Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-03624-58

Healthcare Inspection

Alleged Patient Safety Concerns in the Operating Room VA Maine Healthcare System Augusta, Maine

February 12, 2014

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to assess the merit of three allegations at the VA Maine Healthcare System (facility), Augusta, ME. Specifically, it was alleged that the operating room (OR) has inadequate personnel, such as a front desk clerk and/or a nurse scheduled in the clean core area, to support OR staff, especially in the event of an emergency; pre-operative anesthesia evaluations of complex patients are inadequate because anesthesia providers frequently evaluate patients just prior to surgery, leaving insufficient time should patients require further evaluations; and the facility's surgical mortality rate is three times the national average, suggesting a systemic issue with surgical quality.

We substantiated that the OR did not have a front desk clerk and/or a nurse scheduled to work in the clean core area. However, due to the absence of a master staffing plan, we could not substantiate that the currently available staff was inadequate to support OR staff. We did not substantiate that pre-operative anesthesia evaluations of complex patients are inadequate. Anesthesia providers told us that there is adequate time to conduct evaluations. We found no timeframe requirement for when the pre-operative anesthesia evaluation of patients should take place. Our review of the surgical mortality data did not identify obvious outliers or negative trends that would indicate systemic quality of care issues in the OR and require further review. In addition to the original allegations, we identified weaknesses in the surgical and OR quality improvement processes. We found that the Surgical Work Group had not yet met and that the OR Committee last met more than a year ago.

We recommended that the Facility Director develop and implement a master staffing plan for the OR based on Association of Perioperative Registered Nurses recommendations to ensure adequate coverage and support for OR staff. We also recommended that the Facility Director ensure that the Surgical Work Group and OR Committee are functioning in accordance with Veterans Health Administration and local policies and that the recommendations made pursuant to a recent protected Veterans Health Administration Surgical Program review are implemented.

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 6–9 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 concerning operating room (OR) staffing, pre-operative anesthesia evaluations of complex patients, and the surgical mortality rate at the VA Maine Healthcare System (facility), Augusta, ME.

Background

Facility Profile. The facility has 67 general medical, surgical, intermediate, and mental health beds, and a 100-bed community living center. It offers primary care, preventative health, and mental health services to approximately 40,000 veterans. The facility is part of the VA New England Healthcare System – Veterans Integrated Service Network (VISN) 1.

Facility surgical subspecialties include urology, general surgery, thoracic surgery, orthopedic surgery, podiatry, ophthalmology, and otolaryngology. OR staff include, but are not limited to, surgeons, anesthesiologists, nurse anesthetists, circulating nurses, scrub nurses, and surgical technicians (STs). The circulating nurse on duty prepares the operating room for surgical cases, monitors patients through the procedures, assists the surgeon and ST or scrub nurse into their gowns and gloves, opens the outside wrappings from sterile instrument trays, and labels specimen containers. The ST or scrub nurse (a nurse who performs the duties of the ST) opens sterile instrument packs, ensures the correct instruments are in the packs, organizes surgical instruments, and hands the correct instruments to the surgeon.

Surgical Quality Data. The Veterans Health Administration's (VHA) National Surgery Office (NSO) establishes policies for surgical programs and collects and disseminates clinical performance data. Within NSO, the VA Surgical Quality Improvement Program (VASQIP) is a nationally-validated, risk-adjusted, outcomes-based program established to measure and improve the quality of surgical care. VASQIP is used to identify a range of statistically acceptable outcome rates for mortality for all surgical procedures combined, as well as by each surgical subspecialty performed at any one facility.

Allegations. The VA OIG Hotline Division received the following allegations:

- The OR has inadequate personnel, such as a front desk clerk or a nurse assigned to the clean core area, to support OR staff, especially in the event of an emergency.

- Pre-operative anesthesia evaluations of complex patients are inadequate because anesthesia providers frequently evaluate patients just prior to surgery, leaving insufficient time should patients require further evaluations.

- The facility's surgical mortality rate is three times the national average, suggesting a systemic issue with surgical quality.

Scope and Methodology

We interviewed the complainant to clarify the allegations. We conducted a site visit August 7–8, 2013. We interviewed the Chiefs of Surgery and Anesthesia; the acting Chief of Staff; OR anesthesia providers, RNs, and STs; and other clinical and administrative staff knowledgeable about surgical and OR quality assurance and data reporting.

We also interviewed the VISN 1 Chief Surgical Consultant and the VHA Surgical OR Nurse Managers Advisory Board Chair. We reviewed facility Mortality and Morbidity Review meeting minutes, OR staffing schedules, and OR utilization reports. We also reviewed VASQIP reports and clinical outcomes data for FYs 2012 and 2013 through June 2013[1]; VHA, VISN, and facility policies; facility medical staff bylaws; and industry standards. Our review period was January 2012 through August 2013.

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.

[1] FY 2013, quarter 3 (April–June 2013) was the last completed and reported quarter available at the time of our review.

