



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Supply, Processing, and Distribution Issues and Quality of Care Concerns William Jennings Bryan Dorn VA Medical Center Columbia, South Carolina

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Executive Summary

The purpose of this review was to evaluate the validity of allegations that insufficient oversight, training, and resources in the Supply, Processing, and Distribution (SPD) Service created unsafe working conditions and compromised patient care. We also evaluated the allegation that a patient received poor care while hospitalized at the medical center. While not one of the complainant's allegations, we evaluated the medical center's use of flash sterilization in the operating room (OR).

We substantiated that staffing levels were not at the authorized level and that communication, supervision, and oversight were inadequate between August 2005 and May 27, 2007, when interim supervisors handled the management of SPD. We also substantiated that SPD inventory did not contain a sufficient number of instruments for the increasing volume of OR cases and that SPD provided some un-sterile surgical instruments to the OR. However, we made no recommendations as the medical center approved the hiring of additional staff, SPD now has a new full-time supervisor, additional instruments were being purchased, and we found that appropriate action was taken when un-sterile instruments were provided.

We did not substantiate that SPD staff received inadequate training. We could not confirm or refute the allegation that vendors did not comply with contract stipulations as there was no documentation of these events.

We did not substantiate the allegation that a patient received poor care due to his wife's history of conflict with her former supervisor at the medical center. We determined that his medication was managed appropriately, and his stroke was not caused by lack of treatment by medical center staff.

We determined that the medical center's use of flash sterilization in the OR was excessive and not in compliance with accepted standards. We noted that during the third quarter, fiscal year (FY) 2007, flash sterilization was used more than 40 percent of the time, although less than 1 percent of the cases in which it was used were considered emergent. We recommended that the VISN Director initiate a thorough external review to assess the medical center's flash sterilization rate.

The VISN and Medical Center Directors agreed with our findings and recommendation and submitted an appropriate action plan. We will follow up on proposed actions until they are completed.



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

TO: Director, VA Southeast Network (10N7)

SUBJECT: Healthcare Inspection – Supply, Processing, and Distribution Issues and Quality of Care Concerns, William Jennings Bryan (WJB) Dorn VA Medical Center, Columbia, SC

Purpose

The VA Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations regarding insufficient oversight, training, and resources in the Supply, Processing, and Distribution (SPD) Service and poor quality of patient care at the WJB Dorn VA Medical Center (the medical center) in Columbia, South Carolina.

Background

The medical center is a tertiary care hospital that provides acute medical, surgical, psychiatric, and long-term care services. The medical center has 124 hospital and 92 nursing home beds and serves a veteran population of about 60,000. The medical center is under the jurisdiction of Veterans Integrated Service Network (VISN) 7.

The medical center's Executive Vice-President of the American Federation of Government Employees Local 1915 submitted several complaints regarding workplace conditions, treatment of employees, and patient care at the medical center to the office of Senator Joseph Lieberman. Senator Lieberman's office referred the complaints to the OIG.

The medical center's SPD Service, a vital component of patient care, is responsible for the receipt, storage, and distribution of medical supplies, and the decontamination and sterilization of reusable medical supplies and equipment.¹ The complainant alleged that

¹ VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, August 16, 2002, Part 1, Organizational Structure, Statement of Mission, Paragraph 1.1, Page 7.

deficiencies in SPD created unsafe working conditions and compromised patient care. Specifically, the complainant alleged that SPD could not function effectively due to:

- Inadequate staffing.
- Inadequate training.
- Inadequate oversight and supervision.
- Poor communication.
- Inadequate inventory.
- Vendor non-compliance with contract stipulations.

SPD employees reported that as a result of the issues listed above, SPD occasionally provided unsterile instruments to the Operating Room (OR). Although not one of the complainant's allegations, we also evaluated the use of flash sterilization in the OR.

The complainant also submitted a statement from a patient's wife. The wife, who had previously been employed as a registered nurse at the medical center, alleged that:

- Her husband received poor care while hospitalized. She attributed this to a conflict she had in the past with one of her former supervisors at the medical center.
- One of her husband's medications was not managed appropriately.
- Her husband's most recent stroke was due to lack of treatment by medical center staff.

