VA | U.S. Department of Veterans Affairs

Office of the General Counsel
Washington DC 20420

APR 1 2014

In Reply Refer To:

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, NW, Suite 300
Washington, DC 20036-4505

RE: OSC File Nos. DI-13-3174

Dear Ms. Lerner:

Enclosed are the redacted and unredacted reports as described in the letter signed by VA Chief of Staff Jose D. Riojas. The Chief of Staff was delegated by Secretary Shinseki to sign the report. We hereby request that your office publish the enclosed redacted version. VA's unredacted response identifies the individuals who were interviewed during the investigation, or who conducted the investigation, by names and job titles.

If you have any questions about this request, please contact Jennifer Gray in the Office of General Counsel at 202-461-7634.

Sincerely,

Renée L. Szybala
Acting Assistant General Counsel

Enclosures

DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

March 27, 2014

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-13-3174

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Department of Veterans Affairs Western New York Healthcare System, (hereafter, the Medical Center) in Buffalo, New York. The whistleblower alleged that the Medical Center's Sterile Processing Service (SPS) engaged in conduct that may constitute a violation of law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health and safety. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary under 5 United States Code § 1213(d)(5).

The Secretary asked the Under Secretary for Health to review this matter and to take any actions deemed necessary under the above code. He, in turn, directed the Office of the Medical Inspector (OMI) to conduct an investigation. In its investigation, OMI did not substantiate the allegation that Medical Center managers had failed to properly train SPS employees and to provide manufacturer's instructions, and the allegation that employees had failed to adequately stock a sufficient number of cardiac crash carts for Medical Center use. OMI substantiated the allegation that SPS employees do not always comply with the Medical Center's standards for wearing personal protective equipment while working in SPS, although it did find evidence that management continues to take action to correct and control the personal protective equipment issue. OMI substantiated that an instrument in an opened catherization tray appeared to have a bright red substance on it, although it could not substantiate that this apparent blood was present during sterile processing, and substantiated that SPS employees occasionally failed to place indicator strips in surgical trays, and mislabeled or miscounted sterile instruments in trays. OMI could not substantiate the allegation that dental hand instruments were improperly cleaned prior to sterilization.

OMI found neither violations of laws, rules, regulations, gross mismanagement, or a substantial or specific danger to public health and safety. It made five recommendations regarding general compliance with procedures, continued training, and ensuring effective communications. Findings from the investigation are contained in the report, which I am submitting for your review. I have reviewed these findings and

agree with the recommendations in the report. We will send your office follow-up information describing actions that have been taken by the Medical Center to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

Report to the
Office of Special Counsel
File Number DI-13-3174

Department of Veterans Affairs
VA Western New York Healthcare System
Buffalo, New York

Veterans Health Administration
Washington, DC

Report Date: January 21, 2014
TRIM 2014-D-15

Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate complaints lodged with the Office of Special Counsel (OSC) by (b) (6) (hereafter, the whistleblower), at the Department of Veterans Affairs (VA), Western New York Healthcare System (VAWNYHS), Sterile Processing Service (SPS) in Buffalo, New York (hereafter, the Medical Center). The whistleblower, a Medical Supply Technician (MST) at the Medical Center from March 2010 to March 2013, consented to the release of her name, and alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule or regulation, gross mismanagement, and a substantial and specific danger to public health and safety. OMI conducted a site visit to the Medical Center on December 9-11, 2013.

Summary of Allegations

- Management's failure to properly train SPS employees and provide cleaning instructions from the manufacturer (allegation 1); and
- Management's failure to take sufficient action to correct or curtail the following behaviors (allegation 2):
  - Employees' failure to properly clean dental hand pieces, washing them only with water rather than using the required enzyme cleaning solution (allegation 2A);
  - Employees' failure to adequately stock essential supplies on cardiac crash carts (allegation 2B); and,
  - Employees' failure to wear personal protective equipment (PPE) while working within SPS (allegation 2C).

Additional Issues Raised by the Whistleblower Onsite

- Issue 1: The whistleblower alleged that on October 22, 2013, two instrument sets opened in the catheterization suite were found to contain blood and had to be returned to SPS for additional cleaning.
- Issue 2: The whistleblower alleged that SPS employees frequently fail to place sterilization indicators in peel pouches and sterilization locks on operating room (OR) trays, and are mislabeling the number of instruments in sets, which requires those items to be reprocessed. On one occasion in 2011, the missing sterilization lock on an OR tray was not discovered until it was about to be opened in the OR.

Conclusions

- OMI did not substantiate the allegation that Medical Center managers have failed to properly train SPS employees and to provide manufacturer's processing instructions. Historically, all full-time SPS MSTs achieved Level 1 required training, and currently they have achieved Level 1 and 2 training certifications. There is evidence that substantive efforts have been made since 2012 to provide both hard copy and online

access to manufacturer's reprocessing instructions and standard operating procedures (SOP). (addresses allegation 1)

- OMI **could not substantiate** the allegation that dental hand instruments were improperly cleaned prior to sterilization. Management (Chief, Dental Service) appropriately provided follow up of a manufacturer's change in sterilization time, which resulted in a change to the SOP. Any delay in identification of the change in the manufacturer's instructions had no reported clinical consequence. (addresses allegation 2A)

- OMI **did not substantiate** the allegation that employees fail to adequately stock a sufficient number of cardiac crash carts for Medical Center use. (addresses allegation 2B)

- OMI **substantiates** the allegation that SPS employees do not always comply with the Medical Center's standards for wearing PPE while working in SPS. (addresses allegation 2C)

- OMI found evidence that management continues to take action to correct and control the PPE issue, providing training for compliance with PPE standards, and appropriately managing cases of noncompliance in their efforts to protect the noncompliant employee. (addresses allegation 2C)

- While OMI **substantiates** that an instrument in an opened catheterization tray appeared to have a bright red substance on it, OMI could not substantiate that this apparent blood was present during sterile processing. The tray was returned to SPS and a replacement tray provided. No delays were reported and there is no evidence of an adverse patient event. (addresses Additional Issue 1)

- OMI **substantiates** the allegation that SPS employees occasionally failed to place indicator strips in surgical trays, and mislabeled or miscounted sterile instruments in trays. (addresses Additional Issue 2)

- OMI cannot make a conclusion about the increase in Close Call reporting of the frequency to "fail to place sterilization indicators in peel pouches and sterilization locks on OR trays, and the mislabeling of instruments in sets, which requires those items to be reprocessed." The increase may be the result of the Medical Center's greater emphasis on reporting and is evidence of a strong quality improvement environment, which supports SPS' opportunity to use the data to strengthen their quality assurance and improvement efforts. (addresses Additional Issue 2)

Recommendations

The Medical Center should:

1. Support the ongoing relationship between Dental Office staff and SPS employees to continue their effective communications, with opportunities for information exchange on instrument processing.

