Alleged Deficiencies in Out of Operating Room Airway Management Processes at the Colmery-O’Neil VA Medical Center within the VA Eastern Kansas Health Care System
Topeka, Kansas
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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to address care and process issues for an Emergency Department patient (subject patient), and out of operating room airway management (OOORAM) processes at the Colmery-O’Neil VA Medical Center (facility) within the VA Eastern Kansas Health Care System (system) in Topeka, Kansas.\(^1\)

An anonymous complainant submitted multiple allegations:

- An Emergency Department advanced practice registered nurse (APRN) missed multiple intubation attempts on the subject patient which resulted in airway trauma.
- The APRN did not document the unsuccessful intubation attempts in the subject patient’s electronic health record (EHR).
- An Emergency Department provider documented a normal neurological exam in the EHR for the subject patient who had a seizure.
- The subject patient was intubated with paralytics but no sedation.
- Emergency Department staff were deficient in training, qualifications, and privileges.
- Emergency Department staff lacked technical skills to perform airway procedures.
- Leaders “turn[ed] a blind eye” for OOORAM at the facility.

In January 2018, OIG staff received and reviewed the allegations and the subject patient’s EHR. On February 28, OIG staff sent a case referral to the Veterans Integrated Service Network (VISN) Director with questions regarding the subject patient’s care, Emergency Department provider OOORAM privileges, and the facility’s OOORAM process. On May 14, OIG staff reviewed the VISN Director’s response and determined that the Director did not provide all requested information. The OIG continued to have concerns related to the facility’s OOORAM processes and initiated an inspection on June 5, 2018.

Due to the anonymity of the complainant, OIG staff were unable to clarify the allegation related to Emergency Department staff deficiencies and lack of skills. Based on the more specific allegations related to the subject patient and VISN responses, the OIG team focused on the facility’s OOORAM processes of training and competency assessments that included Emergency Department staff. Similarly, the OIG team was unable to clarify the allegation related to leaders turning “a blind eye.” As Veterans Health Administration (VHA) issued a new directive in 2018

\(^1\) VHA Directive 2012-032, *Out of Operating Room Airway Management*, October 26, 2012. This directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1157(1), *Out of Operating Room Airway Management*, June 14, 2018, amended September 19, 2018.
that revised the OOORAM process, the OIG team focused on leaders’ efforts in implementing the new OOORAM directive.

During the inspection, the OIG noted other findings related to VetPro documentation and the Cardiopulmonary Resuscitation (CPR) Committee meeting minutes.2

The OIG substantiated that the APRN caused airway trauma while unsuccessfully attempting intubation based on the interviews with the providers involved and review of documentation. However, the bleeding was minor and of no lasting impact. OIG staff determined that the other aspects of the subject patient’s emergency care were appropriate.

The OIG substantiated that the APRN did not document the intubation attempts. The APRN informed the OIG that the Associate Chief of Staff for Education said there should only be one procedure note written by the person who performed the procedure. Another provider intubated the subject patient and that provider entered a note in the EHR. The Associate Chief of Staff for Education confirmed teaching staff to only write one procedure note so as to not give the appearance of double billing a patient. However, VHA policy states that “[t]he practitioner who treats a patient is responsible for documenting and authenticating the care provided.”3 The OIG team concluded that the APRN who performed the intubation attempts on the subject patient should have personally documented the procedure in the patient’s EHR, even if the attempts were unsuccessful.4

Due to the anonymity of the complainant, OIG staff were unable to clarify the allegation related to the documentation of a normal neurological exam in the subject patient. The OIG substantiated that a provider documented that the subject patient had a normal neurological exam. Upon arrival, the subject patient was ambulatory and interacting with staff. Documenting a normal neurological exam was likely appropriate when the subject patient first arrived in the Emergency Department. During the course of the Emergency Department stay, the subject patient experienced active seizures that limited the Emergency Department provider’s neurological examination.

The OIG did not substantiate that the subject patient was inadequately sedated prior to receiving paralytics for the intubation. The subject patient’s EHR indicated that 15 minutes elapsed between the administration of lorazepam (a benzodiazepine that exerts a sedative effect) and the completed intubation. Based on known duration of lorazepam, the OIG concluded that the

2 VetPro is an internet enabled data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate and complete credentials file; VHA Directive 2012-030, Credentialing of Health Care, October 11, 2012. This directive expired October 31, 2017, and has not been recertified or replaced.
3 VHA 1907.01, Health Information Management and Health Records, March 19, 2015.
4 VHA 1907.01.
sedative effects of lorazepam remained active.\textsuperscript{5} Furthermore, the patient who needed to be intubated was unresponsive; therefore, did not likely need additional sedatives.

Facility leaders lacked a consistent process for completing and tracking the three parts of the assessment required for OOORAM competency. The subject matter expert stated reviewing emergency intubations quarterly and recorded them on the master list. OIG staff determined that the master list was incomplete for fiscal years 2016, 2017, and 2018. Quality Management staff told the OIG team that there was a gap of almost one year in OOORAM data collection due to changes in staffing.

The OIG team found that some facility staff were performing OOORAM procedures without having completed required training and competency assessment for privileging. VHA and facility policies require that all clinical staff requesting OOORAM privileges are assessed by a subject matter expert and complete a three-part competency process.\textsuperscript{6}

The OIG found that facility leaders did not follow the VHA directive while assessing competencies for the APRN’s OOORAM privileges.\textsuperscript{7} The APRN underwent the three-part competency assessment process out of its intended order and intubated two patients. The APRN completed only the simulation portion (Part 2), and the live intubation training (Part 3) approximately one month prior to performing OOORAM on the subject patient. The APRN did not complete the didactic training (Part 1) until July 1, 2018.

The OIG team determined there is no consensus based on medical literature on the number of intubations providers need to perform to achieve OOORAM competency.\textsuperscript{8} The Chief of Anesthesia told the OIG team that the facility did not have the personnel to train staff who did not already have intubation skills, and facility staff have limited opportunities for intubations. OIG staff found that the lack of intubation opportunities could impact compliance with the skills assessment portion of the OOORAM training policy.

\textsuperscript{5} Lorazepam is a drug administered for seizures and preoperative sedation. The sedative effect occurs within two to three minutes of intravenous administration and continues for a period of approximately six to eight hours.

\textsuperscript{6} Clinical privileges and scope of practice are used to delineate the extent and limit of the provision of health care a provider can practice. VHA Directive 2012-032; VHA Directive 1157(1) has similar language regarding subject matter expert and three-part competency process but delineates a new three-level competency; Health System Policy Management No. 112-4, Out of Operating Room Airway Management, August 14, 2014.