Methodology

We visited the medical center September 10–12, 2007. We interviewed the complainants, the Associate Medical Center Director for Patient Care Services (AMCD/PCS), the OR and SPD supervisors, the Assistant Chief of Surgery, eight SPD employees, and others with direct knowledge related to these allegations. We reviewed patient medical records, patient advocate reports, incident reports, employee training records, Infection Control Committee (ICC) minutes and reports, surgical reports, and Veterans Health Administration (VHA) and local policies related to the operation of SPD.

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

Results

Issue 1: Use of Flash Sterilization

We found that the medical center's use of flash sterilization² was excessive and not in compliance with accepted standards. We reviewed OR documentation of flash sterilization during the 3rd quarter of fiscal year (FY) 2007 and noted that flash sterilization was used more than 40 percent of the time, although less than 1 percent of the cases in which it was used were considered emergent. We also found that flash sterilization was used on some instruments for which it is not recommended.

The Association of Operating Room Nurses (AORN) guidelines state that, "Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization should not be used as a substitute for sufficient instrument inventory." AORN further states, "Flash sterilization should be used only in selected clinical situations and in a controlled manner. Use of flash sterilization should be kept to a minimum." VA Handbook 7176 states that flash sterilization is not to be performed for routine sterilization of surgical instruments. The Handbook further states that the flash sterilizer may be used during a surgical procedure for an unanticipated event such as unplanned multiple emergency procedures. The VA SPD Training Manual for Level 1 Training³ references requirements of The Joint Commission,⁴ Association for the Advancement of Medical Instrumentation, and AORN regarding flash sterilization. These requirements state that flash sterilization use should be on an emergency basis for items dropped during surgery and/or single instruments that may be called for during a case and are not already sterile.

We reviewed flash sterilizer log sheets and other OR documentation for the two OR sterilizers between April 1–June 30, 2007, and found that there were 768 OR procedures performed with 313 instances (40.7 percent) of flash sterilization during this period. OR reports showed that 7 of the 768 procedures (0.91 percent) were considered emergent, and 2 of the 7 procedures used instruments that were flash sterilized.⁵ We also found 24 instances where instrument "sets" were flash sterilized, although the SPD Supervisor told us and manufacturer instructions specifically state that instrument sets should not be flash sterilized.

VHA Handbook 7176 requires clinicians to test the proper functioning of the sterilizers by using a monitoring device at least once each day they are in use. The device contains

² Flash sterilization is the process used to sterilize surgical instruments for immediate use without the benefit of a package or method to maintain sterility.

³ *VA Supply, Processing, and Distribution Training Manual – Level 1 Training, Sterilization, Paragraph 10, Flash Sterilization, Page 104-105.*

⁴ The Joint Commission, formerly known as Joint Commission of Accreditation of Healthcare Organizations or JCAHO.

⁵ Emergent cases could create a situation where SPD would not be able to meet the turn-around-time for complete sterilization.

organisms that are killed (as evidenced by a “negative” test result) when a sterilizer is working properly. Any device with a “positive” test result, indicating the presence of live organisms, must be submitted to the microbiology department for further testing. Results of these tests must be reported to the OR staff.

We found that the testing was not conducted for the two OR sterilizers on five separate occasions in April and June of 2007, although the sterilizers were in use on those dates. This information was reported to the ICC; however, their minutes do not reflect corrective action to resolve this deficiency.

We reviewed surgical site wound infection (SSWI) data to determine if there was an increased incidence of SSWIs in patients whose procedures involved the use of instruments that were flash sterilized. ICC meeting minutes documented 12 cases of SSWI between March and July 2007. The infection control nurse reviewed these cases and told us that none of the procedures for these 12 patients required the use of instruments that were flash sterilized.

We noted that the use of flash sterilization was reported regularly in ICC minutes, which were sent to the Executive Leadership Board. At each reporting, action to decrease this practice was suggested. However, we saw no evidence that an action plan was created. OR staff told us that the use of flash sterilization was approved by the Chief of Staff, but the medical center was unable to provide documentation of this.

