



Department of Veterans Affairs Office of Inspector General

Review of Patient Safety in the Operating Room in Veterans Health Administration Facilities

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Executive Summary

This review was conducted to evaluate Veterans Health Administration (VHA) medical facilities' efforts to ensure patient safety in the operating room (OR). Our purpose was to determine whether: (1) facility leaders established and implemented effective policies, procedures, and guidelines to ensure patient safety in the OR; (2) facility leaders established a surgical improvement program that identifies potential problem areas needing improvement; and (3) there was coordination between Supply, Processing, and Distribution (SPD) and the OR.

We found that most OR personnel followed the five steps outlined in VHA policy to ensure correct surgery; however, not all elements of the policy were consistently followed. Several environment of care issues needed management's attention. The facilities did not collect, trend, and analyze patient related variance specific to the OR. The facilities did not properly document surgical resident supervision or disclose adverse events in the medical records. Mortality assessments were not consistent with VHA policy, and morbidity and mortality peer reviews were not completed for quality improvement as required. Local policies did not clarify which OR providers require basic or advanced cardiac life support training. Lastly, we found that SPD was not consistently providing a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the ORs. We made recommendations to address all of these issues.

The Acting Under Secretary for Health agreed with our findings and recommendations and provided appropriate action plans. We will follow up until all planned actions are completed.



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

TO: Acting Under Secretary for Health

SUBJECT: Review of Patient Safety in the Operating Room in Veterans Health Administration Facilities

Introduction

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections conducted an evaluation of Veterans Health Administration (VHA) medical facility efforts to ensure patient safety in the operating room (OR). The purposes of this evaluation were to determine whether: (1) facility leaders established and implemented effective policies, procedures, and guidelines to ensure patient safety in the OR; (2) facility leaders established a surgical improvement program that identifies potential problem areas needing improvement; and (3) there was coordination between Supply, Processing, and Distribution (SPD) and the OR.

Background

In August 1998, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a Sentinel Event Alert examining the problem of wrong site surgery, including a review of 15 cases that had been reported to them. The JCAHO sentinel event database included 150 reported cases of wrong site, wrong person, or wrong procedure surgery, of which 126 had root cause analysis (RCA) information. Of the 126 cases, 41 percent related to orthopedic/podiatric surgery; 20 percent related to general surgery; 14 percent to neurosurgery; 11 percent to urologic surgery; and the remaining to dental/oral maxillofacial, cardiovascular-thoracic, ear-nose-throat, and ophthalmologic surgery. Seventy-six percent involved surgery on the wrong body part or site, 13 percent involved surgery on the wrong patient, and 11 percent involved the wrong surgical procedure.

A search of the VHA National Center for Patient Safety (NCPS) Patient Safety Information System database (referred to as SPOT) for surgical procedures involving

retained sponges,¹ revealed more than 70 cases, of which 58 percent were adverse events and 42 percent were close calls. The search covered the years 2000–2004.

NCPS RCA data revealed 41 percent of cases had incorrect sponge counts; 21 percent were reported as correct; in 38 percent, no counts were documented. Sponges were left in the neck, chest, peritoneum, knee, groin, mediastinum,² retroperitoneal cavity, and pelvis. Gauze sponges have been discovered in a patient's airway after a tracheostomy,³ defecated following use as a throat pack during a maxillectomy,⁴ and found visibly extruding from an abdominal incision. Retained sponges were discovered before and after wound closure and were also found when searches were initiated after incorrect sponge counts were reported. In some cases, evidence of a retained sponge was not apparent until days, weeks, or years later, when x-rays were taken of patients with symptoms of pain, swelling, or signs of occult infection. Radiologists also observed sponges in unrelated routine x-rays, and pathologists discovered them during autopsies.

A 2004 report issued by VHA's Office of Medical Inspector disclosed three patient incidents that occurred at a VA medical center (VAMC). The incidents involved a retained surgical instrument, a retained surgical sponge, and an incorrect count.

In August 2004, an OIG report cited incidents of missing instruments, wrong instruments, broken instruments, and contaminated instruments at another VAMC.⁵ The review found that SPD staff were unable to provide sterile equipment and needed supplies to the OR, resulting in the cancellation of 81 elective operations (37 in November 2003 and 44 in February 2004).⁶

The following information is presented to further explain the roles of the surgical staff. Surgeons, scrub nurses, surgical assistants, and surgical technicians are scrubbed in and wear sterile gowns, shoe covers, caps, and masks. The main duties of the scrub nurse or surgical techs include opening all sterile instrument packs, ensuring the right instruments are in the packs, organizing surgical instruments on the sterile field, handing the correct instrument to the surgeon, and doing needle and instrument counts at completion of the procedure. The nurse circulator (also known as the circulating nurse) is a registered nurse who wears clean surgical scrubs, shoe covers, cap, and mask. However, the nurse circulator is not sterile and does not touch items or enter the sterile area of the operating room known as the sterile field. The nurse circulator's main duties include assisting the surgeon, scrub nurse, or surgical assistants into their gowns and gloves, opening the

¹ A sponge is a porous, absorbent mass, such as a pad of gauze or cotton surrounded by gauze.

² The region between the pleural sacs, containing the heart and all of the thoracic viscera except the lungs.

³ A tracheostomy is an opening surgically created through the neck into the trachea (windpipe).

⁴ Surgical removal of the maxilla, the major bone of the upper jaw.

⁵ *Issues at VA Medical Center Bay Pines, Florida and Procurement and Deployment of the Core Financial and Logistics System (CoreFLS)*, No. 04-01371-177, August 11, 2004.

⁶ *Interim Report – Patient Care and Administrative Issues at the Bay Pines VA Medical Center, Bay Pines, FL*, No. 04-0371-108, March 19, 2004.

outside wrappings from sterile instrument trays, labeling specimen containers, keeping the sponge count, obtaining unexpected equipment/instruments, keeping the intraoperative nursing documentation records, and helping to escort the patient to the recovery room.

The distribution area within SPD performs a major role in not only getting the correct medical supplies and equipment to users, but also in assuring that these supplies are in the correct quantity, quality, location, and condition for use. More specifically, SPD is responsible for cleaning, wrapping, and sterilizing equipment for use in the OR and other areas. This allows clinical staff to focus their time and attention on patient care needs.

Scope and Methodology

The scope of this inspection included eight VHA medical facilities from October 3, 2005, through May 8, 2006. The eight facilities we visited represented a mix of facility size, geographic location, and Veterans Integrated Service Networks (VISNs). We interviewed OR, SPD, Pathology and Laboratory Medicine Service, and infection control employees and managers, as well as surgical quality managers, to determine if effective policies, procedures, and guidelines to ensure patient safety in the OR have been developed and implemented.

We evaluated local policies, procedures, and guidelines for compliance with VHA/VA directives and handbooks, as well as Association of periOperative Registered Nurses (AORN) standards. We also examined committee minutes and surgical quality management reports and improvement plans to determine if trends and potential problems were identified and appropriate corrective actions implemented.

We observed staff performing surgeries in the ORs to ensure that:

- The correct surgery (right patient, procedure, and side) was performed.
- Surgical counts (of sponges, sharps,⁷ and instruments) were conducted according to AORN standards.
- Operating suite areas were environmentally clean and free of potential hazards (such as biological or pathological).

We observed SPD areas to determine if SPD staff provided a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to all points of use.

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

⁷ Sharps are needles and other penetrating surgical instruments or any device having corners, edges, or projections capable of cutting or piercing the skin.

Results and Conclusions

Issue 1: Compliance with VHA Directives, AORN Guidelines, and JCAHO Standards

Findings

It is VHA policy that in VHA facilities where surgery and invasive procedures are performed, specific steps must be implemented in order to reduce the likelihood of incorrect surgeries. VHA Directive 2004-028⁸ provides specific information on what steps must be taken to ensure that the indicated surgical procedure was performed on the correct patient, at the correct site, and if applicable, with the correct implant. The five steps described in the directive are:

- The consent form is administered and executed properly.
- The operative site is marked.
- The patient is actively identified using required techniques.
- A “time-out” briefing⁹ is conducted in the OR prior to starting the surgical procedure.
- Two members of the OR team review pertinent radiological images prior to commencing the surgical procedure.

