



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 13-04005-296

Healthcare Inspection

Out of Operating Room Airway Management Concerns W.G. (Bill) Hefner VA Medical Center Salisbury, North Carolina

September 30, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a confidential complainant regarding out of operating room airway management (OOORAM) at the W. G. (Bill) Hefner VA Medical Center (the facility) in Salisbury, NC. The complainant alleged the facility was not meeting specific requirements of Veterans Health Administration (VHA) Directive 2012-032, *Out of Operating Room Airway Management*, issued on October 26, 2012.

We substantiated that the facility's local policy for OOORAM was not updated as required and, when a new policy was implemented, it did not contain all the components required by VHA Directive 2012-032. We also substantiated that the facility's OOORAM training and competency assessments were not consistently completed as required, not enough staff were authorized to perform OOORAM and some staff performed OOORAM without authorization, highly portable video laryngoscopes were not always immediately available, and required analysis after patient care events involving intubation by unauthorized facility staff did not always occur.

We did not substantiate that there was an unacceptable number of "Code Blues" (an emergency situation announced in a hospital to indicate a patient requires immediate resuscitation) and found the facility reviewed events where cardiopulmonary resuscitation was attempted as required.

During the course of this review, we found the facility had not updated the scope of practice for a non-licensed independent practitioner who was authorized to perform OOORAM.

We recommended that the Facility Director ensure the facility's OOORAM policy is updated to include all VHA requirements, that processes be strengthened to complete OOORAM training and competency requirements as outlined by VHA and local policies, that processes be strengthened to provide OOORAM coverage as required, that highly portable video laryngoscope equipment is immediately available, that an analysis is performed for the five identified patient care events in our report, and that the scope of practices are updated for non-licensed independent practitioners who perform OOORAM.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 7–10 for the Directors' comments.) We will follow up on the planned actions until they are completed.



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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a confidential complainant regarding out of operating room airway management (OOORAM) at the W. G. (Bill) Hefner VA Medical Center (the facility) in Salisbury, NC.

Background

Facility. The facility is a tertiary care medical center and has over 68,000 unique veteran patients. Inpatient services include acute medicine, cardiology, surgery, psychiatry, and physical medicine and rehabilitation, as well as sub-acute and extended care. The facility is located in Veterans Integrated Service Network (VISN) 6, the VA Mid-Atlantic Health Care Network.

Airway Management. Airway management is the process of ensuring an open pathway to the lungs in order to maintain adequate oxygenation. Generally, this process occurs in the operating room (OR) prior to induction of an anesthetic agent that paralyzes a patient's ability to maintain normal breathing. OR anesthesia staff are highly trained and experienced to provide this service.

The requirement for emergency airway management arises outside the OR when a patient experiences respiratory distress, and is generally referred to as OOORAM.

A major challenge in airway management is the placement of an endotracheal tube, which is inserted through the mouth or nose into the trachea (intubation). If inserted incorrectly, the patient may not receive proper oxygenation, which could result in brain damage or death. Adverse events may occur as a result of inadequate or difficult ventilation or improper esophageal, versus endotracheal, intubation. The risk for adverse outcomes increases when staff are not well trained or competent to perform emergency airway support.

VHA OOORAM Policy. On August 8, 2005, Veterans Health Administration (VHA) issued Directive 2005-031, *Out of Operating Room Airway Management*. The Directive outlined OOORAM requirements, such as appropriate competencies of practitioners who performed OOORAM, and the use of devices to confirm successful endotracheal tube placement. On October 26, 2012, VHA rescinded Directive 2005-031 and issued Directive 2012-032, *Out of Operating Room Airway Management*. The updated directive included a requirement (among others) that each non-exempt facility¹ have a written policy in place no later than October 31, 2013.

VHA Directive 2012-032 outlines certain mandatory requirements that must be in the facility's OOORAM policy. The Directive requires that facilities have a process for ensuring the competency of staff performing OOORAM during all hours when patient

¹ Exempted facilities are those that call 911 and offer only basic life support until relieved by 911 Emergency Medical Services responders.

care is provided. The Directive also requires that staff are observed intubating patients to ensure competency and states that clinical competence cannot be assumed based on Advance Cardiac Life Support² certification, or job title, which includes physicians.