2. Continue their program of providing SPS employees training on the importance of using PPE.

3. In conjunction with Human Resources leadership, develop an appropriate approach to deal with SPS employees who continue to be noncompliant with PPE use.

4. Continue SPS' practice of two-person sterile tray inspections and two-person signature sign-offs on sterile processing product inspections.

5. Develop a systematic approach to analyzing SPS Close Call quality improvement data. Trending and tracking this information can be used to develop action items and to monitor changes.

Summary Statement

OMI's investigation and review of its findings did not find violations or apparent violations of statutory laws, mandatory rules, or regulations.

I. Introduction

USH requested that OMI investigate complaints lodged with the OSC by the whistleblower about the Medical Center's SPS. The whistleblower was an MST at the Medical Center from March 2010 to March 2013; she consented to the release of her name, and alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule or regulation, gross mismanagement, and a substantial and specific danger to public health and safety. OMI conducted a site visit to the Medical Center on December 9-11, 2013.

II. Facility Profile

The Medical Center is part of Veterans Integrated Service Network (VISN) 2 and consists of two health care facilities in Buffalo and Batavia, as well as community-based outpatient clinics in Dunkirk, Jamestown, Lackawanna, Lockport, Niagara Falls, Olean, and Springville. Opened in 1950, the Medical Center provides medical, surgical, mental health, and long-term care services through a range of inpatient and outpatient programs. It is the main referral center for cardiac surgery, cardiology, and comprehensive cancer care for central and western New York and northern Pennsylvania. The Medical Center is academically affiliated with the State University of New York at Buffalo, along with 66 additional universities and professional schools in biomedical sciences, medicine, nursing, nurse anesthesia, occupational and physical therapy, pharmacy, psychology, speech pathology, and social work.

III. Allegations

The whistleblower's allegations are:

- Management's failure to properly train SPS employees and provide cleaning instructions from the manufacturer (allegation 1); and
- Management's failure to take sufficient action to correct or curtail the following behaviors (allegation 2):
  - Employees' failure to properly clean dental hand pieces, washing them only with water rather than using the required enzyme cleaning solution (allegation 2A);
  - Employees' failure to adequately stock essential supplies on cardiac crash carts (allegation 2B); and,
  - Employees' failure to wear PPE while working within SPS (allegation 2C).

IV. Conduct of Investigation

An OMI team consisting of (b) (6) M.D., Deputy Medical Inspector for Professional Services; (b) (6), M.D., Medical Investigator; (b) (6), R.N., F.N.P., Clinical Program Manager; (b) (6), R.N., F.N.P., Clinical Program Manager; and a VA subject matter expert, (b) (6), Health Systems Specialist, National Program Office for Sterile Processing, conducted the site visit. OMI conducted

telephone interviews with the whistleblower on Friday, December 6, 2013, and with the acting nurse executive, (b) (6), R.N., (newly hired as Associate Director for Patient Nursing Services/Nurse Executive) on December 11, 2013. While onsite, OMI conducted in-person interviews with the individuals noted in the list below. In addition, OMI received a written statement from the Chief, Dental Service, (b) (6), D.D.S. OMI reviewed relevant policies, procedures, reports, memorandums, and additional documents as listed in Attachment A. OMI toured the SPS twice: one scheduled tour during the day shift, and one unscheduled tour during the evening shift. OMI also toured the OR area. Entrance and exit briefings were held with Medical Center leadership.

OMI interviewed the following individuals during the site visit:

- (b) (6), R.N. (formerly, Nurse Executive)
- (b) (6), R.N., OR Nurse Manager
- (b) (6), R.N., OR Nurse (formerly, Chief, SPS)
- (b) (6), R.N., OR Assistant Manager (formerly, Assistant Chief, SPS)
- (b) (6), MST, SPS
- (b) (6), Chief, SPS (2013)
- (b) (6), R.N., Assistant Chief, SPS (2013)
- (b) (6), MST, SPS
- (b) (6), MST, SPS
- (b) (6), M.D., Orthopedic Surgeon
- (b) (6), Administrative Officer assigned to SPS
- (b) (6), MST, Gastrointestinal Service
- (b) (6), R.N., Infection Preventionist
- (b) (6), R.N., Chief, Performance Management
- (b) (6), R.N., Risk Manager

Office of General Counsel reviewed OMI's findings to determine whether there was any violation of law, rule, or regulation.

OMI **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. OMI **did not substantiate** allegations when the facts showed the allegations were unfounded. OMI **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

V. Background

The Centers for Disease Control and Prevention (CDC) reported that, in 2010, an estimated 51.4 million inpatient surgical procedures were performed, with earlier data suggesting that a nearly equal number of outpatient surgeries or procedures are done in the United States on an annual basis.[1,2] Most procedures place the patient in contact

[1] CDC, Inpatient Surgery, National Hospital Discharge Survey: 2010 table, Procedures by selected patient characteristics – Number by procedure category and age. Retrieved from http://www.cdc.gov/nchs/fastats/insurg.htm.

with medical devices or surgical instruments, with the risk for exposing the individual to pathogenic, or dangerous, microorganisms. The proper selection and use of cleaning, disinfecting, and sterilizing techniques for devices or instruments is critical to the prevention of transmission of environmental and person-to-person pathogens.[3]