We found that six of the eight facilities (75 percent) had policies that, for the most part, paralleled the VHA Directive, while two facilities (25 percent) had policies that only addressed side/site verification. We found certain aspects of the directive had not been incorporated into the local policies. One facility did not have steps addressing actively identifying patients using the required techniques. Only two facilities (25 percent) addressed the requirement of staying with the patient (once identified) until the patient is brought into the OR. Another facility did not have a written procedure whereby OR team members reviewed and verified radiological images.

A. Ensuring Correct Surgery

In order to determine if the five steps identified in VHA Directive 2004-028 were followed, we observed 88 various surgical procedures, including joint replacements, prostatectomies, colon resections, hernia repairs, cataract removals, craniotomies, hysterectomies, and open heart surgeries.

⁸ *Ensuring Correct Surgery and Invasive Procedures*, June 25, 2004.

⁹ The time-out briefing is verification of the correct patient, correct procedure, correct site, and correct implant (where applicable) by specific personnel in the OR prior to the start of the operation, and at a time when the patient and required OR personnel are present in the OR.

Step 1 – Informed Consent

We found that the facilities properly administered and executed the informed consent. However, we did observe an isolated incident where a nurse circulator wrote additional information on the consent form. The operation/procedure written on the consent form was “Left Clavicular Osteotomy.”¹⁰ The nurse circulator wrote “Left Rotator Cuff Repair¹¹ & Shoulder Decompression”¹² on the consent form. The nurse informed the patient the addition was further clarification of the surgical procedure.

The nurse circulator initialed the change, but did not notify the attending surgeon of the changes to the consent form. The attending surgeon’s pre-operative note states the surgical procedure planned was “Left Shoulder Rotator Cuff Tear with Clavicular Osteotomy.” The facility policy stated that if the consent form is incomplete or invalid, and if no emergency regarding the patient exists, the responsible practitioner will postpone the procedure/treatment until a valid consent has been obtained. We informed management of the nurse circulator’s actions.

Step 2 – Marking the Site

According to the VHA Directive, it is a requirement to mark virtually all operative sites, including those on the midline, face and groin. The directive allows for the use of a special-purpose wristband in cases where the site is awkward or problematic such as the perineum. Most (75/88) facility surgeons or privileged providers marked the operative site or used special-purpose wristband as substitution for marking. However, at one facility, the patients were directed to mark their own operative sites, which was a direct violation of the VHA Directive. At this facility, we also observed the nursing staff mark the patient’s operative site. Furthermore, we observed a nurse write “yes” on the ace bandage wrapped around a patient’s ankle (the patient was scheduled for removal of hardware from his right ankle). After the ace bandage was removed in the OR, the operative site was left unmarked. The directive required that the mark be placed so that it will be visible in the operative field after the site is prepped and draped.

At another facility, we observed that the operative site was not marked for a patient that had a radical retropubic prostatectomy. This facility also did not mark the site of patients undergoing open heart surgery, including the leg where the vein was harvested.

Step 3 – Patient Identification

The nurse circulators were responsible for identifying patients prior to bringing them into the OR. They asked the patients to verbally state their full name (84/88) and social

¹⁰ The surgical cutting of a bone.

¹¹ Re-attach the detached/torn rotator cuff muscle.

¹² Make more space available for the tendons of the rotator cuff. Enlarging or “decompressing” the space between the acromion and the head of the humerus can relieve the symptoms of impingement.

security number (81/88), and to identify the operative site (87/88). The patients' responses were checked against the signed consent forms (69/88), the patients' identification bands (87/88), as well as to the marked sites (76/88).

The VHA Directive required that the patient state, not confirm this information. On several occasions (7/88) the patients were asked to state the last four of their social security number (SSN). We also observed an OR staff member ask an aphasic patient to provide the required information (full name and SSN). The patient responded by saying "yes yes" and gesturing. The staff then asked him to confirm his unique information and the operative procedure and site. When ever possible, in cases where patients cannot provide the correct responses themselves, another person with knowledge of the patient, such as a family member, should be asked to state the name of the patient and the site to be operated on. The staff did not ascertain if the patient had someone with him to assist with his identification.

Several facilities implemented the iMedConsent™¹³ software program. However, the facilities did not have portable or hand-held computers to access the consent form by which to compare the patient's responses. While some facilities printed a copy of the consent and had it available during the identification process, others used a patient label, stamped with the patient's name and SSN.

We also observed incomplete patient identifications. Part of the identification process included verifying the marked site with the consent form. On a few occasions the nurse identified the patients even though the patients' operative sites had not yet been marked. The patients were not re-identified until they were brought into the OR during the time-out briefing.

The VHA Directive also stated that once the active identification is performed, the staff member who performed the identification must stay with the patient until the patient is transported into the OR. We only observed 78 percent (69/88) compliance.

Step 4 – Time-Out Briefing

A time-out briefing is a final check prior to the start of the surgical procedure. We found that the facilities had procedures in place that require verification of the correct patient, the correct procedure, the correct site, and the correct implant (where applicable) by personnel in the OR prior to the start of the operation, and at a time when the patient and required OR personnel were present in the OR. During a time-out briefing, a designated member of the team verbally states the patient's information. After the statement, other members of the team verbally state that they concur with this information before the procedure begins. At minimum, this process must include the surgeon, the nurse circulator, and the anesthesia provider. In most or many cases the patient will be under

¹³ iMedConsent™ is a patient-signed informed consent entered directly into the electronic medical record system.

sedation or unconscious when the time-out briefing occurs and is not expected to participate in this process.

Although the facility staff consistently performed time-out briefing (87/88), we found one facility that performed the time-out briefing shortly after the patient was brought into the room and placed on the OR table. The patient was asked to state his name, SSN, and the procedure (including laterality, if applicable) to be performed. The patient's responses were checked against his armband, but the responses were not checked against the consent form; and the marked site was not verified.

At another facility, we also observed one incident when the surgical procedure was initiated prior to the time-out briefing. While observing a litholopaxy¹⁴ with transurethral resection of prostate¹⁵ (TURP), the surgeon dilated the patient's urethra prior to the time-out briefing. Once the nurse circulator became aware that the surgeon had initiated the procedure, she immediately asked the surgeon to stop and called for the time-out briefing.

At times, we found that all members of the OR team did not give their full attention to the time-out briefing. The nurse circulators had to solicit verbal concurrence from the surgeons or anesthesia providers.

Step 5 – Imaging Data

We observed 27 (31 percent) procedures where physicians referred to pre-existing radiological images. Two members of the OR team were required to confirm that the images were correct, properly labeled (name and side of anatomy), and properly presented and oriented (right or left and up and down). We observed that two OR team members inconsistently confirmed the radiological image simultaneously. The surgeon, resident, and nurse circulator viewed the radiological image separately and we could not ascertain what elements of the image they reviewed. Nor did we see the two team members confirm with each other verification of the images. Furthermore, we found two images that were not appropriately labeled. In one case, the radiological image (left knee), which came from a community hospital, was not labeled with the side of the anatomy. In the second case (right ankle), we found no patient identifiers on the image. Nonetheless, the nurse circulators documented in the Intraoperative Report that the radiological images were appropriately verified 100 percent (27/27) of the time.

B. Surgical Counts

At the start of our review, VHA did not have a directive addressing surgical counts; therefore, for purpose of this review, we used AORN recommended practices to determine compliance, as detailed in each section following. Individual facility surgical counts policy/procedure varied. Half of the facility policies did not address what surgical

¹⁴ Crushing stones in the bladder, followed by washing out the fragments.

¹⁵ Resection of the prostate by means of a cystoscope passed through the urethra.

procedures would allow exclusion of instrument counts. All facilities with the exception of one (12.5 percent) had a policy that addressed counting sharps (such as needles, blades, and bovie¹⁶ tips). Half of the local policies did not define what was a sponge or sharp. Nor did their policies provide guidance to the nursing staff when additional counts must be performed. We only found two facilities (25 percent) that addressed the sequence of surgical counts in their local policy.

