Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 16-02094-219

Healthcare Inspection
Environment of Care and Other Quality Concerns
Cincinnati VA Medical Center
Cincinnati, Ohio

May 3, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Senator Sherrod Brown to assess allegations concerning the environment of care, emergency airway management (EAM) of patients, and clinical practice by a former Acting Chief of Staff at the Cincinnati VA Medical Center (facility), Cincinnati, OH. We were asked to determine whether:

- Clean and dirty materials were stored together in the same location after an OIG 2015 recommendation to store clean and dirty materials separately.
- Reduced availability of EAM providers may have led to a "close call" [delayed intubation of a patient].
- Deficiencies regarding the former Acting Chief of Staff's professional clinical practice had been identified by the facility during Ongoing Professional Practice Evaluations.

We substantiated that clean and dirty patient care equipment were stored together in the Community Living Center following closure of an OIG recommendation made during a review of the facility in October 2014 (*CAP Review of the Cincinnati VA Medical Center, Cincinnati, Ohio*, Report No. 14-04215-99, February 4, 2015).

We did not substantiate a reduction in availability of facility providers for EAM or a delay in providing EAM for a patient.

We did not substantiate reported deficiencies in the clinical practice of the former Acting Chief of Staff.

We recommended that the facility Director ensure that clean and dirty patient care equipment items in the Community Living Center are stored separately, that managers monitor compliance, and that monitors include shower litters and wheelchairs as specific items.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 8–10 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) conducted a healthcare inspection at the request of Senator Sherrod Brown to assess allegations regarding the environment of care (EOC), emergency airway management (EAM) of patients, and clinical practice by a former Acting Chief of Staff (COS) at the Cincinnati VA Medical Center (facility), Cincinnati, OH.

Background

The facility is a 117-bed tertiary care facility that provides inpatient care as well as primary healthcare, specialized care, and mental health services. It provides extended care including long-term nursing care, short-term rehabilitative care, and hospice care at a 64-bed Community Living Center (CLC) located in Fort Thomas, KY.

Patient Care Equipment Storage

Facility managers monitor the safety, security, and general maintenance of the hospital environment, including patient care equipment, through assessments made during EOC rounds. The Veterans Health Administration (VHA) requires facility managers to conduct routine EOC rounds twice yearly in patient care areas and requires them to timely resolve EOC issues.[1]

During OIG Combined Assessment Program (CAP) EOC reviews, inspectors assess facility practices and determine compliance with applicable requirements. Inspectors present identified EOC deficiencies and make recommendations to facility managers who then develop improvement strategies and track improvements through to resolution. Facility managers provide OIG with documentation of sustained improvement to support closing a recommendation.

In October 2014, OIG conducted a CAP review of the facility (*CAP Review of the Cincinnati VA Medical Center, Cincinnati, Ohio*, Report No. 14-04215-99, February 4, 2015). The EOC review identified co-location of clean and dirty patient care equipment in the 6N inpatient unit (blood pressure measuring devices) and in the CLC (wheelchairs and litters). Based on the applicable Joint Commission standard,[2] OIG recommended that the facility store clean and dirty items separately and that facility managers monitor compliance.

[1] VHA *Environment of Care (EOC) Assessment and Compliance Rounding Process Guide*, August 3, 2014. The guide assigned responsibility to conduct rounds to Nurse Managers, Clinical Center Directors, Service Chiefs, and/or Business Managers.
[2] The Joint Commission, "*Comprehensive Accreditation and Certification Manual*", Hospital Accreditation Requirements, IC.02.02.01, EP 4, which states, "The hospital implements infection prevention and control activities when doing the following: storing medical equipment, devices, & supplies."

EAM

Airway management is the process of ensuring an open pathway to the lungs in order to maintain adequate oxygenation. Generally, highly trained and experienced Anesthesia Service practitioners perform this service in the operating room (OR).

The need for EAM arises outside the OR when patients experience respiratory distress.[3] VHA defines *urgent airway management* as the management of a patient whose respiratory status is deteriorating and who is in need of airway support and eventual intervention, such as intubation (insertion of a flexible tube through the nose or mouth to maintain an open airway). VHA defines *emergent airway management* as the management of a patient who needs immediate support and intervention.[4]

VHA requires facilities to have a process for ensuring the competency of staff performing EAM during all hours when patient care is provided.[5] Some VHA facilities provide anesthesia coverage 24 hours per day, 7 days per week, and these facilities would not need to designate other practitioners for EAM coverage; however, facilities that do not have 24-hour anesthesia coverage must designate other clinical staff who are competent in airway management.

