Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Medical Device Recall Process in Veterans Health Administration Medical Centers

Report No. 07-02369-107 **April 3, 2008**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Executive Summary

The VA Office of Inspector General conducted an inspection in selected Veterans Health Administration (VHA) medical centers to assess medical device recall processes and specific responses to a Patient Safety Alert. This alert detailed time-limited actions to be taken by each VA medical center. We evaluated the consistency and effectiveness of the recall process and identified best practices.

Congress enacted the Safe Medical Devices Act of 1990 to increase the amount of information the Food and Drug Administration (FDA) and device manufacturers receive about problems with medical devices. When a product is determined to be potentially hazardous, FDA is responsible for monitoring voluntary manufacturer action to ensure that all users of the product are notified and instructions are provided for removal or recall, if necessary. Based on information from the FDA, VHA issues Recall Notices, Patient Safety Alerts, and Patient Safety Advisories to notify VA users about risks associated with drugs, subsistence items, medical devices, medical products, or human tissue. Patient Safety Alerts disseminate urgent notices that require immediate, specific action on the part of VHA medical centers to address actual or potential threats to the life or health of patients and staff.

We conducted unannounced inspections at 23 VA medical centers on June 7, 2007, to determine if medical centers had responded appropriately to a Patient Safety Alert dated May 18, 2007. We selected facilities based on their purchases of the specific manufacturers' related products and geographical locations that allowed inspectors to perform as many reviews as possible on one day.

Although medical centers responded appropriately to the requirement to sequester products and no patients received recalled products after VHA issued the alert, we identified opportunities to improve the recall process. To improve safety, we recommended that VHA medical centers:

- Identify a back-up facility recall coordinator.
- Develop and implement a recall plan, with Veterans Integrated Service Network review and approval that meets VHA requirements.
- Perform all required elements as directed in product recalls, patient safety alerts, and/or patient safety advisories.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health (10)

SUBJECT: Healthcare Inspection – Medical Device Recall Process in Veterans Health Administration Medical Centers

Purpose

The Department of Veterans Affairs Office of Inspector General's (OIG's) Office of Healthcare Inspections (OHI) conducted an inspection in selected Veterans Health Administration (VHA) medical centers to assess medical device recall processes and specific responses to Patient Safety Alert AL07-08, dated May 18, 2007. We evaluated the consistency and effectiveness of the recall process and identified best practices.

Background

Congress enacted the Safe Medical Devices Act of 1990 (SMDA) to increase the amount of information the Food and Drug Administration (FDA) and device manufacturers receive about problems with medical devices. When a product is determined to be potentially hazardous, FDA is responsible for monitoring voluntary manufacturer action to ensure that all users of the product are notified and instructions are provided for removal or recall, if necessary. If a manufacturer does not take the appropriate voluntary action, the FDA may seek legal action under the Food, Drug, and Cosmetics Act.

VHA Directive 2004-047, *Recall of Defective Medical Devices and Medical Products,* dated August 31, 2004, establishes policy on recalls involving medical devices and medical products. VHA issues Recall Notices, Patient Safety Alerts, and Patient Safety Advisories to notify VA users about risks associated with drugs, subsistence items, medical devices, medical products, or human tissue.

Recalls are issued to notify medical centers of an actual or potential threat to life or health. Items recalled may include unsafe or defective medical devices, medical products, drugs, food and food service products, implantable devices, or prosthetic products. Problems with items must be corrected and/or removed from service or use. Patient Safety Alerts disseminate urgent notices that require immediate, specific action on

the part of VHA medical centers to address actual or potential threats to the life or health of patients and staff. Patient Safety Advisories are issued when a potential threat due to equipment design, product failure, procedural issues, or training has been identified; actions are more general in nature; and implementation may be subject to local judgment contingent on local conditions.

The Office of Product Recall, located in the VHA Clinical Logistics Office, is responsible for coordinating and monitoring the recall program, and disseminating recall information within VHA. The recall information is coordinated through the Designated Service Area Specialist (DSAS), Network Recall Coordinator (NRC), Facility Recall Coordinator (FRC), and the Facility Designated Area Specialist (FDAS). The DSAS serves as the primary contact within their area of expertise and/or specialty. The National Center for Patient Safety (NCPS) works closely with other VHA program offices to develop and forward Patient Safety Alerts and Patient Safety Advisories that contain recall-related actions to the Deputy Under Secretary for Health for Operations and Management for distribution.

