Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality Control Issues in Supply Processing and Distribution Carl T. Hayden VA Medical Center Phoenix, Arizona

Report No. 07-02121-168 **July 13, 2007**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Executive Summary

The purpose of this review was to determine the validity of the allegations that the Supply Processing and Distribution (SPD) department at the Carl T. Hayden VA Medical Center delivered contaminated instruments to the Operating Room (OR), and management threatened retaliation if staff cancelled OR cases.

We substantiated the allegation that SPD had ongoing problems including contaminated instruments, damp wrappers, and torn or discolored instrument wrappers from August 11, 2006 through April 30, 2007. However, infection control data did not show any increase in surgical infections during this time period, nor were contaminated instruments used in surgery. Medical center managers aggressively identified and corrected SPD issues, including completion of the SPD construction project, weekly meetings, consultative services by two established VA experts, hiring additional SPD staff, staff education and training, increased sterilizer maintenance checks, and ongoing Quality Management monitoring. Despite all efforts to improve SPD processes and procedures, orthopedic surgeons, some anesthesia staff, and some OR nurses remained reluctant to trust that SPD could consistently deliver instruments that are properly cleaned and sterilized.

We did not substantiate the allegation that staff were fearful of management reprisal if they cancelled surgery. Because the complainant was anonymous, we were unable to clarify this issue further. However, we interviewed numerous clinicians including orthopedic and general surgeons, anesthesiology clinicians, OR nurses, and SPD staff. Every clinician we interviewed told us that they felt comfortable with reporting SPD issues or cancelling surgery if necessary.

We recommended that management suspend scheduled total joint surgeries, seek consultative services from an external SPD expert, and follow the recommendations. We also recommended that they provide a copy of the external consultant report to us. Management concurred with our recommendations and suspended all total joint surgeries on May 4, 2007. An external SPD consultation was completed on May 18, 2007. The consultant noted that she "would have no reservations about having Orthopedic or any other type of surgery at this facility." Total joint surgeries resumed on May 25, 2007. A copy of the SPD consultant's report was sent to our office. Based on actions taken, we consider all recommendations closed.

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

TO: Director, Veterans Integrated Service Network (10N18)

SUBJECT: Healthcare Inspection ─ Alleged Quality Control Issues in Supply Processing and Distribution, Carl T. Hayden VA Medical Center, Phoenix, Arizona

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections (OHI), was requested by the Chairman of the United States Senate Committee on Veterans' Affairs, to conduct an inspection at the Carl T. Hayden VA Medical Center (medical center), Phoenix, Arizona. OHI was asked to determine the validity of allegations regarding the Supply Processing and Distribution (SPD) department delivering contaminated instruments to the Operating Room (OR) and management retaliation if staff cancelled OR cases.

Background

An anonymous complainant submitted the following allegations to the Chairman of the United States Senate Committee on Veterans' Affairs:

- SPD department delivered contaminated instruments to the OR for the past 8 months with no improvement.
- Staff was fearful of management retaliation if they cancelled surgery because managers threatened to fire them.

The medical center is a teaching hospital providing a full range of patient care services, as well as education and research. The facility has 132 hospital beds, 102 nursing home care unit beds and 48 mental health beds and treats patients residing in Veterans Integrated Service Network (VISN) 18.

Scope and Methodology

We conducted a site visit at the medical center on May 2–3, 2007. We reviewed policies, Quality Management (QM) data, sterilization logs, committee minutes, and consultation

reports. We inspected the OR and SPD for cleanliness and compliance with regulations. We interviewed OR, anesthesia, and surgical clinicians, and SPD staff. We interviewed senior managers, including the Quality Manager, SPD Chief, OR Nurse Manager, the Nurse Executive, the Chief of Staff (COS), the Associate Director, and the Director. We also conducted telephone interviews with the two Veterans Health Administration (VHA) SPD expert consultants who have been involved with SPD/OR issues at the medical center since September 2006.

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

Inspection Results

Case Review

The medical center's SPD department was under construction for renovation from January 2006 through February 2007. SPD provides sterile instruments and supplies, and disposable clinical items to all medical departments including the OR.

In August 2006, the OR cancelled nine orthopedic surgery cases due to damp wrappers and holes in the external instrument wrappers.

