



**Department of Veterans Affairs
Office of Inspector General**

Healthcare Inspection

**Alleged Endoscope Reprocessing Issues
St. Louis VA Medical Center
St. Louis, Missouri**

To Report Suspected Wrongdoing in VA Programs and Operations:

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Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding ongoing issues in the Supply, Processing, and Distribution (SPD) department related to endoscope reprocessing and communication at the St. Louis VA Medical Center, St. Louis, Missouri. A complainant alleged that endoscope reprocessing issues have been ongoing. It was further alleged that there were breakdowns in communication with regard to adverse events and outcomes.

We substantiated the allegation that endoscope reprocessing issues have been ongoing. We reviewed documentation related to three contaminated gastrointestinal (GI) endoscopes, which were identified prior to patient use. We also reviewed documents notifying managers that damage and repairs to endoscopes had increased. We requested the 2009 repair log and associated costs from SPD and found that a majority of the scopes that were damaged or needed repair belonged to the GI service.

We substantiated the allegation of breakdowns in communication of adverse events and outcomes. We found minimal documentation as well as communication failures for two of the three adverse event reports (AER) reviewed.

In addition, we conducted an unannounced inspection of the SPD area. We identified several items related to reusable medical equipment reprocessing and staff safety that needed improvement as required by VHA policies.

We recommended that the AER reporting process is clearly defined, timely, and well-documented and that implemented action plans are monitored for compliance to eliminate ongoing endoscope damage and reprocessing issues. We also recommended that SPD meets VHA policy and is monitored for compliance.

The VISN and Medical Center Directors agreed with the findings and recommendations. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.



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

TO: Director, VA Heartland Network (10N15)

SUBJECT: Healthcare Inspection – Alleged Endoscope Reprocessing Issues,
St. Louis VA Medical Center, St. Louis, Missouri

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding ongoing issues in the Supply, Processing, and Distribution¹ (SPD) department related to endoscope reprocessing and communication at the St. Louis VA Medical Center (the medical center), St. Louis, Missouri.

Background

The medical center is a two-division, tertiary care facility in Veterans Integrated Service Network (VISN) 15. The John Cochran division is located in downtown St. Louis. It has 136 acute care beds and provides acute medical and surgical programs with a wide range of specialty care. The Jefferson Barracks division is located in south St. Louis County. This division provides primary care and has 102 acute beds (70 psychiatry and 32 spinal cord injury), a 50 bed domiciliary, and a 71 bed nursing home.

Over the past year, the medical center has experienced turnover in several key staff positions. There have been four changes in the Acting Medical Center Director (AMCD) position and two changes in the Associate Director for Patient/Nursing Care Service (AD/PNCS) position. The current AMCD and AD/PNCS have been in place since October 2009. Due to ongoing SPD concerns, the AMCD closed SPD during the weeks of December 3, 2009 and January 15, 2010. During these closures, SPD staff was retrained and all endoscopes were reprocessed.

¹ The SPD department is a section of the medical center that is dedicated to the receiving, storage, and distribution of medical supplies and the decontamination and sterilization of reusable medical supplies and equipment.

Additionally, there was one change in SPD leadership stemming from an approval of the Executive Review Board in July 2009 that the Chief position was to be filled by an operating room nurse. The medical center hired an SPD Chief in November; however, at the time of the onsite review the SPD leadership was in flux.

SPD provides centralized supply support of the medical center's patient care programs, while assuring appropriate aseptic conditions, economy of operation, and consistency in processing, storing, and distribution, all under strictly controlled conditions. The major goal of SPD is to allow the professional medical staff every opportunity to concentrate on direct patient care.² While SPD operations vary from facility to facility, SPD is centralized in this medical center.

Contaminated reusable medical equipment (RME), including endoscopes, must be reprocessed after each use to remove potential sources of infection. Whether manual or automated, reprocessing requires pre-cleaning, disinfecting, rinsing, flushing, and storage. SPD is responsible for reprocessing endoscopes at the medical center.

A complainant alleged that endoscope reprocessing issues have been ongoing. It was further alleged that there were breakdowns in communication with regard to adverse events and outcomes.