In July 2004, Veterans Integrated Service Network (VISN) 22 developed an electronic means of tracking recall notices, patient safety alerts, and patient safety advisories. All VISNs implemented the electronic tracking system by February 15, 2006. The Alert and Recall Management System is hosted by VISN 22 and is maintained by Materiel Management Staff at the Network Logistics Office. The system is set up to facilitate communication from various sources for the DSAS, NRC, FRC, and FDAS and includes communication from FDA, manufacturers, distributors, and the NCPS.

VHA maintains multiple databases for medical products and devices. The National Prosthetics Patient Database (NPPD) includes orthotic, prosthetic, and sensory devices dispensed to veterans nationwide. The NPPD was developed as a tool for oversight and monitoring of the VA Prosthetics Service and to provide clinicians with information regarding prosthetic prescription practices. VHA also has databases for implantable cardioverter-defibrillators (ICDs) and pacemakers. These are the VA National ICD and the Western and Eastern Pacemaker Surveillance Centers. Every medical center uses the Generic Inventory Package (GIP) to manage the receipt, distribution, and maintenance of supplies utilized throughout the facility. Clinicians also enter implantable device information in the electronic medical record through a national surgery computer program.

Patient Safety Alert AL07-08

On April 17, 2007, the FDA seized all implantable medical products manufactured by Shelhigh, Inc. On May 2, 2007, the FDA issued a press release disclosing a formal request to Shelhigh, Inc. to recall all of its medical products because of sterility concerns. The FDA stated that the company's deficiencies could compromise the safety and

effectiveness of the products. The affected products include heart valves, conduits, surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings (to repair heart valves), and arterial grafts. Shelhigh, Inc. did not agree with the FDA and did not implement the requested recall.

Based on the FDA recall press release and the concern for potential contamination of specified products, VHA issued Patient Safety Alert (PSA) AL07-08, dated May 18, 2007. This alert detailed time-limited actions to be taken by each VA medical center. The required actions were:

- Determine if the facility had any of the affected medical products, remove them from inventory, and sequester.
- Purchase alternative medical products from other suppliers to replace the affected items.
- Notify all primary care physicians (PCP) of the potential for contamination of the specified products.
- Retrieve and review a list of patients with the affected products sent to the facility Patient Safety Manager.
- Review patient records for all patients with implanted devices to identify those implanted with affected products.
- Only use the sequestered medical products in emergency cases. The use of these products requires the review and written approval from the Chief of Staff or Acting Chief of Staff.

On June 22, 2007, Shelhigh, Inc. entered a consent order for condemnation and permanent injunction and agreed to stop manufacturing and distributing all components and devices until their methods, facilities, and controls used to manufacture their devices comply with FDA law.

Scope and Methodology

We conducted our inspection at 23 VA medical centers on June 7, 2007 (See Appendix B for list of medical centers). We selected facilities based on their purchases of Shelhigh, Inc. related products and geographical locations that allowed inspectors to perform as many reviews as possible on one day. We interviewed medical center management and staff involved in the medical device recall process. We reviewed medical center, VISN, and VHA policies and procedures; and communication related to PSA AL07-08. We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Our inspection covered the following areas:

- Evaluation of the management of medical device recalls.
- Evaluation of response to PSA AL07-08.
- Identification of best practices.

Inspection Results

Issue 1: Management of Medical Device Recalls

The management of medical device recalls was generally effective, but it could be strengthened in some areas to prevent lapses in the recall process.

Facility Recall Coordinator and Back-Up Coordinator

VHA requires that each medical center have a FRC and identified back-up FRC. The FRC has a critical role in the local medical device recall process. The FRC is generally responsible for reviewing product hazard or recall notices, and distributing these notices to the potentially affected areas. The FRC maintains records that detail the steps taken to resolve recalls; such as distribution lists, response times, number of items identified, final disposition of affected items, and date resolved. The FRC provides feedback on all Class I recalls with the requested information and provides information on alerts with required actions to the NRC. The FRC provides reports to the medical center's committees, documenting local response to recalls, patient safety alerts, and patient safety advisories.