Allegations. The complainant contacted the OIG Hotline Division and alleged the facility was not in compliance with VHA Directive 2012-032. The allegations were referred to VHA in July 2013 and again in December 2013. After evaluating VHA's responses, the Office of Healthcare Inspections initiated a review in April 2014.

The complainant alleged the following:

- The facility's OORAM policy was not updated timely.
- OORAM training and competency assessments were not completed as required.
- Not enough competent staff were available to perform OORAM.
- Not enough OORAM equipment was available.
- Specific patient care events were not reviewed as required.
- The number of "Code Blues"³ was unacceptably high.

Scope and Methodology

We conducted a site visit April 22–23, 2014. We interviewed the facility Director, Chief of Staff, and Nurse Executive/Associate Director for Patient Care Service. We also interviewed the Chiefs of Anesthesia, Medicine, and Surgery Services; the Chief of Performance and Quality; the lead hospitalist; the Respiratory Therapy Service Manager; and the Emergency Department (ED) section Chief. We also interviewed other clinical and administration staff.

We reviewed facility local policies and VHA policies, directives, and handbooks; patients' electronic health records; training and competency records; quality management information; and other relevant documents.

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

² Airway management is part of Advanced Cardiac Life Support training.

³ An emergency situation in which a patient is in cardiopulmonary arrest that requires a team of providers to rush to the specific location and begin immediate resuscitative efforts is called a Code Blue team at some facilities.

Inspection Results

Issue 1. Facility Policy

We substantiated the allegation that the local facility OOORAM policy was not updated as required.

At the time of the complaint, the facility's local OOORAM policy, dated March 12, 2012,⁴ had not been updated as required. On April 15, 2014, the facility implemented a new policy for OOORAM.⁵ However, we determined the new policy did not contain all required components outlined in VHA Directive 2012-032. For example, the facility policy did not require that highly portable video laryngoscopes⁶ be immediately available at all times for use by clinicians or that clinicians who have previously been determined competent for OOORAM be reassessed for continued competency at the time of reappraisal of privileges or Scopes of Practice.

VHA Directive 2012-032 required that each facility, unless exempt, have a written policy that included specific, mandatory components in place no later than October 31, 2013.

Issue 2. Training and Competency

We substantiated the allegation that the facility's OOORAM training and competency process was not consistently completed as required. We reviewed training and competency documentation and found 13 (43 percent) of the 30 staff authorized by the facility to perform OOORAM at the time of our review did not complete the required didactic program or procedural skills validation.

VHA Directive 2012-032 requires that facilities develop a process for assessing and establishing competency for staff performing OOORAM. The required training and assessment of competency includes the successful completion of a didactic program with specific content and written test and the validation of cognitive and procedural skills.⁷

Issue 3. Staffing

We substantiated the allegation that an insufficient number of OOORAM authorized staff was available to ensure safe airway management 24 hours-a-day, 7 days-a-week (24/7) for the facility.

Clinical leaders stated that OOORAM is an essential job requirement for both ED providers and hospitalists and that the hospitalists have the primary responsibility to provide OOORAM for the facility. The facility policy requires that all hospitalists are

⁴ Medical Center Memorandum 659-112A-1, *Out-Of-Operating Room Airway Management*, March 12, 2012.

⁵ Medical Center Memorandum 659-112A-1, *Out-Of-Operating Room Airway Management*, April 15, 2014.

⁶ A video laryngoscope uses digital technology to allow the clinician to view the larynx on a screen during intubation.

⁷ VHA Directive 2012-032.

members of the “Code Blue” team and respond to medical emergencies, which includes the loss of airway.⁸

To evaluate OORAM coverage, we reviewed the ED providers’ and hospitalists’ January 1–31, 2014, work schedules. We determined the ED staff were not able to provide appropriate 24/7 OORAM coverage during 4 (13 percent) of the 31 days reviewed, and hospitalist staff were not able to provide appropriate 24/7 OORAM coverage during 18 (58 percent) of the 31 days reviewed. Overall, we determined the facility had no authorized ED and hospitalist staff to perform appropriate 24/7 OORAM coverage during 4 (13 percent) of the 31 days reviewed.

VHA requires that a qualified physician is present at all times in the ED and is not to be responsible for any inpatient activities, unless certain requirements are met⁹ and the facility has a formal waiver from VHA.¹⁰ The facility does not have a waiver. Although VHA does not require that all providers are trained, facilities must have a sufficient number of providers deemed competent in OORAM to respond to respiratory compromise events, including cardiopulmonary arrest, during all hours when patient care is provided.¹¹

Issue 4. Highly Portable Video Laryngoscopes

We substantiated the allegation that highly portable video laryngoscopes were not always immediately available at the time of allegation.