\textsuperscript{7} VHA Directive 2012-032.

Ineffective OOORAM tracking practices prevented facility leaders from assuring staff were properly trained to perform intubations in emergency situations, which is one of the purposes of the OOORAM Directive. Additionally, the OIG team found that facility staff had been re-privileged; however, there was a lack of verification that all OOORAM competencies had been met.

OIG staff found that facility leaders did not use VA Form 10-0544 consistent with VHA policies, leading to inaccuracies with OOORAM privileging verification. The VHA directive states that VA Form 10-0544 is used to verify OOORAM competencies for providers transferring into the facility from prior VA medical centers or non-VA facilities. The facility policy states that the form be used to verify contract and new providers who have responsibility for OOORAM.

The OIG team found that between July 2016 and August 2018, 67 percent of providers transferring into the facility had forms that were either incomplete or illegible. OIG staff also found that VA Form 10-0544 was erroneously used to verify 7.4 percent of internal providers seeking OOORAM re-verification.

In December 2016, a facility Emergency Department provider signed VA Form 10-0544 indicating that the APRN had successfully performed intubation on at least one patient in the last two years. The OIG team found that the APRN had no previous experience as a primary intubation operator prior to joining the facility. The APRN’s prior airway management experience was mainly as an Emergency Department registered nurse assisting in intubations. Furthermore, OIG staff determined that because the APRN was applying for OOORAM privileges for the first time and was not transferring into the facility, VA Form 10-0544 should not have been used.

OIG staff were unable to clarify the allegation related to leaders “turn[ed] a blind eye.” OIG staff found that facility leaders did address issues regarding OOORAM training and privileging when they became aware of it. On May 11, 2018, facility leaders sent a letter stating they were made aware that several providers needed to update or complete the training requirements for OOORAM credentialing. The requirements were outlined, along with information regarding increased opportunities to complete the training, and the expectation that this would be completed by June 30, 2018.

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9 VA form 10-0544, Privilege and Competency Verification, states “[f]or transfers in from other VA Medical Centers competency may be established by certification from prior VA Medical Center or non-VA facility. The certification must be done by the individual’s evaluating superior.”

10 Health System Policy Management No. 112-4, Out of Operating Room Airway Management, August 14, 2014.

11 Health System Policy Management No. 112-4.

12 The Emergency Department provider has since left the VA.
The OIG team found processes had been initiated for implementation of VHA Directive 1157(1); however, the OIG team determined the facility’s Process Improvement groups were not sharing information.

OIG staff found that four out of 26 facility OOORAM providers did not have a credentialing file in VetPro.\textsuperscript{13} VHA directive requires all facility providers to enter credentialing information into VetPro.\textsuperscript{14} Additionally, facility policy required service chief documentation in VetPro that indicated when provider data were uploaded and reviewed to include education, training, licensure, certifications, and peer references.\textsuperscript{15} Without consistent VetPro processes, it is unclear if provider data is reviewed.

The OIG team determined that fiscal year 2018 CPR Committee meeting minutes lacked documentation of discussion related to resuscitative events, to include data analysis and implementation of desired changes.\textsuperscript{16} VHA directive requires a CPR Committee or equivalent reviews elements as outlined in VHA Directives 2008-063 and 1177 for analysis of aggregate data and implementation of desired changes. The data must be aggregated, analyzed, and compared internally over time and benchmarked with published studies when available. The data are used to identify and implement desired changes.\textsuperscript{17}

OIG inspectors made seven recommendations to the System Director related to OOORAM documentation, review of OOORAM policy, OOORAM training and competency, use of VA Form 10-0544, OOORAM implementation of VHA Directive 1157(1), documentation in VetPro, and CPR Committee review of resuscitative events.

\textsuperscript{13} VHA Directive 2012-032.
\textsuperscript{14} VHA Directive 2012-030.
\textsuperscript{15} Service Chiefs are responsible for recommending the criteria for clinical privileges that are relevant to the care provided in the service line in which they function. They also review all credentials and requested clinical privileges, and make recommendations regarding appointment and privileging actions, and documentation of these recommendations in VetPro; VA Eastern Kansas Health Care System Policy Memorandum No. 11-33, Credentialing and Privileging of Licensed Independent Practitioners and Midlevel Providers, April 7, 2016.
\textsuperscript{16} A resuscitative event would be one in which there is a cardiopulmonary arrest. Cardiopulmonary arrest is the loss of airway, spontaneous breathing, or meaningful circulation necessary to maintain life that would result in death if not treated, often referred to as a “code.” VHA Directive 2008-063, Oversight and Monitoring of Cardiopulmonary Resuscitative Events and Facility Cardiopulmonary Resuscitation Committees, October 17, 2008. This directive was in place at the time of the events described in this report. This directive was rescinded and replaced by VHA Directive 1177, Cardiopulmonary Resuscitation, August 28, 2018, and contains similar language related to resuscitative events.
\textsuperscript{17} VHA Directive 2008-063, October 17, 2008, and VHA Directive 1177, April 6, 2017. These directives were in place at the time of the events described in this report. These directives were rescinded and replaced by VHA Directive 1177, Cardiopulmonary Resuscitation, August 28, 2018, and contain similar language related to review of resuscitation events and data analysis.
Comments

The VISN and System Directors concurred with the findings and recommendations and provided acceptable action plans. (See Appendixes C and D, pages 28–32, for the Directors’ comments.) The OIG will follow up on the planned actions until they are completed.

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Abbreviations

ACOS  Associate Chief of Staff
APRN  advanced practice registered nurse
COS   Chief of Staff
CPR   cardiopulmonary resuscitation
CRNA  certified registered nurse anesthetist
CT    computed tomography
EHR   electronic health record
ETT   endotracheal tube
FPPE  focused professional practice evaluation
IV    intravenous
mg    milligram
OIG   Office of Inspector General
OOORAM out of operating room airway management
OPPE  ongoing professional practice evaluation
RN    registered nurse
SME   subject matter expert
VHA   Veterans Health Administration
VISN  Veterans Integrated Service Network
Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to address care and process issues for an Emergency Department patient (subject patient), and out of operating room airway management (OOORAM) processes at the Colmery-O’Neil VA Medical Center (facility) within the VA Eastern Kansas Health Care System (system) in Topeka, Kansas.\textsuperscript{18}

System Background

The system is comprised of two campuses—the facility in Topeka, Kansas, and the Dwight D. Eisenhower VA Medical Center (VAMC) in Leavenworth, Kansas. The system is part of Veterans Integrated Service Network (VISN) 15 and serves a patient population of approximately 104,000 throughout 39 counties located in Kansas and Missouri.

