Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Evaluation of Management of Moderate Sedation in Veterans Health Administration Facilities

Report No. 04-00330-15 **November 1, 2005**

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Washington, DC 20420

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

TO: Under Secretary for Health (10/10B5)

SUBJECT: Healthcare Inspection – Evaluation of Management of Moderate Sedation in Veterans Health Administration Facilities

1. Summary

The Department of Veterans Affairs Office of Inspector General's (OIG) Office of Healthcare Inspections completed an evaluation of Veterans Health Administration (VHA) medical facilities' moderate sedation programs. The purpose of the evaluation was to determine whether patients who receive moderate sedation during invasive procedures performed outside the operating room (OR) receive a commensurate level of care as patients who have procedures performed in the OR, thus meeting Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards.[1]

During Combined Assessment Program (CAP) reviews from February 1 through September 30, 2004, we reviewed 30 facilities that had non-anesthesia clinicians administering moderate sedation outside the OR. The review did not include facilities where anesthesiologists or certified registered nurse anesthetists administered moderate sedation outside the OR.

There is no official VHA Directive regarding moderate sedation administered by non-anesthesia clinicians. *VHA Handbook 1123 Anesthesia Service*, which was due for recertification in March 2003, establishes the programmatic structure, policies, and procedures that are to be used for the practice of anesthesia in VHA.[2] However, it was developed for the Anesthesia Service in the OR and has not been updated. There is information regarding moderate sedation on the VHA National Anesthesia Service website, including sample policies and links to other related sites, but not all facilities were aware of that resource.

[1] JCAHO, Comprehensive Accreditation Manual for Hospitals: (CAMH), 2004.
[2] VHA Handbook 1123, Anesthesia Service, March 27, 1998.

Of the 30 facilities reviewed, 10 (33 percent) facilities provided the same level of care for patients receiving moderate sedation outside the OR. All 30 facilities had developed local policies and procedures for sedation/analgesia, but the scope and quality varied; not all facilities complied with their own policies and procedures. We made recommendations for corrective actions in 20 (67 percent) of the 30 facilities (see Appendix A). Corrective actions will ensure quality care for patients undergoing procedures outside the OR. The majority of the recommendations were in the following six program areas:

- Cardiopulmonary resuscitation training.
- Moderate sedation training.
- Clinical privileges.
- Pre-sedation assessment and re-evaluation immediately prior to sedation.
- Patient transport to recovery rooms after sedation.
- Trending and analysis of adverse events.

2. Background

In 1996, VHA required all facilities to develop plans for invasive ambulatory care procedures as a cost effective alternative to inpatient care.[3] Many procedures, once staffed by anesthesiologists and performed in traditional operating rooms, have moved to other more cost effective settings. These may include, but are not limited to, procedure areas such as pulmonary, gastroenterology, nuclear medicine and radiology suites, emergency departments, cardiology, and dental clinics. Management of pain and anxiety is vital in providing quality patient care during invasive and diagnostic procedures.

Moderate sedation/analgesia is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.[4] Clinicians frequently administer moderate sedation because there are fewer side effects, including less nausea. Patients usually recover quicker, and there is a partial level of amnesia so they do not remember the procedure. The goals of moderate sedation are to facilitate the performance of a procedure, control pain and anxiety, and return the patient to a state in which safe discharge is possible.

Any level of anesthesia has the potential for complications, and patients can progress to a deeper level of sedation. Areas outside the OR are traditionally not staffed by anesthesiology and may not have the proper equipment, competent employees, or effective processes for safe administration and monitoring of sedation. The same anesthesia standards of care required in the OR also apply to these areas.

VHA Anesthesia Service follows guidelines and standards as described by JCAHO, the American Society of Anesthesiologists (ASA), and the American Association of Nurse Anesthetists. JCAHO requires that facility managers provide the same standard of care

[3] VHA Directive 96-046, July 16, 1996.
[4] American Society of Anesthesiologists, October 13, 1999.

throughout a facility. All patients in all care settings should receive comparable and acceptable quality of sedation/analgesia care.

This review determined whether appropriate guidelines were in place and followed for the assessment, administration, monitoring, and discharge of patients receiving moderate sedation outside the OR.

