Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-01351-296

Healthcare Inspection

Alleged Sterile Processing Service Deficiencies
VA Puget Sound Health Care System
Seattle, Washington

September 3, 2013

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to assess the validity of allegations regarding clinical and administrative operations within the Sterile Processing Service (SPS) at VA Puget Sound Health Care System (the system) Seattle, WA. The complainant alleged that improper sterilization of equipment placed patients at harm and that this risk was not disclosed. It was also alleged that SPS reprocessed single-use devices (SUDs) without approval to do so, failed to keep standard operating procedures (SOPs) current, did not provide staff training, and did not maintain accurate staff competencies.

We substantiated that equipment was used in a sterilizer for which its use is not approved by the Food and Drug Administration; however, we did not substantiate that this caused the instruments involved to be unsterile or that patients were placed at risk. We did not substantiate that SPS and system leadership knowingly covered-up and failed to disclose to physicians and patients processing problems associated with equipment.

We did not substantiate the allegation that the system reprocessed SUDs without approval to do so; however, we did find that the system resterilized SUDs. Reviews conducted by the system and the VHA National Program Office for Sterile Processing found that while resterilization was neither necessary nor approved, all sterilization parameters were met.

We did not substantiate that SPS SOPs are not accurate and current. We reviewed SOPs of select reusable medical equipment items and found them to be current and consistent with Manufacturer Instructions which is essential to avoid improper reprocessing. Upon physical inspection we found that SOPs were located within reprocessing areas and that staff could articulate the location of the SOPs and the process used to communicate updates. We did not substantiate the allegation that SPS has not provided sufficient training. We found that training was provided at daily briefings, weekly training sessions, and through online modules and job mentoring.

We did not substantiate the allegation that SPS staff competency folders might be inaccurate and include falsified documents. However, we did find deficiencies in the manner in which the files were organized. Supervisors and staff lacked an efficient way to verify current competencies.

We recommended that the System Director ensure that SPS has a process in place to identify SUDs and decrease the risk of SUDs being resterilized and that processes be strengthened to ensure that SPS staff competency records are well organized and that managers are able to readily determine the current competence of each employee on each task.

Comments: The Veterans Integrated Service Network and Facility Directors concurred with our recommendation(s) and provided an acceptable action plan. (See Appendixes A and B, pages 10–12 for the Directors' comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations regarding clinical and administrative operations within the Sterile Processing Service (SPS) at VA Puget Sound Health Care System (the system), Seattle, WA. Specifically, the complainant alleged:

- Genesis pans™[1] were used in a sterilizer for which their use is not approved by the FDA, causing instruments to be unsterile.
- Improperly sterilized equipment might have been used in hundreds of urology cases.
- SPS and executive leadership knowingly covered-up and failed to notify physicians and patients of processing problems associated with the Genesis pans.
- SUDs are being reprocessed without an FDA permit ("approval").
- Standard Operating Procedures (SOPs) are not accurate and current in SPS.
- SPS has not provided sufficient training and staff competency folders may be inaccurate and include falsified documents.

Background

The system is part of Veterans Integrated Service Network (VISN) 20 and includes two divisions in the Puget Sound region and seven community-based outpatient clinics in neighboring counties. The system has 474 authorized beds, 283 of which are operational. The Seattle Division is a tertiary care facility serving as a VISN 20 referral center for specialty care needs. Services provided at the Seattle division include inpatient and outpatient medical, surgical, mental health, specialty, long-term care, and research. The American Lake Division provides outpatient medical, mental health and specialty clinics, a domiciliary, blind rehabilitation unit, and community living center. Reusable Medical Equipment (RME) reprocessing is performed at both divisions.

Single-Use Devices

A Single-Use Device (SUD) is a device that is intended for use one time or on a single patient during a single procedure.[2] However, to save costs and reduce medical waste, the Food and Drug Administration (FDA) has approved a process for reprocessing and

[1] Containers holding items as they go through the sterilization process.
[2] U. S. Food and Drug Administration, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121090.htm, accessed on 5/14/13.

reusing SUDs. This guidance document, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, was released by the FDA in 2000.

The FDA defines a reprocessed SUD as an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. Entities that reprocess SUDs must be reviewed by the FDA. In order to be on the FDA list of third-party reprocessors of SUDs, a facility must register with the FDA and adhere to all of the regulatory requirements applicable to the original equipment manufacturer. Once registration is complete, internal policies and procedures must be developed to ensure compliance.

RME

RME refers to devices that are designed for use on multiple patients and made of materials that can withstand repeated reprocessing. These devices must be properly cleaned[3], disinfected[4] and/or sterilized between patients to ensure safe use. If these devices are not adequately reprocessed, they may be contaminated and compromise patient safety. RME reprocessing generally involves three steps: (1) initial decontamination and cleaning at the point of use; (2) thorough cleaning in the reprocessing area; and (3) low-intermediate-level disinfection, high-level disinfection, or sterilization, depending on the intended use of the device, its risk of infection transmission, and the materials from which it is made. Each device has manufacturer instructions (MI) for use which specify the FDA approved process(es) for sterilization.