We reviewed the VHA Directive 2006-030, *Prevention of Retained Surgical Items*, dated May 17, 2006.¹⁷ The directive required that a written facility policy be in effect no later than June 30, 2006, which states that the surgical teams must take the necessary steps to prevent the retention of foreign bodies from surgical procedures. These steps include surgical counts for all surgical procedures except for those where retention of a foreign body is virtually impossible (such as cataract extraction and diagnostic cystoscopy, as defined in the original directive dated April 3, 2006). Methods for counting instruments, sharps, and sponges must comply with the published 2005 standards of the AORN and AORN standards on the topic as directed by the VHA Director for Surgical Services. The directive also addresses what steps must be taken if any discrepancy in a count of a surgical item is discovered.

Sponge and Sharps Counts

AORN guidelines recommend that sponges and sharps should be counted on all procedures in which the possibility exists that a sponge or sharp could be retained. They advised that counts should be taken:

- Before the procedure to establish a baseline.
- Before closure of a cavity within a cavity.
- Before wound closure begins.
- At skin closure or end of the procedure.
- At the time of permanent relief of either the scrub person or the circulating nurse.¹⁸

We did find rare occasions where the sponge and sharp counts were not conducted as prescribed by AORN as follows:

Count Not Taken	Sponge	Needle
Before the procedure to establish a baseline	1	1
Before closure of a cavity within a cavity	1	1
Before wound closure	1	1
At skin closure or end of the procedure	2	3

¹⁶ An instrument used for electrosurgical cauterization.

¹⁷ It rescinded VHA Directive 2006-030, *Prevention of Retained Surgical Items*, dated April 3, 2006.

¹⁸ AORN, Inc., *Standards, Recommended Practices, and Guidelines*, (2005).

We observed four occasions when the counts were not performed when the scrub person or nurse circulator was permanently relieved. We also found one facility that performed sponge and sharps counts before and after the lunch relief.

AORN recommended that sponges should be separated, counted audibly, and concurrently viewed during the count procedure by two individuals, one of whom should be a registered nurse circulator. Although this was generally practiced at all the facilities, the practice was inconsistent. The scrub person did not consistently separate sponges, particularly the laparotomy pads that were held together with retention bands. We also observed the nurse circulator add sponges and needles to the field, but they were not concurrently counted with the scrub person; however, the nurse circulator recorded the item(s) on the count board or count sheet.

We observed two surgeries (orthopedic and neurologic surgeries) where the sharps counts were incorrect. In both cases, a needle was missing. The surgeons were informed of the incorrect count and attempts were made to find the missing needle. The nurse circulator and scrubbed person asked the surgeons to conduct manual searches of the wounds to locate the missing needles. The scrub person and nurse circulators did manual and visual searches, respectively, of the sterile area surrounding the wound and the remainder of the sterile field. The nurse circulators conducted searches of the nonsterile areas of the room in an attempt to locate the needle(s). Radiology was called to take an intraoperative x-ray. The needle in the orthopedic case was located prior to radiology arriving. The missing needle in the neurologic surgery was not detected on x-ray. The x-ray was read by the resident and the attending surgeon, not the radiologist. The nurse circulator initiated an incident report.

Instrument Counts

Instruments should be counted for all procedures in which the likelihood exists that an instrument could be retained. AORN advised that counts should be taken:

- Before the procedure to establish a baseline.
- Before wound closure begins.
- At the time of permanent relief of either the scrub person or the circulating nurse.

Although half of the facilities delineated the surgical procedures that were exempt from instrument counts, we found that they did not always follow their own policy/procedure. Some facilities defined exceptions for instrument counts by listing the surgical procedures, while other used the size of the incision. Of the 88 surgical procedures we observed, 39 (44 percent) performed instrument counts.

We found that one facility had a provision in their instrument count procedure that stated, “The scrub and circulating nurses perform the initial count, or they may BOTH agree to the count being done only by the scrub nurse.” We observed one case where the scrub

person did the initial count alone. We were told that they had initiated this practice in order to accelerate the baseline counting process.

The facilities usually conducted the surgical counts after the patients were brought into the OR. However, we found at one facility, that they would not bring a patient into the OR until all counts had been completed. This allowed them to focus their full attention on the counting process without distractions.

We found several instrument trays that contained an excessive number of instruments for the cases planned. Those instrument trays took longer to count and made it difficult to maintain an organized back table. The OR staff stated some of the orthopedic instrument trays felt like they weighed over the 17 pound maximum recommended according to VA policy.¹⁹ We found no scales in the OR suites. Three (37.5 percent) facility SPD sections did have a scale to weigh instrument trays, but they were not utilized.

The new VHA Directive requires that all surgical instruments must be counted, except for procedures that are routinely concluded with a radiograph prior to closing the surgical wound (for example, an orthopedic case to assure proper alignment of a bone or implant). The directive also stipulated that:

- Instrument sets are standardized with the minimum types and number of instruments needed for the procedure.
- Preprinted count sheets that are identical to the standardized set be used for documenting counts.
- Instruments counts are performed in the same sequence each time utilizing the preprinted count sheet.

C. Environment of Care

We generally found the eight facilities clean, the staff members motivated toward their job responsibilities, and staff demonstrated abilities to work well within a multidisciplinary team environment. Environmental and engineering staff members generally followed VA directives and JCAHO standards. However, there was at times a lack of consensus on interpretation of JCAHO standards versus VA Central Office (VACO) directives. We found the following areas that needed improvement.

¹⁹ VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements* issued August 16, 2002.

Heating, Ventilation, and Air Conditioning

VHA design standards (2004) stipulate the four operational parameters for OR heating, ventilation, and air conditioning (HVAC) systems as shown below:

VHA OR-HVAC Design Criteria	
Air Changes/Hour (AC/H)	15 AC/H Minimum
Room Pressurization	Positive
Relative Humidity (RH)	44 – 55 percent
Temperature	62.6°F – 80.6°F

We reviewed facility documentation of periodic testing of HVAC systems serving the OR environments. We found six facilities (75 percent) not in compliance with the JCAHO standard.²⁰ One facility had not had the HVAC system tested for over 5 years. A second facility recently completed an OR renovation, including the HVAC system, and had received a testing report from the contractor. The testing report identified two OR rooms that did not meet the 15 AC/H requirements.²¹ The facility elected to use both rooms for patient invasive (endoscopic) procedures. A third facility had recently completed an OR-HVAC Certification Study and could not produce any prior studies for comparison or review. The remaining facilities did not report complete HVAC performance data (temperature, humidity, AC/H, and positive pressurization) to the facility's review committee and the governing body. Only two facilities provided data and committee minutes documenting that they met this required testing. We could not locate VHA guidance to field facilities concerning the department's standard for OR-HVAC certification.

Failure to adhere to OR-HVAC design criteria places patients in an environment lacking appropriate AC/H, temperature, and humidity conditions; compromises infection control measures; and could contribute to increased patient infection rates.

²⁰ JCAHO criteria as described in the EOC Guidebook, 2005 Update (EC 1.7), specifically asks, "Is there a policy that describes how air filtration, air exchange and pressure relationships are maintained and tested in the following areas: operating rooms, special procedure rooms, delivery rooms, negative isolation rooms, protective isolation rooms, clinical laboratories, pharmacies and sterile supply areas? Are these tests performed and documented on a periodic basis?"

²¹ E-mail with VACO Clinical Engineering Section (McCrone & Safdie), September–October 2005.

Equipment Management

We reviewed the equipment records, preventive maintenance inspection (PMI) schedules, and equipment histories for OR equipment (such as anesthesia machine, operating table, cell saver, and portable x-ray machine) contained in the Engineering Service files. Facility summaries are shown below:

Equipment Type	Total	Facilities PMI Current	Percent PMI Current	Facilities PMI Not Current	Percent PMI Not Current
Anesthesia machine	8	7	87.5%	1	12.5%
C-arm (portable x-ray machine)	7	4	57.1%	3	42.9%
Bovie (cauterizing machine)	8	7	87.5%	1	12.5%
Perfusion pump (heart-lung machine)	3	3	100%	0	0.0%
Cell saver	5	3	60.0%	2	40.0%
Operating table	8	4	50.0%	4	50.0%
Total	39	28	71.8%	11	28.2%

For 28 percent (11/39) of the equipment items reviewed, we found facility equipment records incomplete, inconsistent, and an ineffective management tool to gauge the program's safety, risk for patients, efficiency, and state of operational readiness. The data reviewed documented improper equipment in-processing, the assignment of specific PMI schedules, the completion of assigned PMI tests, and the completion of repair work orders.

