Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-04310-280

Healthcare Inspection

Operating Room Concerns
Marion VA Medical Center
Marion, Illinois

May 5, 2016

Washington, DC 20420

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various Federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

To Report Suspected Wrongdoing in VA Programs and Operations:
Telephone: 1-800-488-8244
E-Mail: vaoighotline@va.gov
Web site: www.va.gov/oig

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a review to determine whether leadership responded to complaints at the Marion VA Medical Center, Marion, IL, that the vacuum suction in the operating room (OR) was not adequate for safe patient care and that patients were harmed as a result of inadequate vacuum suction.

We did not substantiate that facility leadership failed to respond to complaints regarding insufficient vacuum suction in the OR. Once a work order was submitted to engineering service about a problem with the vacuum suction, facility leadership initiated multiple actions.

We did not substantiate that the vacuum suction was unacceptable for safe airway management. In mid-June 2014, testing showed the vacuum suction was meeting the Advanced Cardiovascular Life Support guideline recommendation. At the time of our site visit in August 2014, all the certified registered nurse anesthetists stated the vacuum suction was adequate to secure a patient's airway.

We did not substantiate the allegation that three patients were harmed as a result of inadequate vacuum suction in the OR. The allegation did not specifically identify the patients who had reportedly been harmed. Based on staff interviews, we identified one patient with similar clinical circumstances as one of the three patients described in the allegation. We interviewed staff who were involved in the patient's procedure who indicated that, for this patient, the vacuum suction level was adequate.

We were unable to identify the other two patients who may have suffered harm as alleged. We spoke with certified registered nurse anesthetists who managed OR patients. They did not identify specific patients who may have aspirated as a result of inadequate vacuum suction in the OR. Additionally, the facility's VA Surgical Quality Improvement Program Nurse, Quality Management Service Chief, and Patient Safety Manager were unable to recall or provide any complaints or documentation of patients aspirating in the OR as a result of inadequate vacuum suction.

While not part of the original complaint, we found inconsistent documentation of repairs and follow-up testing of the facility's medical gas system. On September 22, 2015, we requested and subsequently reviewed 4 quarters of the facility's engineering service monitoring tool showing implementation of the action plan to monitor the medical gas system in the OR and post anesthesia care unit. Because the facility had initiated activities to review the finding and implemented action items, we made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report. (See Appendixes A and B, pages 6–7 for the Directors' comments.) No further action is required.

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

Purpose

The VA Office of Inspector General Office of Healthcare Inspections conducted a review to determine whether leadership responded to complaints at the Marion VA Medical Center (facility), Marion, IL, that the vacuum suction in the operating room (OR) was not adequate for safe patient care and that patients were harmed as a result of inadequate vacuum suction.

Background

The facility provides general medical, surgical, and a full range of patient care services to approximately 44,247 veterans residing in southern Illinois, southwestern Indiana, and northwestern Kentucky. Comprehensive health care is provided through primary care, specialty care, and long-term care, with services in medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. Additional specialty care is available by referral to other VA or contacted facilities. Part of Veterans Integrated Service Network (VISN) 15, the facility has 31 acute care beds; an 8-bed intensive care unit; 3 ORs; an endoscopy room, which is located in the OR; a 3-bed post-anesthesia care unit (PACU); and a 60-bed community living center.

The concerns regarding the OR vacuum suction follow.

- Facility leadership failed to respond to complaints regarding insufficient vacuum suction in the OR.
- Vacuum suction in the OR was unacceptable for safe airway management.
- Three patients were harmed as a result of inadequate vacuum suction in the OR.

Scope and Methodology

The period of our review was FY 2014 through FY 2015. We conducted a site visit August 26 and 27, 2014.

We interviewed the Facility Director, Associate Director, Chief of Staff, Quality Management Service Chief, facility VA Surgical Quality Improvement Program Nurse, Patient Safety Manager (PSM), Chief of Engineering, OR Nurse Manager, Chief of Surgery/Acting Chief of Anesthesia, Biomedical Supervisor, Maintenance and Operations Supervisor, certified registered nurse anesthetists (CRNAs), and other staff as appropriate. We also reviewed a patient's electronic health record, patient safety reports, maintenance work orders, vendor reports, emails, committee minutes, quality management documents, and Advanced Cardiovascular Life Support guidelines.[1] On

[1] Advanced Cardiovascular Life Support refers to a set of clinical interventions for the treatment of medical emergencies. Http://cpr.heart.org, accessed February 12, 2016.