The facility Emergency Department has six beds, with additional three overflow beds available. There are 18 beds on the medical surgical floor and eight beds in the Intensive Care Unit/Progressive Care Unit. The facility is designated as a standard surgical complexity level.\textsuperscript{19} The facility has two operating rooms in the surgical department that were closed at the time of the site visit due to temperature and humidity issues.

Prior OIG Reports

A search of prior facility healthcare inspections from the last three years identified one OIG report from the facility with similar issues.

The OIG published a report on June 18, 2018, concerning inpatient care at the facility.\textsuperscript{20} There were six resulting recommendations; all six are closed. The two recommendations related to this report were

- The facility develops facility-specific provider privileges, and

\textsuperscript{18} VHA Directive 2012-032, \textit{Out of Operating Room Airway Management}, October 26, 2012. This directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1157(1), \textit{Out of Operating Room Airway Management}, June 14, 2018, amended September 19, 2018.


The facility meets the requirements for physician staffing for inpatient coverage, pre-operative risk and anesthesia assessments; and anesthesia services provides in-house coverage as required by VHA Directive.\(^\text{21}\)

**Allegations and Related Concerns**

An anonymous complainant submitted multiple allegations:

- An Emergency Department advanced practice registered nurse (APRN) missed multiple intubation attempts on the subject patient which resulted in airway trauma.
- The APRN did not document the unsuccessful intubation attempts in the subject patient’s EHR.
- An Emergency Department provider documented a normal neurological exam in the EHR for the subject patient who had a seizure.
- The subject patient who had a seizure was intubated with paralytics but no sedation.
- Emergency Department staff were deficient in training, qualifications, and privileges.
- Emergency Department staff lacked technical skills to perform airway procedures.
- Leaders “turn[ed] a blind eye” for OOORAM at the facility.

In January 2018, OIG staff received and reviewed the complaint and the subject patient’s EHR. On February 28, OIG staff sent a case referral to the VISN Director with questions regarding the subject patient’s care, Emergency Department provider OOORAM privileges, and the facility’s OOORAM process. On May 14, OIG staff reviewed the VISN Director’s response and determined that the Director did not provide all requested information. The OIG continued to have concerns related to the facility’s OOORAM processes and initiated an inspection on June 5, 2018.

The OIG team addressed the allegations specific to the subject patient in section 1. Due to the anonymity of the complainant, OIG staff were unable to clarify the allegation related to Emergency Department staff deficiencies and lack of technical skills. The OIG team therefore focused on the facility’s OOORAM processes of provider training and competency assessment including the Emergency Department staff (section 2). Similarly, the OIG team was unable to clarify the allegation related to leaders turning a blind eye. As VHA issued a new directive in 2018 that revised the OOORAM process, the OIG team focused on leaders’ efforts in implementing the new OOORAM directive (section 3).

During the inspection, the OIG noted other findings related to VetPro documentation and the Cardiopulmonary Resuscitation (CPR) Committee meeting minutes (section 4).

\(^{21}\) VHA Directive 2010-018.
Scope and Methodology

The OIG staff initiated the healthcare inspection on June 5, 2018, and conducted a site visit at the facility from August 14 through August 16. OIG staff toured the Emergency Department and the simulation area for OOORAM training. In addition, the OIG team reviewed the patient’s EHR including medications administered and neurological assessment. An OIG medical consultant reviewed the care of the two other patients who required multiple OOORAM intubation attempts in fiscal year (FY) 2018. OIG staff reviewed relevant Veterans Health Administration (VHA) directives and facility policies and procedures, facility meeting minutes, staff training records for OOORAM, credentialing and privileging forms, and other relevant documents. OIG staff also reviewed medical literature regarding intubation and airway trauma.

OIG staff interviewed the following facility personnel onsite: Chief of Staff (COS), Associate Chief of Staff (ACOS) for Education, Associate Director for Patient Care Services, Chief of Anesthesia, a certified registered nurse anesthetist (CRNA), an Emergency Department physician (MD), an APRN, nurses, a pharmacist, Credentialing and Privileging staff, Chief of Quality Management, and respiratory therapy staff. Quality Management staff and a clinical educator were interviewed by teleconference. OIG staff interviewed the VA Central Office Chief of Anesthesiology Service and the National Director for Anesthesia and received billing information from the VA Central Office Health Information Management point of contact. In addition, an OIG medical consultant spoke with a representative from the GlideScope® manufacturer.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

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

22 Each patient had two unsuccessful attempts by a physician prior to successful first pass intubation by a CRNA.
Sequence of Events

The subject patient was in their 70s with a history of stroke with resulting speech difficulties, and end-stage lung cancer who was diagnosed with metastases to the brain in late 2017. The subject patient had no prior history of seizures. Eleven days after the diagnosis, the patient’s spouse called a facility oncology registered nurse (RN) stating that the patient had a seizure for about a minute but had returned to their baseline. The patient’s spouse requested to drive the patient to the facility Emergency Department for an evaluation instead of calling an ambulance.

The oncology RN went to the facility Emergency Department to notify staff that the patient was being brought to the Emergency Department. The APRN directed the oncology nurse to call the patient and divert them to the nearest hospital. However, the oncology nurse walked out of the Emergency Department and noticed that the patient was at the Emergency Department check-in desk. The patient was alert and greeted the oncology nurse.

Within five minutes of arrival, an Emergency Department nurse triaged the patient at 1:35 p.m. and placed them in an Emergency Department bed. The Emergency Department MD evaluated the patient at 1:40 p.m. and indicated in an EHR note that the patient was alert and oriented, with pupils that were equal and reactive, had full muscle strength and had “no gross sensory or motor deficits.” While waiting for the patient’s head computed tomography (CT) scan, at 2:30 p.m., the patient’s family notified a nurse that the patient was having another seizure. The patient’s RN notified the Emergency Department MD who arrived at the patient’s bedside with an APRN. At 2:35 p.m., the patient received two milligrams (mg) lorazepam through an intravenous (IV) line which aborted the seizures, but the patient remained unresponsive. At 2:42 p.m., the rapid response team was called because of the need for an emergent intubation to protect the patient’s airway. The patient’s RN documented in the patient’s EHR that at 2:46 p.m. the patient received succinylcholine (paralytic) 200mg IV, ondansetron (antiemetic) four mg IV and fentanyl (pain medication) 100[mg] IV.