In response to the surgery cancellations, medical center managers organized a multidisciplinary team including staff from SPD, OR, biomedical engineering, COS office, QM, Infection Control, and orthopedic surgeons to address the issues. The group implemented the following actions:

- Discontinued use of foam inserts used to provide extra support of instrument trays.
- SPD would process orthopedic instrument trays as the last loads of the day.
- SPD staff received additional education and training on sterilization procedures.
- Sterilizer drying times extended from 30 to 45 minutes.
- Decreased weight of instrument trays.
- Steam pressure in sterilizers checked by the Biomedical Engineering department and the manufacturer's representative. Results were within the normal limits.
- Chief of SPD developed a checklist to monitor the times of sterilization and the humidity levels in the work environment.
- Chief of SPD monitored staff performance more closely.
- A Surgeon and the Chief of SPD met with sales representatives requesting the delivery of orthopedic total joint instrument trays 48 hours before the scheduled procedure.

In early September 2006, the OR again cancelled five total joint cases because of damp wrappers. The medical center suspended total joint cases and fee based urgent patients to community hospitals from September 11 through October 16, 2006. The committee recommended increasing the sterilizer drying times and running test packs of instruments. They also converted sterilizers in OR to pre-vacuum cycles to test total joint instrument trays but the wrappers remained damp. Medical center mangers contacted the VHA (headquarters) Chief of SPD and the Chief of SPD from the VA Health Care System, Amarillo, Texas (Amarillo VAHCS) to provide consultative services.

On September 26–27, it was again noted that there were holes in instrument wrappers, lint particles on towels, and the loaner instrument trays were in poor condition. The Chief of Orthopedic Surgery met with sales representatives to discuss the weight and condition of their company orthopedic instrument trays. The sales representatives assured that the instrument trays would be intact and that each tray would weigh less than 16 pounds. The Chief of SPD began monitoring holes in wrappers and ongoing problems. On September 27, managers met with the Chair of the Surgical Department, the Chief of Orthopedics, all of the orthopedic surgeons, the Chief of Acquisition and Material Management, Quality Management staff, Infection Control staff, SPD staff, and Pathology staff to discuss concerns.

On October 3–4 and October 11–13, the VHA Chief of SPD conducted two on-site visits to complete a review of decontamination, cleaning, and sterilization processes in SPD. There were no infection control concerns. However, he found several new instrument wrappers with visible holes and determined that the wrappers were defective. He authorized the purchase of a comparable wrapper from a different vendor. Facilities Services installed appropriate barriers to help contain the construction activities and agreed to alter the current renovation plan. The construction project was divided into four phases to minimize the impact on SPD. The VHA Chief of SPD recommended that all SPD staff be retrained on SPD processes.

The Chief of SPD from Amarillo VAHCS was on site from October 4–6, 2006, and provided education and training to the medical center's SPD staff. She recommended the installation of magnification lights, maintenance checks for sterilizers to ensure proper functioning for instrument drying, and the installation of a dedicated internal phone line between the decontamination and preparation areas. She also recommended that SPD staff discontinue the use of color-coded tape applied on instruments and that terry cloth towels be removed from preparation areas. Additionally, access to all SPD areas was limited to authorized staff wearing appropriate attire. Medical center managers implemented all recommendations.

The VHA Chief of SPD noted that even though SPD experienced an atmospheric humidity increase, the level was not elevated enough to cause damp packs. He recommended that the SPD Chief monitor processes to ensure that staff was allowing

adequate cooling time for instruments in sterilizers before bringing them out into room temperature. This precaution prevented condensation. He recommended that the biomedical engineering department and the manufacturer check the steam lines. He also recommended increasing the staffing levels through initiation of immediate and ongoing recruitment. Medical center managers implemented all recommendations and reported by May 14, 2007, that an additional seven SPD staff were hired and oriented. In addition, mangers have identified five candidates for the other vacancies.

On October 7–9, based on consultant recommendations, all OR operations were stopped to allow SPD staff to reprocess and re-sterilize all instruments and to clean all sterilizers and instrument carriers. On October 18, there was only one operational sterilizer in SPD because of the construction. Consequently, the COS limited the total number of all surgeries to 15 per day, including one orthopedic case twice per week on nonconsecutive days. There was one total knee arthroscopy cancellation because of a hole in the wrapper in October 2006.