Three terms that are critical to understanding sterile processing of devices and instruments are the concepts of cleaning, disinfecting, and sterilizing. CDC defines them as:

> **Cleaning** is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.
>
> **Disinfection** describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health care settings, disinfection usually occurs with liquid chemicals, or wet pasteurization. An agent that kills germs on living tissue is referred to as an antiseptic.
>
> **Sterilization** is a process that physically or chemically destroys or eliminates all forms of microbial life. This can be accomplished through steam under pressure, dry heat, gases, and liquid chemicals.[4]

Factors that impact processing success are the type and levels of contamination, the necessary germicidal concentrations and exposure times, the physical structure of the medical equipment, and the temperature and humidity of the decontamination and sterilization environment.[5]

An effective approach, devised 30 years ago by Earle H. Spaulding to organize disinfection and sterilization processes, categorizes patient care equipment, medical items, and surgical supplies according to the degree of risk for infection involved in their use.[6] For example, a *critical* item that is contaminated with microorganisms might confer a high risk for infection; this category includes instruments, cardiac and urinary catheters, implants, and probes used in sterile body cavities. *Critical* items require sterilization. *Semicritical* items come in contact with mucous membranes and nonintact skin. This group of items might include respiratory and anesthesia equipment, scopes

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[2] CDC National Center for Health Statistics, Press Release: January 28, 2009. Retrieved from http://www.cdc.gov/media/pressrel/2009/r090128.htm.

[3] CDC: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Rutala, W. A., Weber, D. J. and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Retrieved from http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf.

[4] Ibid, p. 9.

[5] Ibid, p. 9.

[6] ibid, p. 10.

that enter the gastrointestinal tract, laryngoscope blades, and some probes or catheters. *Semicritical* items require, at a minimum, high-level disinfection, usually accomplished through chemical disinfection, with a goal to prevent infection. *Noncritical* equipment and supplies may come into contact with intact (unbroken) skin, but not mucous membranes. *Noncritical* items may include patient care equipment (bed pans, blood pressure cuffs) or environmental surfaces. Usually, *noncritical* items can be cleaned at the point of use, and are not processed in SPS.[7]

During the whistleblower's employment, VA guidance for leaders and employees on the supply, processing, and distribution of medical supplies, including decontamination and sterilization of reusable medical supplies and equipment included: VA Handbook 7176, Supply, Processing, and Distribution (SPD): Operational Requirements, August 16, 2002; Veterans Health Administration (VHA) Directive 2009-004, Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities, February 9, 2009; and VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements, June 26, 2009. On March 13, 2012, VA Directive and Handbook 7176, dated August 16, 2002, was rescinded, with the notation that the critical elements of the SPD section were realigned under the VHA National Program Office for Sterile Processing, and the Procurement and Logistics Office. National guidance directed that all medical centers were to follow the current VA directives on RME (2009) and the current sterilization process standards set forth by the American Association of Operating Room Nurses, Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Settings (updated annually); the American National Standards Institute (ANSI)/American Advancement of Medical Instrumentation (AAMI) publication, *ST79:* Comprehensive Guide to Steam Sterilization and Sterility Assurance for Health Care Facilities (ANSI/AAMI ST79) (2010); and the International Association of Healthcare Central Service Materiel Management: Healthcare Leadership Manual (2010), and the 7th Edition Central Service Technical Manual (2007).

The Medical Center has local policies in place to guide and support SPS services: VAWNYHS Center Memorandums No. 00-169, Sterilization Processing (SPS) Functions and Organizational Alignment; No. 11-036, Guidelines for the Maintenance, Cleaning, High-Level Disinfection/Sterilization and Transport of Endoscopes; and No. 00-084, Guidelines for the Cleaning and Disinfection of Noncritical Reusable Medical Equipment.

VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements, June 26, 2009, directed a national change in SPS structure and oversight, by creating VISN SPD Management Boards and aligning the day-to-day supervision of local SPS functions and oversight of the Chief, SPS, under the Nurse Executive. To comply with

[7] CDC: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Rutala, W. A., Weber, D. J. and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Retrieved from http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. p. 11.

this Directive, the Medical Center updated its policies and structure, and hired a new Chief, SPS, in 2009. OMI was provided an historical perspective of these actions, learning that a significant effort was required to bring SPS policies and employee training in compliance. Through interviews, OMI learned that in mid-2012, Medical Center leadership had concerns about the progress in SPS, and this resulted in SPS leadership changes. The new SPS leadership requested a technical assistance visit from the National Program Office for Sterile Processing to guide them with implementation changes to improve SPS training and compliance. The Program Office made two visits: October 22-26 and November 5-9, 2012. Areas for improvement were identified and action plans developed. The Medical Center Director assigned an Acting Nurse Executive and detailed an experienced OR clinical nurse leader to the role of Acting Chief, SPS. In early 2013, the Medical Center hired an experienced, permanent Chief, SPS, and assigned the OR clinical nurse leader to the role of Assistant Chief, SPS. In October 2013, the Medical Center Director also assigned the Business Manager for Clinical Operations to a year-long SPS detail to assist with administrative operations. Recently, the Director selected the Acting Nurse Executive for the permanent position of Associate Director for Patient Nursing Services/Nurse Executive. She assumed her duties the week following OMI's site visit.

VI. Findings

Allegation 1

Management's failure to properly train SPS employees and provide cleaning instructions from the manufacturer.

Findings

VHA Directive and VA Handbook 7176, in effect through March 12, 2012, required an initial orientation and continued on-the-job training for all SPS employees with SPS Level 1 training, to occur in the initial 20 weeks of work. After completion of Level 1 training, SPS employees can take a certification examination, which confers Level 2 training proficiency. Level 2 training certification must be renewed annually through documentation of annual continuing education. OMI reviewed competency folders and found that all SPS employees, prior to 2012, had earned Level 1 training and had participated in documented continuing education.