Inspection Results

Issue 1: OR Staffing

We substantiated that the OR did not have a front desk clerk and/or a nurse scheduled to work in the clean core area. However, due to the absence of a master staffing plan, we could not substantiate that the currently available staff was inadequate to support OR staff.

According to OR staff, the adequacy of staffing, although much improved, is an ongoing issue. Staff told us that, generally, no one is available in the immediate area, such as the OR clean core or front desk, to call for help if blood products need to be retrieved during a procedure, laboratory tubes need to be delivered to the laboratory for immediate testing, or to meet other emergency needs. Currently, if OR staff need assistance, some staff said they would call on the adjacent Post Anesthesia Care Unit staff, if available, while others felt that there are periods of vulnerability when there is no one to call for assistance.

Despite being without a front desk clerk and/or a nurse available in the clean core area, staff could not recall an instance where patient safety had been compromised. OR managers were diligent about scheduling and reassigning staff to areas of priority, including operating/procedure rooms. Staff cited several reasons why certain staff positions are unfilled. For example, in late December 2012/early January 2013, the facility lost two STs, but facility managers authorized only one of the two ST positions to be filled. At the time of our review (approximately 8 months later), the ST position that was authorized to be filled had not been posted for recruitment. Staff also explained the importance of balancing the right numbers of surgeons, anesthesia providers, nurses, and STs for optimal OR utilization and patient flow but acknowledged the challenge in maintaining a balance of staff. Due to staff attrition, annual or sick leave, light duty, and other instances in which staff shortages may exist, ongoing staffing fluctuations occur. At the time of our onsite review, and in addition to the ST vacancy, the facility had one vacant position for an RN.

The Association of Perioperative Registered Nurses (AORN) publishes recommendations and guidance on how to calculate minimum staffing of direct and indirect patient caregivers.[2] The guidance provides a framework for developing a master staffing plan to cover the continuum of care for surgical patients, from case scheduling to post-operative follow-up care. The AORN calculation factors in relief replacement, to relieve staff who are on annual or sick leave, a lunch break, or otherwise unavailable. Facility and OR managers told us that they follow AORN standards and guidelines; however, they had not developed a master staffing plan, an expectation of the VHA National Surgical Advisory Board, to ensure that OR staffing meets AORN minimum staffing recommendations for the three ORs currently in use. A

[2] AORN Guidance Statement: Perioperative Staffing, in *Perioperative Standards and Recommended Practices* (Denver: AORN, Inc., 2009) 281–287.

master staffing plan is especially important considering the facility's plan to eventually activate the other two equipped ORs.

Issue 2: Pre-Operative Anesthesia Evaluations of Complex Patients

We did not substantiate the allegation that pre-operative anesthesia evaluations of complex patients are inadequate because anesthesia providers frequently evaluate patients just prior to surgery, leaving insufficient time should patients require further evaluations. While VHA requires that anesthesia providers evaluate patients prior to administering anesthesia, there is no timeframe defined as to when the pre-operative anesthesia evaluations of patients should take place.

All five anesthesia providers (anesthesiologists and nurse anesthetists) told us that there is adequate time to conduct anesthesia evaluations of complex patients just prior to surgery. They also stated that, while they cannot recall a case where they have had to delay or cancel a patient's surgery based on clinical assessment of the patient or need for further evaluation (for example, reviewing outside records or conducting laboratory testing), they would be comfortable making the recommendation to delay or cancel a patient's surgical procedure for further evaluation should the need arise.

Issue 3: Surgical Mortality Rate

Our review of VASQIP surgical mortality data for FY 2012 and FY 2013 through March 2013 did not identify obvious outliers or negative trends that would indicate systemic quality of care issues in the OR, or that would require further review. However, after our onsite visit, VASQIP mortality data for quarter 3 of FY 2013 were issued. Prompted by the surgical mortality data, VISN officials, as required by VHA policy, appropriately initiated a review of the facility's surgical program, which included reviews of recent deaths, meeting minutes, internal and external reports, and interviews with key surgical staff. The surgical program review resulted in multiple recommendations to the Facility Director. VASQIP data and resulting reviews are confidential and privileged under the provisions of Title 38, U.S. Code section 5705.

Issue 4: OR and Surgical Quality Management

During the course of our review, we identified weaknesses in OR quality improvement processes. As of January 2013, VHA required surgical facilities to form a Surgical Work Group to meet at least monthly to review VASQIP surgical quality reports, oversee and manage surgical outcomes data, identify gaps with surgical care and recommend actions, and perform various other quality assurance and performance improvement activities.[3] When we requested meeting minutes from the facility's Surgical Work Group, we found that the group had not yet met.

Additionally, local policy requires the OR Committee to meet monthly, to problem-solve functional and quality issues that have been identified, and to proactively address

[3] VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013.

potential issues that may hinder the daily functions of the OR. When we requested OR Committee minutes, we found that the committee had not met in over a year.[4]

Conclusions

We substantiated that the OR did not have a front desk clerk and/or a nurse scheduled to work in the clean core area. However, due to the absence of a master staffing plan, we could not substantiate that the currently available staff was inadequate to support OR staff.