All 23 medical centers inspected had a designated FRC. Two of the 23 (9 percent) did not have an identified back-up FRC. The FRC and back-up FRC perform a critical and integral role in the local medical device recall process. Without a back-up FRC, a lapse in the process could occur if a recall was not received or properly managed.

Recall Plan

VHA policy requires VA medical centers to have procedures to address, review, and take action on defective medical device and medical product recalls. The local recall plan is an individualized policy and program for the management, documentation, and resolution of recalls. Each medical center director is responsible for the development of a VISN approved recall plan.

Twenty of the 23 medical centers (87 percent) had local policies or plans to manage recalls. Two medical centers did not have local policies, but instead they referred to their VISN recall policy. The third medical center had an expired policy limited to local

medical device incident reporting. This medical center had a draft policy for hazardous product recalls and alerts but it was not approved.

Without a local policy or plan, there is no approved process in place to take action on recalls, report to local committees, and to document the medical center's response to recalls, patient safety alerts, and patient safety advisories.

Issue 2: Response to Patient Safety Alert AL07-08

We did not identify any patients who received Shelhigh, Inc. related products after the PSA was issued. Overall, medical centers' response to the PSA was generally effective. However, some medical centers did not complete all the PSA requirements.

Notification of Primary Care Physicians

There was confusion regarding the requirement to notify all PCPs of the product recall.

According to PSA AL07-08, medical centers were required to notify all PCPs of the potential for contamination of the specified products. The intent of the notification was to alert providers to the recall in case patients under their care had received one of the implants.

Twelve of the 23 medical centers (52 percent) did not notify PCPs of the alert. The medical centers that did not notify PCPs were confused about the requirement and felt that if they had not purchased the products locally or did not have patients on the received list, there was no need to inform their PCPs. However, patients could have received an implant from another VA or non-VA facility.

The PSA specified the notification of primary care physicians rather than all primary care providers, which would have included non-physician providers. Although we were not told this added to the notification confusion, it was not accurate and should have included all disciplines who are primary care providers. Without notifying all PCPs of the recall, they would not be aware of the potential threat for patients who may have a possible contaminated implant.

Local Record Review

Some medical centers did not perform the required local record reviews.

Based on the national prosthetics database of patients with affected implanted products, 54 medical centers had patients who were potentially affected by the recall. The NCPS sent a list of patients to those medical centers. Each medical center receiving the list was to review the list for potentially affected patients and review patient records for other patients who might not have been included in the prosthetics database.

Seventeen of the 23 medical centers we inspected were part of the 54 facilities that received the NCPS list. All had completed a review of the list, but 4 of the 17 (24 percent) did not complete the additional review of their local records, as specified by the PSA.

The medical centers that reviewed their local records used a variety of sources to identify potentially affected patients. These included local prosthetics database, vendor database, National Surgical Quality Improvement Program database, infection control database, GIP review, and computer query of medical records.

We identified a best practice at the Durham VA Medical Center (VAMC), where an infection control nurse reviewed records of 29 patients to ensure that post-operative infections were not related to recalled implants. The Cincinnati VAMC completed a computer query of their medical records, resulting in the identification of an additional patient who was not on the NCPS list who could have been affected by the recall. This review emphasizes the need to review local records to ensure the identification of all patients.

Inventory Review and Product Usage

Each medical center was required to review their inventory for any of the affected medical products and remove them from inventory. All the medical centers had completed a review of their inventory. Three of the 23 medical centers (13 percent) had identified potentially affected products and removed them from inventory. No medical center used the affected products after the PSA was issued.

Conclusions

We concluded that medical centers responded appropriately to the PSA requirement to sequester products and that no patients received recalled products after the PSA was issued. All of the medical centers had processes in place to ensure compliance with medical device recall notifications.