On November 3, there was one total joint surgery cancellation because OR staff found rust colored stains on cloth towels and wrappers. From November 7 through December 15, medical center managers cancelled all total joint surgeries until both sterilizers were operational. SPD continued to function with one sterilizer. During the week of November 13, OR staff continued to note rust colored stains on cloth towels and wrappers. The biomedical engineering department found no problems with water lines. They installed new filters in sterilizers; however, staff continued to observe stains. They collected water samples and sent them to an independent laboratory for analysis. The laboratory results indicated that the source material was carbon, and that the staining was not related to the trays or instruments.

In December, there were no reported incidents involving contaminated instruments. Medical center managers authorized the installation of a dedicated air conditioning unit in SPD and resumed three total joint replacement surgeries per week. On December 26, administrative oversight of SPD was transferred to the Nurse Executive.

In January 2007, one orthopedic joint surgery was cancelled because of instrumentation problems. Staff did not report any sterilization issues. Both sterilizers and all washers in SPD were operational. All SPD staff education and retraining was completed. An evening SPD supervisor was hired.

In February, there were no reported incidents involving contaminated surgical instruments. Medical center managers authorized two total joint surgeries per day on nonconsecutive days.

In March, there were three orthopedic joint surgery cancellations because of debris on instruments and holes in wrappers. The orthopedic sales representatives did not supply

backup sets of instruments as required by contract. Medical center managers again met with them to discuss expectations and consequences for noncompliance.

In April, there was one orthopedic joint surgery cancellation because of sterilization issues. The Chief, SPD continued to educate staff on sterilization processes.

On April 27, the Amarillo VAHCS Chief of SPD conducted an onsite follow-up visit. Her report indicated that the renovated SPD environment was adequate for decontamination, preparation, and sterilization of instruments. She noted that there were still staffing vacancies; however, active recruiting continued. Overall, she noted that the majority of the SPD staff was very qualified to produce the expected results. She commented that OR staff cancelled total joint cases as a first option instead of the last option, and recommended that SPD, OR, and surgery staff work as a team. She reported that based on staff discussions, about 75 percent of the staff felt that SPD was performing at an adequate or better level. She recommended that SPD create an SPD/OR liaison to help with communication and relationships and that both departments need to put the past behind them and move forward.

On May 3, the infection control staff reported that overall there had been no spike in surgical or orthopedic infection rates.

On May 4, medical center managers suspended all total joint surgeries until completion of the external consultation visit.

Issue 1: SPD Issues

We substantiated that SPD had ongoing problems including contaminated instruments, damp wrappers, and torn or discolored instrument wrappers, resulting in 20 orthopedic surgery cancellations from August 11, 2006, through April 30, 2007. Because OR nurses were vigilant in checking instrument wrappers during the SPD construction project, surgeries were cancelled when problems were identified. Staff never used contaminated instruments during any surgical procedure. Infection control data did not show any increase in surgical infections from August 2006 through April 2007.

Medical center managers organized a multidisciplinary team to address the ongoing SPD issues beginning August 29, 2006**.** They suspended scheduled total joint cases at the medical center on September 11 through October 16 and again on November 7 through December 15. Urgent cases were fee based to community hospitals.

Medical center managers continued ongoing aggressive action plans to identify and correct SPD issues, including completion of the SPD construction project, weekly meetings, consultative services by two established VA experts, hiring additional SPD staff, staff education and retraining, increased sterilizer maintenance checks, and ongoing

QM monitoring. Despite these efforts to improve SPD processes and procedures, orthopedic surgeons, some anesthesia staff, and some OR nurses remain reluctant to trust that SPD can consistently deliver instruments that are properly cleaned and sterilized.

Issue 2: Management Reprisal

We did not substantiate the allegation that staff were fearful of management reprisal if they cancelled surgery because of increased timeliness performance measures. Because the complainant was anonymous, we were unable to clarify this issue further. However, we interviewed numerous clinicians including orthopedic surgeons, general surgeons, anesthesiology clinicians, OR nurses, and SPD staff. They told us that medical center managers had never threatened them with firing or other personnel action for cancelling surgery. Every clinician we interviewed told us that they felt comfortable with reporting SPD issues or cancelling surgery if necessary.