We learned that, at the time of the complaint, only one portable video laryngoscope was immediately available in the facility. It was located in the ED. In March 2014, the facility obtained another video laryngoscope, which the intensive care unit and medical/surgical unit shared. Clinical leaders stated they submitted documentation for more video laryngoscopes in April after a review of medical emergency data identified a need for additional portable video laryngoscopes to ensure immediate availability.

VHA requires that highly portable video laryngoscope equipment is immediately available on a 24/7 basis.¹²

Issue 5. Specific Patient Care Events Analysis

We substantiated the allegation that staff without authorization to perform OORAM performed intubations and that the facility did not analyze these specific patient care events as required.

The complainant provided one patient care event, and the facility provided an additional four patient care events. We determined the five patients were intubated by

⁸ Medical Center Memorandum 659-11-26, *Emergency Response System*, January 21, 2014.

⁹ Requirements vary; an example is a designation of Veterans Rural Access Hospital.

¹⁰ VHA Handbook 1101.04, *Medical Officer of the Day*, August 30, 2010.

¹¹ VHA Directive 2012-032.

¹² VHA Directive 2012-032.

unauthorized staff, and the facility was unable to provide documentation that an analysis was completed for these specific patient care events.

VHA policy allows that, in extraordinary circumstances where an individual with the required competency in OOORAM is not available, clinicians may exercise their judgment as to the appropriate response with the overarching goal being the care and safety of the patient. VHA Directive 2005-031 required that the facility analyze why the vulnerability existed and initiate appropriate system fixes to minimize a repeat occurrence. VHA Directive 2012-032, which replaced Directive 2005-031, requires that facilities complete a Root Cause Analysis and that appropriate system fixes are completed when these patient care events occur.

Issue 6. “Code Blue” Reviews

We did not substantiate that there was an unacceptable number of “Code Blues” at the time of the allegation. We also determined the facility reviewed each episode of care where resuscitation was attempted as required.

For the period 2006 through 2014, we reviewed from tracking, trending, and analysis of “Code Blue” data. We noted variations year to year, with an increase in the number of code events from 2011 to 2012 and then a decrease from 2012 to 2013. We did not determine the increase in code events in 2012 as unacceptable when compared to the data and analysis for other years.

We found the facility reviewed each episode of care where resuscitation was attempted as required by VHA.¹³

Issue 7. Scope of Practice for Respiratory Therapists

During the course of this review, we found the facility had not updated the scope of practice for one of two respiratory therapists (RTs) who were authorized to perform OOORAM. VHA requires that non-licensed independent practitioners (non-LIPs), such as RTs, must have OOORAM competencies present in the establishment of a scope of practice.¹⁴

Conclusions

We substantiated the allegation that the facility’s 2012 local OOORAM policy was not updated as required, and when a new policy was implemented, it did not contain all required components. We also substantiated the allegations that the facility’s OOORAM training and competency assessments were not consistently completed as required, that there were periods of time when an OOORAM authorized staff was not available as required, that highly portable video laryngoscopes were not always readily

¹³ VHA Directive 2008-063, *Oversight and Monitoring of Cardiopulmonary Resuscitative Events and Facility Cardiopulmonary Resuscitation Committees*, October 17, 2008.

¹⁴ VHA Directive 2012-032.

available, that unauthorized staff performed intubations and that those events were not analyzed as required.

We did not substantiate that there was an unacceptable number of “Code Blues,” and we found the facility reviewed each episode of care where resuscitation was attempted as required by VHA.

During the course of this review, we found the facility had not updated the scope of practice for a non-LIP who was authorized to perform OORAM.

We made six recommendations.