Specifically our review found:

- Personal Property Managers (PPM) did not properly in-process new and leased equipment onto VA property. This was observed at all facilities. At one facility, vendors were observed entering the SPD while bringing in medical equipment that was not safety inspected and was out-of-date for recurring PMI inspection. The equipment was to be used in an ongoing operative procedure.
- At six facilities (75 percent), PPM and engineering sections were not entering verified information into the PPM and Automated Equipment Management System/Mechanical Equipment Reporting System (AEMS/MERS) software programs to effectively account for and manage equipment accountability, PMI, and repair.
- At six facilities (75 percent), PPM and engineering sections do not work in partnership to ensure equipment information is properly entered into each section's respective component within the AEMS/MERS software system.
- At six facilities (75 percent), Engineering Service staff had not entered PMI information into the AEMS/MERS software package to properly prepare PMI

schedules, PMI completed, PMI incomplete, and maintenance and repair work orders for assigned equipment.

The above findings affect the monitoring, validation, and verification of the safe operating capabilities and conditions of clinical equipment actively used on patients in the operating rooms on a daily basis.

Anesthesia Medication Cart Security

At five facilities (62.5 percent), we found anesthesia medication carts unsecured during our inspections. We found the carts closed but the keys were still in the locks. We also found filled syringes left on top of the carts unattended. OR employees assumed and functioned with the understanding that the OR environment was a “secure” area.



National Fire Protection Association Life Safety Code requires secondary egress from the OR area. Employees were observed using these egress pathways for routine exit as well as entrance, providing validation that unauthorized individuals can readily gain access to the OR and the vacant OR suites where various drugs and medications were available.

Conclusions

We found that most OR personnel followed the five steps outlined in VHA Directive 2004-28. Some facilities marked the site only when laterality was involved. The use of iMedConsent™ software caused some logistical problems, making it difficult for staff to compare the information provided by the patient against the consent form.

The OR team members did not consistently stay with the patients after they had been identified. Although nursing personnel documented verification of images, we did not consistently see two OR team members confirm the radiological image simultaneously. Also, it was difficult to ascertain what elements of the images were reviewed.

Individual facility policy/procedure for surgical counts varied. Nonetheless, revision of facility surgical count policy is required in order to comply with the new (May 17, 2006) VHA Directive 2006-030.

Facilities surveyed were not testing the operation of the HVAC systems serving the OR areas and reporting the test results to a medical center standing committee. VHA does not have a policy or directive for field facilities that clarifies VHA interpretation of JCAHO standards for “periodic” OR-HVAC system certification.

VAMC facilities were not effectively using computer-based software for the management of their clinical equipment.

VAMC facilities were not monitoring medication cart security; they needed to ensure surgical service staffs secure anesthesia medication carts and that medications are in locked drawers or disposed of at the conclusion of each operative procedure.

Recommended Action 1. We recommend that the Acting Under Secretary for Health, in conjunction with VISN and Medical Center Directors ensure that:

(a) Local facility policy adheres to VHA Directive 2004-028 concerning: (i) confirmation of patient information against informed consent, (ii) staying with patients after they are identified and until they are brought into the OR, and (iii) verification of radiological images.

(b) VHA Directive 2006-030 is implemented and monitored for compliance.

(c) Healthcare Engineering disseminates to all field facilities VHA's interpretation of JCAHO's standard of “periodic” testing of OR-HVAC systems. Healthcare Engineering should consider the possibility of guidance that includes a suggested maximum interval to: (i) ensure field facilities review the operational testing data for OR-HVAC systems against the four operational parameters for OR-HVAC systems and (ii) results of the testing are reported to the appropriate standing committee and governing bodies.

(d) Facility managers' AEMS/ MERS information for clinically-based equipment items is complete and accurate.

(e) Entry/Exit doors serving the OR suite, but not directly observable from the main OR entry area, should allow access only to authorized personnel to ensure the security of unattended medications, anesthesia carts, and OR equipment and supplies.

Issue 2: Surgical Performance Improvement Program

Findings

In general, the facilities inspected had comprehensive policies and procedures to follow Quality Management and Patient Safety guidelines in the OR. However, we did not find that the facilities collected, trended, and analyzed patient related variance such as surgical delays and cancellations, equipment or instrumentation problems, incorrect counts, return to OR within 24-hours, medication problems, and other issues specific to the OR. Only two facilities had an OR Committee where these issues could be discussed and corrective actions developed to improve their surgical programs.

We found that two facilities (25 percent) had incident or near miss incorrect surgery events in fiscal year (FY) 2005. The first facility reviewed the event of the wrong site surgery (right, instead of the planned left side inguinal hernia repair) and determined that (a) the surgeon did not possess the consent form when the site was marked, (b) the nurse circulator did not mention the variance between the marked site and the consent, and (c) a time-out briefing with the informed consent was not performed.

Based on the findings of their review, the following suggested improvements were made to their *Ensure Correct Surgery* poster on display in the OR suite:

- The operative site must be marked by a practitioner after reviewing the consent and in consultation with the patient. The enforcer of this step would be the nurse circulator, who will not take the patient back to the OR until the site is marked and in agreement with the consent.
- Ownership of patient identification was assigned to the nurse circulator. The nurse circulator was also assigned responsibility to identify other documents, to include the attending note and the history and physical (H&P).
- The ownership for the time-out briefing process was spelled out as follows: “within the OR when the patient is present and prior to beginning the procedure, the surgeon will call a time-out and the nurse circulator, anesthesiologist and surgeon will review for correct patient using the chart and the name band, proper positioning, proper marked site, procedure to be performed with the consent, and availability of the correct implant.” The enforcer of the time-out briefing was the scrub nurse or scrub technician who would not pass the necessary scalpel, scope, or other equipment if a time-out briefing had not been performed.

For the most part, we observed that the corrective actions had been implemented and followed. However, this was the facility where the time-out briefing was not initiated prior to the TURP procedure. The scrub technician stated the surgeon removed the instrument off the back table. Although the scrub technician did not pass the equipment

to the surgeon, he did not inform the surgeon or nurse circulator that a time-out briefing had not been conducted.

At the second facility, a patient had the wrong eye anesthetized (blocked). The non-operative site was blocked by the surgeon. The incident was reviewed and monitors were developed and implemented to ensure the correct site was identified and marked. We found no further incidents of near miss or wrong site surgery at the facility.

We also found opportunities for improvement at several facilities in five of the following areas:

Resident Supervision

VHA policy²² requires that surgical residents treat patients within their scope of practice with proper supervision. Evidence of supervision is documented in one of four ways: (1) a supervising physician progress note, (2) a supervising physician progress note addendum, (3) co-signature of the resident progress note by the supervising practitioner, or (4) a resident progress note documenting discussion with the supervising physician including agreement with the diagnosis and plan of treatment. We reviewed documentation of selected records of 70 patients from a sample of 210 encounters that involved Pre-Operative notes, H&P notes, and Brief Operative notes at seven facilities. One facility did not have a resident program. The results indicated:

- Ninety percent (63/70) compliance with Pre-Operative notes.
- Fifty-three percent (37/70) compliance with H&P notes.
- One-hundred percent (68/68²³) compliance with the Brief Operative notes.

Disclosure of Adverse Events

VHA policy²⁴ requires prompt disclosure to patient and families about pertinent clinical facts associated with procedure errors, complications, or unexpected death related to surgery or invasive procedures. The policy requires that the attending or senior practitioner or designee disclose the adverse events within 24 hours of the practitioner's discovery of the event. We found that three (37.5 percent) facilities failed to document disclosure of adverse surgical events. The facilities did not disclose events involving retained foreign bodies, anesthesia block to the wrong surgical site, and unexpected deaths. All of these issues were considered reviewable Sentinel Events. A summary of some of the cases follows:

²² VHA Handbook 1400.1, *Resident Supervision*, July 27, 2005.