The Chief, SPS, reported that, per current policy, on-the-job training and continuing education requirements remain intact and that all eight current, full-time SPS employees have both Level 1 and Level 2 training. These training and education requirements are consistent with the recommendations made by ANSI/AAMI ST79 (2010) under 4.3 Training and Continuing Education.[8]

[8] ANSI/AAMI *ST79:* 2010, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, is a recommended resource for steam sterilization and sterile processing activities. Personnel engaged in sterile processing should receive both an initial orientation and on-the-job training. A day-to-day orientation program is recommended and should be designed to lead to

Two new employees are in the process of completing Level 1 training. The Medical Center also has a new SPS employee orientation checklist that provides guidance and documentation for a minimum of 12 weeks of training with ongoing competency assessments.

When new equipment is purchased or loaned to the Medical Center, SPS employees on both tours of duty are trained by the manufacturer's representative, and competency is documented on the SPS Master Index.[9]

While OMI could not determine the number of SOP documents that were available prior to 2011, we learned that, since 2009, there has been an ongoing effort to convert all manufacturers' processing instructions to SOPs. OMI viewed the current SPS Master Index, a list of 131 individual SOPs, and the dates of completed reviews by each SPS employee and found that the 8 current, full-time SPS employees have each completed from 107 to 118 SOP reviews, with 1 new employee achieving 29 SOPs to date. The overall completion rate of 72 percent includes the new employees. There is an ongoing process to update and add new SOPs, with the goal of each employee accomplishing 100 percent of SOP reviews.

During its tour of the clean preparation area of SPS, OMI viewed three circular vertical files that contained labeled shelves with hard copies of each SOP (see Attachment B.); these are available as a resource to all SPS employees. Additionally, current policy and training books are available on nearby shelves.

All SPS employees interviewed reported an awareness of oneSOURCE®, the national online database for locating manufacturer's processing instructions, and all knew how to access the information.[10] The Medical Center provided SPS employees with guidance and access to oneSOURCE® in mid-2013.

Conclusion

- OMI **did not substantiate** the allegation that Medical Center managers have failed to properly train SPS employees and provide manufacturer's processing instructions. Historically, all full-time SPS MSTs achieved Level 1 required training, and currently, they have achieved Level 1 and 2 training certifications. There is evidence that substantive efforts have been made since 2012 to provide both hard copy and online access to manufacturer's reprocessing instructions and SOPs.

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competency-based knowledge and skills in all tasks performed in the sterile processing department (p. 38).

[9] SPS Master Index is a Medical Center SPS database worksheet containing all current SOPs and the names of SPS employees, with ongoing records of SOP review and competency assessments.

[10] Best Practice Professionals, Inc. developed the oneSOURCE® document site, an electronic database that provides immediate access to manufacturers' Instructions for Use documents. Retrieved from http://www.onesourcedocs.com/member/.

Two new employees are in the process of completing Level 1 training. The Medical Center also has a new SPS employee orientation checklist that provides guidance and documentation for a minimum of 12 weeks of training with ongoing competency assessments.

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Conclusion

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Recommendation

None

Allegation 2

Management's failure to take sufficient action to correct or curtail the following behaviors:

A. Employees' failure to properly clean dental hand pieces, washing them only with water rather than using the required enzyme cleaning solution;
B. Employees' failure to adequately stock essential supplies on cardiac crash carts; and
C. Employees' failure to wear PPE while working within SPS.

Findings

Allegation 2A

Employees' failure to properly clean dental hand pieces, washing them only with water rather than using the required enzyme cleaning solution.

A handbook of current dental SOPs and manufacturers' instructions is available in the SPS resource area. OMI reviewed SOPs for several types of dental equipment. Dental hand instruments (e.g., mirrors, probes) are cleaned and sterilized, and may be precleaned using water, enzymatic, or nonenzymatic solutions. They often receive precleaning at the point of use.[11] Other types of dental hand pieces include drill parts and low speed hand pieces.

OMI queried the Chief, Dental Service, about any reported concerns on the failure to properly clean dental hand pieces. The Chief described an issue that occurred in 2012 of inadequate sterilization relating to a specific type of dental hand piece, called a Star Titan straight nose cone with motor (no longer used at the Medical Center). The equipment was only used for adjusting acrylic dentures when they were outside of the mouth. Since the cone was not used intraorally, it is classified as a semicritical item. The original SOP recommended a sterilization time of 4 minutes; however, in 2012, the manufacturer changed the recommended sterilization time to 10 minutes. While the Medical Center could not provide documentation of receipt of this change in sterilization times from the manufacturer, the Chief, Dental Service made SPS aware of the change, and a new SOP and competency checklist for the SPS staff were developed and implemented.

[11] American Dental Association, July 2009, Sterilization and Disinfection of Dental Instruments, and CDC: Guidelines for Infection Control in Dental Health Care Settings – *2003*. MMWR 2003; 50 (No RR-17). Retrieved from http://www.ada.org/sections/professionalResources/pdfs/cdc_sterilization.pdf.

After becoming aware of the changes in hand piece sterilization times, the Chief, Dental Service also reviewed the dental postprocedure infection rates, and found no increase. He noted that dental postprocedure infection rates are monitored and reported to the Medical Center's Surgical and Invasive Procedure Performance Improvement Committee: there have been no statistically significant changes in this data over the past several years.

Conclusion

- OMI **could not substantiate** the allegation that dental hand instruments were improperly cleaned prior to sterilization. Management (Chief, Dental Service) appropriately provided follow up of a manufacturer's change in sterilization time, which resulted in a change to the SOP. Any delay in identification of the change in the manufacturer's instructions had no reported clinical consequence.

Recommendation

The Medical Center should:

1. Support the ongoing relationship between Dental Office staff and SPS employees to continue effective communications, with opportunities for information exchange on instrument processing.

Allegation 2B

Employees' failure to adequately stock essential supplies on cardiac crash carts.

During her interview, the whistleblower described this allegation as SPS' failure to have a sufficient number of backup crash carts available for the Medical Center on weekends and holidays. She did not provide specific dates or details for this allegation, nor did she describe any evidence of threats to patient safety.

