Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care and Management Issues in Surgical Service John D. Dingell VA Medical Center Detroit, Michigan

Report No. 07-01400-16 **October 29, 2007**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Executive Summary

The purpose of this inspection was to determine the validity of allegations reported by an anonymous complainant to the Hotline Section regarding two patients scheduled for procedures in the surgical endoscopy suite. Allegedly, the patients were not appropriate candidates for moderate sedation as defined by John D. Dingell VA Medical Center's local policy.

We did not substantiate problems with the administration of moderate sedation for the two patients identified by the complainant.

Additional concerns that were identified during our inspection included:

- Competency of operating room (OR) nurses in the administration of moderate sedation
- Discrepancies between Veterans Health Administration (VHA) and medical center policies
- Quality management trending, tracking, and analyzing of the medical center's moderate sedation adverse events
- Communication between management and front-line staff
- Alleged patient abuse by a physician

We made recommendations that the Veterans Integrated Service Network Director ensure that the Medical Center Director requires that:

- Administrative Investigative Board recommendations are implemented.
- Local policy reflects VHA policy in cardiopulmonary resuscitation and moderate sedation.
- VHA Surgical Site Visit recommendations are implemented.
- Policies and procedures specify requirements for independent supervisory reviews of incidents.

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

TO: Veterans Integrated Service Network Director (10N11)

SUBJECT: Healthcare Inspection – Quality of Care and Management Issues in Surgical Service, John D. Dingell VA Medical Center, Detroit, Michigan

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI), reviewed allegations reported to the OIG Hotline regarding two patients scheduled for procedures in the surgical endoscopy suite. These patients were allegedly not appropriate candidates for moderate sedation as defined by John D. Dingell VA Medical Center's (medical center) local policy. The purpose of this inspection was to determine the validity of the allegations.

Background

Located in Detroit, Michigan, the medical center provides a broad range of inpatient and outpatient services. Outpatient care is also provided at two community based outpatient clinics located in Yale and Pontiac, Michigan. The medical center is part of Veterans Integrated Service Network (VISN) 11 and serves a veteran population of about 331,000 in a primary service area that includes 4 counties in Michigan.

An anonymous complainant contacted the OIG Hotline and reported that two patients who were scheduled for procedures in the surgical endoscopy suite were not appropriate candidates for moderate sedation[1] according to local medical center policies. Additionally, the complainant alleged that staff were insufficiently educated and trained to administer moderate sedation.

[1] Moderate sedation, also referred to as "conscious sedation," is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands. No interventions are required to maintain an airway, and spontaneous ventilation is adequate.

Scope and Methodology

We reviewed Veterans Health Administration (VHA) policies, medical center policies, and various administrative documents. We interviewed senior management, the Chief of Surgery, the Chief of Anesthesia, the operating room (OR) clinical nurse manager (CNM), and OR nurses who are intermittently assigned to work in the surgical endoscopy suite, and other staff.

We conducted an on-site inspection March 27–30, 2007, and completed telephone interviews on May 15, 2007. We reviewed functional (job) statements, staff meeting minutes, Reports of Contact, surgery schedules, and paper medical records. We also conducted computerized patient record system (CPRS) reviews.

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

Inspection Results

Issue 1: Administration of Moderate Sedation

We did not substantiate problems with the administration of moderate sedation for the two identified patients.

The complainant alleged that two patients, who were scheduled for procedures in the surgical endoscopy suite on November 30, 2006, were inappropriate candidates to receive moderate sedation. It was alleged that administration of moderate sedation was contraindicated by local policies due to their American Society of Anesthesiologists (ASA) scores. Further allegations were that one patient's ASA score was lowered in an effort to circumvent the need to enlist Anesthesia Service support.

In 1961, the ASA adopted a five-category physical status classification system for assessing a patient before surgery. A sixth category was later added. The categories are:

I. A normal healthy patient.
II. A patient with mild systemic disease.
III. A patient with severe systemic disease.
IV. A patient with severe systemic disease that is a constant threat to life.
V. A moribund patient who is not expected to survive without the operation.
VI. A declared brain-dead patient whose organs are being removed for donor purposes.