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23 The OIG uses the singular form of they (their/them) to protect the patient’s privacy.
24 Metastases refer to the distant spread of cancer. The patient’s primary cancer was in the lung, but it had spread to his brain.
25 While other documentation indicated the Emergency Department MD evaluated the patient at 1:40 pm, the note was signed at 15:59.
26 Lorazepam is a drug administered for management of seizures and preoperative sedation. Intravenous means in or within a vein. The lorazepam was administered intravenously.
27 Rapid response teams are summoned to the bedside when a patient demonstrates signs of imminent clinical deterioration.
28 Fentanyl is typically dosed in micrograms. This likely represents a transcription error in the nurse’s note.
The APRN told the OIG team that on the first intubation attempt, the patient’s vocal cords were visualized with the GlideScope® and placed the endotracheal tube (ETT) in the vocal cords. However, the APRN was unable to pass the ETT into the trachea. The APRN also stated that all the airway instruments were removed and the patient was re-oxygenated with a bag-valve-mask. When the APRN made a second attempt with the GlideScope®, blood was pooling at the back of the patient’s throat, and the vocal cords could not be visualized.

A CRNA, who worked on the same floor as the Respiratory Department, went to the Emergency Department when a respiratory technician moving a ventilator and told the CRNA that there was an intubation in the Emergency Department. On arrival, the CRNA found the APRN attempting to intubate the patient but was unsuccessful; the staff oxygenated the patient with a bag-valve-mask. The CRNA told the OIG team,

[The APRN] asked me if [the APRN] could try again. I said sure. So that was when [the APRN] went and started the second intubation and I did notice some blood in the back of the throat. And for all of its wonderfulness, the GlideScope® being able to see, there’s a huge learning curve at being able to hold that stylet and ET tube just right, that blade takes up so much of the mouth, to try to work that in there very gently and get it to where it needs to be and (uh) and there, there was a bit of a struggle there, and [the] sats [oxygen saturation] had started to kind of trend down. Always stayed above 90 percent. We bagged [bag-mask-valve] [the patient] back up, and I said you know what let me take a look. And so I intubated [the patient].

The CRNA documented in the EHR that “blood was beginning to pool” in the patient’s throat secondary to the “multiple attempts” and “vigorous suctioning.” The CRNA told the OIG that after applying suction, a small tear at the back of the throat was seen. The CRNA was able to see a clear view of the patient’s airway, and at 2:50 p.m., successfully intubated the patient.

According to the patient’s EHR, the patient’s RN informed the APRN at 2:55 p.m. that the patient was agitated; an order for midazolam two mg IV was received. The patient

29 A bag-valve-mask ventilation provides oxygen to the lungs when a patient is unable to protect the airway. Bucher JT, Cooper JS. Bag Mask Ventilation (Bag Valve Mask, BVM) [Updated 2017 Jun24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2018 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441924/ (The website was accessed on October 12, 2018.)

30 A CRNA is an APRN who has obtained specialized training in anesthesia. The CRNA is autonomous in the provision of anesthesia and pain care services for patients in all acuity levels. A CRNA may respond to emergency situations to assist with the provision of airway management.

31 While the CRNA did not document the number of attempts, the APRN and MD both reported two attempts in their interviews.

32 Midazolam is a benzodiazepine, used for similar indications as lorazepam.
continued to be agitated, and the patient’s RN recommended a propofol drip. The APRN and Emergency Department MD told OIG staff that they were concerned that propofol might lower the patient’s blood pressure. At 3:02 p.m., the APRN ordered vecuronium (a paralytic medication) 10mg IV. At 3:15 p.m., the patient again became agitated. The patient’s RN informed the APRN and again recommended propofol. At 3:20 p.m., the patient’s RN medicated the patient with another dose of vecuronium 10mg IV and lorazepam two mg IV with resolution of the patient’s agitation. The patient also received dexamethasone (steroid) 10mg IV. At 3:57 p.m. the patient was transferred from the Emergency Department to an Intensive Care Unit in a community hospital. Two days later, the patient was discharged home from the community hospital. Several months later, the patient was enrolled in hospice and died in spring 2018.

33 Intubated patients need to be adequately sedated for the ventilator to work effectively. Propofol is a fast-acting sedative but can cause low blood pressure as a side effect.
34 If the patient’s seizures were from his brain metastases, dexamethasone may decrease the swelling in the brain caused by the metastases.
35 Records of the hospitalization were not available for OIG review.
Inspection Results

1. Quality of a Patient’s Emergency Department Care

The OIG addresses the specific allegations related to the subject patient’s Emergency Department care in this section including the APRN’s intubation and documentation. The OIG team determined that other aspects of the patient’s emergency care were appropriate. (See Appendix A for emergency medicine and intubation information.)

APRN Attempted Out of Operating Room Intubation

The OIG substantiated that the APRN attempted to intubate the patient and caused airway trauma evidenced by bleeding at the back of the throat during the attempt. However, the bleeding was minor and of no lasting impact.

The patient did not have a difficult airway. Both the APRN and the CRNA described having a full view of the patient’s anatomical structures for intubation. Although the patient had received a medication that should have temporarily paralyzed the patient’s muscles including the facial and jaw muscles, the APRN stated that during placement of the GlideScope® into the patient’s mouth, the patient bit down on it. The ability of the patient to bite down suggested that the paralytic was not yet exerting its full effect. The OIG team determined that if the APRN had waited for the paralytic medication to take full effect, the patient would not have bitten the scope. The lack of completed paralysis placed the patient at increased risk of oral injuries. The APRN also stated being unable to advance the ETT into the trachea on his first attempt. The OIG team determined that this likely was due to the APRN’s relative inexperience with the GlideScope® and the techniques needed to maneuver the scope and ETT into proper position.