Medical Center SOP No. 140, Pharmacy Service, Cardiopulmonary Resuscitation Medication Kit and IV Solution Kit Replacement Procedure, states that the Medical Center has 30 cardiac arrest carts maintained by SPS. Twenty-five carts are deployed throughout the Medical Center at locations designated by the policy, including the Emergency Department, radiology, OR, intensive care units, cardiac catheterization lab, inpatient wards, dialysis, pacemaker clinic, endoscopy suites, and other units. There are up to five backup crash carts available as replacements. OMI viewed multiple backup carts in the SPS-Logistics area during its tours.

SOP No. 140 describes the procedures for cleaning and restocking carts after use, and for resupplying expired supplies or medications. Pharmacy stocks each cart with a cardiopulmonary resuscitation medication kit and an intravenous solution kit, and maintains an additional 5 kits of each as backup, for a total of 35 kits. OMI learned that if cardiac crash carts are used on a weekend, replacements are provided from the pool

of extra carts in the SPS-Logistics area on the third floor (see Attachment D), or a cart can be appropriated from one of several clinical areas where patients are not present on weekends. A crash cart log board, outside of the SPS-Logistics area, specifies the location and status of each crash cart. Fully stocked, backup cardiac crash carts are stored outside of SPS-Logistics. While SPS is responsible for processing any RME stocked on the cardiac crash carts, medications are stocked by pharmacy; Logistics maintains all other crash cart restocking activities.

Presently, Logistics is responsible for restocking crash carts, although SPS employees are available at all times, should they be needed to clean resuscitation equipment. In February 2012, the Medical Center instituted an on-call policy for the SPS MSTs. When called during a night, holiday, or weekend, the SPS MST is expected to report for duty within 30 minutes.

Per the policy, Medical Center Memorandum No. 11-018, Cardiopulmonary Resuscitation Management, October 25, 2013, the Cardiopulmonary Resuscitation Committee reviews all cardiac crash cart events and notes any concerns or problems in its quality assurance reports. A Cardiopulmonary Resuscitation Committee member, who conducts postresuscitation reviews and orients all intensive care unit staff, informed OMI that there have not been any reports or evidence of unavailable cardiac crash carts.

Conclusion

- OMI **did not substantiate** the allegation that employees fail to adequately stock a sufficient number of cardiac crash carts for Medical Center use.

Recommendation

None

Allegation 2C

Employees' failure to wear PPE while working within SPS.

During interviews with staff, supervisors, and leadership, OMI learned that there is a history of some SPS employee noncompliance with the appropriate use of PPE while working in SPS, in both the decontamination and the clean preparation areas. This issue was addressed during the National Program Office for Sterile Processing's 2012 site visits. Employees told OMI that since the 2012 site visits, they have seen improvement in educating SPS employees on PPE, and in management's enforcement of compliance with PPE use. During an unannounced visit to SPS on the evening shift, OMI observed a partial PPE noncompliance: an individual working in the decontamination area was not wearing the recommended gloves; instead he was

wearing two sets of nitrile gloves (this type of glove is not considered protective enough for an employee in decontamination).[12]

Medical Center policies providing guidance on the use of PPE include Medical Center Memorandum 00-113, Infection Prevention and Control Program; Medical Center Memorandum 11-047; Exposure Control Plan for Blood Borne Pathogens; and Medical Center Memorandum 00-035, Personal Protective Equipment Program. These policies follow Occupational Safety and Health Administration (OSHA) regulations and guidelines provided by the CDC (health care associated infections) and ANSI/AAMI ST79.

ANSI/AAMI ST79 details the requirements for SPS staff attire in section 4.5. Attire for SPS employees in decontamination areas is based on OSHA regulation, 29 Code of Federal Regulations (CFR) 1910.1030, requiring that each facility have in place the engineering and work place controls to protect employees from environmental contaminants and blood-borne pathogens.[13] ANSI/AAMI ST79, section 4.5.2 and 4.5.3, details each specific article of PPE to be worn by employees in decontamination and sterilizing areas. The Chief, SPS, is currently drafting a Medical Center SPS S1007, Dress Attire, on appropriate dress and PPE use in SPS. During its tours of SPS, OMI observed PPE information posters in both decontamination and sterile preparation areas.

OMI reviewed employee folders for evidence they were held accountable for the proper use of PPE, and found documentation (in more than one record) that supervisors and SPS leadership advised and counseled employees on compliance with PPE.

Conclusions

- OMI **substantiates** the allegation that some SPS employees do not always comply with the Medical Center's standards for wearing PPE while working in SPS.

- OMI found evidence that management continues to take action to correct and control the issue, providing training for compliance with PPE standards, and appropriately managing cases of noncompliance, in their efforts to protect the noncompliant employees.

Recommendations

The Medical Center should:

[12] Nitrile gloves are latex-free disposable gloves, not recommended for personal protection in decontamination areas.

[13] Occupational Safety and Health Administration (OSHA), Occupational Safety and Health Standards: Occupational exposure to blood-borne pathogens (29 CFR Part 1910.1030). Retrieved from http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title29/29cfr1910_main_02.tpl.

2. Continue their program of providing SPS employees training on the importance of using PPE.
3. In conjunction with Human Resources leadership, develop an appropriate approach to deal with SPS employees who continue to be noncompliant with PPE use.

***Additional Issues*: the whistleblower's additional SPS concerns.**

Additional Issue 1

The whistleblower alleges that on October 22, 2013, two instrument sets opened in the catheterization suite were found to contain blood and had to be returned to SPS for additional cleaning.

Findings

The whistleblower told OMI that her last day of work at the Medical Center was (b) (6) 2012, and that her final day of employment was (b) (6) 2013. The alleged event had occurred more than 6 months later. The whistleblower claimed that, "a bunch of trays went to the 'cath lab' with blood still on them," adding that people were not performing or taking their jobs seriously. OMI found no evidence that this was witnessed by the whistleblower; it did not occur during her term of employment.

OMI interviewed the Chief, SPS, and reviewed the Close Call report for this event, which included photographs of the forceps and the SPS tray count sheet.[14] The Chief reported he was notified by OR staff of this discovery. He went to the catheterization suite and viewed the first tray, reporting that he saw nothing untoward in that tray. He was shown a second tray that contained a forceps with "obvious blood." He provided a replacement sterile instrument tray, and queried OR staff about the event. He observed that the blood on the instrument appeared to be bright red, not dark-colored (as blood would appear if it had been present during sterilization). The Chief concluded that the blood was fresh and thus must have contaminated the instrument after the tray was opened in the catheterization suite.

