalled. Class I recalls are those that FDA has determined that there is a probability that use of, or exposure to, the product could cause serious adverse health consequences or death. Class II recalls are those for which FDA has determined that the use of, or exposure to, the product could cause temporary or medically reversible adverse health consequences or that the probability of serious adverse health consequences is remote. For class III recalls, FDA has determined that use of, or exposure to, a device is not likely to cause adverse health consequences. FDA advises the manufacturer of the assigned recall classification and posts information about the recall in its weekly enforcement reports.

Appendix IV: Comments from the Department of Veterans Affairs

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of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON

March 8, 2024

Ms. Sharon M. Silas
Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Silas:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office (GAO) draft report: ***VETERANS HEALTH CARE: Improvements Needed in Patient Tracking for Non-Biological Implantable Medical Devices*** (GAO-24-106621).

The enclosure contains technical comments and the action plan to address the draft report recommendations. VA appreciates the opportunity to comment on your draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Jackson".

Kimberly Jackson
Chief of Staff

Enclosure

**Appendix IV: Comments from the Department
of Veterans Affairs**

Enclosure

Department of Veterans Affairs (VA) Response to the
Government Accountability Office (GAO) Draft Report
***VETERANS HEALTH CARE: Improvements Needed in Patient Tracking for Non-
Biological Implantable Medical Devices***
(GAO-24-106621)

Recommendation 1: The Under Secretary of Health should ensure VHA includes requirements in its policies that non-biological orthopedic implantable medical devices be effectively tracked to the patient level and ensure that VHA national level offices have access to the information from the tracking systems for oversight.

VA Response: Concur. The Veterans Health Administration (VHA) Office of the Assistant Under Secretary for Health (AUSH) for Clinical Services, in collaboration with the National Center for Patient Safety, Procurement and Logistics Office, Prosthetics and Sensory Aids Service, and other subject matter experts as needed, will coordinate policy review, and as needed, policy development with respect to the tracking of non-biological orthopedic implantable medical devices. These collaborating VHA national program offices will develop and recommend options for VHA national level offices to have access to the tracking information for oversight.

Target Completion Date: March 2025

Recommendation 2: The Under Secretary of Health should undertake an assessment across all clinical specialties to identify where other gaps exist in its ability to effectively track non-biological implantable medical devices to individual patients and take actions to address any identified gaps. Such actions should include ensuring appropriate policies are in place, requiring the use of data systems for tracking, and ensuring that VHA national level officials have access to the information from the tracking systems for oversight. Actions may also include identifying one program office with ultimate responsibility for implantable medical device oversight at the national level, which could be one of the national offices such as NCPS or an interdisciplinary team such as VHA's Biological Implant Tracking Integrated Project Team.

VA Response: Concur. The Government Accountability Office (GAO) has identified an area in VHA's oversight that has not previously been evaluated and will require considerable research and resources to fully understand its complexity. We expect this large effort will require additional funding that is not currently included in this fiscal year's budget submission. It may also require establishing new national program offices or reorganizing current program offices. To fully understand the scope and ramifications of such an assessment, the AUSH for Clinical Services, in collaboration with VHA's Office of Integrity and Compliance Enterprise Risk Management, will develop a risk assessment framework for consideration by the VHA Governance Board. The AUSH for Clinical Services will execute the selected risk management framework, which will determine VHA's approach to GAO's recommended assessment.

**Appendix IV: Comments from the Department
of Veterans Affairs**

Enclosure

Department of Veterans Affairs (VA) Response to the
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***VETERANS HEALTH CARE: Improvements Needed in Patient Tracking for Non-
Biological Implantable Medical Devices***
(GAO-24-106621)

Target Completion Date: March 2025

Accessible Text for Appendix IV: Comments from the Department of Veterans Affairs

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Target Completion Date: March 2025

Appendix V: GAO Contacts and Staff Acknowledgments

GAO Contact

Sharon M. Silas, (202) 512-7114 or silass@gao.gov.

Staff Acknowledgments

In addition to the contact named above, Karin Wallestad (Assistant Director), Kristeen McLain (Analyst-in-Charge), Carmen Rivera-Lowitt, Fatima Sharif, and Brian Schmidt made key contributions to this report. Also contributing were Sonia Chakrabarty, Laurie Pachter, Joycelyn Cudjoe, Eric Peterson, and Ethiene Salgado-Rodriguez.

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