



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection Patient Safety Issues VA Caribbean Healthcare System San Juan, Puerto Rico

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Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections received allegations regarding quality of care and patient safety related to the reprocessing of reusable medical equipment (RME) at the VA Caribbean Healthcare System (the system) in San Juan, Puerto Rico.

A complainant alleged that transvaginal ultrasound transducer equipment was not properly disinfected at the Mayaguez outpatient clinic (OPC), and that leak tests were not performed on endoscopes in three other areas in the system. The complainant also alleged that the system inaccurately reported compliance with RME reprocessing procedures and training requirements and ignored evidence and warnings of unsafe practices in reprocessing RME since February 2009.

We substantiated the allegation that endovaginal transducers at the Mayaguez OPC were not submitted to high-level disinfection as required after each patient procedure for approximately 2 years. We also learned the same condition existed at the hospital in San Juan.

We substantiated the allegation that leak testing was not performed on colonoscopes in the Operating Room for at least 9 months or on laryngoscopes in Radiotherapy and at the Ponce OPC for 9 months and 3 years respectively. We also learned that pre-cleaning was improperly performed on the laryngoscopes in Radiotherapy and one of the laryngoscopes had a leak while it was in service during this time.

We substantiated the allegation that the system inaccurately certified compliance with RME reprocessing procedures and training on three occasions. We also substantiated the allegation that senior system leadership and responsible managers were aware of these issues but took no action to assess the risk to patients.

As a result of our review, issue briefs (IB) on each area were discussed on pre-CRAAB (Clinical Risk Assessment Advisory Board) conference calls. Based on information provided by the system, the risk to patients was determined to be negligible. As information about inadequate pre-cleaning of laryngoscopes in Radiotherapy was not included in the IB, this issue should receive further review. An Administrative Investigation Board (AIB) was completed after our visit to address management responsiveness.

We recommended that an appropriate risk assessment, based upon findings of improper laryngoscope cleaning in Radiotherapy, be performed and appropriate actions taken. We also recommended that the VISN Director follow up on all recommendations from the AIB and take appropriate administrative action.



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

TO: Director, VA Sunshine Healthcare Network (10N8)

SUBJECT: Healthcare Inspection – Patient Safety Issues, VA Caribbean Healthcare System, San Juan, Puerto Rico

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding quality of care and patient safety related to the reprocessing of reusable medical equipment (RME) at the VA Caribbean Healthcare System (the system) in San Juan, Puerto Rico.

Background

The system includes a tertiary care facility, the San Juan VA Medical Center (hereafter referred to as the hospital) in San Juan, with Community Based Outpatient Clinics in Arecibo, Guayama, and the U.S. Virgin Islands. There are satellite outpatient clinics (OPC) located in Mayaguez and Ponce. The system is part of Veterans Integrated Service Network (VISN) 8.

RME reprocessing is an area of high visibility within the VA and has received considerable media attention. The National Center for Patient Safety (NCPS) released Patient Safety Alert AL09-07, *Improper Set-Up and Reprocessing of Flexible Endoscope Tubing and Accessories*, on December 22, 2008. This alert required facilities to report issues they identified with incorrect set-up or failure to adequately clean or reprocess flexible endoscopic equipment in an Issue Brief (IB) through their network office to the VA Central Office. According to VHA policy,¹ “clinicians and organizational leaders are to work together to ensure that appropriate disclosure to patients or their personal representatives is a routine part of the response to a harmful or potentially harmful adverse event.” The Deputy Under Secretary for Health for Operations and Management (DUSHOM) is responsible for reviewing adverse events that may require large scale disclosure. This process is accomplished through the Clinical Risk Assessment Advisory Board (CRAAB).

¹ VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

The DUSHOM sent a memorandum to all facility directors on January 28, 2009, outlining his expectations that all sites conduct a review of their set-up and reprocessing procedures. VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment in VHA Facilities*, which established a detailed set of procedures for RME reprocessing within VHA facilities, was issued on February 9. An Endoscope Step-up Week was held on March 9–13. VISN 8 issued an action item on April 2 that instructed all facilities to review directive 2009-004, and “provide the network with any questions or concerns which may prevent compliance.” An “Accountability” memorandum sent by the acting DUSHOM on June 24 emphasized the need for facility leadership to be “fully cognizant of VHA Directive 2009-004” and to address non-compliance with disciplinary action when indicated.