Sterilization Process and Monitoring

Sterilization is an act or process used to destroy or eliminate all forms of life, especially microorganisms. Ensuring the consistency of sterilization practices for medical equipment requires a comprehensive program that ensures operator competence and proper methods of cleaning and unwrapping instruments, loading the sterilizer, operating the sterilizer, and monitoring the entire system.[5]

Sterilization monitoring is required to assure that medical devices have been adequately sterilized. Three distinct monitors are part of the total system of sterilization monitoring: mechanical, chemical, and biological. Used in conjunction with one another, they create a check and balance for the sterilization process designed to eliminate the potential use of non-sterile instruments. The system is based on the premise that if sterilization fails and the malfunction is not detected by the biological indicator, then a chemical indicator and the functional monitoring built into the sterilizer should detect the malfunction.[6]

[3] Cleaning usually involves water and detergents or a presoak solution to break down and remove foreign material.
[4] Disinfection is any process, chemical or physical, that destroys most pathogens (infectious microorganisms).
[5] CDC, "*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008."*
[6] CDC "*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.*"

Mechanical Monitors

The critical parameters of mechanical monitoring are time, steam, and temperature. Sterilization department staff conducts an assessment of the equipment's temperature record chart which plots cycle time and temperature to ensure that required parameters are met.

Sterilizer printouts are verified at the end of each cycle by the technicians. When proper conditions are not met, the printout will show a cycle failure. Items that were processed during a cycle that resulted in a failure are not considered sterile and should not be used for patient care.

Chemical Monitors

Chemical monitors should be used with each package that is sterilized and can be used to monitor sterilization conditions in the sterilization chamber or from within the load[7]. These indicators are designed to detect problems associated with incorrect packaging, incorrect loading, or sterilization process malfunction. While these indicators establish that a package has been processed through a sterilization cycle, they do not prove that sterilization has been achieved.

Biological Monitors

Biological monitoring is generally recognized as the most effective method of monitoring the sterilization process. Biological indicators function by introducing highly resistant bacterial spores[8] into the sterilization system. If these spores are destroyed, it is assumed that any other contaminants in the load have also been killed, as these organisms have lower resistance than the spores and are present in lower numbers. Biological indicators must be approved by the FDA for use with particular sterilizers.

Used simultaneously, mechanical, chemical, and biological monitoring processes significantly decrease the risk of non-sterile instruments being used.

Disclosure

Disclosure is the act of making information known. VHA outlines procedures to ensure consistent processes among VHA facilities in disclosing to patients, or to patients' personal representatives, the occurrence of adverse events related to the patient's clinical care.[9] VHA recognizes three types of disclosure: clinical, institutional, and large-scale. Appropriate disclosure may include any or all types.

An adverse event[10] is an untoward incident, diagnostic or therapeutic misadventure, iatrogenic injury,[11] or other occurrence of potential harm directly associated with care or

[7] The tray of medical equipment to be sterilized.
[8] Spores are reproductive cells produced by fungi and bacteria.
[9] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients* (October 2, 2012).
[10] VHA Handbook 1004.08.
[11] Iatrogenic injuries are those induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedure.

services provided within the jurisdiction of VHA. VHA facilities are required to have processes in place to determine whether an occurrence meets the definition of an adverse event and which incidents need to be considered for a root cause analysis.

Clinical Disclosure

> A clinical disclosure is a process by which the patient's clinician informs the patient or the patient's personal representative as part of routine clinical care that a harmful or potentially harmful adverse event has occurred during the patient's care.[12]

Institutional Disclosure

> An institutional disclosure is a formal process by which facility leaders together with clinicians and others, when appropriate, inform the patient or patient's representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury. The patient is also provided specific information about patients' rights and recourses.[13]

Large-scale Disclosure

> A large-scale disclosure is sometimes referred to as notification. It is a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue. This process usually includes public notification and direct communication to key stakeholders.[14]

Scope and Methodology

We reviewed VHA directives, handbooks, memorandums, and professional manuals. We also reviewed SOPs and MIs for selected RMEs, VISN briefings, Executive-level committee minutes, RME Oversight Committee minutes, Infection Control Committee minutes, IC reviews of SUD and RME related incidents, Clinical Product Review Committee minutes. Internal and external reviews of the SPS program, SPS staff training and competency records, and correspondence from VHA National Program Office for Sterile Processing.

We interviewed SPS managers and staff, Surgery Service managers, the Nurse Executive, Infectious Disease and IC staff, quality management staff, the RME coordinator, and logistics and equipment managers. We conducted a site visit at the Seattle Division April 24-25, 2013, and toured the SPS and Gastroenterology Service areas.