When SPD functions efficiently, professional medical staff in the OR are allowed to concentrate on direct patient care with the assurance that needed supplies will be available. Without efficient operations, managers could not ensure patient safety and adequate infection control.

Recommendation 1: We recommended that the VISN Director initiate an external review of the medical center’s flash sterilization practices.

The VISN and Medical Center Directors agreed with our findings and recommendation and submitted an appropriate action plan. The OR Nurse Manager and SPD Chief from another medical center in the VISN will conduct a site visit to review flash sterilization practices on February 19, 2008. We will follow up on proposed actions until they are completed.

Issue 2: SPD Deficiencies

Staffing: We substantiated that SPD staffing levels were not at the authorized level. The medical center’s organizational chart, dated June 2002, showed the approved SPD staffing ceiling of 11 full time equivalent employees, including a supervisor, a lead technician, and 9 staff technicians. At the time of our visit, there were two vacancies including one staff and one lead technician. SPD staff we interviewed told us that medical center managers recently decided to increase the number of SPD staff to 15 to

allow for a 3:00 p.m.–11:00 p.m. shift. Managers are currently recruiting for the lead technician position and two staff technician positions. The SPD supervisor told us that she recently received a SPD Staffing Analysis Tool that she plans to complete when the current vacancies are filled. This tool utilizes workload and staffing levels to evaluate adequacy of staffing. Additional staff will be requested, if needed, when the analysis is completed. As the hiring of additional staff has been approved, we made no recommendations.

Training: We did not substantiate the allegation of insufficient staff training. We reviewed SPD staff training records and found that all technicians had at least completed the VA SPD Level 1⁶ mandatory training, and four of the eight technicians had attained VA Certified Medical Supply Technician designation. The current supervisor, new to the VA system, was certified through the International Association of Healthcare Central Service Materiel Management, and was VA SPD certified on October 19, 2007. For the period FY 2006 and FY 2007, we determined that SPD staff received all required training. The training topics included hand piece cleaning and sterilization, and demonstrations of cleaning and sterilization techniques for new instruments and equipment. It appeared that SPD staff received adequate training to allow them to effectively perform their jobs.

Oversight and Supervision: We substantiated the allegation that supervision of SPD staff and oversight of SPD operations was inadequate between August 2005 and May 27, 2007, when interim supervisors handled the management of SPD. During this period, SPD was not managed effectively, efficiently, or in compliance with VA requirements.⁷ VHA Handbook 7176 indicates that the SPD supervisor is responsible for aligning administrative controls and planning, communicating, training, and directing the functional activities of SPD and must understand the principles of asepsis, sterilization, and sterile and unsterile supply storage. Since responsibility for SPD was a collateral duty, interim supervisors could not provide the monitoring and supervisory controls needed in SPD. As the new full-time SPD supervisor has extensive experience and exceptional qualifications, we made no recommendations.

Communication: While we substantiated that there was inadequate communication between August 2005 and May 2007, we could not determine the extent to which that may have affected SPD employee performance. SPD staff meetings were not held regularly during that time, and we could not find evidence, with the exception of training sessions and the few staff meetings that were held, of any consistent communication related to issues between SPD and the OR. We learned that the new SPD supervisor attends the weekly OR staff meeting and shares information learned in that meeting with

⁶ *Supply, Processing and Distribution Training Manual* - Level 1, Department of Veterans Affairs TP-90-2, January 1995.

⁷ VA Handbook 7176, Part 1, Organization, Paragraph 3.b, Supervisory Responsibilities, Chief, SPD, and Paragraphs (1)-(8), Page 7-8.

the SPD staff. In addition, SPD now conducts weekly staff meetings and the SPD supervisor is a member of the ICC. As communication has improved, we made no recommendations.