The system has a task force (hereafter referred to as the system task force) that monitors the reprocessing of endoscopic equipment and the operation of sterilization equipment. System task force members conducted unannounced observations and inspections in areas where reprocessing occurred. Their findings resulted in corrective action plans to bring the system into compliance with reprocessing procedures, competencies, and standard operating procedures (SOP). The system task force became the RME Committee in June 2009.

The OIG received allegations from a complainant, who provided more than 137 pieces of evidence to support allegations that:

- Transvaginal ultrasound transducer equipment was not properly disinfected at the Mayaguez OPC.
- Leak tests were not performed on endoscopes in the Radiotherapy Department and in the Operating Room (OR) at the hospital, or at the Ponce OPC.
- The system inaccurately reported compliance with RME procedures and reprocessing and training requirements.
- Since February 2009, system managers ignored evidence and warnings of unsafe practices in reprocessing RME.

Scope and Methodology

We conducted a site visit at the hospital August 25–28, 2009. Prior to our visit, we interviewed the complainant via telephone. During our site visit, we interviewed senior managers including the System Director, Associate Director (AD), Chief of Surgery, and Chief of Staff (COS). We also interviewed the Staff Assistant to the Associate Director, the Patient Safety Manager (PSM), and the Quality Manager (QM) who chaired the system task force. We also interviewed members of the system task force inspection team, including the Acting Chief of Infection Control, the Chief of Supply Processing and Distribution (SPD), a health systems specialist (HSS) in the patient safety office, and a HSS in the quality management office. We interviewed a biomedical engineer and

other members of the system task force and RME Committee. We interviewed several staff responsible for reprocessing RME, including the urology clinic supervisor, a registered nurse (RN) in the Radiotherapy Department ear, nose and throat (ENT) area, and an ENT technician. While on site, we reviewed RME Committee minutes, e-mail messages, Veterans Health Administration (VHA) certifications, policies, SOPs, and manufacturer's instructions related to RME. We reviewed SPD inspection reports and VHA National SPD Quality Management Observational Assessment Tools and related action plans.

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

INSPECTION RESULTS

Issue 1: RME Disinfection

We substantiated the allegation that endovaginal transducers at the Mayaguez OPC were not subjected to high-level disinfection (HLD)² as required after each patient procedure.

A member of the system task force inspection team and a biomedical engineer visited the Mayaguez OPC on July 16, 2009, to inventory RME. They discovered that a technician performing endovaginal ultrasounds was not subjecting the endovaginal transducers to HLD. The technician who performed the endovaginal ultrasounds reported that she did not perform HLD on the transducers, but that she sprayed them with a disinfectant spray. The technician also reported that she covered the transducers with two latex sheaths before use. The manufacturer's instructions, the SOPs, and the device-specific competency for this procedure clearly defined the requirement for HLD, including immersion in the disinfecting solution Cidex OPA. A system task force inspector told us and a clinic log confirmed that Cidex OPA solution had not been used in the clinic since 2007.

The members of the system task force inspection team reported the issue immediately for appropriate follow-up. We received a copy of an e-mail reporting this condition to senior managers. The Medical Director of the Mayaguez OPC cancelled endovaginal procedures immediately, and required that staff be re-trained by September 2009.

When system managers were informed of the issue in Mayaguez, they determined that the same condition existed in the hospital and therefore stopped endovaginal ultrasound procedures performed there as well. However, because SPD staff were properly disinfecting similar equipment, managers reassigned the reprocessing of endovaginal transducers to SPD and resumed procedures in the hospital.

² Refers to the destruction of all microorganisms with the exception of high levels of bacterial spores.

System managers did not provide an IB to the VISN to review for referral to the CRAAB despite the fact that this condition existed for approximately 2 years. No actions were taken to identify patients who may have been at risk for infection.