[12] VHA Handbook 1004.08.
[13] VHA Handbook 1004.08.
[14] VHA Handbook 1004.08.

Inspection Results

Issue 1: Identification and Disclosure of Potentially Adverse Events

Genesis™ Pan Usage

We substantiated the allegation that Genesis™ pans were used in a sterilizer for which their use is not approved by the FDA. However, we did not substantiate that this caused the instruments to be unsterile.

System leadership was aware of this allegation and the use of the Genesis™ pans in a non-approved sterilizer prior to our review. Once identified, the practice was discontinued immediately and SPS staff was educated regarding the incorrect pairing of equipment. In addition, the system conducted a risk assessment to determine the level of harm, or potential for harm, to patients.

We found that the facility developed a new process for purchasing medical devices and equipment. A major component of the issue with the Genesis™ pans was the reliance of SPS management on the vendor rather than internally validating the MIs. The newly implemented process for equipment purchasing ensures alignment between the equipment to be purchased and the ability to use it. The CPRC is responsible for vetting the equipment prior to purchase. The CPRC routes requests through SPS, the RME Oversight Committee, and other appropriate groups and individuals to ensure that it can be properly cleaned with current equipment, that there is sufficient space, and other related issues. The CPRC began meeting and facilitating this process in April 2012.

Usage of Improperly Sterilized Equipment in Urology Cases

We did not substantiate that improperly sterilized equipment might have been used in hundreds of urology cases.

We found that the system's SPS consistently uses all three monitors available – mechanical, chemical (internal and external), and biological. In the case of the Genesis™ pans, the system was able to demonstrate that the equipment from any failed sterilization cycles was immediately pulled and not used in surgery.

SPS and Leadership Failure to Disclose

We did not substantiate that SPS and facility leadership knowingly covered-up and failed to disclose to physicians and patients processing problems associated with the Genesis™ pans.

VHA requires that for the use and reprocessing of RME, the system Director ensure there is an organizational structure that includes an interdisciplinary approach to monitoring the compliance with the established processes and documents outcomes

related to the defined processes.[15] This approach should include participation by the Chief of SPS, a representative of Quality and Risk Management, a Nursing Service representative, an IC Professional, a Patient Safety Manager, and a representative of Bio-Medical Engineering.

VHA provides clear guidelines as to the RME-related reports that are required to go to the Executive Committee of the Medical Staff.[16] Those reports include but are not limited to: validation of initial and on-going competency of staff, results of compliance with established SOPs, requirements of infection prevention and control monitoring, and risk management related activities.

During our review we found that the system established appropriate RME oversight through multidisciplinary representation on their RME Oversight Committee. While this Committee relies on input from a variety of sources, it also provides routine reports on various RME topics and issues to the Clinical Executive Board[17], IC Committee, and other leadership groups as needed. We also identified discussions at many of these committees related to several RME-related inspections, site visits, and internal reviews/reports.

Utilizing the structure that was in place, the system appropriately managed the Genesis™ pan incident once it was identified. Upon identification, the system pulled together appropriate subject matter experts in order to conduct a risk assessment. A thorough review was conducted, system issues identified, and action plans developed. Through the risk analysis process, it was determined that the occurrence did not rise to the level of an adverse event since the SPS staff had utilized the appropriate monitoring techniques and no equipment from any failed cycles had been used in surgery. It was determined that the events did not present any harm or potential harm to patients. Therefore, no disclosure was needed. System leadership was involved throughout the process and consulted with the VISN in making this determination.

Issue 2: Reprocessing of SUDs

We did not substantiate the allegation that the system reprocessed SUDs without a FDA permit ("approval") to do so; however, we did find that the system resterilized SUDs.

We found that the following three types of SUDs had been resterilized rather than reprocessed because the items in question were sterile and had not been used prior to resterilization. Once used, these items were disposed of. These SUDs were:

- Medtronic Clearview Blower/Mister tubing #22150
- Conmed Sternal Saw Blade #5059-532
- Medicon #10 Blade BS2982

[15] VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (February 9, 2009).
[16] VHA Directive 2009-004.
[17] The CEB is the Executive Committee of the Medical Staff at VAPSHCS.

The system determined that while resterilization was neither necessary nor approved, all sterilization parameters were met and therefore, the infection risk was similar to any steam sterilized surgical instrument. Additionally, the VHA NPOSP conducted a review which had similar findings.

Issue 3: Management of SOPs

We did not substantiate the allegation that SPS SOPs are not accurate and current.