He, nevertheless, addressed the matter with SPS staff, reinforcing the requirement that sterile trays receive two SPS inspection signatures before sterilization. The matter was reviewed and closed by the Risk Manager. OMI reviewed photos of the instrument tray, confirming the bright red color on the forceps. OMI also reviewed the photo of the SPS tray count sheet for this specific tray, and confirmed the presence of two signatures. The Close Call report did not indicate a delay in care or an adverse event.

Conclusions

- While OMI **substantiates** that an instrument in an opened catheterization tray appeared to have a bright red substance on it, OMI **could not substantiate** the

[14] Close Call reports are filed by OR staff with the Patient Safety Manager when an event occurs that is considered to be problematic, but no patient injury or harm occurred.

implication that this apparent blood was present on the instrument during sterile processing. The tray was returned to SPS and a replacement tray provided. No delays were reported and there is no evidence of an adverse patient event.

Recommendation

The Medical Center should:

4. Continue the SPS practice of two-person sterile tray inspections and two-person signature sign-offs on sterile processing product inspections.

Additional Issue 2

The whistleblower alleges that SPS employees frequently fail to place sterilization indicators in peel pouches and sterilization locks on OR trays, and are mislabeling the number of instruments in sets, which requires those items to be reprocessed. On one occasion in 2011, the missing sterilization lock on an OR tray was not discovered until it was about to be opened in the OR.

Findings

OMI learned that the Medical Center has identified issues related to the failure to place integrators in peel pouches, and the mislabeling of instrument counts, or missing instruments.[15] OMI reviewed 154 OR Close Call reports, involving SPS that were submitted to the Patient Safety Manager from March 2010 through September 2013. There were 8 reports for 2010, 11 reports for 2011, 49 reports for 2012, and 86 reports for 2013. When queried, Medical Center leadership attributed this increase to the arrival in 2011 of a new OR Nurse Manager who encouraged event reporting. To add perspective to these numbers, the Medical Center's VA National Surgical Quality Improvement Program (VASQIP) data indicate that there were 1,445 surgeries (all types) performed at the Medical Center from July 1, 2012, to June 30, 2013.[16]

OMI identified 76 Close Call reports between 2011-2013 where instruments were missing or the instrument count was incorrectly documented. OMI found 44 incidents

[15] Sterile processing integrating indicators (integrators) are placed inside surgical instrument packs to monitor critical parameters of steam sterilization. They contain a colored bar that represents a clear and unambiguous indicator of successful sterilization. Retrieved from http://www.steris.com/products/view.cfm?id=3250. Indicator tapes are placed on the outside of packages for sterilization. They can be used as tape to close the peel pack, which is designed to be opened without compromising the sterility of the contents. There are indicator tapes that may be used with steam or gas process sterilization. After sterilization, the indicator print changes color. Retrieved from http://www.sterislifesciences.com/Products/Process-Indicators/Chemical-Indicators/Indicator-Tapes.aspx?utm_source=google&utm_medium=cpc&utm_campaign=LS-Process+Indicators&utm_term=indicator%20tapes&utm_content=sAYIJla2Z_dc|pmt|b|pkw|indicator%20tapes|pcrid|32182414195&gclid=CMbTjOiUx7sCFY47Mgodn2IAiA.

[16] VASQIP is the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. National VA Surgical Quality Improvement Program.

where the surgical procedure was either delayed or cancelled because of a problem originating within SPS. OMI found four cases where integrators were missing in the sterile pouches and the RME could not be used. One report in 2013 described a problem with a missing lock. OMI was unable to determine whether the lock was not placed in SPS or had become dislodged after leaving SPS. Other events reported broken or damaged instruments, improper cleaning, or compromised sterility. The current Chief, SPS, who has occupied the position for about 6 months, reported that he requires two SPS employees to cosign the count sheet for sterile processing trays, and conducts spot checks of trays as part of a quality control program.

OMI queried SPS staff about sterilization locks. Tamperproof instrument container locks are used to seal surgical instruments inside a case prior to sterilization; the lock contains an indicator that changes color when exposed to sterilizing conditions (see Attachment C). The tamperproof lock would indicate compromised sterilization if broken.

The previous Chief, SPS, reported she discovered that the sterilization locks used by SPS did not have color sterilization indicators, and so she purchased the new type of lock with the indicator. She brought in the manufacturer's representative to provide training to both shifts of SPS employees. OMI did not learn of any other problems with the locks, other than the absence of one reported in a 2013 Close Call report in which the tray was removed from service and not used. The current Chief, SPS, tracks the collective data from Close Call reports involving SPS.

OMI reviewed the Medical Center's surgical data captured in the VASQIP, selecting postoperative sepsis rate as the best potential indicator that SPS failed to properly sterilize surgical supplies and instruments.[17] The Medical Center's postoperative sepsis rate for 2011 through the fourth quarter of 2013 has declined, and is less than VA's national average.[18] The data are reflected in a graph and table (Attachment E).

Conclusions

- OMI **substantiates** the allegation that SPS employees occasionally failed to place indicator strips in surgical trays, and mislabeled or miscounted sterile instruments in trays.

- OMI cannot make a conclusion about the increase in Close Call reporting of the frequency to "fail to place sterilization indicators in peel pouches and sterilization locks on OR trays, and the mislabeling of instruments in sets, which requires those items to be reprocessed." The increase may be the result of the Medical Center's greater emphasis on reporting and is evidence of a strong quality improvement

[17] Postoperative sepsis rate is a measure of patient infections following surgical procedures. Rates are usually calculated as number of infections per 1,000 applicable surgeries, risk adjusted.
[18] VHA Support Service Center, Strategic Analytics for Improvement and Learning (SAIL), VISN 2 Buffalo. Retrieved from http://vssc.med.va.gov.

environment, which supports SPS' opportunity to use the data to strengthen their quality assurance and improvement efforts.