September 22, 2015, we requested and subsequently reviewed 4 quarters of engineering service's medical gas monitoring tool showing implementation of an action plan to monitor the medical gas system in the OR and PACU.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. We **did not substantiate** allegations when the facts showed the allegations were unfounded. We **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

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.

Inspection Results

Issue 1. Facility Leadership Response

We did not substantiate that facility leadership failed to respond to complaints regarding insufficient vacuum suction in the OR.[2] Once a work order was submitted to engineering service about a problem with the vacuum suction, facility leadership initiated multiple actions.

Facility leaders told us they were not aware of an issue with insufficient vacuum suction before May 2014 when a work order was submitted to the engineering service.[3] One day after the work order was submitted, engineering service staff checked the vacuum pumps and found the vacuum pumps working and with sufficient vacuum pressure.

Approximately 3 weeks later, engineering service staff conferred with the anesthesia machine manufacturer service representative who informed staff that the normal operating range for the vacuum suction with no restriction should be 200 centimeters of water (cm H_2O) and no greater than 600 cm H_2O with a restriction. Engineering service staff checked each vacuum outlet and found them to be within normal operative range.

Although engineering service staff findings were normal in June, the PSM received an email regarding low vacuum suction in the OR. At that time, engineering service staff and a vendor[4] representative conducted tests of the vacuum system concentrating on one anesthesia machine. All tests indicated that the anesthesia machine's vacuum system was working properly. Facility management requested that the vendor perform a complete preventive maintenance check on the other anesthesia machines, which was completed and the vendor confirmed that all five anesthesia machines were ready for use.

Issue 2. Airway Management and Vacuum Suction

We did not substantiate that the vacuum suction in the OR was unacceptable for safe airway management. The Advanced Cardiovascular Life Support guideline recommends a vacuum suction of more than 300 millimeters of mercury (equivalent to 408 cm H_2O) when the tube is clamped (restriction is present). In mid-June, facility engineering service staff determined the OR vacuum suction was 250 cm H_2O with no restriction and just past 600 cm H_2O with restriction.

The Chief of Surgery and a pulmonologist who performed procedures in the OR told us that vacuum suction had not been an issue. The PSM also reported that no patient incident reports had been submitted concerning a problem with vacuum suction in the

[2] The OR's vacuum system begins at the compressor and provides vacuum to the inlets in the OR and endoscopy room. Hoses are attached to the vacuum inlets in the OR and endoscopy room which provides vacuum to the equipment in the OR and endoscopy rooms, such as the five facility anesthesia machines.
[3] Engineering service includes biomedical and maintenance and operations staff.
[4] The facility contracts with a vendor that installs, manages, and provides services for the anesthesia machines.

OR. At the time of our site visit in August 2014, all CRNAs stated the vacuum suction was adequate to secure a patient's airway.

Issue 3. Quality of Care

We did not substantiate the allegation that three patients were harmed as a result of inadequate vacuum suction in the OR. The complainant did not specifically identify the patients who had reportedly been harmed.

Based on staff interviews, we identified one patient with similar clinical circumstances as one of the three patients described in the allegation. We interviewed the Chief of Surgery and the two CRNAs directly involved in that patient's procedure and they indicated that, for this patient, the vacuum suction level was adequate.

We were unable to identify the other two patients who may have suffered harm as alleged. We spoke with CRNAs who managed OR patients. They did not identify specific patients who may have aspirated as a result of inadequate vacuum suction in the OR. Additionally, the facility's VA Surgical Quality Improvement Program Nurse, Quality Management Service Chief, and PSM were unable to recall or provide any complaints or documentation of patients aspirating in the OR as a result of inadequate vacuum suction.