We did not substantiate that pre-operative anesthesia evaluations of complex patients are inadequate because anesthesia providers frequently evaluate patients just prior to surgery, leaving insufficient time should patients require further evaluations. Anesthesia providers told us that there is adequate time to conduct evaluations of complex patients, even if it is just prior to surgery. Furthermore, we found no timeframe requirement for when the pre-operative anesthesia evaluation of patients should take place.

Our review of VASQIP surgical mortality data did not identify obvious outliers or negative trends that would indicate systemic quality of care issues in the OR and require further review beyond the recommendations of the internal VISN review.

In addition to the original allegations, during the course of our review we found that the Surgical Work Group had not yet met as required by VHA policy, and that the OR Committee last met more than a year ago. The Surgical Work Group and OR Committee serve important roles in monitoring and improving surgical quality of care and overall OR efficiency and functioning.

Recommendations

1. We recommended that the Facility Director develop and implement a master staffing plan for the operating room based on Association of Perioperative Registered Nurses recommendations to ensure adequate coverage and support for operating room staff.

2. We recommended that the Facility Director ensure that the Surgical Work Group and Operating Room Committee are implemented and functioning in accordance with Veterans Health Administration and local policies.

3. We recommended that the Facility Director implement the recommendations made during a protected Veterans Health Administration Surgical Program review.

[4] Facility Circular 00-12-15 (112), *Operating Room Committee*, March 7, 2012.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: December 27, 2013

From: Director, VA New England Healthcare System (10N1)

Subject: **Healthcare Inspection – Alleged Patient Safety Concerns in the Operating Room, VA Maine Healthcare System, Augusta, ME**

To: Director, Bedford Office of Healthcare Inspections (54BN)

Cc: Director, Management Review Service (VHA 10AR MRS OIG Hotline)

I have reviewed and concur with the action plans regarding the Healthcare Inspection: Alleged Patient Safety Concerns in the Operating Room, VA Maine Healthcare System, Augusta, ME.

(original signed by:)
Glen B. Gechlik, MD
Acting Deputy Network Director

for

Michael F. Mayo-Smith, MD, MPH
Network Director

Appendix B

System Director Comments

Department of Veterans Affairs

Memorandum

Date: December 24, 2013

From: Director, VA Maine Healthcare System (402/00)

Subject: **Healthcare Inspection – Alleged Patient Safety Concerns in the Operating Room, VA Maine Healthcare System, Augusta, ME**

To: Director, VA New England Healthcare System (10N1)

I have reviewed and concur with the action plans included in the attached hotline transmittal memorandum regarding VA OIG Healthcare Inspection Draft Report: Alleged Patient Safety Concerns in the Operating Room, VA Maine Healthcare System, Augusta, ME (issued December 16, 2013).

(original signed by:)
Amy Gartley

for

RYAN S. LILLY

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 develop and implement a master staffing plan for the operating room based on Association of Perioperative Registered Nurses recommendations to ensure adequate coverage and support for operating room staff.

Concur

Target date for completion: 2/28/14

Facility response: VA Maine Healthcare System (HCS) Nursing Services will update the Scope of Care and Practice – Operating Room (attachment G) of the Nursing Scope of Service and Master Staffing Plan, Memorandum No. 118-13-08 to provide reference to AORN standards and clarification regarding staffing in the operating room.

Recommendation 2. We recommended that the Facility Director ensure that the Surgical Work Group and Operating Room Committee are implemented and functioning in accordance with Veterans Health Administration and local policies.

Concur

Target date for completion: 3/28/14

Facility response: VA Maine HCS has determined that the responsibilities of the Surgical Work Group outlined in VHA Handbook 1102.01 encompass similar responsibilities of existing VA Maine HCS Operating Room and Invasive Procedure Committees. Due to this redundancy, VA Maine HCS surgical leadership has incorporated the committees' functions and formed a new Surgical Work Group that has met on a monthly basis since October 2013 in accordance with Veterans Health Administration and local policies. In addition, per local policy regarding committee procedures, a committee circular will be developed to serve as functional statement and detail the specific purpose of the Surgical Work Group/Committee, membership, committee's authority, and meeting dates. Circular will be completed by 3/28/14.

Recommendation 3. We recommended that the Facility Director implement the recommendations made during a protected Veterans Health Administration Surgical Program review.

Concur

Target date for completion: 3/28/14 (tentative)

Facility response: Our facility continues to work with VISN surgical leadership in making improvements to the surgical infrastructure and back up sub-specialty support in VA Maine HCS surgical program.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Clarissa Reynolds, CNHA, MBA, Team Leader Monika Gottlieb, MD Jeanne Martin, PharmD Claire McDonald, MPA

Appendix D

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