3. Scope and Methodology

We conducted this review in conjunction with OIG CAP reviews of VA medical facilities from February 1 through September 30, 2004. Four facilities did not meet review criteria and were not included in the data collection because they either did not provide moderate sedation or had anesthesia clinicians providing that care. The 30 facilities included in the data collection represented a mix of facility size, affiliation, geographical location, and Veterans Integrated Service Networks (VISNs). To evaluate moderate sedation programs at the 30 facilities, we interviewed key employees; evaluated policies and procedures; assessed patient treatment areas; and reviewed patient treatment records, results of the most recent JCAHO survey, moderate sedation outcome monitors, training records, credentialing and privileging folders, and scopes of practice. Our objectives were to: a) determine if facility policies and procedures complied with JCAHO and VHA standards in the approach to the management of patients receiving moderate sedation and b) evaluate patient safety related to the administration and monitoring of moderate sedation.

We evaluated the following:

- Qualifications of clinicians.
- Patient selection, preparation, and assessment prior to sedation, including patient education and informed consent.
- Appropriateness of equipment for care and resuscitation.
- Appropriateness of monitoring during sedation.
- Documentation of care.
- Patient recovery post-sedation, including discharge criteria and instructions.
- Trending and analysis of adverse events.

Prior to each CAP visit, we reviewed medical staff bylaws and policies to determine if there were facility specific requirements for clinicians administering and monitoring moderate sedation outside the OR, and if those policies and procedures complied with JCAHO standards. Facilities identified areas where moderate sedation was provided, the names of patients who received moderate sedation in the prior quarter, and the names of clinicians administering and monitoring moderate sedation. Inspectors randomly selected 10 patient records for review, including a sample from each area where moderate sedation was administered. Inspectors randomly selected five clinicians, including physicians and nurses, who administered or monitored moderate sedation in the different areas. These providers' credentialing folders, training records, and scopes of practice were reviewed to determine if they were qualified to manage patients receiving moderate sedation. Three treatment areas were randomly selected for review to determine if appropriate equipment was immediately available, if processes were in

place for safe administration, and to determine how adverse events were reported. Inspectors evaluated outcome analyses and quality improvement processes for moderate sedation.

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

4. Inspection Results

Issue 1: VHA Anesthesia Guidance

All 30 facilities had current sedation/analgesia policies, but 20 (67 percent) of the 30 facilities needed to improve aspects of their programs to comply with all of the JCAHO anesthesia standards. Not all policies included the required elements from JCAHO standards. There was a variance in practice among facilities because VHA has not defined national requirements for the administration of moderate sedation outside the OR.

VHA Handbook 1123 Anesthesia Service, dated March 27, 1998, provides guidance for the anesthesiology services and sections in VHA medical treatment facilities. The handbook was due to be recertified in March 2003, but it has not been updated. The Director of Anesthesia Service for VHA stated that the handbook was developed for anesthesia services performed by anesthesiologists and does not address moderate sedation performed by non-anesthesia clinicians outside the OR. JCAHO standards define moderate sedation as a level of anesthesia no matter where it is administered.

In order to standardize practice throughout facilities and ensure patient safety, VHA needs to develop national guidelines that define the minimal level of cardiopulmonary resuscitation (CPR) training required for clinicians administering and monitoring moderate sedation by non-anesthesia clinicians outside the OR. This should include specific standards of practice for clinicians who administer and monitor moderate sedation, certification and training requirements for clinicians, patient assessments, pre and post procedure monitoring requirements, discharge processes, and analysis of adverse events. Once policies and procedures are established, facilities need to ensure they are meeting their own requirements.

Issue 2: Cardiopulmonary Resuscitation Training

Clinicians who administered or monitored moderate sedation at 11 (37 percent) of the 30 facilities did not have current CPR certification, as required by local policy. VHA Directive 2002-046 requires that each medical facility have a policy that defines appropriate staff training in CPR and Advanced Cardiac Life Support (ACLS).[5] This directive requires all clinically active staff have had CPR Training.

At the facilities that had CPR training deficiencies, 22 (40 percent) of the 55 sampled clinicians did not have the required CPR certification. We based our review of training on what was required by local policy. Requirements ranged from basic CPR to ACLS certification. Because clinical managers did not always define the appropriate staff training in local policies, there was

[5] VHA Directive 2002-046, Staff Training in Cardiopulmonary Resuscitation and Advanced Cardiac Life Support, July 31, 2002.

a variance in training among clinicians. In some facilities, registered nurses (RN) had completed ACLS training but physicians had not completed basic CPR training. In one facility, contract physicians did not have either CPR or ACLS training, as required by local policy. Facilities were not consistently tracking CPR and ACLS certifications to ensure that clinicians remained current. Without current CPR, there is no guarantee that clinicians have received the continued training necessary to ensure patient safety. JCAHO standards require clinicians to be qualified to manage a compromised airway and to provide adequate oxygenation and ventilation should a patient experience complications and a deeper level of sedation occur.