Issue 4. Other Issues

While not part of the original complaint, during the onsite review we found inconsistent documentation of repairs and follow-up testing of the facility's medical gas system. A vendor completes annual testing of the facility's medical gas system, and the test involves various aspects of the oxygen, medical air, and vacuum systems. We examined the 2013 and 2014 results of the testing of the OR vacuum outlets, which included the endoscopy room and PACU.

On December 19, 2013, the vendor completed the facility's annual testing of the medical gas system and found seven vacuum outlet configurations in the OR and PACU. Six of the seven vacuum outlet configurations passed the vacuum flow test. Engineering staff reported the deficient vacuum outlet was repaired but was unable to provide documentation to confirm the repair work. There was no documentation of follow-up testing to confirm the work performed corrected the failures until June 2014. Engineering staff acknowledged the inconsistent documentation and, prior to publication of this review, implemented a quarterly monitoring tool of the medical gas system in the OR and PACU. On September 22, 2015, we requested and subsequently reviewed 4 quarters of engineering's medical gas monitoring tool showing implementation of an action plan to monitor the medical gas system in the OR (including the endoscopy room) and PACU. Because the facility had initiated and implemented an action plan, we made no recommendations.

Conclusions

We did not substantiate that facility leadership failed to respond to complaints regarding insufficient vacuum suction in the OR. Once a work order identifying the issue was submitted in May 2014, we found the facility leadership initiated multiple actions.

We did not substantiate that the vacuum suction was unacceptable for safe airway management. In mid-June 2014, testing showed the vacuum suction was meeting the Advanced Cardiovascular Life Support guideline recommendation. At the time of our site visit in August 2014, all CRNAs stated the vacuum suction was adequate to secure a patient's airway.

We did not substantiate that three patients were harmed as a result of inadequate vacuum suction in the OR. We did not have specific information about patients who had reportedly been harmed. Based on staff interviews, we identified one patient with similar clinical circumstances as one of the three patients described in the allegation. According to staff involved in that patient's procedure, the vacuum suction level was adequate.

We were unable to identify the other two patients who may have suffered harm as alleged. We spoke with CRNAs who managed OR patients. They were unable to identify specific patients who may have aspirated as a result of inadequate vacuum suction in the OR. Additionally, the facility's VA Surgical Quality Improvement Program Nurse, Quality Management Service Chief, and PSM were unable to recall or provide any complaints or documentation of patients aspirating in the OR as a result of inadequate vacuum suction.

While not part of the original complaint, we found inconsistent documentation of repairs and follow-up testing of the facility's medical gas system. We reviewed 4 quarters of engineering's medical gas monitoring tool showing implementation of the action plan to monitor the medical gas system in the operating room and PACU. Because the facility had initiated activities to review the finding and implemented action items, we made no recommendations.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: March 15, 2016

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Operating Room Concerns, Marion VA Medical Center, Marion, Illinois

To: Director, Kansas City Office of Healthcare Inspections (54KC)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to collaborate on continuous performance improvement.

2. For additional questions please feel free to contact Mary O'Shea, VISN 15 Quality Management Officer at 816-701-3000.

(original signed by:)
William P. Patterson, MD, MSS
Network Director
VA Heartland Network (VISN 15)

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: 3/11/16

From: Director, Marion VA Medical Center (657A5/00)

Subj: Healthcare Inspection—Operating Room Concerns, Marion VA Medical Center, Marion, Illinois

To: Director, VA Heartland Network (10N15)

Acknowledge and concur with review.

X

Frank Kehus
Interim Medical Center Director

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Larry Selzler, MSPT, Team Leader James Seitz, RN, MBA Thomas Jamieson, MD

Appendix D

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Heartland Network (10N15)
Director, Marion VA Medical Center (657A5/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Richard J. Durbin, Mark Kirk, Daniel Coats, Joe Donnelly
Mitch McConnell, Rand Paul, Roy Blount, Claire McCaskill
U.S. House of Representatives: Mike Bost, Larry Bucshon, William Lacy Clay, S. Brett Guthrie, Blaine Luetkemeyer, John Shimkus, Ann Wagner, Ed Whitfield

This report is available on our web site at **www.va.gov/oig**.