Recommendation

The Medical Center should:

5. Develop a systematic approach to analyzing SPS Close Call quality improvement data. Trending and tracking this information can be used to develop action items and to monitor changes.

Attachment A
Documents and Resources Reviewed by the OMI

1. American National Standards Institute/American Advancement of Medical Instrumentation ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, 2010/2011.

2. Association of Perioperative Registered Nurses, Perioperative Standards and Recommended Practices, 2012.

3. Centers for Disease Control and Prevention: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Rutala, W.A., Weber, D.J. and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

4. Centers for Disease Control and Prevention: Ambulatory and inpatient procedures in the United States, 1996. Atlanta, GA, 1998:1-39.

5. Centers for Disease Control and Prevention: Guidelines for Infection Control in Dental Health Care Settings *(2003).* MMWR 2003; 50 (No.RR-17).

6. Centers for Disease Control and Prevention: Healthcare-associated Infections (HAI). Retrieved from http://www.cdc.gov/hai/.

7. International Association of Healthcare Central Service Materiel Management, (2010): Healthcare Leadership Manual. Chicago, IL.

8. International Association of Healthcare Central Service Materiel Management, (2007): Central Service Technical Manual (7^{th} ed.) Chicago, IL: International Association of Healthcare Central Service Material Management.

9. One Source® Documents: http://OneSourcedocs.com.

10. VA Handbook 7176, Supply, Processing, and Distribution (SPD) Operational Requirements, August 16, 2002 (rescinded March 13, 2012).

11. VA Notice 12-01, Rescission Notice, March 13, 2012.

12. VAWNYHS, Center Memorandum No. 00-035, Personal Protective Equipment Program, February 1, 2013.

13. VAWNYHS, Center Memorandum No. 00-113, Infection Prevention and Control Program, January 28, 2013.

14. VAWNYHS, Center Memorandum No. 00-169, Sterilization processing (SPS) Functions and Organizational Alignment, March 1, 2012.

15. VAWNYHS, Center Memorandum No. 11-84, Guidelines for the Cleaning and Disinfection of Noncritical Patient Care Equipment, February 1, 2012.

16. VAWNYHS, Center Memorandum No. 11-36, Guidelines for the Maintenance, Cleaning, High-level Disinfection/Sterilization and Transport of Endoscopes, January 15, 2010.

17. VAWNYHS, Center Memorandum No. 11-036, Guidelines for the Maintenance, Cleaning, High-level Disinfection/Sterilization and Transport of Endoscopes, January 29, 2013.

18. VAWNYHS, Center Memorandum No. 11-047, Exposure Control Plan for Blood-Borne Pathogens, November 16, 2012.

19. VAWNYHS, Standard Operational Procedure No. 140: Pharmacy Service, Cardiopulmonary Resuscitation Medication Kit and IV Solution Kit Replacement Procedure, April 2013.

20. VAWNYHS, Center Memorandum No. 11-018, Cardiopulmonary Resuscitation Management, October 25, 2013.

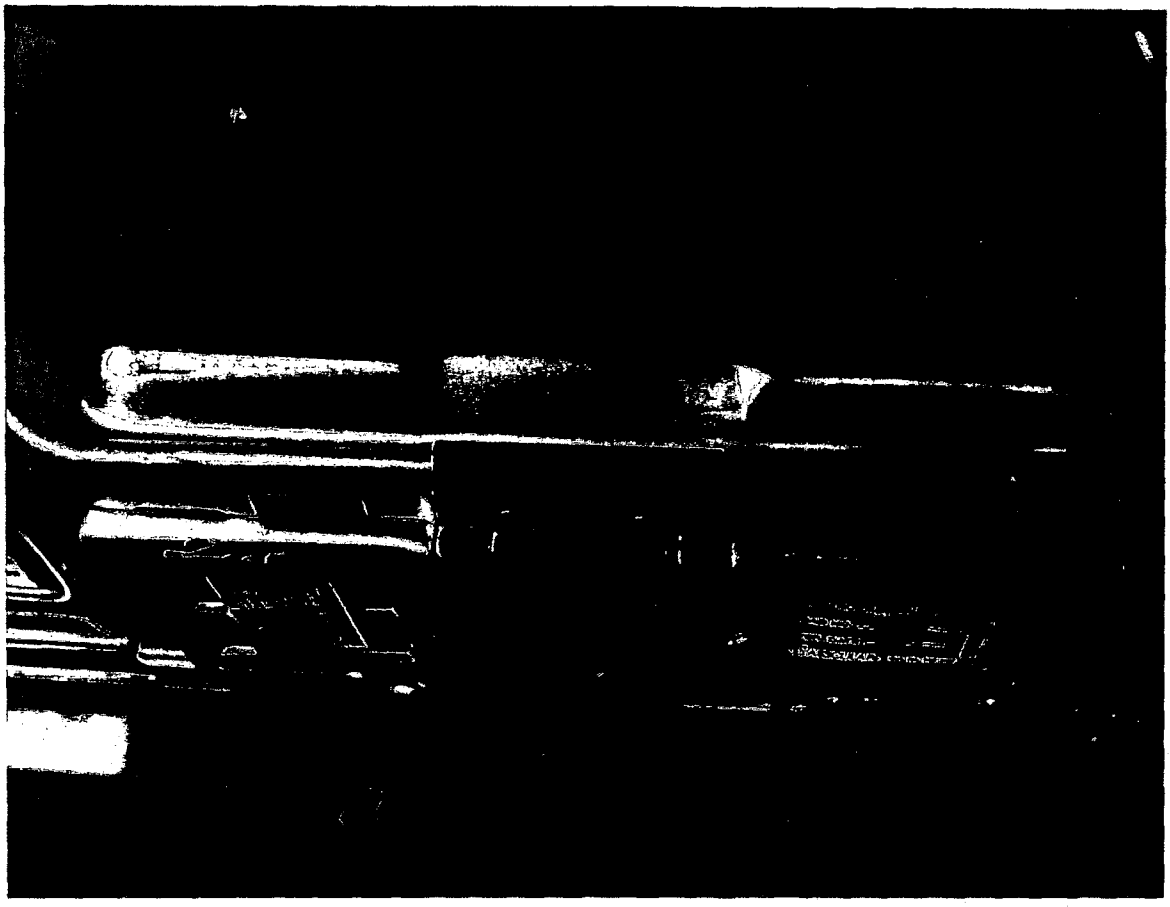
21. VHA Directive 2009-004, Use and Reprocessing of Reusable Medical Equipment (RME), February 9, 2009.