Airway Trauma

The CRNA found a small tear in the back of the patient’s throat which was likely attributable to a traumatic intubation. Recent medical literature found higher rates of throat injuries with video

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36 The OIG team did not have videographic evidence available to review the actual procedure: An APRN is a registered nurse with a master’s or post master’s degree who can assess, diagnose, order tests, and prescribe medications to manage patient care. APRNs with full practice authority undergo the same clinical privileging process as a licensed independent practitioner; American Association of Nurse Practitioners®. https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner (The website was accessed on March 21, 2019.); VHA Directive 1350, Advanced Practice Registered Nurse Full Practice Authority, September 13, 2017, grants full practice authority for APRNs “to practice to the full extent of their education, training and certification, without the clinical supervision or mandatory collaboration” of a provider. A licensed independent practitioner provides “patient care services independently…without supervision or direction, and in accordance with individually-granted clinical privileges.”
laryngoscopy compared to traditional direct laryngoscopy.\(^{37}\) (See Appendix A for video laryngoscopy information.) A provider may not notice the traumatic force exerted on the airway during an emergency intubation and insert the scope too deep, causing airway trauma.\(^{38}\)

**APRN’s Intubation Experience**

The OIG team found that the APRN had no experience as a primary intubation operator prior to joining the facility. In addition, OIG staff found the APRN had performed direct laryngoscopy on a simulator but not a live patient. The APRN stated prior airway management experience was mainly as an Emergency Department RN assisting in intubations. The APRN had only performed direct laryngoscopy in the simulation lab, although VHA directive requires performing direct laryngoscopy on at least one live patient as part of the skills assessment.\(^{39}\) The OIG team determined that nonadherence to established VHA directives and processes, combined with the APRN’s inexperience in intubations, placed patients at risk for complications.

**APRN Documentation**

The OIG substantiated that the APRN did not document the failed intubation attempts in the patient’s EHR.\(^{40}\) While the OIG team found that the APRN’s actions were recorded in the CRNA’s procedure note, the team determined that the APRN’s failure to document was not in alignment with VHA documentation requirements.\(^{41}\)

The APRN told OIG staff that the ACOS for Education told facility staff there should only be one procedure note written by the person who performed the procedure. The ACOS for Education confirmed that staff were taught to only write one procedure note so as to not give the appearance of double billing the patient. Providers should document patient interactions,

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\(^{39}\) VHA Directive 2012-032; VHA Directive 1157. Both directives contain the same or similar language regarding training and competency assessment required to perform OOORAM.

\(^{40}\) In the VISN response, the Director also substantiated that the APRN did not document his attempted intubation but indicated the lack of his documentation was not an issue as the CRNA documented the missed attempt in her note.

\(^{41}\) VHA Handbook 1907.01.
assessments, diagnostic evaluations, and treatments. VA Central Office staff outlined that professional coders review all billable cases to validate and code intubations once documented.\(^{42}\)

For providers to be recertified, the VHA OOORAM Directives 2012-032 and 1157(1) both require a “review of provider specific data on airway management” in the period since the provider was certified.\(^{43}\) Accurate record keeping is imperative for coordinated patient care and allows facility leaders to track providers who may need additional OOORAM training. VHA Handbook on Health Information Management requires staff to “maintain complete, accurate, timely, clinically-pertinent, and readily-accessible patient health records, which contain sufficient recorded information to serve as a basis to plan patient care, support diagnoses, warrant treatment, measure outcomes, support education, research, and facilitate performance improvement processes and legal requirements.”\(^{44}\) (See Appendix A for health information management and health records information.) The directives also require continued demonstration of competency using ongoing professional practice evaluation (OPPE) or annual assessment, for recredentialing.\(^{45}\)

OIG staff determined that the APRN should have personally documented the attempted intubation in the patient’s EHR, even if the attempts were unsuccessful. The use of multiple procedure notes should not affect VHA’s ability to accurately code and bill for a procedure.\(^{46}\) Accurate documentation also allows for collection of accurate data for OPPE assessment for recredentialing.

**Neurological Examination Documentation**

Due to the anonymity of the complainant, OIG staff were unable to clarify the allegation related to the documentation of a normal neurological exam in a seizure patient. OIG staff were unable to determine whether the complainant was referring to the pre-Emergency Department seizure or post-Emergency Department seizure timeframe. OIG staff substantiated that the Emergency Department MD documented a brief normal neurological examination and determined that this was adequate given the emergent circumstances. The documentation of a non-focal neurological

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\(^{42}\) Coding is the process of assigning a number that properly identifies and defines medical services, procedures and diagnoses. Coding serves two primary purposes: to create records for the retrieval of diagnosis or procedures and to create details for reimbursement. Coders are the trained professionals that assign a number to the medical services, procedures and diagnoses; [https://www.aapc.com/medical-coding/medical-coding.aspx](https://www.aapc.com/medical-coding/medical-coding.aspx). (The website was accessed on January 29, 2019); VHA Handbook 1907.03 (Transmittal sheet), Health Information Management Clinical Coding Program Procedures, November 2, 2007.

\(^{43}\) VHA Directive 2012-032; VHA Directive 1157(1).

\(^{44}\) VHA Handbook 1907.01.

\(^{45}\) VHA Directive 2012-032; VHA Directive 1157(1).

\(^{46}\) Medical billing is based on accurate coding of diagnosis, procedures, medical services and equipment based on medical record documentation. Medical coders ensure codes are correct for the medical billing process.
exam was appropriate when the patient first arrived in the Emergency Department. During the course of the Emergency Department stay, the patient experienced active seizures, which precluded an Emergency Department MD from performing further neurological examination. VHA Handbook on Health Information Management requires Emergency Department providers to document “history and objective data relevant to the presenting problem.” If this is not possible, the provider needs to record the reason. The Emergency Department MD documented that the patient had uncontrolled active seizures in the Emergency Department which limited an Emergency Department provider from performing all components of a neurological examination.

**Intubation with Paralytics but No Sedation**

The OIG did not substantiate the patient was inadequately sedated prior to receiving paralytics for the intubation. The most common emergency intubation technique is rapid sequence intubation which consists of induction with a sedative medication followed by a paralytic medication. The patient had received lorazepam two mg IV at 2:35 p.m. for seizures, but lorazepam is also a sedative used for intubation. The sedative effects of IV benzodiazepines (including lorazepam) generally starts within 15–30 seconds to a few minutes. There was no documentation of when the intubation attempts started, but the patient was successfully intubated at 2:50 p.m. The OIG determined that the lorazepam would have been exerting its intended sedative effect. Furthermore, the patient, who needed to be intubated, was unresponsive therefore did not likely need additional sedatives.

**2. Facility OOORAM Processes**

The OIG found that the facility was not in compliance with OOORAM three-part competency assessments, including didactic instruction, simulation, and actual intubation. The OIG considered competency as the successful completion of instruction and demonstration of technical skills (simulation and actual intubation), as required per VHA Directive 2012-032. OIG’s analysis was based on VHA Directive 2012-032 that recognized one competency level. The new directive, however, categorizes competencies into three levels with varying

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47 VHA Handbook 1907.01.
50 The sedation effects of lorazepam start within two to three minutes following IV administration and duration range is approximately six to eight hours.
requirements for training and demonstration of technical skills.\textsuperscript{51} (See Appendix A for OOORAM directives and policy information.)