An SOP is a written document containing the specific steps required to complete a task. SOPs are important references for staff who reprocess RME. VHA requires that SOPs be current and consistent with MIs.[18] It is essential that SOPs mirror MIs in order to avoid improper reprocessing which could result in transmission of pathogens to patients and affect the functionality of the RME item. We reviewed SOPs of select RME items and found they were current and consistent with MIs. While this had been an area of weakness, at the time of our review, the system had a process in place, including updates provided by the VHA NPOSP Update Team, to ensure that modifications to MIs were received and communicated to staff.

VHA requires that SOPs be located within reprocessing areas for easy reference by employees.[19] We conducted physical inspections of the SPS and Gastroenterology Service procedure areas and found current SOPs located within the reprocessing areas. Staff were able to articulate the locations of SOPs and the process used to keep them current.

Issue 4: Staff Training and Competencies

VHA requires that staff involved in the use and reprocessing of RME have documented training on all aspects of equipment use leading to initial competency and validation of all competencies on an annual basis.[20] SPS is to have a mechanism in place to ensure that supervisors and staff know the status of their competencies. Staff should not be allowed to use equipment for which their competency has not yet been established or has expired.

We did not substantiate the allegation that SPS supervisors had not provided sufficient training. We found that training was provided at daily briefings and weekly training sessions as well as through the use of online modules and on-the-job mentoring. Staff reported being well trained.

We did not substantiate the allegation that SPS staff competency folders may be inaccurate and include falsified documents. However, we found deficiencies in the manner in which the files were organized. During our review of staff competency records, we found documentation of current staff competencies. While the information

[18] VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements* (June 26, 2009).
[19] VHA Directive 2009-031.
[20] VHA Directive 2009-004.

for each record was accurate, we found the approach used to organize staff files was ineffective and chaotic. Supervisors and staff lacked an efficient way to verify current competencies, putting staff at risk of using equipment for which their documented competence had expired.

Conclusions

We concluded that the system generally complied with clinical and administrative processes within SPS at the system. We found areas needing improvement in the management of SUDs and the maintenance and tracking of SPS staff competency files.

Recommendations

1. We recommended that the System Director ensure that Sterile Processing Service has a process in place to identify single-use devices and mitigate the risk of single-use devices being resterilized.

2. We recommended that the System Director ensure that processes be strengthened to ensure that Sterile Processing Service staff competency records are well organized and that managers are able to readily determine the current competence of each person on each task.

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 23, 2013

From: Director, Northwest Network (10N20)

Subject: **Healthcare Inspection – Alleged Sterile Processing Services Deficiencies, Puget Sound VA Health Care System, Seattle, WA**

To: Director, Seattle Office of Healthcare Inspections (54SE)

1. Thank you for the opportunity to provide a status report on follow-up to the findings from the Alleged Sterile Processing Services Deficiencies of the VA Puget Sound Health Care System, Seattle, Washington.

2. Attached please find the facility concurrences and responses to each of the findings from the review.

3. If you have additional questions or need further information, please contact Susan Gilbert, Survey Coordinator, VISN 20 at (360) 567- 4678.

(original signed by:)

Lawrence H. Carroll

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 19, 2013

From: Health Care System Director, VA Puget Sound Health Care System (663/00)

Subject: **Healthcare Inspection – Alleged Sterile Processing Services Deficiencies, VA Puget Sound Health Care System, Seattle, WA**

To: Director, Northwest Network (10N20)

1. Thank you for the opportunity to respond to the recommendations from OIG Hotline visit at VA Puget Sound Health Care System, Seattle, Washington.

2. Attached please find the facility responses to each of the findings from the review.

3. If you have additional questions or need further information, please contact Jane Penny, Director, Quality Improvement at (206) 764-5522 or via email at Jane.Penny@va.gov.

(original signed by:)

Michael J. Murphy, FACHE

Attachment:

1. Response – Healthcare Inspection – Alleged Sterile Processing Services Deficiencies, VA Puget Sound Health Care System, Seattle, WA

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the System Director ensure that Sterile Processing Service has a process in place to identify single-use devices and mitigate the risk of single-use devices being resterilized.

Concur

Target date for completion: September 1, 2013

Facility response: Based on the preliminary discussion with the OIG team, facility leadership tasked Sterile Processing Service (SPS) to conduct an inventory of instrument trays and peel packed instrumentation to establish a baseline of single use devices. Leadership also tasked SPS with implementation of training for the identification and proper deployment of single use devices.

The single use device inventory, staff training, and revised standard operating procedures will be completed by September 1, 2013.

Recommendation 2. We recommended that the System Director ensure that processes be strengthened to ensure that Sterile Processing Service staff competency records are well organized and that managers are able to readily determine the current competence of each person on each task.

Concur

Target date for completion: September 1, 2013

Facility response: Based on the preliminary discussion with the OIG team, facility leadership tasked Sterile Processing Service to develop a competency-tracking tool designed to identify employee specific requirements, completed July 18, 2013.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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