Conclusion

Medical center managers and staff confirm that they identified, monitored, and evaluated numerous SPD issues. Despite implementing recommendations by consultants and internal experts, SPD issues continued to arise. Consequently, some anesthesia, orthopedic and OR clinicians do not have confidence that SPD problems have been substantively corrected. We discussed the clinician concerns with the medical center managers, and they agreed to suspend total joint replacement surgery effective immediately on May 4, 2007, until an outside consultant confirms that SPD can deliver safe and sterile equipment to the OR.

Recommendations

Recommendation 1. We recommended that the VISN Director insure that the Medical Center Director suspend scheduled total joint surgeries effective May 4, 2007.

Recommendation 2. We recommended that the VISN Director insure that the Medical Center Director seek consultative services from an external SPD expert and follow all recommendations.

Recommendation 3. We recommended that the VISN Director insure that the Medical Center Director provide a copy of the external consultant report to OHI.

Comments

The VISN and Medical Center Directors concurred with the findings and recommendations of this inspection and provided acceptable improvement plans. The director suspended all total joint surgeries on May 4. An external SPD consultation was completed on May 18, 2007. The consultant noted that she "would have no reservations

about having Orthopedic or any other type of surgery at this facility." Total joint surgeries resumed on May 25, 2007. A copy of the SPD consultant's report was sent to our office on May 31, 2007. Based on actions taken, we consider all three recommendations closed (see Appendixes A and B, pages 8–11, for the full text of the Directors' comments).

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 1, 2007

From: Director, Veterans Integrated Service Network (10N18)

Subject: **Healthcare Inspection, Alleged Quality Control Issues in Supply Processing and Distribution, Carl T. Hayden VA Medical Center, Phoenix, Arizona**

To: Director, Kansas City Office of Healthcare Inspections (54KC)

Director, Management Review Office (10B5)

I concur with the facility response. See Medical Center Director Comments for specific actions. Please contact Joan Funckes, Executive Assistant to the Network Director, VISN 18 at (602) 222-2692, for any questions.

Patricia A. McKlem

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 31, 2007

From: Director, Carl T. Hayden VA Medical Center (644/00)

Subject: **Healthcare Inspection, Alleged Quality Control Issues in Supply Processing and Distribution, Carl T. Hayden VA Medical Center, Phoenix, Arizona**

To: Director, Veterans Integrated Service Network (10N18)

1. The draft report of the Healthcare Inspection, Alleged Quality Control Issues in Supply Processing and Distribution, was reviewed. The facility's comments and implementation plan to address the recommendations are noted on the next page.

2. If you have any questions regarding this report, please contact Ms. Sally Compton, QM Program Manager, Quality Management Department at 602.277.5551, ext. 6777.

DONALD F. MOORE, R.Ph., M.B.A.

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

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

OIG Recommendation(s)

Recommended Improvement Action 1. Suspend scheduled total joint surgeries effective May 4, 2007.

Concur **Target Completion Date:** Complete

Scheduled total joint surgeries were suspended effective May 4, 2007 in response to the discussion with the OIG inspectors, facility clinical staff, and medical center management until such time as an outside consultant review was done of SPD delivering safe and sterile equipment to the OR.

External consultation was completed on May 18, 2007. The consultant noted that she "would have no reservations about having Orthopedic or any other type of surgery at this facility." Total joint surgeries resumed on May 25, 2007.

Recommended Improvement Action 2. Seek consultative services from an external SPD expert and follow all recommendations.

Concur **Target Completion Date:** July 31, 2007

Nancy Chobin, RN, CSPDM, Director, Medical Center Education Services, a recognized national SPD expert, performed a sterilization consultation at this facility on May 18, 2007. We are in the process of implementing the consultant's recommendations. Some involve work that will be done when the OR is closed for annual maintenance which is scheduled for late June/early July.

Recommended Improvement Action 3. Provide a copy of the external consultant report to OHI.

Concur **Target Completion Date:** Complete

The external consultant report was provided to the Office of Healthcare Inspections on May 31, 2007.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Virginia L. Solana, Director Kansas City Regional Office of Healthcare Inspections (816) 426-2023
Acknowledgments	Reba B. Ransom Marilyn Stones George Wesley, M.D.

Appendix D

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