Patient #1. We found that this patient did not in fact receive moderate sedation. The patient was scheduled for a flexible sigmoidoscopy on November 30 for follow-up management of abnormal pathology results from tissue samples collected during a November 22 bowel resection surgery. Prior to the procedure, a surgical resident entered a pre-procedural sedation note. However, this note was not necessary because the patient was not scheduled for, nor did he receive, moderate sedation. It would be unusual to use moderate sedation for this type of procedure.

The complainant alleged that the patient became angry when the physician informed him that he would not receive sedating medications. A surgeon told us that he had educated the patient prior to the procedure and that sedation was not an expectation after that discussion. A surgeon's note entered December 1 states that the patient remembered the procedure and was comfortable.

Patient #2. The patient was scheduled for a colonoscopy on November 30, 2006. The patient's past medical history included sleep apnea, chronic obstructive pulmonary disease, and hypertension. The complainant alleged that the patient was an inappropriate candidate for moderate sedation.

We reviewed the patient's CPRS documentation and paper medical records and found that the patient was classified as ASA II. Versed® (midazolam) 3 mg and Demerol® (meperidine) 50 mg intravenously were administered. The Chief of Anesthesia told us that in his opinion the patient should have been classified as ASA III. Of note, however, no medical center policy specifies that patients receiving moderate sedation must be classified ASA I or II. The medical center's Risk Manager reported no adverse outcomes involving the administration of moderate sedation.

At the time of our inspection, the surgical endoscopy suite had been closed since December 13, 2006, and it has remained closed as of the date of our report. All procedures are now performed in the medical endoscopy suite. This closure, directed by the Chief of Staff, was intended to ensure patient safety while allowing time for review of allegations of patient abuse by a physician practicing in the surgical endoscopy suite and an evaluation of interpersonal relationships among OR staff members.

Issue 2: Moderate Sedation Training and Education

VHA's moderate sedation policy[2] requires individuals administering, monitoring, and/or supervising moderate sedation have competency-based education, training, and experience in:

[2] VHA Directive 2006-023, *Moderate Sedation by Non-Anesthesia Providers*, issued May 1, 2006.

1. Evaluating patients before performing moderate sedation.
2. Performing moderate sedation, including rescuing patients who slip into deep sedation.
3. Knowing the pharmacokinetics of the drugs typically used for moderate sedation, as well as the potential effects of the drugs on vital functions.
4. Training in cardiopulmonary resuscitation (CPR), airway management, and management of cardiac arrhythmias.

Local policies are required to specify that a sufficient number of qualified staff (in addition to the individual performing the procedure) is present to evaluate the patient, help with the procedure, and provide sedation, monitor, and recover the patient. The person performing the procedure cannot be the primary individual monitoring the patient's cardiac status, airway, and other physical assessments.

We interviewed OR nurses and asked about their training and level of comfort in administering moderate sedation. The nurses informed us of an on-line training course provided by the VA Employee Education System (EES). The course was completed in a group effort, and the answers to questions were chosen after group discussion and agreement. We received 15 completion certificates giving 2 educational contact hours for the assigned OR nurses and found 13 were completed on August 30, 2006. The EES course objectives do not include cardiac arrhythmia recognition.

We found that only one OR staff nurse had Advanced Cardiac Life Support (ACLS) certification, even though medical center policy states that registered nurses assigned to the surgical endoscopy suite must have this certification. We were informed that OR staff nurses had recently begun to take the ACLS course in 1-hour segments. Some of the OR staff nurses expressed that they had not been trained in irregular heart rhythm recognition and that this added to their anxiety in administering moderate sedation.

Physicians informed us that they are responsible for monitoring moderate sedation patients, inferring that the responsibility is solely theirs. Managers informed us that 1 week prior to closure of the surgical endoscopy suite, critical care nurses assigned to intensive care units replaced OR nurses for the care of patients requiring moderate sedation.

The medical center's local moderate sedation policy states that one person involved in the procedure needs ACLS certification. This is in conflict with VHA policy, which states that all participants monitoring or administering moderate sedation need training in cardiac arrhythmias, which can be obtained through ACLS certification or by other means.

We reviewed moderate sedation competency checklists for a sample of OR nurses. The OR CNM completed the EES moderate sedation training program on the same day as the

rest of the OR staff and signed the checklists. The OR CNM is not ACLS certified. We found no evidence of involvement of practitioners or educators with expert knowledge in the area of moderate sedation to support the OR nurses in acquiring this knowledge base or skills. During our interviews, we asked the nurses about the few common reversal agents used in moderate sedation for opiates and sedatives. Most were unable to answer correctly.