Scope and Methodology

We interviewed the complainant by telephone on February 11, 2010. We conducted a site visit at the medical center February 16–18 and interviewed medical center leadership, quality management (QM) managers, clinical service chiefs, physicians, nurses, SPD reprocessing technicians, and biomedical engineering staff. We reviewed QM documents, adverse event reports (AER), local and Veteran's Health Administration (VHA) policies, and other pertinent information.

We conducted the inspection in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Issue 1: Endoscope Reprocessing

We substantiated the allegation that endoscope reprocessing issues have been ongoing.

Contaminated Endoscopes

We reviewed documentation related to three events involving contaminated endoscopes that Gastrointestinal Endoscopy (GI) staff identified through quality control checks prior

² VHA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, August 16, 2002.

to patient use. The first event occurred in late 2008. The medical center was unable to produce additional information or documentation of an investigation or outcome related to this event. The second event was reported on September 28, 2009. We received conflicting accounts from managers about the outcome of this event's investigation; however, one manager determined SPD was not using the correct connectors. The AMCD closed SPD December 3–7 to retrain staff and reprocess endoscopes. The third event was reported on December 23.

On January 8, 2010, the AMCD convened an urgent meeting to discuss ongoing concerns related to SPD and GI. After this meeting, the AMCD immediately issued memos to detail a QM nurse to SPD and to assemble a team to conduct Health Failure Modes and Effects Analysis in the SPD service. SPD was again closed January 15–17 for staff retraining, endoscope reprocessing, and will be monitored for quality assurance. Four employees were added to GI and SPD. An additional meeting was held with the Chief Engineer and Associate Director to discuss the new space in GI to reprocess endoscopes.

Damaged Endoscopes

We reviewed documents notifying managers that damage and repairs to endoscopes had increased. Staff interviews and written documentation indicated that endoscopes were being improperly placed in the reprocessor, which resulted in pinching and/or crushing of the endoscopes.

We interviewed the Chief Biomedical Engineer (CBE) and were told that some damaged endoscopes are repaired in-house and those that are outside the scope of the biomedical department are sent to a contracted repair vendor. We requested the 2009 repair log and associated costs from SPD and found that a majority of the scopes that were damaged or needed repair belonged to the GI service (see Table 1 on the next page). The CBE was unaware that there were increasing repair costs and a high incidence of damage to endoscopes. After reviewing repair data, the CBE told us that the RME committee would now review endoscope repair data during all future monthly meetings.

Table 1. GI Endoscope Monthly Repair Costs.

| Month of 2009 | # of Work Orders | Total Cost |
|----------------------|-------------------------|---------------------|
| JAN | 3 | \$ 1,426.80 |
| FEB | 3 | \$ 1,415.96 |
| MAR | 7 | \$ 4,796.66 |
| APR | 4 | \$ 4,498.28 |
| MAY | 6 | \$ 3,483.86 |
| JUN | 12 | \$ 12,163.10 |
| JUL | 10 | \$ 8,803.88 |
| AUG | 12 | \$ 9,412.49 |
| SEP | 6 | \$ 2,600.26 |
| OCT | 8 | \$ 5,957.82 |
| NOV | 25 | \$ 13,685.36 |
| DEC | 7 | \$ 11,628.14 |
| Grand Total | 103 | \$ 79,872.61 |

Issue 2: Communication of Adverse Events and Outcomes

We substantiated the allegation of breakdowns in communication of adverse events and outcomes.

For two of the three AERs reviewed, we found minimal documentation as well as communication failures. For example, on September 28, 2009, a contaminated scope AER was filed. We interviewed the investigating staff and received conflicting responses for the root cause of the adverse event. Staff interviews revealed that they did not clearly understand the AER reporting process. They also stated that infection control was not always involved with contaminated scope investigations. Staff also told us that they noted improvements after the recent leadership changes and implemented SPD action plans.

In November 2009, the medical center leadership established a RME committee to address multiple compliance issues and VHA policy requirements. The committee is co-chaired by the Chief of Infectious Disease and the AD/PNCS. Members of this committee include representatives from all services where RME are used as well as QM, SPD, and the patient safety manager.