²³ We found two patients who did not have a Brief Operative note in the medical record; thus changing the denominator.

²⁴ VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005.

- At one facility, two patients had to return to surgery with partially retained drains. It was determined in both cases that the breaks occurred not from a defect in the drains but from technical error. Only one patient's medical record had documentation of the patient being informed of the adverse event. However, the resident, not the attending surgeon, documented that he discussed the events with the patient and the need to return to the OR to remove the drain. The second surgeries, in both cases, did not result in any further adverse outcomes.
- At a second facility, the surgeon administered a regional block into the wrong eye. The procedure was aborted prior to initiating the surgery. We found no documentation that the patient had been informed about the adverse event. We also found that the facility did not document any disclosure of several unexpected deaths. In one case, the patient died in the OR. We found no documentation in the medical records that the events were discussed with the family. We did find a progress note, 4 months after the death, addressing the complaints of the family member concerning frustration about their inability to obtain information.
- In the third facility, we reviewed three surgery-related deaths that involved delay in diagnosis or treatment. We obtained the medical records for review; in none of the cases did we find documentation of event disclosure.

Morbidity and Mortality Peer Review

VHA policy²⁵ requires all surgical mortalities and all major morbidities undergo peer review, and Directive 2005-056²⁶ requires that these reviews be done within 30 days of the original procedure. Five (62.5 percent) of the facilities visited had limited morbidity and mortality (M&M) conferences onsite. Instead, a majority of the patients were discussed at the affiliated university. The documentation of the conference was not shared with the VA facilities.

One facility could not produce documentation of onsite M&M reviews. Also no records were available to indicate the required quality assurance data from any such reviews were used to help with performance improvement in the Surgical Service.

One facility completed only 2 of 29 (7 percent) mortality reviews within the required timeframe of 30 days in FY 2005. Another facility reviewed only 7 of 32 (22 percent) mortalities.

Mortality Assessment

VHA Directive 2005-056 requires that deaths be trended by facility, ward, service line, shift time, and provider. We found two of the facilities did not properly trend deaths in all required elements. One medical facility did not include shift time and provider; the

²⁵ VHA Directive 2004-054, *Peer Review for Quality Management*, September 29, 2004.

²⁶ VHA Directive 2005-056, *Mortality Assessment*, December 1, 2005.

other did not have service line analysis. Trend analysis is necessary to evaluate potentially suspicious or unusual events.

Credentialing and Privileging

A majority of the credentialing and privileging (C&P) files were well organized and contained the required documentation. VHA policy²⁷ indicates that clinical staff working in the OR may need Basic Cardiac Life Support (BCLS) and/or Advanced Cardiac Life Support (ACLS) certification in accordance with local committee policies. Four of the eight facilities had issues in this area. We reviewed 24 C&P files and found 6 providers with no certification and 2 with expired certification. Local policies were not always clear regarding who required which type of certification. One facility had a policy in draft form only.

Conclusions

The facilities did not collect, trend, and analyze patient related variance specific to the OR. We concluded that facilities were not properly documenting surgical resident supervision or documenting disclosure of adverse events in the medical records. Mortality assessments were not consistent with VHA policy, and M&M peer reviews were not completed for quality improvement as required. We found that local policies did not clarify which OR providers require ACLS and BCLS training.

Recommended Action 2. We recommend that the Acting Under Secretary for Health, in conjunction with VISN and Medical Center Directors, ensure that facility managers:

- (a) Encourage facilities to establish an OR/Invasive Procedures Committee that will collect, trend, and analyze patient related variance specific to the OR such as, but not limited to, adverse events and near misses, surgical delays and cancellations, equipment or instrument problems, and incomplete and or incorrect operative consent.
- (b) Comply with VHA Handbook 1400.1 regarding documentation of surgical resident supervision.
- (c) Comply with VHA Directive 2005-056 regarding mortality assessment.
- (d) Disclose and document adverse event discussion with patients and families in the medical records as required by VHA Directive 2005-049.
- (e) Initiate M&M reviews as required by VHA Directive 2004-054.

²⁷ VHA Directive 2002-046, *Staff Training in Cardiopulmonary Resuscitation and Advanced Cardiac Life Support*, July 31, 2002, was in effect at the time of our review.

(f) Delineate which OR providers require ACLS and BCLS training by: (i) implementing a system for monitoring the maintenance of ACLS or BCLS certification or training, (ii) determining where this information will be maintained and how it will be disseminated to staff who need to know of this qualification, and (iii) taking appropriate action to assure timely renewal of all certifications or the consequences if not maintained.

Issue 3: SPD Coordination with the OR

Findings

We assessed SPD operations to determine whether SPD provided a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the ORs. We found that SPD at two (25 percent) of the eight medical centers needed improvements in providing a more acceptable level of service to the ORs. Instrument trays and/or surgical case carts containing missing, broken, or incorrect instruments were issues at both facilities; one of the facilities experienced supply shortages and the OR receiving contaminated instruments. This occurred because quality control (QC) monitors were not effective, although they had been implemented in an effort to resolve the issues of missing, broken, or inaccurate instruments in instrument trays and surgical case carts.

OR management at one facility attributed the problems to lack of knowledge on the part of the SPD staff; OR management at the second facility felt that SPD's lack of attention to detail led to the identified problems. We did not identify any adverse patient events due to SPD issues, because OR staff ensured that the instruments were not contaminated and that all instrument trays and case carts contained the proper instruments prior to each surgery.

Availability of Supplies

Medical supplies are expendable hospital, surgical, laboratory, and radiology items used in patient care and medical research. Medical supplies include such items as examination gloves, catheters, disposable scalpels and syringes, respirators, sutures, and x-ray film. We assessed the availability of surgical supplies to the ORs at eight medical facilities during this evaluation; we found that, except for isolated incidents at seven of the eight facilities, surgical supplies were generally available to the OR staff as needed. In some instances, the OR experienced minor delays while SPD located or borrowed supplies from an affiliated medical facility.

At one of the eight facilities, the OR staff provided copies of e-mails between SPD and OR staffs that were used to report shortages of high-use items such as sterile drapes, basins, gloves, and disposable towels. While not a daily occurrence, supply issues occurred often enough to produce a high level of frustration for the OR staff affected by the shortages. However, based on the evidence we gathered, OR staff experienced only minor delays and no cancellations due to supply issues at the medical center. The OR

staff managed “work arounds” for the supply issues, often substituting available items for the out-of-stock ones.

Missing, Broken, and Incorrect Instruments

VA Handbook 7176, *SPD Operational Requirements*, dated August 16, 2002, states that SPD is dedicated to the receiving, storage, and distribution of medical supplies. SPD decontaminates and sterilizes reusable medical supplies and equipment to ensure a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to all points of use. The distribution area of SPD performs a major role in not only getting the correct supplies and equipment to ORs but also in ensuring that these supplies are in the correct quantity, quality, location, and condition for use, allowing clinical staff to spend their time on patient care needs.

At two of the eight medical facilities there were frequent occasions where instruments were missing, broken, or incorrect. QC procedures that had been implemented to ensure that the proper instruments were in instrument trays at both facilities were not effective. QC monitors, as used by these facilities, are locally developed checklists. One employee lists the types of instrument trays or surgical case carts prepared and notes the date and time of preparation; a second employee checks the items in the tray or cart against a checklist of required items for the noted surgical procedure and notes the date and time the check was completed prior to the tray or cart being sent to the OR.

The QC monitors used at the two medical facilities to ensure the accuracy of instrument trays and surgical case carts were not effective. We were unable to determine the exact number of incidents because OR staff at both medical centers had stopped completing “Patient Incident Reports” and “Reports of Contact” for specific instances of missing, broken, or inaccurate instruments. OR staff stated that the reports were time consuming to prepare, and they had not been effective in resolving the problem. However, OR staff at both facilities provided us numerous e-mails documenting that they had notified the SPD Chiefs and the next level supervisors of these problems, but they were still experiencing the same problems.