Until VHA has developed and issued minimal standards that define the minimum level of CPR training, as discussed in Issue 1, facilities need to ensure that local requirements are defined and all clinically active staff have current CPR certification.

Issue 3: Moderate Sedation Training and Competency Assessments

Clinicians had not completed the facility required training to administer or monitor moderate sedation in 5 (17 percent) of the 30 facilities. If facility policies required specific training for the administration and monitoring of moderate sedation, we reviewed clinicians' training records to determine if they had received that training. JCAHO requires that clinicians be qualified to provide moderate sedation and have competency based education and training and experience in evaluating patients prior to performing moderate sedation. Included in these qualifications is the ability to administer pharmacologic agents to predictably achieve the desired level of sedation and to monitor patients carefully in order to maintain the desired level of sedation.

We found a wide variance in training requirements and program development among facilities. One tertiary medical center had developed a training course with the other university affiliated hospitals in the community and required all residents to complete training and a refresher course every two years. Other facilities had no training requirements or competency assessments regarding moderate sedation or had not ensured that all clinicians completed the required training. Patients are put at risk if clinicians do not have appropriate training and ongoing competency assessments.

VHA needs to define minimal training requirements and every facility needs to have training and competency assessments clearly defined in local policy.

Issue 4: Clinical Privileges

In 3 (10 percent) of the 30 facilities, clinicians did not have current clinical privileges to administer moderate sedation. JCAHO and VHA require that physicians must have privileges approved by the medical staff. Eight physicians did not have privileges that included the administration of moderate sedation. One of those physicians performed all of the gastroenterology procedures in the facility. Facility directors and chiefs of staff had not ensured that all physicians were privileged to perform procedures.

Issue 5: Pre-Sedation Assessments and Re-Evaluations Immediately Prior to Sedation

Clinicians at 10 (33 percent) of the 30 facilities had not completed pre-sedation assessments and re-evaluations immediately prior to the administration of moderate sedation. JCAHO requires

that all patients receiving moderate sedation have a pre-assessment within 30 days of the procedure, which must include a review of medical, anesthesia, and medication history; a physical exam; an assignment of an ASA classification; an anesthesia plan of care; and a discharge plan. The ASA classification is a ranking of the patient's physical status and corresponding risk of sedation that determines whether an anesthesia consult is recommended. A re-evaluation is required immediately before the procedure to ensure that the patient's condition has not changed since the pre-assessment.

All patients were assessed for the medical reason for the procedures. However, assessments did not always include an anesthesia or medication history and an ASA classification. In some cases, clinicians were not aware of the JCAHO requirements and had not received proper training. In other cases, they were not following local policies and procedures.

Patients are at risk for possible complications if not properly assessed prior to administration of moderate sedation. Pre-assessments are important to rule out the need for anesthesia clinicians to perform sedation, or to have the procedure done in the OR with more intense monitoring. This standard was not consistently met, and not all patients had their respiratory and cardiac status assessed prior to starting sedation.

Issue 6: Transport to Recovery Rooms after Sedation

In two facilities, patients' cardiac and respiratory status were not continuously monitored during transport from procedure rooms to the recovery area. JCAHO standards specify that patients need to be monitored immediately after moderate sedation until they are discharged from the recovery area. ASA practice guidelines for sedation and analgesia by non-anesthesiologists dated October 17, 2001, require monitoring of oxygenation during sedation and analgesia. Hypoxemia is more properly monitored by pulse oximetry than by clinical assessment alone.

The recovery units at these two facilities were located on different floors from the procedure rooms, and monitoring equipment was not available during transport. Patients were transported as soon as they were alert (approximately five minutes after completion of the procedure) and remained in the recovery areas until they were fully recovered, which could take up to two hours. Portable oximetry monitoring units would alert RNs to changes in the patients' conditions during transport. Transporting patients without proper equipment places them at risk for cardiac and respiratory complications.

Although patient monitoring following moderate sedation was only a concern in two facilities, the potential for an adverse outcome was significant.

Issue 7: Adverse Event Trending and Analysis to Improve Patient Care

Clinical managers needed to improve tracking and trending analysis of adverse events in 5 (17 percent) of 30 facilities. JCAHO requires that facility managers systematically aggregate and analyze data and use the information to implement changes and to evaluate these changes to determine whether the expected results were achieved. The five facilities that needed to improve did not capture adverse events from all areas performing moderate sedation or did not report events for evaluation of performance.