We interviewed the Chief of Anesthesia and asked if his service was involved in any education and training for the OR nursing staff, particularly in airway management and sedation. He described plans and a desire to provide staff education, but said that a severe shortage of staff precluded Anesthesia Service from participating in any education and training initiatives.

During our interviews, we found nurses were not familiar with local medical center policy regarding moderate sedation. Some nurses expressed anxiety and felt it was against policy to administer moderate sedation drugs to patients with an ASA score greater than II.

Issue 3: Medical Center Policies Conflict with VHA Policies

Moderate Sedation Policy. We reviewed the medical center's moderate sedation policy and found the policy required vital signs be recorded every 10 minutes. VHA policy requires vital signs be documented every 5 minutes. We found in our record review that vital signs were documented every 5 minutes.

ACLS training. VHA policy states the CPR Committee will make the determination of which critical staff will maintain ACLS certification. Managers informed us that the Critical Care Committee, which is a subcommittee of the CPR Committee, makes this determination. In addition, the medical center policy states registered nurses working in the surgical endoscopy suite must have ACLS certification. Only one nurse among the OR nursing staff was reported to have ACLS certification.

CPR training. VHA policy requires that all clinical active staff have CPR education. The medical center policy only requires that medical staff with appointments of one-eighth (1 day a week) or greater complete CPR education. We reviewed three credentialing and privileging folders and found one provider, a consultant, who did not have evidence of CPR training at the time of privileging.

Managers informed us that they would review and correct the policies to comply with VHA policies.

Issue 4: Quality Management Concerns

We reviewed moderate sedation data collected from December, January, and February of fiscal year 2007, but found no other data. The absence of information from prior periods

is inconsistent with VHA policy. Moderate sedation adverse events are expected to be reviewed and analyzed in conjunction with operating room anesthesia adverse events, and used to improve performance. Staff told us that the previous Chief Nurse Anesthetist reviewed this data; however, there was no evidence of previous data analysis in the OR or in Quality Management (QM) records. The Chief of Anesthesia is also the Moderate Sedation Committee chairperson. The committee is supposed to meet monthly and review any problems with moderate sedation. A QM coordinator told us that a new process was recently implemented which involved the development of a software spreadsheet by which providers will input monthly moderate sedation data.

Issue 5: Communication

VHA officials, at the request of the VISN Director, conducted a Surgical Site Visit on February 13–14, 2006. The purpose of the site visit was to review leadership and processes related to Surgical Service and to review three prior incidents, two of which involved previous OIG casework. Several recommendations were made. The Site Visit report noted that trust between OR staff and OR managers needed to improve and that team-building exercise could be beneficial. We were informed of forums that have occurred allowing select OR staff to verbalize issues to management, but found little evidence of a concerted effort to build effective teams and maintain effective leadership.

Despite attempts to resolve concerns, unrest and lack of trust between leaders and staff persist. There have been constant changes in OR nursing leadership at various supervisory levels. During our interviews, staff expressed fear of reprisal due to our inspection.

We were told that the Operating Room Executive Leadership Council, comprised of the Chief of Staff, the Associate Director for Patient Care Services, the Associate Chief Nurse for Surgical Services, and the Chief of Surgery, has been meeting on a weekly basis. However, there was no documentation that these meeting occurred. The Chief of Surgery told us that he frequently meets informally with the OR CNM to address specific issues.

Issue 6: Patient Abuse

Staff told us that during the course of our inspection an Administrative Investigative Board (AIB) was charged with reviewing allegations of patient abuse involving a physician who performed procedures in the surgical endoscopy suite. Staff alleged that the physician did not administer appropriate amounts of analgesia, he ignored a patient's request to abort the procedure until a manager intervened, and that his procedures were long when compared to other providers. Staff told us that they had reported these occurrences to former CNMs and to the Chief of Surgery verbally and in multiple Reports of Contact. Management officials, however, informed us that they had no knowledge of these reports.