Professional Practice Evaluation

Clinical privileging is the process by which a facility grants a practitioner's request "to independently provide specific medical or other patient care services that are within the scope of the practitioner's license and/or clinical competence."[6] Provider competence is "determined by peer references, professional experience, health status (as it relates to the individual's ability to perform the requested clinical privileges), education, training, and licensure and registration."[7]

Clinical privileges are granted for a period not to exceed 2 years. During initial and subsequent privileging, VHA requires a practitioner's service chief to review all credentialing information and document that the results of quality of care activities have been considered in recommending individual privileges. Upon completion of this assessment, the service chief recommends approval, disapproval, or a modification of the requested clinical privileges. The request for privileges continues through an approval process that concludes with final approval by the Facility Director.

Requesting, granting, and renewing clinical privileges for chiefs of staff must follow the procedures as outlined for other practitioners. The request for privileges must be reviewed, and a recommendation made, by the relevant service chief responsible for the particular specialty area in which the COS requests privileges.

[3] Emergency Airway Management is also called Out-of-OR Airway Management.
[4] VHA Directive 2012-032, *Out of Operating Room Airway Management,* October 26, 2012.
[5] Ibid.
[6] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012.
[7] Ibid.

Focused Professional Practice Evaluation (FPPE) is an oversight process to evaluate the competence of a practitioner who does not already have documented evidence of competence in performing the requested privilege(s) at the facility. After competence is documented, a facility evaluates privileged practitioners by Ongoing Professional Practice Evaluation (OPPE) through activities such as direct observation, clinical discussions, and clinical pertinence reviews.

Allegations

In February 2016, the OIG received a letter from Senator Sherrod Brown listing allegations noted in recent press reports, asking that we determine whether:

- Clean and dirty materials were stored together in the same location after an OIG 2015 recommendation to store clean and dirty materials separately.
- Reduced availability of EAM providers may have led to a "close call" [delayed intubation for a patient].
- Deficiencies were identified by the facility during Ongoing Professional Practice Evaluations for the former Acting COS professional clinical practice.

Scope and Methodology

We conducted our review from February 2016 through April 2016. We made a site visit March 21–25, 2016. We reviewed relevant facility policies and procedures; committee meeting minutes; records of training, clinical practice evaluation, and privileging of facility providers. We also reviewed quality management records regarding EOC, EAM, lists of providers on call for EAM during the 2 months prior to our visit, and a patient's electronic health record (EHR). We conducted unannounced EOC inspections of the 6N inpatient unit and the CLC. We interviewed facility leaders and staff from the Surgery, Anesthesia, and Quality Management services.

We **substantiate** allegations when the facts and findings supported that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is 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: Patient Care Equipment Storage

We substantiated recurrent non-compliance with the OIG CAP recommendation to store clean and dirty patient care equipment items separately in the CLC.

The facility responded to the 2014 OIG CAP review recommendation, stating: "The shower litter was removed from the CLC. Dirty equipment has been removed from clean storage areas. Clean and dirty items are being stored separately. Compliance will be monitored by designated CLC and 6N managers."[8] The facility provided data to demonstrate compliance with the requirement. We closed the recommendation based on the facility's sustained improvement rates over a 3-month period. However, during the unannounced EOC inspection we conducted of the 6N inpatient unit and the CLC for the current review, we found clean and dirty items stored together in the CLC, including wheelchairs. The 6N inpatient unit maintained separate storage of clean and dirty patient care equipment.

Issue 2: Reduced Availability of EAM Providers

We did not substantiate that reduced availability of EAM providers led to a delay in intubating a patient. At the time of our inspection, from February 2016 through April 2016, facility providers in the Anesthesia Service provided EAM 24 hours per day. We did not identify a reduction in the availability of EAM providers or a patient who was not timely intubated.

EAM Providers

According to facility policy dated September 16, 2013, surgeons and/or Anesthesia Service staff provided EAM.[9] Anesthesia Service staff were available in-house from 0900 to 2200 on Monday through Friday and remained on call from home for emergency surgery coverage. On weekends, Anesthesia Service staff were in-house from 0630 to 2200. After hours EAM coverage was provided by facility surgeons. The revised facility EAM policy dated September 4, 2014 gave responsibility to Anesthesia Service staff in-house on a 24-hour basis.[10]

Historically, the facility managed 24-hour EAM through a variety of processes that sometimes differed from policy that included the following:

[8] OIG Publication, *CAP Review of the Cincinnati VA Medical Center, Cincinnati, Ohio*, (Report No. 14-04215-99, February 4, 2015).
[9] Cincinnati VA Medical Center Memorandum-No. 11-107. *Out of Operating Room Airway Management*, September 16, 2013.
[10] Cincinnati VA Medical Center Memorandum-No. 11-107. *Out-of-Operating Room Airway Management (OORAM),* September 4, 2014.