There are multiple alert systems within VHA, and some FRCs were aware of the potential recall of Shelhigh, Inc. products before the PSA was officially issued. Several FRCs reported that the many product notifications they receive are overwhelming, duplicative, and confusing. Although VHA's electronic medical record and databases facilitate the recall process, there is duplication and redundancy. At the same time, there is not one definitive database for implantable medical devices.

Not all facilities notified the primary care providers or conducted a review of their local records for patients potentially affected, since there was general confusion about those requirements. Clarity of communication could be improved.

Recommendations

Recommendation 1. The Under Secretary for Health needs to ensure that VHA takes action to identify a FRC back-up.

Recommendation 2. The Under Secretary for Health needs to ensure that VHA takes action to develop and implement a recall plan, with VISN review and approval that meets VHA requirements.

Recommendation 3. The Under Secretary for Health needs to ensure that VHA takes action to perform all required elements as directed in product recalls, patient safety alerts, and/or patient safety advisories.

Comments

The Under Secretary for Health agreed with our findings and recommendations and provided acceptable improvement plans. (See Appendix A, pages 8–11, for the full text of the comments.) We will follow up on planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: March 21, 2008

From: Under Secretary for Health (10)

Subject: **Healthcare Inspection – Medical Device Recall Process in Veterans Health Administration Medical Centers, Project No. 2007-02369-HI-0344 (WebCIMS 400070)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have carefully reviewed your draft report, and I concur with the findings and recommendations. The report accurately reflects that the Veterans Health Administration (VHA) responded promptly and appropriately to the potential contamination of specified products by issuing Patient Safety Alert (PSA) AL07-08, sequestering all recalled products, and directing VHA facilities to take detailed, immediate actions. As a result, VHA quickly identified and reviewed patients potentially affected by the recall and ensured that no patients received any potentially contaminated products after issuance of the PSA. At the same time, your report cites valuable opportunities for improving the effectiveness and clarity of the recall process that need to be addressed, and I am committed to promptly addressing them.

2. It is important to note that the Office of Product Recall, formerly located in the Prosthetics and Clinical Logistics Office, is now under the Office of Patient Safety and is known as the National Center for Patient Safety Product Recall Office. As part of this reorganization, the Product Recall Office is currently revising VHA Directive 2004-047, *Recall of Defective Medical Devices and Medical Products*, and will shortly issue a new directive to provide a clear and effective national policy. I look forward to reviewing the new directive and providing you a copy when available.

3. Attached is VHA's complete plan of corrective action, which provides a summary of specific initiatives that appropriately address

identified issues in the report. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)
Michael J. Kussman, MD, MS, MACP

Attachments

Under Secretary for Health Comments to Office of Inspector General's Report

The following Undersecretary for Health comments are submitted in response to the recommendation(s) in the Office of Inspector General's Report:

OIG Recommendations

The Under Secretary for Health needs to ensure that VHA takes action to:

Recommendation 1. Identify a FRC back-up.

Concur In Process **Target Completion Date:** May 30, 2008

VHA's standing policy on medical device and product recalls, VHA Directive 2004-047, *Recall of Defective Medical Devices and Medical Products*, requires that every VHA facility must identify a primary and a back-up Facility Recall Coordinator. While VHA is currently revising this directive, the soon-to-be-issued new directive will similarly address the requirements for the primary and back-up Facility Recall Coordinators in two ways. First, the Facility Director will be responsible for designating a primary and a back-up Facility Recall Coordinator and providing this information to the Network Recall Coordinator. Second, the Network Recall Coordinator will be responsible for submitting and updating names, phone numbers, and email addresses of the primary and the back-up Facility Recall Coordinators within the Network Facility Recall Coordinator email group to the National Center for Patient Safety Product Recall Office. As such, the Product Recall Office will coordinate with each Network Recall Coordinator to ensure that each facility is in compliance with these requirements. All Network Recall Coordinators must submit the names of each facility's primary and back-up Facility Recall Coordinator, and the Product Recall Office will update all Network Recall Coordinator email groups in Microsoft Outlook by May 30, 2008.

Recommendation 2. Develop and implement a recall plan, with VISN review and approval, that meets VHA requirements.