Issue 3: SPD Issues

We conducted an unannounced inspection of the SPD area. We identified items that needed improvement as required by VHA policies.^{3,4}

Reprocessing

SPD does not have defined clean and dirty areas. Staff told us that internal and external engineers are currently working on plans to redesign the physical layout. Standard operating procedures and manufacturer's instructions were not in the area where reprocessing occurs and not separated in plastic sleeves. The humidity reading was 20 percent (required range is 35–75 percent). Staff told us that a work order had been submitted. Two adjacent wall thermometers displayed two different temperatures, one of which exceeded required parameters. Rags and disposable gloves were strewn about in the processing and decontamination areas. Cidex filters require monthly changing; however, the last documented filter change was in July 2009. In addition, two bottles of chemical test strips, used to verify the efficacy of Cidex OPA solution, were open and exposed to air and without written expiration dates. Also, a dry endoscope was connected to and sitting in an unattended open reprocessor. The SPD Chief, SPD Supervisor, and reprocessing technician were unsure of its status in the reprocessing cycle.

Staff Safety

A Material Safety Data Sheet book, which tells staff how to treat accidental chemical exposure, was not accessible to staff in areas where employees handle hazardous chemicals. A written emergency action plan, which outlines procedures to follow in case of an ethylene oxide (EtO) leak or spill, was not posted adjacent to the EtO sterilizer. A reprocessing technician was not wearing the appropriate personal protective equipment as required in the decontamination area. Also, a fire exit door and emergency pathways in the supply room were blocked.

Conclusions

Although we substantiated ongoing issues with reprocessing GI endoscopes and communication, we determined that the current AMCD took significant actions including:

- Initiating an RME committee.
- Closing SPD twice to assure staff competence and to reprocess endoscopes.

³ VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, August 16, 2002.

⁴ VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009.

- Detailing an operating room nurse as Acting Chief, who is familiar with reprocessing requirements, to monitor SPD.
- Initiating an Executive Officer Action Line, a phone number staff may call anytime to alert executive staff of any concern.

In December 2009, the AMCD revised the governance structure to address decision making and communication regarding quality, safety and operations. At that time, the Patient Safety Coordinator was added as a daily reporting member to the daily Morning Briefing. Additionally, the AMCD meets weekly with the facility QM and Patient Safety Coordinator to discuss quality and safety issues in general.

The VISN and AMCD have approved and funded a plan to renovate SPD which will begin about September 2010.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that implemented action plans are monitored for compliance to eliminate ongoing endoscope damage and reprocessing issues.

Recommendation 2. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that the AER reporting process is clearly defined, timely, and well-documented.

Recommendation 3. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that SPD meets VHA policy and is monitored for compliance.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations (see Appendixes A and B, pages 7–11, for the Director’s comments). The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 1, 2010
From: Director, VA Heartland Network (10N15)
Subject: **Healthcare Inspection – Alleged Endoscope Reprocessing Issues,
St. Louis VA Medical Center, St. Louis, Missouri**
To: Director, Denver Office of Healthcare Inspections (54DV)
Thru: Director, Management Review Service (10B5)

I have reviewed and concur with the St. Louis Acting Medical Center Director's response to the Healthcare Inspector report as it relates to the Alleged Endoscope Reprocessing Issues at the St. Louis VA Medical Center, St. Louis.

Appropriate actions have been initiated and/or completed as detailed in the attached response.



James Floyd, FACHE
Network Director, VISN 15

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 1, 2010

From: Acting Director, St. Louis VA Medical Center (657/00)

Subject: **Healthcare Inspection – Alleged Endoscope Reprocessing Issues,
St. Louis VA Medical Center, St. Louis, Missouri**

To: Director, VA Heartland Network (10N15)

I have reviewed and concur with the findings and recommendations in the Healthcare Inspector report as it relates to the Alleged Endoscope Reprocessing Issues at the St. Louis VA Medical Center, St. Louis.

