Department of Veterans Affairs
Office of Inspector General

Combined Assessment Program Summary Report

Evaluation of Moderate Sedation in Veterans Health Administration Facilities

Report No. 13-01743-192

May 2, 2013

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections completed an evaluation of moderate sedation in Veterans Health Administration facilities. The purpose of the evaluation was to determine whether Veterans Health Administration facilities used safe processes for the provision of moderate sedation that complied with selected requirements.

Inspectors evaluated moderate sedation at 44 facilities during Combined Assessment Program reviews conducted from October 1, 2011, through September 30, 2012.

We identified three areas where Veterans Health Administration facilities needed to improve compliance. We recommended that the Under Secretary for Health ensures that:

- Clinicians consistently document all required elements of comprehensive pre-procedure assessments and that facilities monitor compliance.
- When there is a provider change, clinicians consistently document that the patient was informed of and agreed to the change and that facilities monitor compliance.
- Clinicians consistently discharge moderate sedation patients appropriately and safely and that facilities monitor compliance.

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

TO: Under Secretary for Health (10)

SUBJECT: Combined Assessment Program Summary Report – Evaluation of Moderate Sedation in Veterans Health Administration Facilities

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections evaluated moderate sedation (MS) in Veterans Health Administration (VHA) facilities. The purpose of the evaluation was to determine whether VHA facilities used safe processes for the provision of MS that complied with selected requirements.

Background

VHA defines MS as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands.[1] No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Additionally, the patient is able to maintain cardiovascular function. MS increases the comfort of patients undergoing these procedures in a non-operating room setting, and the patient quickly returns to an alert state so that clinicians can safely discharge the patient in a timely manner.

VHA clinicians routinely perform procedures under MS in gastroenterology, pulmonary, cardiology, dental, interventional radiology, and intensive care and in emergency departments. Procedures performed by an anesthesiologist or nurse anesthetist are not considered MS cases.

In 2004, the VA OIG conducted an evaluation of the management of MS and recommended that VHA:

a. Develop and implement a policy for the administration of MS outside the operating room.
b. Ensure compliance with VHA requirements for cardiopulmonary resuscitation training.

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

c. Ensure that all clinicians administering MS maintain current training and clinical privileges/scopes of practice.
d. Ensure that MS events are reported, trended, and analyzed in conjunction with operating room anesthesia adverse events and that the data is used to improve performance.

Scope and Methodology

Inspectors evaluated MS at 44 facilities during Combined Assessment Program reviews conducted from October 1, 2011, through September 30, 2012. These facilities were a stratified random sample of all VHA facilities. The selected facilities represented a mix of size, affiliation, geographic location, and Veterans Integrated Service Networks (VISNs). We reviewed facility policies, electronic health records, and training records. Additionally, we interviewed staff and observed timeouts.

We generated an individual Combined Assessment Program report for each facility. For this report, we summarized the data collected from the individual facility Combined Assessment Program reviews. For each of the 44 facilities, we reviewed a sample of patients' electronic health records. The patient sample within each facility was not a probability sample, and thus does not represent the entire patient population of that facility. Therefore, the summary results presented in this report are not generalizable to the entire VHA.

Inspectors conducted the reviews in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Pre-Sedation Documentation

VHA requires clinicians to perform and document pre-sedation assessments, which may include relevant history and physical examination information.

We reviewed 465 electronic health records. We found that histories and physicals were generally performed within 30 days of procedure, as required. However, we found non-compliance in pre-sedation documentation in the following areas:

- Time and nature of last oral intake: 28 percent (130/465)
- Review of substance use/abuse: 23 percent (105/465)
- History of previous sedation: 22 percent (100/465)
- Airway assessment: 13 percent (59/465)

We recommended that clinicians consistently document all required elements of comprehensive pre-sedation assessments and that facilities monitor compliance.

Issue 2: Informed Consent

VHA requires that the informed consent form note the name of the provider performing the procedure. If a different provider is substituted for the one on the consent, VHA requires that a progress note be entered indicating that the patient was informed about who was to perform the procedure and agreed to the change.

We found that in general, informed consents were completed and included the name and reason for procedure. However, for 11 of the 21 cases (52 percent) where the name of the provider did not match the name on the consent, there were no notes indicating that the patient was informed about the change in provider.

We recommended that when there is a provider change, clinicians consistently document that the patient was informed of and agreed to the change and that facilities monitor compliance.

