April 2, 2014

VETERANS' HEALTH CARE

Oversight of Tissue Product Safety

GAO Highlights

Highlights of GAO-14-463T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

Why GAO Did This Study

In fiscal year 2013, approximately 59,000 tissue products were used to provide care to veterans at VAMCs; bone and skin grafts were the most common. While tissue products can repair the body and improve function and feeling, there is also the risk that communicable diseases can be transmitted from the donor to the recipients, potentially resulting in severe complications. FDA is responsible for regulating the manufacture of tissue products to help ensure the safety of such products marketed in the United States. For purchasing purposes, VHA considers tissue products to be a type of surgical implant and a prosthetic—items that support or replace a body part or function.

At recent hearings of this subcommittee, concerns were raised about VA's oversight of surgical implant purchases and its ability to identify veterans who received an implant that is being recalled by the manufacturer or FDA. This testimony addresses (1) whether VHA received tissue products that may have been contaminated and (2) VHA's safeguards to prevent the receipt and use of contaminated tissues, including VHA's ability to ensure the quality of its vendors and to respond to recalls of tissue products. GAO reviewed FDA and VHA data on recalls and adverse reactions related to tissue products and VHA purchasing data. GAO also interviewed VA, VA OIG, and FDA officials on tissue product safety requirements and oversight actions. GAO focused on the policies and procedures at the VA and VHA level.

View GAO-14-463T. For more information, contact Marcia Crosse at (202) 512-7114 or CrosseM@gao.gov.

What GAO Found

Data from the Veteran's Health Administration (VHA), within the Department of Veterans Affairs (VA), do not show evidence of VHA receiving contaminated tissue products, although, it is difficult to link adverse events in recipients to such products. VA's National Center for Patient Safety (NCPS), which began operation in 1999, has not issued any patient safety alerts—mandates for action to address actual or potential threats to life or health—or advisories—guidance to address issues such as equipment design and product failure—related to tissue products potentially received by VA medical centers (VAMC) in the last 10 years. NCPS issues patient safety alerts and advisories for recalls that require specific clinical actions to ensure patient safety. Since NCPS began issuing and recording data on recalls in November 2008, NCPS has notified VAMCs of 13 recalls for tissue products from vendors from which VHA could have received affected products—none of these recalls have resulted in patient safety alerts or advisories. For 6 of the recalls, 27 VAMCs reported to NCPS that they had identified and removed the recalled products from their inventories. For the other 7 recalls, none of the VAMCs had the affected tissue products in their inventories. The13 recalls were not issued for known tissue product contamination. Instead, most were initiated because of the possibility of contamination, such as compromise of product sterility and incomplete donor records. Further, VHA officials told us that their analysis of VHA data found no evidence of reported adverse events among VHA patients that were caused by contaminated tissue products. According to officials from the Food and Drug Administration (FDA), post-surgical infections often occur, even in the absence of tissue use, and it is often not possible to definitively attribute such infections to a tissue product.

VHA's identification of recalled tissue products may be limited, although recent actions by the agency may help. VA and VHA rely on FDA to ensure the quality of tissue vendors—who are generally required to register with FDA—but VA and VHA policies do not require that a vendor's FDA registration status be checked for most purchases. In addition, VHA's ability to track recalled tissue products in its inventories may be limited by poor inventory management practices. After receiving a recall notice, VAMCs are required to search their inventories for recalled products; however, GAO and VA Office of Inspector General (OIG) have previously reported concerns with the completeness and accuracy of VHA's inventory data and have made recommendations to improve VHA's ability to accurately identify all recalled products in VAMCs inventories. VA is in the process of responding to these recommendations. Further, while VAMCs are responsible for checking for and accurately identifying all implanted, applied, or injected tissue products subject to a recall, GAO found that VA and VHA conduct no oversight to ensure this is done and rely on VAMCs, which may have limited ability to conduct this check. For example, VHA officials stated that it is difficult to search for information on implanted tissue products, in part, because there is no automated search capability. VA is taking steps that may enhance its ability to identify tissue products after they have been used.

VA and FDA reviewed facts GAO developed in preparing this testimony. VA and FDA provided technical comments, which were incorporated as appropriate.