Inventory: We substantiated that the SPD inventory did not contain a sufficient number of instruments for the increasing volume of OR cases. SPD staff told us that they often did not have adequate turn-around-time to properly process instruments if the case volume exceeded SPD staffing and inventory resources. This shortage resulted in the frequent use of flash sterilization in the OR. The medical center completed a needs assessment in May 2007 to determine the funding needed to purchase additional instruments for surgical specialties. Managers provided documentation showing that additional instruments were being purchased, and the SPD supervisor informed us that the medical center has begun to receive the requested instruments. Therefore, we made no recommendations.

Vendor Compliance: We could not confirm or refute the allegation that vendors did not comply with contract stipulations and that this negatively impacted patient care. SPD staff told us that vendors occasionally delivered unclean instruments and case sets. We were also told that one vendor routinely does not provide OR instruments and trays at least 48 hours prior to the start of a procedure as required. These allegations could not be validated since SPD staff had not kept any documentation of these events. We suggested that SPD begin documenting when supplies arrive less than 48 hours prior to surgery or when they arrive unclean so that appropriate corrective actions can be initiated.

Instrument Sterility: We substantiated that SPD provided some unsterile surgical instruments to the OR. We reviewed nine incident reports submitted between October 4, 2006, and September 5, 2007. All reported events involved orthopedic cases and each case was cancelled or delayed until the instruments were properly sterilized. The incident reports documented issues with surgical sets that were outdated, incorrectly wrapped, or had punctured wrapping. Other incidents involved incomplete biological spore testing, untimely sterilization, and a foreign body found in a vendor-packaged surgical instrument basin. Prior to our visit, the SPD supervisor, a vendor representative, and a surgeon discussed the possible cause of the wrapping punctures. They determined that knobs on the bottom of the instrument tray were stressing the plastic wrap and causing the punctures. The medical center was working with the vendor to resolve the issue while we were on site.

Two of the incident reports identified events that occurred during an operation. In one case, an additional surgical set was required during the procedure. When SPD was contacted to deliver the needed set, the OR was notified that the set was outdated. The issue was discussed with medical center management and the surgeon decided to proceed with the case because community practice is to use outdated sets as they remain sterile unless damaged or compromised. In the second case, during the procedure, a small amount of foreign debris was found in the basin containing the total joint drape pack. In

both cases, the events were disclosed to the patient. Since the medical center had taken appropriate action when these events occurred, we made no recommendations.

Issue 3: Quality of Patient Care

Case History

The patient is a 58-year-old male with a past medical history significant for hypertension, hyperlipidemia,⁸ diabetes, stroke, and renal disease. He is partially blind in one eye and is 100-percent service-connected for post-traumatic stress disorder. The patient lives at home with his wife, who was employed as a nurse at the medical center. The patient has both small vessel and large vessel vascular disease and has had multiple strokes. He was followed by a neurologist at the medical center who reported he was receiving maximal prophylactic therapy with both Aggrenox⁹ and additional aspirin.

The patient's previous strokes left him with minimal left-sided weakness and mild cognitive deficits; however, he was able to function fairly independently. He was evaluated by the neurologist in January 2007 and given an appointment to return in 6 months. On March 15, 2007, the patient's wife called the Telephone Advice Program (TAP) and reported she felt that her husband was getting worse and may have had a "mini stroke." She reported he was having difficulty with speech, swallowing, breathing, balance, and gait. A computed tomography (CT) scan of the head taken that day revealed no acute changes.

On April 17, the patient's wife again contacted the TAP to report her husband was having severe weakness in both legs and was unable to walk or stand on his own. She was advised to bring him to the medical center emergency room (ER). The ER physician's evaluation revealed weakness in the patient's gait, more pronounced on the right side. A CT of the head was negative. The patient was admitted to the hospital for evaluation. Magnetic resonance imaging revealed "diffuse atrophy involving the brain with multiple old lacunar infarctions"¹⁰ and a new stroke in the left hemisphere. The patient was evaluated by Neurology and Speech Pathology and referred to Physical Medicine and Rehabilitation (PM&R) for kinesiotherapy (KT)¹¹ and occupational therapy (OT) assessments and treatment. On April 20, the patient was discharged to a private rehabilitation facility. In July 2007, when last seen by Neurology, the patient had improved and was able to ambulate without a walker.