ORs experienced minimal surgical delays and no cancellations due to SPD issues, because the OR staff at both facilities ensured that all supplies and instruments were available and ready prior to each surgery. Some of the missing, broken, or incorrect instruments were general use items that OR staff could borrow from other trays or obtain from bins where extra supplies such as scissors, clamps, and sutures were maintained by SPD in the OR areas. Other instruments were specialized and crucial to the performance of particular procedures. For example, the OR staff at both medical centers reported that scopes required for laparoscopic procedures were often sent to the ORs with mismatched parts. The scopes were acquired from three different suppliers; if the pieces from the different vendors were interchanged, the scopes could not be used.

In November 2004, one facility instituted a Daily Tray Preparation Inspection monitor that required two SPD employees to inspect the instrument trays and certify that the trays were complete and accurate before sending them to OR. (OR staff there prepared the case carts as they needed them with instrument trays and supplies furnished by SPD). However, OR staff were still experiencing problems with missing, broken, and incorrect instruments in the trays SPD prepared. We observed OR staff prior to upcoming surgeries opening instrument trays with missing, broken, or incorrect instruments, even though both SPD employees had signed the count sheets signifying that the QC reviews had been performed. There were no patient care issues because OR staff always ensured that they had the proper instruments prior to each surgery.

At the other medical center, SPD had implemented a QC monitor to verify whether case carts were complete and accurate before the carts were sent to OR. A QC procedure had not been implemented for instrument trays. However, we still found that surgical case carts and instrument trays sent to OR had missing, broken, or incorrect instruments. Our survey of 25 OR, Anesthesia, and Surgery Service staff members resulted in 22 (88 percent) of the respondents stating that SPD was not providing an acceptable level of service to the OR.

Contaminated Surgical Instruments

Contaminated items from the OR enter the SPD decontamination area in covered containers. Once in the decontamination area, surgical instruments must be inspected for tissue or bone fragments remaining in the teeth or grooves of the instruments. This debris is to be removed by holding the instrument under the surface of the cleaning solution and scrubbing the area with a specifically-designed tool. All items are to be cleaned and disinfected before leaving the decontamination area.

At one of the two medical centers with missing, broken, or incorrect instruments, we identified three occasions where OR staff received instrument trays with contaminated instruments that had to be returned to SPD for decontamination and sterilization before they could be used. No adverse patient incidents occurred, because OR staff ensured the instruments were not contaminated prior to each surgery. The three incidents occurred in August 2005 within a few days of each other; after the third incident of the OR receiving “dirty” instruments, SPD implemented a QC procedure to monitor the decontamination process. One SPD employee logs in and inspects the surgical instruments for tissue or bone fragments remaining in the teeth or grooves of the instruments before they are decontaminated; and a second employee inspects the instruments after they have been sterilized. Both employees initial the QC checklist. OR staff confirmed there had been no subsequent incidents since the QC monitor was implemented.

Conclusion

VA Handbook 7176 states that the major goal of SPD is to allow the professional medical staff every opportunity to concentrate on direct patient care. SPD optimizes its support of the medical facility by ensuring a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to all points of use. We found that SPD at two medical centers were not providing this level of service to the OR. In addition, one of the sites was regularly experiencing supply shortages of high use items like gloves and sterile drapes. Although QC procedures had been implemented to ensure the accuracy and completeness of instrument trays and case carts, the corrective actions were not effective. As a result, OR staff continued to receive instrument trays and case carts with missing, broken, or incorrect instruments that were crucial to the scheduled surgeries. We did not identify any adverse patient events due to SPD issues, because OR staff ensured that the instruments were not contaminated and that all instrument trays and case carts contained the proper instruments prior to each surgery.

Recommended Action 3. We recommend that the Acting Under Secretary for Health ensures that SPD provides a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the ORs.

Comments

We inspected eight different VA medical facilities between October 3, 2005 and May 8, 2006, using VHA directives, AORN guidelines, and JCAHO standards. As a result of this review, we made recommendations that:

- Local facility policies adhere to VHA Directive 2004-028, *Ensuring Correct Surgery and Invasive Procedures*.
- VHA Directive 2006-030, *Prevention of Retained Surgical Items*, is implemented and monitored for compliance.
- VA Central Office – Clinical Engineering clearly defines and disseminates to all field facilities VHA’s interpretation of Joint Commission on Accreditation of Healthcare Organization’s standard of “periodic” testing of OR-heating, ventilation, and air conditioning systems.
- Information for clinically-based equipment items is complete and accurate.
- Entry/Exit doors serving the OR suite, but not directly observable from the main OR entry area, should allow access only to authorized personnel.
- Compliance with VHA Handbook 1400.1, *Resident Supervision*, regarding documentation of surgical resident supervision.
- Compliance with VHA Directive 2005-056, *Mortality Assessment*, regarding mortality assessments.

- Disclosure and documentation of adverse event discussions with patients and families in the medical records as required by VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*.
- Initiation of morbidity and mortality reviews as required by VHA Directive 2004-054, *Peer Review for Quality Management*.
- Each facility should clearly delineate which OR providers require advanced cardiac life support and basic cardiac life support training.
- SPD provides a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the ORs.

The Acting Under Secretary for Health agreed with our findings and recommendations and provided a detailed action plan addressing each recommendation, with a goal of improving policy implementation and compliance monitoring. (See Appendix A, pages 24–37 for the full text of the comments.)

The proposed actions are appropriate and responsive to the recommendations. We will follow up on the planned actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Acting Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: December 21, 2006

From: Acting Under Secretary for Health

Subject: OIG Draft Report, **Review of Patient Safety in the Operating Room in Veterans Health Administration Facilities**, Project No. 2005-00379-HI-0048 (WebCIMS 367759)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the recommendations. Patient safety in the operating room (OR) is an important clinical issue, and the report cites valuable opportunities for improvement that need to be addressed. I was, however, pleased with your acknowledgement that the majority of Veterans Health Administration (VHA) OR personnel follow the steps described in VHA Directive 2004-028, *Ensuring Correct Surgery and Invasive Procedures*. As an organization, we work diligently to provide a consistent and high level of patient care in the OR by taking the necessary steps to ensure that the indicated surgical procedure is performed on the correct patient, at the correct site, and if applicable with the correct implant. I believe continued reliance on and adherence to the steps laid out in VHA guidance is an important component of maintaining a safe operating room environment, and all VHA facilities need to consistently comply with the standards.

2. To this point, your report highlights the lack of consistency across the reviewed facilities in complying with the pertinent VHA and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards. I share your concern that VHA needs do a better job of ensuring that local facility policies adhere to and reflect a standardized

interpretation of national policies and required JCAHO elements. A major component of realizing this standardization is improving policy implementation and compliance monitoring. To this end, VHA's Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will work with the National Center for Patient Safety and the Office of Patient Care Services, National Director of Surgery to further reinforce the elements of VHA Directive 2004-028 and VHA Directive 2006-030, *Prevention of OR-Retained Surgical Items*. The National Director of Surgery will further share the report's findings and reinforce adherence to these Directives with the surgical quality boards including the National Surgical Quality Improvement Program, Continuous Improvement in Cardiac Surgery Programs, and the Neurological Surgery Board. OIG Draft Report, Review of Patient Safety in the Operating Room in Veterans Health Administration Facilities, Project No. 2005-00379-HI-0048 (WebCIMS 367759)

3. On the topic of surgical counts, it is important to note that while VHA did not have a directive addressing surgical counts at the beginning of your review, we issued VHA Directive 2006-030, *Prevention of OR-Retained Surgical Items*, on May 17, 2006. Although you used Association of Perioperative Registered Nurses (AORN) recommended practices to determine compliance for surgical counts in your review, I want to highlight the fact that VHA's new Directive goes beyond AORN standards in two important ways: 1) it requires that a methodical wound exploration precede closing the patient; and 2) it requires that in cases where there is a discrepancy in a counted items (e.g., sponge, instrument, or sharp), a radiograph must be obtained within 30 minutes to help determine if the discrepant count is actually associated with a retained surgical item.