- November 2009–April 2013: Anesthesia Service staff available for EAM on call in-house

- April 2013–February 2014: Anesthesia Service staff available for EAM on call in-house from 0630 to 2200; surgeons available for EAM on call in-house from 2200 to 0630

- February–June 2014: Anesthesia Service staff available on call from home after completion of last OR case daily. Surgeons available for EAM on call in-house overnight

- June 2014–March 25, 2016: Anesthesia Service staff available for EAM on call in-house

Although the 2013 policy outlined a specific call schedule for Anesthesia Service staff and surgeons, interim modifications were made to facility practice given staffing availability and budgetary concerns, which contributed to the 2014 revision to the policy.

During our CAP review in October 2014, we evaluated EAM training and competency documentation for non-Anesthesia Service practitioners who provided EAM. We found that the facility maintained EAM coverage by surgeons with documented competence or by competent Anesthesia Service practitioners, and we made no recommendations to the facility. As of our March 2016 site visit, we found the facility maintained EAM coverage by Anesthesia Service practitioners on call in-house.

Alleged Close Call/Delayed Intubation in a Patient With a Difficult Airway

VHA policy recognizes that, "For some patients, airway management…may be predicted to be difficult due to prior patient experience, history, or observed anatomic and situational contexts."[11] The allegation related to a "close call" and delayed intubation did not include specifics about the patient's identification; however, staff described a patient who was admitted with a history of morbid obesity, obstructive sleep apnea, and neck surgery all of which increased his risk for difficulty during intubation. This patient required EAM by a surgeon during the period of time when facility surgeons provided in-house coverage on call.

The patient was admitted to a medical unit with abdominal pain. Two days later, he developed increasing lethargy, and in the evening, a nurse called the rapid response team to evaluate the patient.[12] The team transferred the patient to the Intensive Care Unit (ICU) where the receiving physician noted mental status changes and acute respiratory insufficiency. Progress notes indicated that a physician established intravenous access through a large central vein about 1 hour after transfer to the ICU. Approximately 1 hour later, the patient became more lethargic; a surgeon and an

[11] VHA Directive 2012-032, *Out of Operating Room Airway Management*, October 26, 2012.
[12] Rapid response teams are designed to intervene before a patient experiences an adverse clinical outcome, such as cardiopulmonary arrest.

Anesthesia Service practitioner were at the patient's bedside. The progress notes indicated that an ear-nose-and-throat (ENT) specialist was called to assist with a "possible intubation or tracheostomy" (opening the patient's airway through an incision in the neck). An ENT specialist came to the ICU and nasally intubated the patient approximately 1 hour later.

The patient was extubated 2 days later. He subsequently developed a bloodstream infection, recovered, and was discharged to a skilled nursing facility for short-term rehabilitation.

The facility's former Acting COS was the surgeon on in-house call for EAM the night of the patient's intubation. Staff who were also present at the time told us that she took appropriate actions after realizing that the patient would be potentially difficult to intubate because of his prior neck surgery and obesity. Staff described that she contacted other clinicians, including the ENT specialist and the Anesthesia Service practitioner, who was on call, to assist in managing the patient's airway.

Progress note documentation in the patient's EHR did not suggest that the patient's providers considered this to be an emergency or that delays occurred in intubating the patient. Staff we interviewed who had knowledge of the events did not describe them as emergent or delayed. The patient's condition stabilized in the ICU and did not deteriorate to cardiopulmonary arrest.

Issue 3: Clinical Practice by the Former Acting COS

We did not substantiate identified deficiencies in the clinical practice of the former Acting COS, from the time of her arrival in 2013 through the last completed 2-year credentialing in 2015. The facility provided copies of her past and current clinical privileges and performance evaluation documentation.[13]

We learned that the former Acting COS participated in thoracic surgery cases but limited her role to that of a surgical second assistant.[14] Another surgeon led the surgical management of patients in the role of the attending surgeon and provided feedback into the former Acting COS' clinical competence for the purposes of clinical practice evaluations. The Chief of Surgery documented his review of relevant credentialing information prior to recommending initial and renewed clinical privileges. FPPE and OPPE documentation of the former Acting COS' clinical expertise was based on her clinical practice in the surgical assistant role; no deficiencies were identified. Her competence in administrative duties in her role as the Acting COS was also considered during the credentialing and privileging process.