**Facility OOORAM Competency**

The OIG reviewed the list of OOORAM providers for FYs 2016, 2017, and 2018 and determined it was incomplete. The OIG also reviewed competency assessments for facility OOORAM providers and specific OOORAM providers who intubated eight patients out of the OR from October 1, 2017, through August 17, 2018. The OIG found incomplete competency assessments for three of the facility staff who performed those intubations.

**OOORAM Provider Tracking Process**

The OIG found that the facility lacked a consistent process for completing and tracking VHA Directive 2012-032’s three-part requirement for OOORAM competency assessment.

The subject matter expert (SME) stated that emergency intubations were reviewed quarterly and recorded on a master list. The OIG team reviewed the facility’s master list and determined it was incomplete for FYs 2016, 2017, and 2018. Facility Quality Management staff told the OIG team that a gap of almost one year in OOORAM data collection was due to changes in staffing.\textsuperscript{52}

The OIG team determined that ineffective OOORAM tracking prevented facility leaders from assuring staff were properly trained to perform intubations in emergency situations. Additionally, the OIG team found that facility staff had been re-privileged; however, there was a lack of verification that all OOORAM competencies had been met.

**Facility OOORAM Competency Assessments**

In April 2018, facility staff initiated a review of OOORAM providers at the facility and identified 12.5 percent compliance with the required components of OOORAM training.\textsuperscript{53} In July, facility staff completed a subsequent review which showed improvement to 51 percent compliance with OOORAM training.

\textsuperscript{51} VHA Directive 1157(1).
\textsuperscript{52} Both VHA Directives 2012-032 and 1157(1) require facilities have a process to assure initial and ongoing competency assessment.
\textsuperscript{53} VHA Directive 2012-032.
Facility Intubations by OOORAM Providers

The OIG team found that six facility staff performed OOORAM intubations for eight patients from October 1, 2017, through August 17, 2018. Three of the identified OOORAM intubators had incomplete competency assessments at the time of the intubations.

One of the three providers with an incomplete competency assessment was the APRN at issue, who underwent the three-part competency assessment process out of its intended order. Records indicate the APRN completed the simulation skills assessment on a mannequin (Part 2) on March 10, 2017, but performed OOORAM intubations on October 14, 2017, and October 27, 2017. The APRN completed the live patient skills assessment (Part 3) in the OR on November 10, 2017. The APRN unsuccessfully attempted to intubate the subject patient on December 29, 2017, having completed two of the three competency assessment requirements. The didactic portion requirement (Part 1) was not completed until July 1, 2018.

Facility Technical Skills Assessment

Three of the eight patients who underwent OOORAM intubations from October 1, 2017, through August 17, 2018, required more than one intubation attempt. The medical literature shows that patients who had more intubation attempts resulted in a higher number of adverse events (from 14 percent for patients who required only one attempt to 53 percent for patients who required multiple intubation attempts.) The OIG team is concerned that the low number of facility OR intubations resulted in limited opportunities for OOORAM providers, and subsequently increased the risk for adverse events.

The OIG team determined that there is no consensus based on medical literature on the number of intubations providers need to perform to achieve OOORAM competency. The VHA 2012 Directive specified the number of intubations needed to establish competency, and required a minimum of two intubations on different live patients, one direct laryngoscopy and the other video laryngoscopy. The facility also required two live patient intubations for initial competency assessment and one live intubation every two years for renewal.

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54 The facility staff provided the OIG the eight patient names.
57 VHA Directive 2012-032.
58 Health System Policy Management No. 112-4.
The Chief of Anesthesia told the OIG team that the facility was identified as a standard surgical complexity; however, it did not have the personnel or clinical material to train staff who did not already have intubation skills. As a result, facility staff did not have enough cases to complete the required operating room intubation practice. OIG staff found that the lack of intubation opportunities could impact compliance with the skills assessment portion of the OOORAM training policy.

The OIG team was told that facility staff were sent to the second system division (Leavenworth VAMC) for intubation experience; however, Leavenworth VAMC had a limited capacity for intubations, as well. The Chief of Anesthesia had attempted to arrange intubation experience for providers with other facilities but was unable to secure agreements.

**Alternate Competency Assessment**

In December 2016, a facility Emergency Department provider signed VA Form 10-0544 indicating that the APRN at issue had successfully performed an intubation on at least one patient in the last two years. However, OIG staff determined the form was erroneously used since it was the APRN’s first application for OOORAM privileges. OIG staff found that facility leaders did not use VA Form 10-0544 consistent with VHA and facility policies, leading to inaccuracies with OOORAM privileging verification.

VHA Directive 2012-032 states that VA Form 10-0544 is used to verify OOORAM competencies for providers transferring into the facility. In addition, facility policy states that the form be used to certify contract and new providers who have responsibility for OOORAM. The facility policy does not specify RNs as designated OOORAM providers. The OIG team found that VA Form 10-0544 was erroneously used between July 2016 and August 2018 to certify two out of 27 (7.4 percent) of internal providers seeking OOORAM recertification. The OIG team also found that four out of six (67 percent) VA Forms 10-0544 for providers transferring into the facility between July 2016 and August 2018 were either incomplete or illegible.

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59 In 2016, the APRN’s work was delineated under a Scope of Practice. The facility Emergency Department provider who signed the form has since left the VA. In September 2017, VA Directive 1350 implemented Full Practice Authority for designated APRNs. The APRN at issue reapplied for OOORAM privileges in October 2017.

60 VHA Directive 2012-032 allows for alternate competency assessment. VA Form 10-0544 states “[f]or transfers in from other VA Medical Centers competency may be established by certification from prior VA Medical Center or non-VA facility. The certification must be done by the individual’s evaluating superior.”

61 Health System Policy Management No. 112-4.

62 Health System Policy Management No. 112-4.

63 For purposes of this report, an internal candidate is one established at the facility, an external candidate is one who is coming from another VA medical center or a non-VA facility.
3. Leaders Awareness of OOORAM Issues

OIG staff determined that leaders did not “turn a blind eye” to issues regarding OOORAM training and privileging. Facility leaders addressed OOORAM issues when they became aware of deficiencies in 2018.\(^{64}\) Processes had been initiated for implementation of VHA Directive 1157(1); however, the facility’s Process Improvement groups that had formed a plan for implementation were not sharing information.