As a result of our review, on September 1, system managers prepared an IB for the VISN which stated that HLD was not done from March 2007 to July 2009 on the RME at Mayaguez and in the hospital. The IB was discussed on a pre-CRAAB conference call September 22, 2009. Although this RME was not submitted to HLD as required at either location, because double latex sheaths were used, the risk of exposure was considered to be negligible and no patients were notified.

Issue 2: Leak Testing

We substantiated the allegation that leak testing was not being performed in the hospital Radiotherapy Department and OR, or in the Ponce OPC. The RME involved included laryngoscopes in the Radiotherapy Department at the hospital and in the Ponce OPC, and colonoscopes in the hospital OR. We confirmed that these endoscopes required leak testing per the manufacturer's instructions.

Leak testing is a critical part of the cleaning phase performed after each procedure to ensure integrity of the external sheath of the instrument, and to prevent fluid invasion into internal components of the scope prior to immersion into an enzyme cleaning solution. This test represents an important step for infection control purposes, as leaks can contaminate the scope and may not allow for proper disinfection between patient procedures.

Radiotherapy Department

We confirmed that leak testing was not performed on a laryngoscope in Radiotherapy between October 2008 and June 26, 2009. We also learned that when the issue was identified, all laryngoscopes were sent to SPD for leak testing and one tested positive. The laryngoscope was immediately removed from service. It is not known how long the leak existed. We interviewed the RN who was responsible for reprocessing the laryngoscope, and had worked in the Radiotherapy area since October 2008. She told us that her orientation did not include information about the need for leak testing and she was never trained to perform leak tests. The RN also reported that the laryngoscope with the leak was the only laryngoscope used during this time period.

System managers were unaware that laryngoscopes were in use in this area until June 26, 2009. Although a recommendation for review of patients potentially exposed to risk of infection during this 9-month period was sent by a member of the system task force inspection team to the PSM, the QM, the Acting Chief of Infection Control, the Chief of SPD and several members of the RME Committee, the review was not conducted.

As a result of our review, on September 1, system managers prepared an IB for the VISN related to the issues in Radiotherapy. The IB was discussed on a pre-CRAAB conference call September 22. The IB was not updated to include information that the RN did not follow proper cleaning procedures. Although this RME required the use of an enzymatic detergent in the pre-cleaning process, the RN reported that her pre-cleaning process consisted of rinsing the laryngoscope under running water in a hand hygiene sink and drying it with a clean gauze pad. Without proper pre-cleaning, adequate disinfection cannot be ensured. As the pre-CRAAB committee did not have all the relevant facts, the issue should receive further review.

Operating Room

We confirmed that leak testing was not performed as required on flexible colonoscopes in the OR. The system task force inspection team conducted an unannounced inspection in the OR on May 9, 2008. The follow-up action plan that was created to address deficiencies identified during the inspection required staff to “Perform a wet leak test when the F.C. [flexible colonoscope] is reprocessed.” The target date for completion was May 30, 2008. However, in October 2008, the system task force inspection team reported a deficiency in leak testing in the OR.

On February 5, 2009, during a repeat inspection of the OR, the system task force inspection team again identified that leak testing was not being performed. During this inspection, two OR technicians were interviewed. One technician stated “we only do leak testing on Friday,” and the other stated “we don’t do the leak test because we are too busy.” Task force inspection team members did not observe leak testing equipment in the OR during their review. SPD supplied OR with a machine for leak testing immediately after this inspection.

This issue was reported to the COS on February 12, 2009. The COS e-mailed the Chief of Surgery who reported that the leak testing equipment was on order since October 10, 2008. In the e-mail, the Chief of Surgery stressed the importance of conducting leak testing. During our site visit, we interviewed the Chief of Surgery to determine how long the OR had been without leak testing equipment prior to October 2008. He told us that he did not know if leak testing had ever been done. Although the deficiency was identified three times between May 2008 and February 2009, managers took no action to assess the risk to patients.

As a result of our review, on September 1, system managers prepared an IB for the VISN. The IB was discussed on a pre-CRAAB conference call on September 22, 2009. The committee felt that the risk of bloodborne pathogen transmission due to failure to leak test was negligible and no patients were notified.