[13] VHA Handbook 1100.19.

[14] The American Board of Surgical Assistants defines a second assistant as "not the primary assistant to the primary surgeon and is hereby defined and designated as a retractor holder." The American Board of Surgical Assistants, https://www.absa.net/definitions.php. Accessed April 13, 2016.

Conclusions

We substantiated that clean and dirty patient care equipment were stored together in the CLC following closure of an OIG recommendation made during a review of the facility in October 2014. We did not substantiate a reduction in availability of facility providers for EAM or that a patient was not timely intubated. We did not substantiate reported deficiencies in the clinical practice by the former Acting COS.

Recommendation

1. We recommended that the Facility Director ensure that clean and dirty patient care equipment items are stored separately in the Community Living Center, that managers monitor compliance, and that monitors include shower litters and wheelchairs as specific items.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: January 19, 2017

From: Director, Veterans Integrated Service Network 10 (10N10)

Subj: Healthcare Inspection—Environment of Care and Other Quality Concerns, Cincinnati VA Medical Center, Cincinnati, Ohio

To: Director, Washington DC Office of Healthcare Inspections (54DC)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Please find attached responses to Healthcare Inspection-Environment of Care Issue and Other Quality Concerns, Cincinnati VA Medical Center. I concur with the Medical Center Director's response.

2. If you have any questions, please contact Rose Birkmeier, VISN 10 Deputy Quality Management Officer, at (734) 845-4307.

(original signed by:)
Robert P. McDivitt, FACHE

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: January 19, 2017

From: Director, Cincinnati VA Medical Center (539/00)

Subj: Healthcare Inspection—Environment of Care and Other Quality Concerns, Cincinnati VA Medical Center, Cincinnati, OH

To: Director, Veterans Integrated Service Network 10 (10N10)

1. **Recommendation**: The facility Director will ensure that clean and dirty patient care equipment items are stored separately in the Community Living Center, that managers monitor compliance, and that monitors include shower litters and wheelchairs as specific items.

2. **Medical Center Response**: The shower litter, as noted in the 2014 Office of the Inspector General (OIG) Combined Assessment Program (CAP) review response, was removed from the Community Living Center (CLC) in Fort Thomas. With the CLC move from the Fort Thomas Division to the main campus in May 2016, all residents now have private bathrooms and private showers; there is no need for, or presence of, shower litters in the new CLC. Dirty equipment, including wheelchairs, have been removed from CLC clean storage areas and will be cleaned prior to being replaced in storage. A monitoring tool has been created (attached) and will be completed two times per week until 100% compliance is achieved for one, eight-week time span, then weekly for four weeks (a total of three months). Compliance will be tracked by the CLC Nurse Managers. Staff education will be completed by documentation of verbal inservices and written instructions of the separation of clean/dirty equipment, the methodology for cleaning and reasons to separate; will begin January 23, 2017 and completion date of February 6, 2017.

(original signed by:)
Vivian T. Hutson, FACHE
Medical Center Director

Comments to OIG's Report

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

OIG Recommendation

Recommendation 1. We recommended that the Facility Director ensure that clean and dirty patient care equipment items are stored separately in the Community Living Center, that managers monitor compliance, and that monitors include shower litters and wheelchairs as specific items.

Concur

Target date for completion:

a. Monitoring for compliance: April 4, 2017
b. Staff Education: February 6, 2017

Facility response: The shower litter, as noted in the 2014 Office of the Inspector General (OIG) Combined Assessment Program (CAP) review response, was removed from the Community Living Center (CLC) in Fort Thomas. With the CLC move from the Fort Thomas Division to the main campus in May 2016, all residents now have private bathrooms and private showers; there is no need for, or presence of, shower litters in the new CLC. Dirty equipment, including wheelchairs, have been removed from CLC clean storage areas and will be cleaned prior to being replaced in storage. A monitoring tool has been created (attached) and will be completed two times per week until 100% compliance is achieved for one, eight-week time span, then weekly for four weeks (a total of three months). Compliance will be tracked by the CLC Nurse Managers. Staff education will be completed by documentation of verbal inservices and written instructions of the separation of clean/dirty equipment, the methodology for cleaning and reasons to separate, will begin January 23, 2017 and completion date of February 6, 2017.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Katharine Foster, RN, Team Leader Randall Snow, JD Julie Kroviak, MD Natalie Sadow, MBA, Lead Program Assistant

Appendix D

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