Patient Care: We did not substantiate the allegation that the wife's previous conflict with her former supervisor at the medical center negatively impacted the patient's care.

⁸ Elevated concentrations of lipids in the blood.

⁹ Aggrenox is a medication prescribed to help prevent stroke. It contains both aspirin and dipyridamole.

¹⁰ Result from disease of the cerebral small vessels.

¹¹ Exercise principles adapted to enhance the strength, endurance, and mobility of individuals with functional limitations or those requiring extended physical conditioning.

The patient was admitted to a medical unit on April 17. The Nurse Manager (NM) of this unit was previously the wife's supervisor for a few days. We learned that the wife was unhappy with training she received while under the NM's supervision and left the position.

When the AMCD/PCS learned that the patient had been admitted to that medical unit, she immediately arranged for a transfer to another medical unit to avoid any conflict; the patient was transferred around 8:00 p.m. that same day. The AMCD/PCS told us that she had known the patient's wife for many years and that she met with the distraught wife the evening of April 19 related to issues involving her husband's care. She then facilitated a meeting with the wife and the Chief of Staff and expedited the patient's transfer to a private rehabilitation facility the next day.

The NM told us that she had brief contact with the wife during the time she was her supervisor; she also said that she was unaware the patient had been admitted to her unit on April 17. She had no contact with the patient or his wife during the hours he was on her unit. We determined that managers appropriately handled this issue. We did not confirm that the history of conflict between the wife and the NM negatively impacted the patient's care. We made no recommendations.

Medication Management: We substantiated the allegation that the patient was instructed to take his Aggrenox in a manner inconsistent with recommended administration of the medication. However, we did not find that this harmed the patient. The patient's neurologist prescribed Aggrenox to be taken "1 capsule by mouth at bedtime for 1 week, then take 2 capsules at bedtime." The patient's wife told us that she saw a private physician who told her that the medication was time released and should be taken once in the morning and once in the evening. We confirmed that the recommended dosing schedule for Aggrenox is one capsule orally in the morning and in the evening. The patient's neurologist told us that the medication can cause headaches and that she frequently instructs patients to take both doses at bedtime to alleviate the effects of headaches during the day. We found no evidence that taking the two Aggrenox capsules at bedtime had a negative impact on the patient. We made no recommendations.

Neurological Evaluation: The complainant alleged that the patient suffered a stroke in April 2007 because the neurologist did not evaluate him following a call to the TAP line in March. We did not substantiate this allegation. We could not conclude that if the patient had been examined in March he would not have had a stroke a month later.

After the March call, the TAP operator communicated the symptoms to the neurologist and reported that the wife asked that the patient "have a CT scan or get an appointment." The records show that the neurologist called the wife 19 minutes after she called the TAP line. The neurologist told us that the symptoms the wife described had been present for 2 months, and that since she did not consider them acute, she ordered a CT scan to rule out intracranial bleeding. The neurologist told the wife the patient did not need an

appointment for examination if this test was negative. The CT scan was ordered for that afternoon and was negative. The patient's medical record shows that he attended another appointment that afternoon following the CT scan and had another outpatient assessment the next day. He attended a dental hygiene appointment on March 20, indicating that his symptoms of March 15 had subsided or improved. When consulted to evaluate the patient again on April 18, the neurologist's impression was "recurrent CVA (cerebrovascular accident or stroke) while on maximal prophylactic therapy (with Aggrenox). Outlook for prevention of future CVAs is poor." The decision to forego evaluation of the patient on March 15 appeared reasonable, and we made no recommendations.

During our interview, the patient's wife expressed two specific complaints about the care he received during his hospitalization from April 17 through April 20:

IVFs. Intravenous fluids (IVFs) ordered for her husband on April 19 around 11:00 a.m. had not been started immediately. The patient's attending physician ordered IVFs due to a slight increase in his creatinine level¹² from the previous day. Progress note documentation shows that around 8:00 p.m. a nurse noted the fluids had not been started. She attempted to start the infusion, but the patient refused because his wife was not present. Documentation shows that the infusion was started later and completed at 4:45 a.m. on April 20. We found no evidence that the delay in starting the IVFs negatively affected the patient. We made no recommendations.