Ponce OPC

We confirmed that leak testing was not performed as required on RME at the Ponce OPC for 3 years. The system task force inspection team visited the Ponce OPC June 18, 2009, to observe endoscope cleaning procedures in the Urology Clinic. During the inspection, it was discovered that endoscopic ENT procedures were being done in the clinic as well. We learned that the physician performing the procedures was reprocessing the equipment himself and that leak testing was not being done after procedures as required. The inventory list confirmed that a Karl Storz™ Laryngoscope was the only laryngoscope in use at the Ponce OPC, and this endoscope required leak testing. System managers took no action to assess the risk to patients.

As a result of our review, on September 22, system managers prepared an IB for the VISN. The pre-CRAAB committee minutes read as follows: “The physician had reportedly been soaking the laryngoscope for 30-40 minutes in Cidex OPA; however, there were not any log books maintained on the use of the disinfectant.” The committee decided that “although the physician was not properly cleaning the laryngoscope and the leak testing was not being properly performed, the patient risk was negligible” and patients were not notified.

Issue 3: Certifications of Compliance

We substantiated the allegation that the system inaccurately certified compliance with endoscope equipment procedures, reprocessing, and training on three occasions.

The NCPS issued a Patient Safety Alert on December 22, 2008 (AL09-07, Improper set-up and reprocessing of flexible endoscope tubing and accessories), which required a response of compliance with reprocessing procedures from the “Facility Director (or designee)” by January 7, 2009. Facilities were to identify all areas in the facility where reprocessing of flexible endoscopes occurred, and ensure that all personnel who performed procedures with flexible endoscopes and/or reprocessed endoscopes and their tubing and accessories read the alert. In addition, facilities were required to confirm that reprocessing personnel had been assessed for competency, and that locally-developed SOPs that were in accordance with manufacturer’s instructions were in place.

The response to the VISN was from the PSM and included an assessment of the gastrointestinal (GI) clinic only, instead of a system-wide review as required by the NCPS alert.

The system director submitted the second certification of compliance to the VISN on March 19, 2009. This annual certification of endoscope processes failed to identify training deficiencies and locations of all endoscopic procedures to include outpatient clinics.

The third certification of compliance was sent to the VISN on June 5, 2009. This document from the system director verified that SOPs were in place for every model of equipment according to manufacturer's instructions, and that competencies by direct observation were completed. However, a VISN staff inspection conducted in July noted the need for staff re-training, new SOPs, reprocessing of some equipment that had already been reprocessed, and development of device-specific competencies.

Issue 4: Management Response

We substantiated the allegation that since February 2009, system managers ignored warnings regarding patient safety issues concerning the reprocessing of RME. During our interviews, we asked system managers if any issues of concern were identified during the system task force inspections. They all answered that none were identified or reported. We were given documents showing that RME Committee members and senior managers were informed of the issues that are detailed in this report. Furthermore, we have testimony from staff that worked in these areas or were part of the system task force inspection team that verified the accuracy of these issues.

One of the members of the system task force inspection team reported these issues to the PSM with a recommendation that a Root Cause Analysis (RCA)³ be conducted to assess the system failures that may have contributed to these deficiencies. The PSM verified that a RCA was recommended but told us she felt that a Healthcare Failure Mode and Effect Analysis⁴ would have been more appropriate. When asked why neither review had been performed, the PSM could offer no explanation.

On August 25, 2009, we asked for all documents related to the VISN site visit of July 2009, including the final report. We were told that no final report was received. The VISN provided us with the final report of the site visit, which was sent to the system on July 13. We discussed our concerns about management responsiveness with the VISN and System Directors and verified that an Administrative Investigation Board (AIB) would be chartered to further investigate and address these issues.

Following our visit, an AIB was chartered and completed and recommended actions are currently under review by the VISN.

Conclusions

We substantiated that endovaginal transducers were not properly disinfected and that leak testing was not performed on endoscopes in Radiotherapy, the OR, and in the Ponce OPC. We substantiated that the system inaccurately certified compliance on three

³ A process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls.