Recommendations

1. We recommended that the Facility Director ensure that the facility’s out of operating room airway management policy is updated to include all Veterans Health Administration requirements.
2. We recommended that the Facility Director ensure that processes be strengthened to complete out of operating room airway management training and competency requirements as outlined by Veterans Health Administration and local policies.
3. We recommended that the Facility Director ensure that processes be strengthened to provide out of operating room airway management coverage as required.
4. We recommended that the Facility Director ensure that highly portable video laryngoscope equipment is immediately available.
5. We recommended that the Facility Director ensure that analysis of the five patient care events identified in this report is completed as required.
6. We recommended that the Facility Director ensure that the scopes of practice are updated for non-licensed independent practitioners who perform out of operating room airway management.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: September 3, 2014

From: Director, VA Mid-Atlantic Health Care Network (10N6)

Subject: Draft Report – Healthcare Inspection—Out of Operating Room Airway Management, W.G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina

To: Director, Region Office of Healthcare Inspections (54KC)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. The attached subject report is forwarded for your review and further action. I reviewed the response of the W. G. (Bill) Hefner VA Medical Center (VAMC), Salisbury, North Carolina and concur with the facility's recommendations.
2. If you have further questions, please contact Lisa Shear, Quality Management Officer at (919) 956-5541.



DANIEL F. HOFFMANN, FACHE

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 27, 2014

From: Facility Director

Subject: Draft Report – Healthcare Inspection—Out of Operating Room Airway Management, W.G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina

To: Director, VA Mid-Atlantic Health Care Network (10N6)

1. I have reviewed the draft report of the Office of Inspector General and I concur with the recommendations.
2. I have included my response in the attached Director's Comments.
3. Please contact me if you have any questions or comments.



Kaye Green FACHE
Director, W. G. (Bill) Hefner VA Medical Center (659/00)

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure that the facility's out of operating room airway management policy is updated to include all Veterans Health Administration requirements.

Concur

Target date for completion: October 1, 2014

Facility response: Medical Center Memorandum 112A-1 Out of Operating Room Airway Management is currently under revision to ensure all VHA requirements are included.

Recommendation 2. We recommended that the Facility Director ensure that processes be strengthened to complete out of operating room airway management training and competency requirements as outlined by Veterans Health Administration and local policies.

Concur

Target date for completion: October 1, 2014

Facility response: A formal competency assessment document for out of operating room airway management was developed. The document includes each requirement that must be met prior to granting privileges. Once the facility subject matter expert (the Anesthesiology Chief) has validated all requirements have been met, the signed document will be presented to the Professional Standards Board. The board will utilize the completed document in their decision when recommending privileges for out of operating room airway management. The document will be added to Medical Center Memorandum 112A-1 as attachment D.

Recommendation 3. We recommended that the Facility Director ensure that processes be strengthened to provide out of operating room airway management coverage as required.

Concur

Target date for completion: Completed

Facility response: Hospitalists have the primary responsibility for providing out of operating room airway management for the facility during respiratory compromise events, including cardiopulmonary arrest. Fifteen Hospitalists have been identified as needing out of operating room airway management privileges and 15 (100 percent)

have completed all required components of the training. The facility now has a sufficient number of qualified providers available 24/7 to perform out of operating room airway management.

Recommendation 4. We recommended that the Facility Director ensure that highly portable video laryngoscope equipment is immediately available.

Concur

Target date for completion: Completed

Facility response: In February 2014 the Code Blue Committee identified five departments in need of video laryngoscopes. The facility has received the additional video laryngoscopes now supplying each department identified with a video laryngoscope immediately available if needed.

Recommendation 5. We recommended that the Facility Director ensure that analysis of the five patient care events identified in this report is completed as required.

Concur

Target date for completion: November 15, 2014

Facility response: An aggregate Root Cause Analysis will be completed to include an analysis of all five cases.

Recommendation 6. We recommended that the Facility Director ensure that the scopes of practice are updated for non-licensed independent practitioners who perform out of operating room airway management.

Concur

Target date for completion: October 1, 2014

Facility response: All Respiratory Therapists eligible for out of operating room airway management privileges will be required to complete all education and training on the Competency Assessment for Out of Operating Room Airway Management in its appropriate sequence. The Competency Assessment will be signed by the facility subject matter expert, returned to the Respiratory Therapist and presented to the Supervisory Respiratory Therapist. Once the Supervisory Respiratory Therapist receives the signed competency document, they will amend the Respiratory Therapist Functional Statement to include out of operating room airway management duties. The Functional Statement will be signed by the Respiratory Therapist, the Supervisory Respiratory Therapist, and by the Chief - Critical Care. Once all signatures have been obtained, the Functional Statement will be sent to Human Resources and presented to the Professional Standards Board to ensure appropriate documentation in the minutes.

OIG Contact and Staff Acknowledgments

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