On July 11, 2007, we received a memorandum dated May 30, 2007, with the signature of the Medical Center Director detailing the conclusions, recommendations, and planned actions of the AIB. The Board did not substantiate patient abuse but concluded that sedation and analgesia were not given in amounts that are commensurate with the duration of the procedure.

We reviewed medical center policy regarding patient abuse. We found two patient incident reports alleging patient abuse and the reports had been signed by the physician alleged to be the abuser. For these occurrences, the physician indicated a severity level of 0 on one and 1 on the other (on a scale of 0 to 3, with 3 being the most severe). Such incidents should be reviewed by an individual who has no vested interest in the case being reviewed; however, local policy does not provide specific guidance in these matters.

Conclusions

We did not substantiate that the two patients identified in the allegation suffered untoward outcomes due to administration of moderate sedation. However, we found that OR nurses were insufficiently prepared to participate in the care of patients requiring moderate sedation and that inadequate training programs were in place.

We found that medical center policies did not meet VHA expectations and that performance improvement activities related to moderate sedation were inadequate. We also found that staff communication continues to be problematic in the OR and that VHA Surgical Site Visit recommendations have not been addressed.

We found that local policy did not provide specific guidance regarding a requirement for independent supervisory review of patient incidents.

We reviewed the medical center's AIB findings, conclusions, and recommendations. The AIB made the following recommendations:

- All endoscopic procedures performed by the surgeon must be monitored to ensure adequate pain control;
- Quality assurance monitors should be put in place to monitor moderate sedation practices;
- All endoscopies should be performed in a single endoscopy suite;
- Annual continuing education should be conducted for all staff involved in the care of patients receiving moderate sedation;
- OR nursing and physician managers should meet monthly to address staff complaints;

- Patient education should include details about the procedure and anticipated potential for pain.

Implementations of these recommendations will improve patient satisfaction and overall management of moderate sedation.

Recommendations

Recommendation 1. We recommend that the VISN Director ensure that the Medical Center Director ensures that AIB recommendations are implemented.

The VISN and Medical Center Directors agreed with the findings and recommendation. The Directors provided acceptable plans to address the AIB recommendations. Implementation actions are ongoing. We will follow up on their actions.

Recommendation 2. We recommend that the VISN Director ensure that the Medical Center Director ensures that local policy reflects VHA policy in CPR and moderate sedation.

The VISN and Medical Center Directors agreed with the findings and recommendation. The local CPR policy is being revised to be consistent with VHA policy. We will follow up on their actions.

Recommendation 3. We recommend that the VISN Director ensure that the Medical Center Director ensures that VHA Surgical Site Visit recommendations are implemented.

The VISN and Medical Center Directors agreed with the findings and recommendation. The Directors provided acceptable plans to address the VHA Surgical Site Visit recommendations. Implementation actions are ongoing. We will follow up on their actions.

Recommendation 4. We recommend that the VISN Director ensure that the Medical Center Director ensures that policies and procedures specify requirements for independent supervisory reviews of incidents.

The VISN and Medical Center Directors agreed with the findings and recommendation. Implementation plans were provided, and we will follow up on planned actions.

Comments

The VISN and Medical Center Directors agreed with all findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 11–18 for the full text of their comments.) We will follow upon on all planned actions until they are completed.

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

Appendix A

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 31, 2007

From: VISN Director (10N11)

Subject: **Quality of Care and Management Communication Issues in Surgical Service**

To: Director, Chicago Office of Healthcare Inspections (54CH)

Per your request, attached is the response from John D. Dingell VAMC, Detroit. If you have any questions, please contact Jim Rice, VISN 11 QMO, at 734-222-4314.

Linda W. Belton, FACHE

Department of Veterans Affairs **Memorandum**

Date: August 31, 2007

From: Medical Center Director (553/00)

Subject: **Quality of Care and Management Communication Issues in Surgical Service**

To: Director, Management Review Service (10B5)

1. I would like to thank the members of the OIG team who were involved in the review of this hotline complaint. Their thoroughness and expert attention to detail have provided the executive leadership team at the John D. Dingell VA Medical Center and the operating room leadership with a roadmap for success.

2. I think that in our response you will find that leadership and staff have worked together to implement recommendations from both the Central Office review of surgical service as well as the recommendations developed after the AIB related to endoscopy procedures in the O.R. It is our intent to fully implement all of these recommendations timely, and to continue to ensure that an environment of improved trust and communication, and excellent patient care are embedded in our day-to-day activities.