On May 11, 2018, facility leaders sent a letter to Emergency Department and inpatient providers, including hospitalists, stating that several providers needed to update or complete the training requirements for OOORAM privileging. The requirements were outlined, along with information regarding opportunities to complete the training, and the expectation that this would have been completed by June 30, 2018.

**Implementation of 2018 VHA OOORAM Directive**

VHA Directive 1157(1), issued in June 2018, requires implementation of the new directive no later than six months after publication to ensure competency of staff performing OOORAM.

The facility through a formal Process Improvement group proposed multiple actions to implement the 2018 VHA OOORAM Directive:

- Email to ensure providers’ awareness of OOORAM requirements.
- Send out a calendar identifying monthly OOORAM training.
- Contact other VHA facilities for additional intubation training opportunities.
- Send training module system alerts three months prior to the need for OOORAM certification renewal.
- Make changes to existing facility OOORAM policy.
- Standardize the process for simulation area requirements.

The COS and CRNA noted that a second group, which was not a formalized group, had initiated a process to implement VHA Directive 1157(1) at the facility.

According to the new directive, the facility director assigns responsibility to the COS or SME designee to assess the competency of providers seeking OOORAM privileges or scopes of practice.\(^{65}\) The Chief of Anesthesia, who was the facility’s SME designee, informed the OIG

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\(^{64}\) VHA Directive 2012-032 and VHA Directive 1157(1) contain the same or similar language regarding training and competency assessment required to perform OOORAM. VHA Directive 1157(1) categorizes competencies into three levels with varying requirements for training and demonstration of technical skills.

\(^{65}\) VHA Directive 1157(1).
Alleged Deficiencies in Out of Operating Room Airway Management Processes at the Colmery-O’Neil VAMC within the VA Eastern Kansas Health Care System, Topeka, Kansas

team that trained respiratory therapists would be the facility’s main group of Level 2 OOORAM providers at the facility; Level 3 providers will be physicians who can order the medications.

The OIG team found limited documentation of progress for implementation of VHA Directive 1157(1) or evidence of information sharing between the two OOORAM working groups at the time of the site visit.

4. Other Findings: VetPro Documents and CPR Committee Meeting Documentation

The OIG team found that facility providers’ credentialing information was not consistently uploaded into VetPro and CPR Committee minutes for FY 2018 were lacking in documentation of discussion related to resuscitative events, data analysis, and actions proposed for improvements. (See Appendix A credentialing and clinical privileging information.)

VetPro Documents

The OIG team found that four of the 26 facility OOORAM providers did not have a credentialing file in VetPro.66 VHA directive requires all facility providers to enter credentialing information into VetPro, which is VHA’s electronic credentialing system.67

Facility policy required service chief documentation in VetPro which indicated that provider data were uploaded and reviewed to include education, training, licensure, certifications, and peer references.68 Without consistent VetPro processes, it is unclear if provider data are reviewed.

CPR Committee Meeting Documentation

VHA directive requires a CPR Committee or equivalent review each resuscitative episode of care.69 The data must be aggregated, analyzed, and compared internally over time and

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66 One of the 27 OOORAM providers reviewed for competency assessment is not included here due to retirement in August 2018; VetPro is an internet enabled data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate, and complete credentialing file. OOORAM providers who would have credentialing files in VetPro include physicians, nurses, and respiratory therapists.

67 VHA Directive 2012-030, Credentialing of Health Professionals, October 11, 2012. This directive expired October 31, 2017 and has not been recertified or replaced; it outlines information that must be in the individual's credentialing file includes certifications and registrations.

68 Service Chiefs are responsible for recommending the criteria for clinical privileges that are relevant to the care provided in the service line in which they function. They also review all credentials and requested clinical privileges, and make recommendations regarding appointment and privileging actions, and documentation of these recommendations in VetPro; VHA Handbook 1100.19.; Health Care System Policy Memorandum No. 11-33, Credentialing and Privileging of licensed independent practitioners and Midlevel Providers, April 7, 2016.

benchmarked with published studies when available. The data are used to identify and implement desired changes.\textsuperscript{70}

In FY 2018 through July 2018, eight CPR Committee meetings were held. OIG staff reviewed the CPR Committee meeting minutes and determined that minutes lacked documentation of elements outlined in VHA Directives 2008-063 for analysis of aggregate data and implementation of desired changes.\textsuperscript{71} While the new August 2018 directive includes a requirement that data must be aggregated, analyzed, and compared, it does not outline the same documentation of elements requirement as the previous directive.\textsuperscript{72}

**Conclusion**

The OIG substantiated that the APRN caused airway trauma while performing intubation attempts based on the interviews with the providers involved and review of documentation. However, the bleeding was minor and of no lasting impact. OIG staff determined that the other aspects of the subject patient’s emergency care were appropriate.

The OIG team found that the APRN had no experience as a primary intubation operator prior to joining the facility. The APRN stated prior airway management experience was mainly as an Emergency Department RN assisting in intubations. The APRN had only performed direct laryngoscopy in the simulation lab, although VHA directive requires performing direct laryngoscopy on at least one live patient as part of the skills assessment.\textsuperscript{73}

The OIG substantiated that the APRN did not document intubation attempts because the ACOS for Education said that there should only be one procedure note written by the person who performed the procedure. The ACOS for Education confirmed teaching staff to only write one procedure note so as to not give the appearance of double billing the patient. Facility practice contradicts VHA documentation requirements, and each treating provider should enter the care they provided.\textsuperscript{74} VHA’s Assistant National Director of Anesthesia confirmed that all attempts at intubation should be documented in the patient’s chart. The APRN did not document the failed

\textsuperscript{70} VHA Directive 2008-063.

\textsuperscript{71} VHA Directive 2008-063, Oversight and Monitoring of Cardiopulmonary Resuscitative Events and Facility Cardiopulmonary Resuscitation Committees, October 17, 2008 and VHA Directive 1177, Cardiopulmonary Resuscitation, Basic Life Support, and Advanced Cardiac Life Support Training for Staff, dated April 6, 2017. These directives were in place at the time of the events described in this report. The 2017 1177 Directive was rescinded and replaced by VHA Directive 1177, Cardiopulmonary Resuscitation, August 28, 2018, and contains similar language related to review of resuscitation events and data analysis.

\textsuperscript{72} VHA Directive 1177.

\textsuperscript{73} VHA Directive 2012-032 and VHA Directive 1157(1) contain the same or similar language regarding training and competency assessment required to perform OOORAM.