KT. The patient received only one complete KT session prior to discharge. His initial KT evaluation was scheduled for April 18. He missed the April 18 appointment, as well as the next scheduled appointment on the morning of April 19, because staff failed to arrange for patient escort to the clinic. His wife brought him to KT on the afternoon of April 19 and the assessment was completed. He attended the appointment scheduled for the morning of April 20, but could not stay to complete that session. The wife chose to transfer the patient to a private rehabilitation facility where he could receive more intensive therapy.

We spoke to medical center management about this issue. They instructed the PM&R Service to utilize escorts to transport inpatients to their scheduled PM&R appointments instead of waiting for patients to arrive and then cancelling their appointments when they did not show. Since corrective action was taken while we were onsite, we made no recommendations.

We did not substantiate any significant quality of care concerns. Although the wife perceived prejudicial treatment during the patient's admission, we determined that the patient received a thorough work-up and appropriate referrals for evaluation and treatment. We substantiated that the patient was instructed to take Aggrenox in a manner

¹² An indicator of renal function. Elevated levels may be indicative of dehydration.

inconsistent with the manufacturer's recommendation; however, we noted that the physician provided a clinical rationale for this decision and the patient did not suffer any harm as a result. While we found that the patient missed his initial KT evaluation due to lack of an escort, managers took appropriate action to ensure escorts are provided for clinical appointments. In general, we found the patient's care to be appropriate.

Conclusion

We determined that the medical center's use of flash sterilization in the OR was excessive and not in compliance with accepted standards. Correction of SPD deficiencies will serve to reduce this practice; however, we recommended that a more thorough review be conducted to fully assess the medical center's flash sterilization rate. An external review was recommended, since one medical center manager had previous supervisory responsibility for SPD and current SPD and OR supervisors are relatively new to their positions. An objective review is essential because of the potential impact on patient safety and infection control.

While we found that the allegations related to SPD deficiencies had merit, by the time we arrived on site, SPD management had changed and corrective actions were in progress. We found no evidence that the patient received poor care due to his wife's history of conflict with her former supervisor at the medical center. Overall, we found the patient received appropriate care.

Comments

The VISN and Medical Center Directors concurred with our findings and recommendation and provided an appropriate action plan. We will follow up on 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 7, 2008

From: Director, VA Southeast Network (10N7)

Subject: **Healthcare Inspection – Supply, Processing, and Distribution Issues and Quality of Care Concerns, WJB Dorn VA Medical Center, Columbia, South Carolina**

To: Associate Director, Atlanta Office of Healthcare Inspections

1. Attached is Columbia's response to the Office of Inspector General (OIG) site visit report 2007-02902-HI-0362.
2. I concur with the comments and actions taken by the Medical Center Director to have an external review of flash sterilization processed by April 30, 2008.

(original signed by:)

Lawrence A. Biro

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: February 6, 2008

From: Medical Center Director (544/00)

**Subject: Healthcare Inspection – Supply, Processing, and
Distribution Issues and Quality of Care Concerns, WJB
Dorn VA Medical Center, Columbia, South Carolina**

To: Director, VA Southeast Network (10N7)

1. We have reviewed the draft report of the Inspector General's Healthcare Inspection - Supply, Processing, and Distribution Issues and Quality of Care Concerns, Project Number: 2007-02902-HI-0362. We concur with the findings and suggestions.

2. We appreciate the opportunity for this review as a continuing process to improve the care to our veterans.

(original signed by:)

Brian Heckert

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

The following VISN 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:

We recommended that the VISN Director initiate an external review of the medical center's flash sterilization practices.

Concur **Target Completion Date:** April 30, 2008

The Charleston OR Nurse Manager and SPD Chief are scheduled to be here February 19, 2008 to review and make recommendations for our programs.

OIG Contact and Staff Acknowledgments

OIG Contact	Christa Sisterhen, Associate Director Atlanta Office of Healthcare Inspections (404) 929-5961
Acknowledgments	Toni Woodard, Health Systems Specialist Jerome Herbers, M.D.

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