Issue 3: Patient Discharge

VHA requires that the MS outpatient is discharged in the company of a responsible, designated adult or discharged to lodging within the facility or that the outpatient is not discharged and is admitted as an inpatient.

For 16 of the 72 patients (22 percent) who were not discharged in the company of a responsible adult, we found no documentation that they were either lodged or admitted.

We recommended that clinicians consistently discharge MS patients appropriately and safely and that facilities monitor compliance.

Conclusions

Most VHA clinicians completed pre-procedure histories and physicals and informed consents, as required. However, they did not consistently include all necessary elements in pre-sedation assessments or comply with requirements for informed consents when one clinician was substituted for another or with requirements for patient discharge.

Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that clinicians consistently document all required elements of comprehensive pre-sedation assessments and that facilities monitor compliance.

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that when there is a

provider change, clinicians consistently document that the patient was informed of and agreed to the change and that facilities monitor compliance.

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that clinicians consistently discharge MS patients appropriately and safely and that facilities monitor compliance.

Comments

The Under Secretary for Health concurred with the findings and recommendations. The implementation plan is acceptable, and we will follow up until all actions are completed.

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

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: April 15, 2013

From: Under Secretary for Health (10)

Subject: **Combined Assessment Program Summary Report – Evaluation of Moderate Sedation in VHA Facilities (2013-01743-HI-0400) (VAIQ 7347895)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the report's recommendations. Attached are corrective action plans.

2. Should you have additional questions, please contact Karen Rasmussen, M.D., Director, Management Review Service, at (202) 461-6643, or by e-mail at karen.rasmussen@va.gov.

Robert A. Petzel, M.D.

Attachment

VHA Action Plan

OIG, Draft Report, CAP Summary Report – Evaluation of Moderate Sedation in Veterans Health Administration Facilities (VAIQ 7347895)

Date of Draft Report: March 14, 2013

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that clinicians consistently document all required elements of comprehensive pre-sedation assessments and that facilities monitor compliance.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management, with guidance from the Office of Specialty Care Services, will present an informational memo for distribution to Veterans Integrated Service Network (VISN) Directors that specifies that the history and physical along with the pre-sedation assessment must, at a minimum, include:

(1) A review of abnormalities of the major organ systems and assessment of the airway;
(2) History of any previous adverse experience with sedation or analgesia as well as regional and general anesthesia;
(3) A review of drug allergies and current medications;
(4) A review of tobacco, alcohol or substance use or abuse;
(5) Time and nature of last oral intake; and
(6) An assessment of risk such as the American Society of Anesthesiologists Physical Status.

Since this is a high-risk issue, the VISN will require quarterly reports of compliance with documentation from each VA Medical Center (VAMC) (all elements defined in recommendations 1, 2, and 3). A standardized process will be developed by June 1, 2013.

Summary reports from each VAMC will be submitted to the VISN until the VAMC reaches and maintains 90 percent compliance for two consecutive quarters. The VISN will also incorporate this topic into annual required evaluations. VHA will include this element as part of the annual VISN Quality Management Attestation verifying there is ongoing monitoring by the VISN.

In progress December 31, 2013

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that when there is a provider change, clinicians consistently document that the patient was informed of and agreed to the change and that facilities monitor compliance.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management, with guidance from the Office of Specialty Care Services, will present an informational memo for distribution to VISN Directors, which will include the statement specifying the requirement that if a different provider is substituted for the one on the consent, a progress note must be entered indicating that the patient was informed about who was to perform the procedure and agreed to the change.

The VISN will require quarterly reports of compliance with documentation from each medical center. Summary reports from each VAMC will be submitted to the VISN until the VAMC reaches and maintains 90 percent compliance for two consecutive quarters.

In progress December 31, 2013

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that clinicians consistently discharge MS patients appropriately and safely and that facilities monitor compliance.

VHA Comments

Concur

The current Moderate Sedation Directive's discharge process requires discharge "in the company of a responsible, designated adult." The Deputy

Under Secretary for Health for Operations and Management, with guidance from the Office of Specialty Care Services, will present an informational memo for distribution to VISN Directors that will require that this information be documented in the Medical Record.

The VISN will require quarterly reports of compliance with documentation from each medical center. Summary reports from each VAMC will be submitted to the VISN until the VAMC reaches and maintains 90 percent compliance for two consecutive quarters.

In progress December 31, 2013

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the OIG at (202) 461-4720
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Appendix C

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