22. VHA Support Service Center, Strategic Analytics for Improvement and Learning (SAIL), VISN 2 Buffalo. Retrieved from http://vssc.med.va.gov.

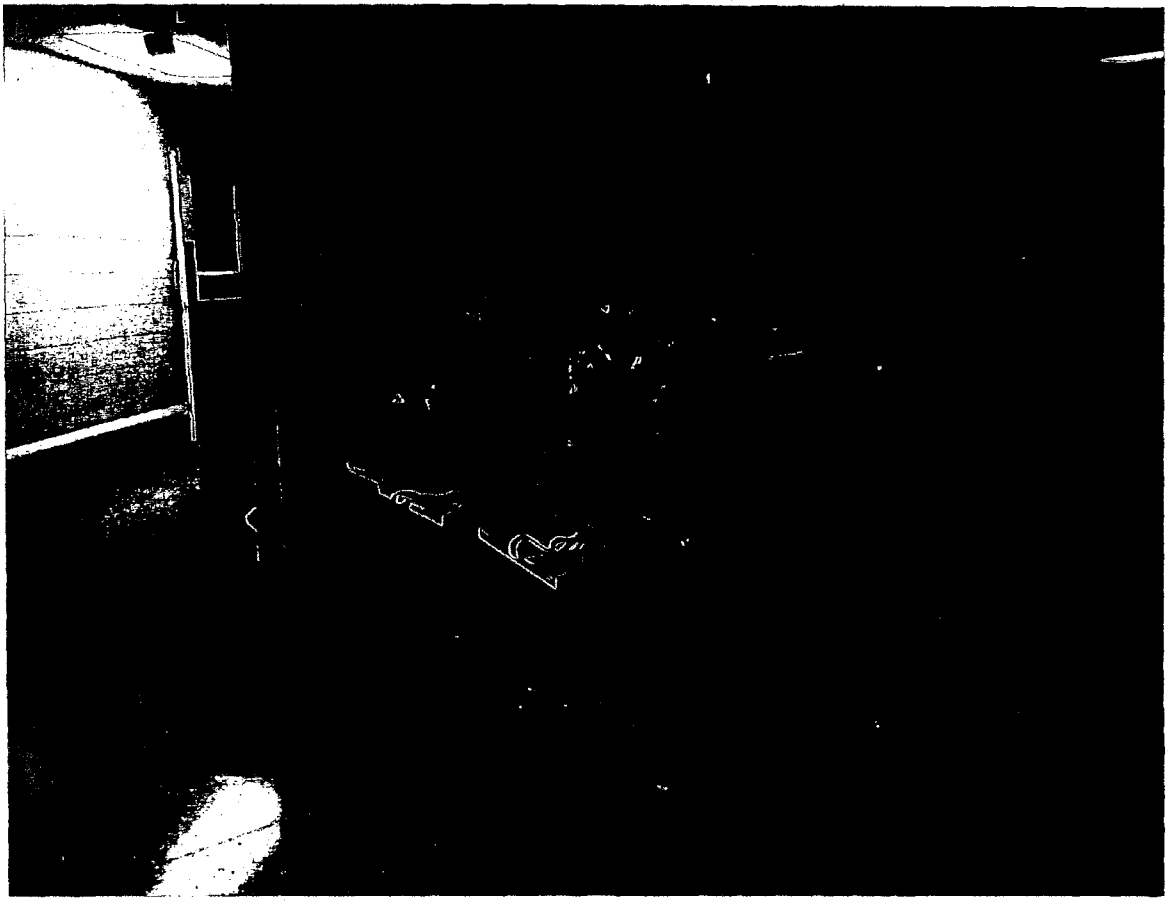
23. VISN 2 Policy 10N-277-07, Capital Equipment Process.

Attachment B
VHAWNYHS SPS SOPs (2013)

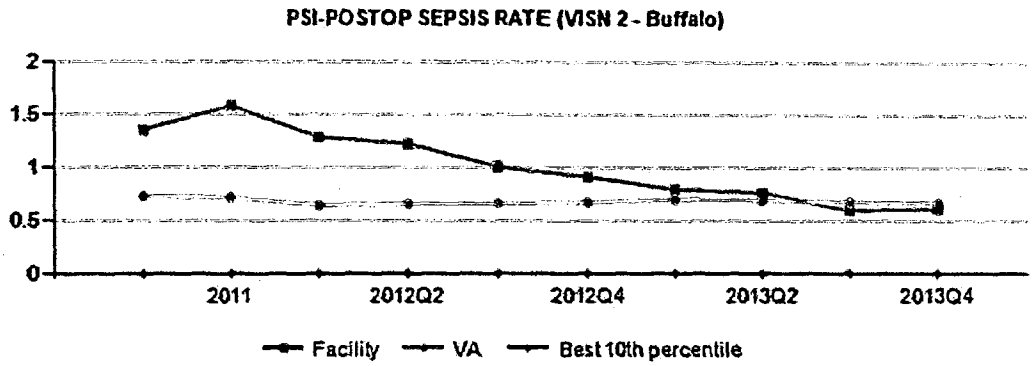
Attachment C
Tamperproof Sterilization Lock



Attachment D
Cardiac Crash Cart Logistics Board and Holding Area



Attachment E
Postoperative Sepsis Rate, VISN 2, Buffalo, 2011-2013



Note: Each data point uses rolling 3 year data. Lower value is preferred.

Postoperative Sepsis Rate, VISN 2, Buffalo, 2011-2013			
	FY2011	FY2012 Q4	FY2013 Q4
Buffalo	1.58	0.91	0.61
VA	0.71	0.67	0.66