We found a wide variance among facilities that ranged from no procedure areas reporting adverse events to facilities where anesthesiologists were actively involved in the review of moderate sedation outcome data to improve clinical practice. When adverse events are not reported or only reported to individual services, it is not possible to identify system-wide problems. Facilities needed to include the mechanism for reviewing adverse events in their local policies.

5. Conclusion

We concluded that the administration of moderate sedation outside of the OR by non-anesthesia clinicians was generally safe and effective. Patients were monitored during procedures and all facilities had defined discharge criteria from recovery areas. We did not find any adverse events that occurred because of unsafe conditions. Equipment was available to monitor patients during procedures and there was adequate staff. The two facilities that were not monitoring patients during transport to recovery rooms have corrected that practice. In general, documentation in medical records was sufficient and reflected the care provided. For these reasons, we determined that patient safety was generally satisfactory.

However, not all clinicians had current clinical privileges to administer or monitor moderate sedation, and there were deficiencies in current certification for CPR. Facilities need to be aware of the importance of maintaining current competencies and qualifications for clinicians.

Pre-sedation assessments need to be improved and should include assigned ASA classifications. Adverse event reporting also needs to be improved. We found that in the facilities where anesthesiologists were involved in the review of moderate sedation outcomes, the data was used to develop educational programs for clinicians and improve patient outcomes.

We concluded that there was a difference in levels of care for patients who receive moderate sedation during invasive procedures performed outside the OR than those who have procedures performed in the OR in 20 of the 30 facilities.

6. Recommendations

We recommended that the Under Secretary for Health:

Recommended Improvement Action(s) 1. Develop and implement VHA policy for the administration of moderate sedation outside the OR that includes specific standards of practice and the required JCAHO elements.

Recommended Improvement Action(s) 2. Ensure compliance with current VHA Directive 2002-046 regarding cardiopulmonary resuscitation training.

Recommended Improvement Action(s) 3. Ensure that all clinicians administering moderate sedation maintain current training and clinical privileges/scopes of practice.

Recommended Improvement Action(s) 4. Ensure moderate sedation adverse events are reported, trended, and analyzed in conjunction with OR anesthesia adverse events, and the data is used to improve performance.

Under Secretary for Health Comments

The Under Secretary for Health concurred with the results of this evaluation. They will develop and issue a comprehensive policy directive and develop national implementation plans.

Inspector General Comments

The Assistant Inspector General for Healthcare Inspections agrees with the response of the Under Secretary for Health to the issues raised in this inspection report. 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

Appendix A

Review Findings

Facility	Outcome Data Analysis	CPR Training	Moderate Sedation Training/ Competency	Monitoring Equipment	MD Privileging	Clarify Policies/ Procedures	Discharge Instructions	Assess-ments	Medical Record
Chillicothe	X								
Southern Nevada								X	
Amarillo	X	X	X					X	
*Memphis				X*					
Chicago		X		X				X	X
Portland		X							
Beckley					X			X	
St. Louis		X				X			
Richmond	X	X	X					X	
Cleveland						X			X
Northern Indiana	X	X	X						
Eastern Colorado					X				
North Texas	X								
Eastern Kansas		X			X	X			
Dayton								X	
Dublin							X	X	
Philadelphia		X		X			X	X	X
Columbia		X	X					X	
Nebraska/ Western Iowa		X	X			X			
Indianapolis		X				X		X	X

Additional facilities that were reviewed but had no recommendations:

Phoenix, Gulf Coast, Central California, New York Harbor, North Florida/South Georgia, Montana, White River Junction, Martinsburg, Hines, and West Texas

*At Memphis, although the monitoring equipment was available, the alarm on a machine was turned off.

Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: OCT 13 2005

From: Under Secretary for Health (10/10B5)

Subj.: OIG Draft Report, *Healthcare Inspection: Evaluation of Moderate Sedation in Veterans Health Administration Facilities*, Project No. 2004-00330-HI-0034 (EDMS 322794)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed this draft report and am pleased the report reflects that the administration of moderate sedation outside the operating room (OR) by non-anesthesia clinicians in the Veterans Health Administration (VHA) is generally safe and effective. I appreciate you meeting with our staff on September 16, 2005 to address some issues concerning the initial draft report. As a result of this meeting and the ensuing changes to the report, I concur with the findings and recommendations of the revised draft report.