I am providing the following information to further clarify portions of the report. First, the three events were identified through quality control checks. In each of these events, the systems in place detected the process failures prior to patient use as they are intended to do. No patients were affected by these events. Second, the damage to the scopes was found prior to use. SPD has experienced increased workload due to increases in the volume and complexity of surgical operation and procedures and a change in screening procedures. The St. Louis Medical Center began utilizing screening colonoscopies as part of its colorectal cancer program in FY2008. The number of procedures grew from 200 per month to 450 per month by the end of FY2009. The changing technology and instrumentation has added more complexity to the SPD requirements. This increase complexity and volume has stressed the infrastructure and staffing. Production pressure, interdepartmental tension, and multi-tasking of staff has contributed to slips in the process. To address this complex problem the facility is investing over \$3 million to remodel and update the environment, equipment, and mechanical systems that support Processing and Decontamination and adjusting staffing to meet increased workload.

No patient exposure occurred as a result of these three events occurring over a 15-month period. The operating room nurse was detailed to be the

Acting Chief prior to the Chief's last day to provide leadership in the interim period until a new chief was in place and oriented to the position. In each of these events, the systems in place detected the process failures prior to patient use as they are intended to do. No patients were affected by these events.

Appropriate actions have been initiated and/or completed as detailed in the attached response.



Rima Ann O. Nelson, RN, MPH/HSA
Acting Medical Center Director

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that implemented action plans are monitored for compliance to eliminate ongoing endoscope damage and reprocessing issues.

Concur **Target Date of Completion: March 22, 2010**

Facility's Response: The Acting Medical Center Director will ensure that the current and any future actions plan are implemented and monitored for compliance. This will be tracked and monitored by the Executive Board which is chaired by the Acting Medical Center Director.

Status: Completed on March 22, 2010. Topic placed as standing agenda item of the Executive Board every two weeks until action plans are completed.

Recommendation 2. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that the AER reporting process is clearly defined, timely, and well-documented.

Concur **Target Date of Completion: June 1, 2010**

Facility's Response: The Patient Safety Manager is to review and revise the Adverse Event Reporting system to meet these requirements and provide medical center wide education on the AER reporting process.

Status: The Patient Safety Manager is working closely with the Chief Information Officer, Privacy Officer and VISN Information Officer to complete implementation of an electronic reporting system.

Recommendation 3. We recommended that the VISN Director ensure that the Acting Medical Center Director requires that SPD meets VHA policy and is monitored for compliance.

Concur

Target Date of Completion: April 1, 2010

Facility's Response: The Acting Medical Center Director will ensure that SPD meet VHA policy and is monitoring for compliance with the following actions:

- Complete hourly quality check by a registered nurse using a tool with required compliance elements, such as temperature, use of correct SOP for cleaning, quality control checks, and presence of MSDS sheets. Results from the check are summarized and reported to the RME Committee. Implemented February 23, 2010.
- Detail Quality Improvement Specialist to Processing and Decontamination section. Completed January 11, 2010.
- Complete SPD Self Assessment Guide will be done quarterly and reported to the RME Committee. Implemented March 1, 2010.
- Recruited permanent Chief with interviews completed March 16, 2010. Selection was made March 18, 2010. Completion date pending completion of hiring process.
- Posted in SPD the contact number (blackberry & pagers) for the Quadrad members. The SPD was instructed to call the Quadrad at anytime for any concerns or issues related to providing quality and safe care to patients through the processing and decontamination of scopes, instruments or RME. Completed March 1, 2010.
- Report compliance with policy requirement by AD/PNS will be provided to the Executive Board every two weeks. Implemented March 22, 2010.
- Completed Healthcare Failure Modes and Effects Analysis (HFMEA) on endoscope reprocessing on March 10, 2010.
- Implement HFMEA action plan that includes additional quality control testing of endoscope internal channels and external surfaces at the end of the reprocessing. Product will be on station and in-servicing complete for implementation on April 1, 2010.

OIG Contact and Staff Acknowledgments

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| OIG Contact | Virginia L. Solana, Director Denver Regional Office of Healthcare Inspections (303) 270-6500 |
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|-----------------|---|
| Acknowledgments | Clarissa B. Reynolds, (Team Leader) Laura L. Dulcie Stephanie B. Hensel Wilma I. Reyes |
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