4. VHA has also increased expectations for supervision of resident physicians in the last five years. With issuance of VHA Handbook 1400.1, *Resident Supervision*, VHA clarified and strengthened requirements outlining an expanded presence of supervising practitioners, proper documentation of resident supervision, and implementation of local monitoring processes and procedures for specific clinical settings. Additionally, in 2004, VHA designed and

implemented a national performance measure that monitors the timeliness of supervising attending admission notes for medicine, psychiatry, and surgery. Subsequent results for this performance measure show impressive improvement in timeliness over the last two years. Such progress notwithstanding, this review of patient safety in the OR, as well as your recently-released draft report, *Review of Resident Supervision Documentation and Billing Practices in Veterans Health Administration Facilities*, find ample opportunities for improvement in documentation of surgical resident supervision.

5. In regard to your findings, I think it is necessary to clarify that both reviews took place during a period of time when compliance with requirements for resident supervision documentation were rapidly changing. Although this review, which concluded on May 8, 2006, states that inpatient surgery compliance for the resident supervision performance measure was only 53 percent, VHA's 3rd Quarter, FY 2006 national performance measure reflects a markedly improved compliance rate of 86 percent. While I agree that the report's low compliance rate for inpatient surgery is indicative of the need for improvement at the eight facilities you inspected, I believe our improving national performance measure data, which utilizes the External Peer Review Program to analyze a large data set of over 30,000 medical records per year, is evidence that VHA is making significant system-wide progress. Nonetheless, I was pleased with your findings that VHA is substantially compliant (90 percent) with pre-operative note requirements and 100 percent compliant with the brief operative note guidelines. In order to maintain this trend of improvement, VHA will continue all current OIG Draft Report, Review of Patient Safety in the Operating Room in Veterans Health Administration Facilities, Project No. 2005-00379-HI-0048 (WebCIMS 367759) measures to enhance resident supervision and resident supervision documentation.

6. Lastly, I fully agree that Supply, Processing, and Distribution (SPD) should provide a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the operating room. To this end, VA does have in place SPD Handbook 7176, *SPD Operational*

Requirements, identifying that SPD performs a major role in getting the correct supplies, instruments, and equipment to users and assuring that these items are in the correct quantity, location, and condition for use. The VA also has SPD Quality Assurance tools and other resources and training in place to assist field facilities. The issues involved in providing SPD support to end users, especially the operating room, are complex. They involve, for example, close coordination between SPD, the end users and vendors. With surgical care, there can also be unanticipated cases which impacts SPD's and other's ability to provide timely, quality support to the operating room which is dependent on each field facility's local circumstances. Efforts have and will continue to be made with the National Surgical Office, National Operating Room Manager's Workgroup, and the DUSHOM's Office, among others, to ensure continuous improvements in activities that involve SPD support, especially to the OR.

7. Attached is VHA's complete plan of corrective action, which provides a summary of specific initiatives that I believe appropriately address identified issues in the report. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)

Michael J. Kussman, MD, MS, MACP

Attachment

Acting Under Secretary for Health 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 Action 1. We recommend that the Acting Under Secretary for Health, in conjunction with VISN and Medical Center Directors ensure that:

(a) Local facility policy adheres to VHA Directive 2004-028 concerning: (i) confirmation of patient information against informed consent, (ii) staying with patients after they are identified and until they are brought into the OR, and (iii) verification of radiological images.

Concur

Target Completion Date: 6/30/2007

VHA Directive 2004-028, issued May 17, 2006 requires facilities to have a written policy in effect to address what steps must be taken to ensure that the indicated surgical or invasive procedure is performed on the correct patient, at the correct site, and if applicable with the correct implant. It also addresses necessary steps surgical teams must take to prevent the retention of foreign bodies during surgical procedures. On June 2, 2006, the Deputy Under Secretary for Health for Operations and Management (DUSHOM) distributed a memo to the Network Directors and Chief Medical Officers (CMO) reinforcing the elements of this Directive.

DUSHOM will work with the National Center for Patient Safety, the Office of Patient Care Services, National Director of Surgery, and the Office of Nursing Service to further reinforce the elements of this Directive, pertaining to (i) confirmation of patient information against informed consent; (ii) staying with patients after they are identified and until they are brought into the operating room (OR); and (iii) verification of radiological images, during CMO conference

calls, monthly conference calls with all Chiefs, and with OR managers. The Office of Patient Care Services, National Director of Surgery will further share the report's findings and reinforce the elements of the Directive with the surgical quality boards including the National Surgical Quality Improvement Program, Continuous Improvement in Cardiac Surgery Programs, and the Neurological Surgery Board as agenda action items for reinforcement.

The National Center for Patient Safety will work with the Office of Patient Care Services, National Director of Surgery and the Office of Nursing Services to develop a checklist for use at the facility and/or network level that will facilitate the review of local policies for the purposes of establishing conformance with the national policy contained in VHA Directive 2004-028. DUSHOM will then distribute the checklist to the field with the opportunity for facility and/or network level staff to ask key VA Central Office program office staff questions regarding the checklist.

Additionally, informed consent workflow analysis and re-engineering was a large part of the iMedConsent™ implementation guidance. The issues identified in the draft report indicate that the sites reviewed have not re-engineered their clinical workflow in the OR suite to account for the need to verify consent forms as outlined in VHA Directive 2004-028. The National Center for Ethics in Health Care is updating this guidance for re-release to help sites find and address pre- and post-implementation challenges such as those observed by the OIG. After, the National Center for Ethics in Health Care gains concurrence, it will work with DUSHOM to distribute and reinforce the updated guidance. This revised guidance will include requirements regarding training for appropriate staff in all specialty areas in the use of iMedConsent™ by local clinical application coordinators as well as completion of informed consent workflow analysis for every specialty in which iMedConsent™ is (or will be) deployed.

(b) VHA Directive 2006-030 is implemented and monitored for compliance.

Concur

Target Completion Date: 6/30/2007

To reinforce the elements of VHA Directive 2006-030, VHA's National Director of Surgery and Director of Policy and Clinical Affairs presented a briefing on *Patient Safety in the Operating Room, Prevention of Retained Surgical Items* to VHA CMOs on November 27, 2006. Likewise, the Office of Patient Safety and the National Director of Surgery presented a briefing on *Ensuring Correct Surgery Data* to VHA CMOs on October 16, 2006. These presentations were also provided to the VHA National Patient Safety Managers in May, 2006.

Furthermore, the DUSHOM will work with the National Center for Patient Safety and the Office of Patient Care Services, National Director of Surgery to further reinforce the elements of this Directive to ensure implementation and monitoring for compliance during CMO conference calls, Monthly Conference Calls with all Chiefs, and with OR managers. The Office of Patient Care Services, National Director of Surgery will further share the report's findings and reinforce the Directive with the surgical quality boards including the National Surgical Quality Improvement Program, Continuous Improvement in Cardiac Surgery Programs, and the Neurological Surgery Board as agenda action items for reinforcement.

The Office of Patient Safety will work with the Office of Patient Care Services, National Director of Surgery and the Office of Nursing Services to develop a checklist for use at the facility and/or network level that will facilitate the review of local policies for the purposes of establishing conformance with the national policy contained in VHA Directive 2006-030. DUSHOM will then distribute the checklist to the field with the opportunity for facility and/or network level staff to ask key VA Central Office program office staff questions regarding the checklist.

(c) Healthcare engineering disseminates to all field facilities, VHA's interpretation of JCAHO's standard of "periodic" testing of OR-HVAC systems. Healthcare Engineering should consider the possibility of guidance that includes a suggested maximum interval: (i) ensure field facilities review the operational testing data for OR-HVAC systems against the four operational parameters for OR-HVAC systems, (ii) results of the testing are reported to the appropriate standing committee and governing bodies.

Concur

Target Completion Date: 3/1/2007

The Office of Healthcare Engineering will seek JCAHO's intended meaning of the word "periodic" in their standards. Once this clarification is provided, Healthcare Engineering will review and consider whether maximum intervals should be established. When a determination is made, Healthcare Engineering will make an announcement on the National Engineering Conference Call to cover VHA's interpretation of JCAHO's standard of "periodic" testing of Operating Room – Heating, Ventilation, and Air Conditioning systems, as well as guidance on review and reporting of operational testing data. In addition, Healthcare Engineering will post the updated guidance on the Center for Engineering and Occupational Safety and Health web site.