⁴ A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome.

occasions. We also substantiated that senior system leadership and responsible managers were aware of these issues and failed to take appropriate action to determine if patient safety concerns were adequately addressed.

Since our onsite review, an AIB and review of RME reprocessing by the VA SPD Executive Program Director have been completed. IBs were submitted for pre-CRAAB reviews. Based on the information provided, the pre-CRAAB committee determined the risk to patients to be negligible. Due to incomplete information contained in the issue brief, further consideration by the pre-CRAAB committee is indicated for the laryngoscope issue in Radiotherapy.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that an appropriate risk assessment, based upon findings of improper laryngoscope cleaning in Radiotherapy, be performed and appropriate actions taken.

Recommendation 2. We recommended that the VISN Director follow up on all recommendations from the AIB and take appropriate administrative action.

Comments

The VISN and Healthcare System Directors concurred with our findings and recommendations and provided an acceptable action plan. See Appendixes A and B (pages 9-11) for the full text of the Directors' comments. We will follow up on the proposed 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: February 24, 2010

From: Director, VA Sunshine Healthcare Network (10N8)

Subject: **Healthcare Inspection – Patient Safety Issues, VA Caribbean Healthcare System, San Juan, PR**

To: Director, St. Petersburg Office of Healthcare Inspections (54SP)

Director, Management Review Office (10B5)

1. I have reviewed and concur with the findings and recommendations contained in the Healthcare Inspection report, as it relates to Patient Safety Issues at the VA Caribbean Healthcare System in San Juan, PR.
2. Appropriate action has been initiated and/or completed, as detailed in the attached report.



Nevin M. Weaver, FACHE

VISN Director Comments to Office of Inspector General's Report

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

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that an appropriate risk assessment, based upon findings of improper laryngoscope cleaning in Radiotherapy, be performed and appropriate actions taken.

Concur: We concur that the Issue Brief did not reflect information obtained from the interviews conducted by the Administrative Investigation Board as it related to the pre-cleaning of laryngoscopes in Radiotherapy.

Status: The Issue Brief, dated September 1, with subsequent updates of September 2 and September 23 did not include information from the interviews conducted by the Administrative Investigation Board. As a result, an update to the Issue Brief will be submitted to include information that may have been omitted from the Pre-CRAAB review that was conducted on September 22, 2009 on this issue.

Target Completion Date: Pending. The VISN 8 Network Director will submit an updated Issue Brief to appropriate VHA officials, which will reflect the information obtained from the interviews conducted by the Administrative Investigation Board, as it relates to the pre-cleaning process of the laryngoscopes in Radiotherapy, to ensure all information is considered in the risk assessment decision.

Recommendation 2. We recommended that the VISN Director follow up on all recommendations from the AIB and take appropriate administrative action.

Concur: We concur that the VISN Director has completed appropriate follow-up of each of the recommendations from the AIB.

Status: An AIB team, chartered by VISN 8 completed its review and finalized the AIB report in December 2009. VISN 8 has forwarded the final recommendations to VHA OHRM and the Office of General Counsel for review and guidance on the appropriate actions that should be taken.

Target Completion Date: Pending. VISN 8 is awaiting the outcome of the final review and recommendations from VHA OHRM and the Office of General Counsel as to the appropriate actions that should be taken.

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: February 23, 2010

From: Director, VA Caribbean Healthcare System (672/00)

Subject: Healthcare Inspection – Patient Safety Issues, VA Caribbean Healthcare System, San Juan, PR

To: Director, VA Sunshine Healthcare Network (10N8)

1. On behalf of the VA Caribbean Healthcare System, I want to express my appreciation to the Office of Inspector General (OIG), Office of Healthcare Inspections for their professional and comprehensive review of patient safety issues, conducted on August 25-28, 2009.
2. I concur with the findings and recommendations of this Office of Inspector General report. The VA Caribbean Healthcare System welcomes the external perspective provided by this report.
3. The VA Caribbean Healthcare System's reply outlines the initiative already taken in response to these findings.



Wanda Mims, MBA

OIG Contact and Staff Acknowledgments

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Acknowledgments	David Griffith Alice Morales-Rullan

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