Michael K. Wheeler

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

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

OIG Recommendation(s)

Recommended Improvement Action:

1. **We recommend that the VISN Director ensure that the Medical Center Director ensures that the AIB recommendations are implemented.**

   Concur Target Completion Date: 10/1/07

   a. All procedures performed by the surgeon have been monitored by a medical GI endoscopist. To date, the surgeon performed only two procedures. A written report from the GI endoscopist indicated there was adequate sedation, adequate pain control, and adequate technique in both procedures. No areas of concern were detected. We will continue to monitor this for 3 months and then re-evaluate the issue.

   b. An organizational change was suggested by the Chief of Staff and approved by the VISN. The organizational change includes the establishment of a new Associate Chief of Staff position for Integrated Clinical Services; effective date is September 2, 2007. Among other duties, this ACOS will review the activities of the Integrated Endoscopy lab and the Conscious Sedation Committee. This committee will be revised to be chaired by the Chief of the Gastroenterology section and include representation from Pulmonary Medicine, Anesthesia, Pain Service, Surgery, Nursing and Pharmacy. This committee will establish monitors to review conscious sedation administration and pain control, and monitor educational and training activities of all individuals involved in conscious sedation in the medical center.

c. The Surgical Endoscopy unit was closed effective 12/13/06 and the decision to make this permanent was effective August 27, 2007. An organizational change was suggested by the Chief of Staff and approved by the VISN. The organizational change includes the establishment of a new Associate Chief of Staff position called ACOS for Integrated Clinical Services. Among other duties, this ACOS will supervise the Integrated Endoscopy Laboratory where all endoscopic procedures by all services will be performed. Status: Completed.

d. **Annual continuing education should be conducted for all staff involved in the care of patients receiving moderate sedation.** Moderate sedation has not been completed by OR nurses since 12/13/06 nor will they be involved anymore. All nursing staff in the Integrated Endoscopy unit are ACLS certified and completed EES Moderate Sedation Course. Status: Completed.

e. **OR nursing and MD managers should meet monthly to address staff complaints.** The OR Clinical Nurse Manager and Chief of Surgery meet weekly to discuss staff/physician complaints, new directives for the OR, SCIP data management, review of incident reports, policy and procedures, discuss reports of contact and position management issues. Status: Completed.

f. All endoscopy procedure consents are now obtained through the IMED system. Information regarding pain and pain management are integral to the electronic consent and are discussed with the patient by the individual performing the procedure using the electronic template on a regular basis. Status: Completed.

2. We recommend that the VISN Director ensure that the Medical Center Director ensures that the local policy reflects VHA policy in CPR and moderate sedation.

Concur Target Completion Date: 10/1/07

a. The local CPR policy is currently being revised to be consistent with VHA policy. Specifically, all physicians practicing at the medical center will be CPR certified.

3. We recommend that the VISN Director ensure that the Medical Center Director ensures that the VHA Surgical Site Visit recommendations are implemented.

Concur Target Completion Date: 10/1/07

[The Medical Center provided the OIG a detailed explanation of their actions to implement VHA's Surgical Site Visit recommendations which is not included here.]

4. We recommend that the VISN Director ensure that the Medical Center Director ensures that the policies and procedures specify requirements for independent supervisory reviews of incidents.

Concur Target Completion Date: Completed

a. The Medical Center will require incidents to be reviewed by an individual that has no vested interest in the case being reviewed, which will ensure an impartial review is done.

b. The written reports are reviewed at the service level.

c. The service level review is discussed by the peer review committee for concurrence if applicable. The peer review committee may agree with or adjust the level assigned by the service chief and may review incident reports when necessary.

d. Peer review committee findings and deliberations are reported to the Chief of Staff and discussed in aggregate during the monthly deliberations of the

Health Leadership Council for Clinical Care, which includes, among other members, all Clinical Service Chiefs. The aggregate reviews are reported quarterly.

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, RN, MN, Director Chicago Regional Office of Healthcare Inspections (708) 202-2672
Acknowledgments	Jerome Herbers, MD, Medical Consultant Jennifer Reed, Health Systems Specialist Judy Brown, Program Support Assistant

Appendix C

Report Distribution

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