(d) Facility managers' AEMS/ MERS information for clinically-based equipment items is complete and accurate.

Concur

Target Completion Date: 2/16/2007

The Office of Healthcare Engineering will make an announcement reminding the field of its responsibilities on the National Engineering Conference Call. Healthcare Engineering will advise field units to review their existing policies to ensure that standard operating procedures are adequate, and that local reminders may be needed to improve compliance.

(e) Entry/Exit doors serving the OR suite, but not directly observable from the main OR entry area, should allow access only to authorized personnel, to ensure the security of

unattended medications, anesthesia carts, and OR equipment and supplies

Concur

Target Completion Date: 2/28/2007

VHA will form a multi-disciplinary task force to include, but not limited to, representatives from the DUSHOM, Office of Patient Care Services, Anesthesia Service, and the Office of Nursing Services, to develop VHA's position and determine how to distribute guidance to the field.

Recommended Action 2. We recommend that the Acting Under Secretary for Health, in conjunction with VISN and Medical Center Directors, ensure that facility managers:

(a) Encourage facilities to establish an OR/Invasive Procedures Committee that will collect, trend, and analyze patient related variance specific to the OR such as, but not limited to, adverse events and near misses, surgical delays and cancellations, equipment or instrument problems, and incomplete and or incorrect operative consent.

Concur

Target Completion Date: 2/28/2007

VHA Program offices including the Office of Patient Care Services, National Director of Surgery, the Office of Quality and Performance (OQP), the National Center for Patient Safety, the Office of Nursing Services, and the Office of the DUSHOM will assure that this recommendation is communicated to all VHA networks and facilities. VHA facilities will have the option to assign this duty to existing committees that review processes and outcomes of care such as Morbidity and Mortality committees or to establish new committees to assure that local issues related to surgery and invasive procedures are identified and addressed.

In addition, the Office of Patient Care Services, National Director of Surgery will brief CMOs and Chiefs of Surgery on conference calls, by memorandum, and as part of quality

improvement programs associated with the National Surgical Quality Improvement Program and Continuous Improvement in Cardiac Surgery Programs to help establish these committees at each facility. The Office of Patient Care Services, National Director of Surgery will further promote the need to collect, trend, and analyze patient related variance specific to the OR during quality site visits and action plan reviews.

(b) Comply with VHA Handbook 1400.1 regarding documentation of surgical resident supervision.

Concur

Target Completion Date: On-going

As the OIG's report shows, VHA is substantially compliant (90 percent) with pre-operative note requirements and 100 percent compliant with the brief operative note guidelines. Similarly, VHA's 3rd Quarter, FY 2006 national performance measure for inpatient surgery (H&P notes) compliance reflects a high compliance rate of 86 percent. As VHA's improved performance measures can attest, it is clear that resident supervision documentation compliance is increasing rapidly system-wide. These improvements are a direct result of Resident Supervision Handbook 1400.1's precise requirements for all facilities to monitor six specific components of clinical care: 1) inpatient care; 2) outpatient care; 3) consultative care; 4) emergency department; 5) operating room (OR) procedures; and 6) non-OR procedures. Subsequently, VHA will continue all current measures to enhance resident supervision and resident supervision documentation.

(c) Comply with VHA Directive 2005-056 regarding mortality assessment.

Concur

Target Completion Date: 6/30/2007

The OQP will discuss the importance of complying with the Mortality Directive at national CMO/Quality Management Officer meetings or conference calls. Specific policies will

be reinforced regarding the reporting of all deaths by facility, ward, service line and provider (when a specific provider can be linked to the care of specific patients). OQP will obtain examples of compliant mortality trending reports created at the facility level through the System-wide Ongoing Assessment and Review Strategy program and/or by contacting selected facilities. OQP will share these templates during the aforementioned meeting and upload them to its website.

The Office of Patient Care Services, National Director of Surgery will support this initiative by reiterating the criteria and guidance for this Directive as required through communication with all Surgical Service Chiefs and quality review groups.

(d) Disclose and document adverse event discussion with patients and families in the medical records as required by VHA Directive 2005-049.

Concur **Target Completion Date: 3/30/2007**

The Office of the DUSHOM will schedule time on the Thursday Network Director call, Friday Hotline call, CMO calls, and Chief Surgical Officer calls to emphasize that VA providers and facilities must appropriately disclose adverse events to patients harmed in the course of their care in VA. DUSHOM will use examples of non-disclosure identified by the OIG in its report to illustrate the discussion.

VHA Directive 2005-049 is currently under revision. Upon re-issuance of the policy, the National Center for Ethics in Health Care will schedule a National Ethics Teleconference to inform the field about the revisions and address misconceptions about the obligation to disclose and document adverse event discussions with patients and families in the medical records as highlighted by this and other OIG reports.

(e) Initiate M&M reviews as required by VHA Directive 2004-054.

Concur **Target Completion Date: 6/30/2007**

The OQP is forming a new committee, which includes the Office of Patient Care Services, the Office of the Medical Inspector (OMI), Network Directors, CMOs, Quality Managers, and Facility Directors, among others, to review the current peer review policy (VHA Directive 2004-054). This review will include the following topics mentioned in the OIG's report: timing of death reviews, documentation of on-site reviews, and sharing of documentation of reviews conducted off-site at affiliated universities. The purpose of this committee will be to develop approaches to address the deficits identified in the report. Additionally, OMI has been conducting surveys on peer review, and OQP will use survey results to further assess local review of deaths.

Additionally, the Office of Patient Care Services, National Director of Surgery and the Office of the Deputy Under Secretary for Operations and Management will redistribute guidelines for Morbidity and Mortality reviews to all Chiefs of Surgery and Chiefs of Staff. The Office of Patient Care Services, National Director of Surgery will seek evidence of these reviews during all site visits for the Surgery Quality Boards, including: National Surgical Quality Improvement Program, Continuous Improvement in Cardiac Surgery Programs, and Neurosurgery Quality Board.

(f) Delineate which OR providers require ACLS and BCLS training by: (i) implementing a system for monitoring the maintenance of ACLS or BCLS certification or training, (ii) determining where this information will be maintained and how it will be disseminated to staff who need to know of this qualification, (iii) taking appropriate action to assure timely renewal of all certifications or the consequences if not maintained.

Concur

Target Completion Date: 6/30/2007

VHA Directive 2002-046, *Staff Training in Cardiopulmonary Resuscitation and Advanced Cardiac Life Support*, dated July 31, 2002 states, "the medical center director is responsible for ensuring that the facility Cardiopulmonary Resuscitation

Committee determines which staff will be required to maintain current Advanced Cardiac Life Support (ACLS) certification.” The directive also states, “Certain clinical staff may need to have current ACLS certification if, for example, they work in the Coronary Care Unit or Emergency Room (see subpar. 4b), or Operating Room, even if they are not participants in the code team.”

The Office of Patient Care Services will work with the Office of Deputy Under Secretary for Operations and Management to ensure that information regarding ACLS and Basic Cardiac Life Support certification are considered as part of a process at each facility that defines scope of practice policy for operating room providers. Each facility will implement and maintain a policy to ensure compliance.

Recommended Action 3. We recommend that the Acting Under Secretary for Health ensures that SPD provides a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to the ORs.

Concur

Target Completion Date: On-going

VHA developed the National Supply SPD Quality Management Observational Assessment Tool because of the occurrence of multiple issues relating to cleaning, decontamination, and sterilization of patient care medical devices. At the national level, the Office of Patient Care Services, Chief Consultant for Infectious Disease will analyze the results of this survey, which was just completed in October 2006, and work with the Office of the Deputy Under Secretary for Operations and Management to guide future national education and mitigation efforts. At the network and facility level, the findings will provide a status report of current operations and opportunities for improvement as needed.

System-wide Ongoing Assessment and Review Strategy (SOARS) program teams also use two different assessment guides developed specifically for review of SPD and the OR. All VHA facilities undergo a SOARS site visit at least once

every three years. Additionally, VHA selected SPD as one of the Self Assessment and Improvement in High Risk areas for the FY07 VHA Monitoring activities. Each facility will complete a self assessment using the SOARS assessment guide during the First Quarter, FY07.

OIG Contact and Staff Acknowledgments

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