GAO Highlights

Highlights of GAO-24-106621, a report to congressional committees

March 2024

VETERANS HEALTH CARE

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

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.

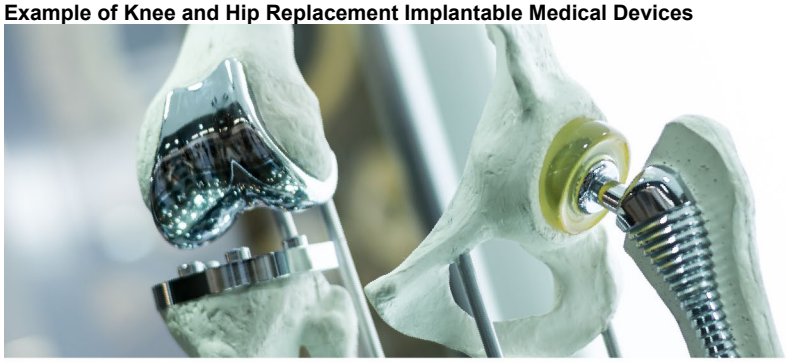
View GAO-24-106621. For more information, contact Sharon M. Silas at (202) 512-7114 or silass@gao.gov.

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

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.