Concur In Process **Target Completion Date:** June 30, 2008

VHA's standing policy on medical device and product recalls, VHA Directive 2004-047, *Recall of Defective Medical Devices and Medical Products*, requires that every VHA facility must develop a plan designed to implement recalls received from VA Central Office and submit the plan to the Network for review and approval. While VHA is currently revising this directive, the soon-to-be-issued new directive will similarly require each Network to ensure that all facilities have a program for responding to recalls. Additionally, the National Center for Patient Safety Product Recall Office will solicit and share best practices as a part of the Frequently Asked Questions (FAQs) addressing the new directive. These FAQs will be available on the National Center for Patient Safety Product Recall Office Web page and will include recall plans and procedures. In the short-term, the National Center for Patient Safety Product Recall Office will coordinate with each Network Recall Coordinator to ensure that each facility has a documented program for responding to recalls that meet VHA requirements. All Network Recall Coordinators must review and approve each facility's plan for responding to recalls and report full compliance to the Product Recall Office by June 30, 2008.

Recommendation 3. Perform all required elements as directed in product recalls, patient safety alerts, and/or patient safety advisories.

Concur In Process **Target Completion Date:** Ongoing

It is critical that VHA facilities complete all the required actions directed in product recalls, patient safety alerts, and patient safety advisories. VHA's standing policy on medical device and product recalls, VHA Directive 2004-047, *Recall of Defective Medical Devices and Medical Products*, requires that all Recall Notices have a title, problem statement, background, action, completion date, point of contact, and, if appropriate, feedback or documentation requirements. While VHA is currently revising this directive, the soon-to-be-issued new directive will also discuss the importance of adhering to all of the actions and feedback requirements for product recalls, patient safety alerts, and patient safety advisories. The new directive will assign responsibility to the Network Recall Coordinator for monitoring recall logistics activities within the Network and following up with facilities (e.g. Facility Recall Coordinator or back-up Facility Recall Coordinator) that have not responded by the due dates identified by the VHA Alert and Recall Management System web site (formerly known as the VISN 22 "VA Desert Pacific Healthcare Network Hazardous Recalls/Alerts").

Appendix B

List of Medical Centers

Asheville VA Medical Center, Asheville, NC
Atlanta VA Medical Center, Decatur, GA
Baltimore VAMC – VA Maryland Health Care System, Baltimore, MD
Bay Pines VA Healthcare System, Bay Pines, FL
Charlie Norwood VA Medical Center, Augusta, GA
Cincinnati VA Medical Center, Cincinnati, OH
Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI
Durham VA Medical Center, Durham, NC
Hunter Holmes McGuire VA Medical Center, Richmond, VA
James A. Haley Veterans' Hospital, Tampa, FL
John D. Dingell VA Medical Center, Detroit, MI
Oklahoma City VA Medical Center, Oklahoma City, OK
Portland VA Medical Center, Portland, OR
Providence VA Medical Center, Providence, RI
Richard L. Roudebush VA Medical Center (Indianapolis VA Medical Center), Indianapolis, IN
VA Ann Arbor Healthcare System, Ann Arbor, MI
VA Boston Healthcare System, West Roxbury Campus, MA
VA Long Beach Healthcare System, Long Beach, CA
VA North Texas Health Care System: Dallas VA Medical Center, Dallas, TX
VA San Diego Healthcare System, San Diego, CA
VA Western New York Healthcare System at Buffalo, Buffalo, NY
Washington, DC VA Medical Center, Washington, DC
William S. Middleton Memorial Veterans Hospital, Madison, WI

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Virginia L. Solana, Director Kansas City Regional Office of Healthcare Inspections (816) 997-6971
Acknowledgments	Jim Seitz, Project Manager Annette Acosta Gail Bozzelli Marisa Casado Bertie Clark Dorothy Duncan Donna Giroux Jennifer Kubiak Karen Moore Katherine Owens Reba Ransom Wilma Reyes Randy Snow Marilyn Stones John Tryboski Marilyn Walls Julie Watrous Sue Zarter

Appendix D

Report Distribution

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