2. The report cites opportunities for improvement, and as an organization, we will continue to work diligently to ensure that the highest quality of care is consistently provided. As Joint Commission on Accreditation of Healthcare Organizations (JCAHO)-accredited institutions, I expect all VHA facilities to meet the JCAHO standards. Although all of the facilities you visited have current sedation/analgesia policies, your report highlights the lack of consistency across the facilities in complying with all of the JCAHO moderate sedation standards. To ensure greater consistency, VHA's Patient Care Services (PCS) will lead the effort in developing and implementing a comprehensive policy directive that includes specific standards of practice and the requirements set forth in the JCAHO standards addressing moderate sedation outside of the OR. The workgroup will be interdisciplinary, consisting of headquarters and field representatives.

3. This directive, when implemented, will also provide guidance to ensure that local facilities have and follow a policy that defines appropriate staff training in cardiopulmonary resuscitation (CPR) for practitioners providing moderate sedation outside the OR. As the draft report highlighted, although all the facilities investigated had policies regarding CPR training (some of which exceeded the JCAHO standard), not all facilities consistently followed their local policy.

4. Attached is VHA's complete corrective action plan. The plan provides a summary of specific initiatives that appropriately address the issues raised and the report's recommendations.

5. 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.

Jonathan B. Perlin, MD, PhD, MSHA, FACP

Attachment

Under Secretary for Health Comments

VETERANS HEALTH ADMINISTRATION
Action Plan
OIG Draft Report: *Healthcare Inspection: Evaluation of Moderate Sedation in Veterans Health Administration Facilities*, Project No. 2004-00330-HI-0034

Recommendations/ Actions	Status	Completion Date

We recommend that the Under Secretary for Health:

Recommended Improvement Action(s) 1: Develop and implement VHA policy for the administration of moderate sedation outside the OR that includes specific standards of practice and the required JCAHO elements.

Concur

VHA Patient Care Services (PCS) will lead a workgroup, which is expected to include representatives from the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) and clinicians in the field representing anesthesia and all the non-OR areas where moderate sedation is administered (at a minimum Gastroenterology, Radiology, Cardiology, Pulmonary, Podiatry and Dental), that will develop a national directive. The national directive will provide the framework to ensure consistency in VHA facility compliance with regulations regarding the administration of moderate sedation outside the OR. In addition to developing the directive, the workgroup will determine a means to assess policy implementation.

Planned	6/30/06

Recommended Improvement Action(s) 2: Ensure compliance with current VHA Directive 2002-046 regarding cardiopulmonary resuscitation training (CPR).

Concur

PCS will, via email, reaffirm the policy and expectations of VHA Directive 2002-046, *Staff Training in Cardiopulmonary Resuscitation and Advanced Cardiac Life Support*, which indicates that, although CPR "certification" is not required, "all clinically active staff must have had CPR education, whether as Basic Cardiac Life Support (BCLS) or through another program." The communication will be addressed to all Veterans Integrated Service Network (VISN) Chief Medical Officers and facility Chiefs of Staff and will also note that the education needs to be documented in the review of clinicians' education and credentials.

Pending Report Publication	12/01/05

Recommended Improvement Action(s) 3: Ensure that all clinicians administering moderate sedation maintain current training and clinical privileges/scopes of practice.

Concur

PCS, in conjunction with the DUSHOM, will reaffirm to all facility directors, chiefs of staff, and nursing directors, the policy and expectations of the JCAHO standards that require "individuals providing moderate or deep sedation and anesthesia have, at a minimum, had competency-based education, training, and experience in the following:

1. Evaluating patients before performing moderate or deep sedation and anesthesia.
2. Performing moderate or deep sedation and anesthesia, including rescuing patients who slip into a deeper-than-desired level of sedation or analgesia. These include the following:
   a. Moderate sedation: are qualified to rescue patients from deep sedation and are competent to manage a compromised airway and to provide adequate oxygenation and ventilation..."

PCS and the DUSHOM will also advise the field that training and documentation of competency should be recorded in the clinicians' training and competency records and reflected in specific privileges or in the scope of practice.

Further, PCS will work with the Employee Education System to develop a uniform education module to offer to the field for moderate sedation.

In Process 6/30/06

Recommended Improvement Action(s) 4: Ensure moderate sedation adverse events are reported, trended, and analyzed in conjunction with OR anesthesia adverse events and the data are used to improve performance.

Concur

VHA will establish and include these requirements for reporting data to Patient Care Services in the directive that Patient Care Services will develop.

In Process 6/30/06

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Dorothy Duncan, Dallas Regional Office, Office of Healthcare Inspections, 214-253-3333
Acknowledgments	Linda DeLong Virginia Solana Roxanna Osegueda

Appendix D

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