\textsuperscript{74} VHA Handbook 1907.01
intubation attempts in the patient’s EHR, which would impact adequate documentation for OPPE.

Due to the anonymity of the complainant, OIG staff were unable to clarify the allegation related to the documentation of a normal neurological exam in a seizure patient. OIG staff were unable to determine whether the complainant was referring to the pre- Emergency Department seizure or post- Emergency Department seizure timeframe. The OIG substantiated documentation of a non-focal neurological exam was appropriate when the patient first arrived in the Emergency Department. During the course of the Emergency Department stay, the patient experienced active seizures, which limited an Emergency Department MD’s neurological examination.

OIG staff did not substantiate that the patient was inadequately sedated prior to receiving paralytics for the intubation. The OIG team determined that there would have been adequate time for the sedative effects of lorazepam to take place. The patient, who needed to be intubated, was unresponsive and therefore did likely not need additional sedatives.

The processes for completing and tracking staff competency assessments for OOORAM privileging lacked cohesion which led to a failure of the process. Absent a single coordinating structure, facility staff were able to attain OOORAM privileges without completion of all the training requirements, forms were used inappropriately, and the program was in general disarray.

OIG staff were unable to clarify the allegation related to Emergency Department staff training, qualification. The OIG team therefore focused on the facility’s OOORAM processes of provider training and competency assessment.

OIG staff found that facility leaders lacked a consistent process for completing and tracking the three parts of the competency assessment required for OOORAM certification. The OIG team determined that facility leaders used VA Form 10-0544 incorrectly, leading to inaccuracies with OOORAM competency verification.

The OIG team found that some facility staff were performing OOORAM procedures without having completed required training and competency assessment for privileging. VHA directive and facility policies require that all clinical staff requesting OOORAM privileges are assessed by a SME and complete a three-part competency process.\(^{75}\)

OIG staff were unable to clarify the allegation related to leadership “turn[ed] a blind eye.” OIG staff found that facility leaders did address the issue when they became aware of it. On May 11, 2018, facility leaders sent a letter stating they were made aware that several providers needed to

\(^{75}\) Clinical privileges and scope of practice are used to delineate the extent and limit of the provision of health care a provider can practice; VHA Directive 2012-032. This directive was in effect at the time of the allegations and was replaced by VHA Directive 1157(1) issued in June 2018, Amended September 19, 2018. These directives contain similar language related to OOORAM training requirements; Health System Policy Management No. 112-4, Out of Operating Room Airway Management, August 14, 2014.
update or complete the training requirements for OOORAM credentialing. The requirements were outlined, along with information regarding increased opportunities to complete the training, and the expectation that this would be completed by June 30, 2018.

The OIG team found processes had been initiated for implementation of VHA Directive 1157(1); however, the OIG team determined the facility’s Process Improvement groups were not sharing information.

The OIG team found that four of the 26 facility OOORAM providers did not have a credentialing file in VetPro.\(^{76}\)

OIG staff determined that FY 2018 CPR Committee meeting minutes lacked documentation of elements outlined in VHA Directives 2008-063 and 1177 including data analysis and implementation of desired changes.\(^{77}\)

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\(^{76}\) VHA Directive 2012-030.

\(^{77}\) A resuscitative event would be one in which there is a cardiopulmonary arrest. Cardiopulmonary arrest is the loss of airway, spontaneous breathing, or meaningful circulation necessary to maintain life that would result in death if not treated, often referred to as a “code.” VHA Directive 2008-063, *Oversight and Monitoring of CPR Events*, October 17, 2008. VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.
**Recommendations 1–7**

1. The VA Eastern Kansas Health Care System Director implements documentation training for facility staff, including the Associate Chief of Staff for Education, and monitors compliance with out of operating room airway management documentation for completeness and accuracy.

2. The VA Eastern Kansas Health Care System Director verifies that facility out of operating room airway management policy and out of operating room airway management providers comply with Veterans Health Administration requirements.

3. The VA Eastern Kansas Health Care System Director ensures that facility out of operating room airway management staff are trained as required and monitor compliance, including tracking verification of out of operating room airway management competencies.

4. The VA Eastern Kansas Health Care System Director ensures that facility policy and use of Veterans Administration Form 10-0544, *Privilege and Competency Verification*, is consistent with Veterans Health Administration requirements.


6. The VA Eastern Kansas Health Care System Director verifies that facility leaders review the VetPro process and ensures all credentialing and privileging files are complete as required by Veterans Health Administration policy and takes action as necessary based on the findings.

7. The VA Eastern Kansas Health Care System Director verifies that the Cardiopulmonary Resuscitative Committee analyzes and aggregates data and implements desired changes, as outlined Veterans Health Administration Directive 1177, *Cardiopulmonary Resuscitation*, and monitors compliance.
Appendix A: Background Information

Emergency Medicine

VHA Directive 1101.05(2) describes the policies and procedures for Emergency Department and Urgent Care Centers. The directive calls for “appropriately educated and qualified emergency care professionals” to be present in the Emergency Department during all operational hours, and strongly recommends providers be board certified/board eligible in emergency medicine (preferred), internal medicine, or family medicine. Providers may work in the Emergency Department without meeting these criteria if “they have appropriate credentials, knowledge, and experience and are recommended by the Chief of Emergency…Services.” Listed among Emergency Department core procedures is non-emergent and emergent airway management meeting the requirements of the OOORAM directive. An APRN and a physician assistant may work in the Emergency Department if they have “appropriate credentials, knowledge, and competence in emergency medicine…to properly evaluate patients,” if they “work within their scope of practice, and a physician is present at all times.” Additionally, VHA Directive 1101.05(2) allows for Emergency Department providers to use anesthetic agents for rapid sequence intubation with documented training in airway management and knowledge of the expected side effects of the medications. VHA Directive 1101.05(2) recommends having video laryngoscopy equipment available for patients with difficult airways.

Intubation

Intubation is a procedure during which a provider inserts a breathing tube into the trachea to provide oxygen into the lungs. Before initiating an urgent or emergent intubation, the provider must make the clinical judgment that the patient is breathing poorly or that the patient is at risk of aspirating stomach contents into the lungs. The provider may directly view anatomical landmarks of the larynx or use a fiberoptic camera of a video laryngoscope to indirectly see the

79 Board certification is a voluntary process by which a certifying body verifies the practicing physician’s mastery of knowledge and skills in the chosen specialty by meeting rigorous standards and maintaining those credentials through continuing medical education. The three largest certifying boards in the United States are the American Board of Physician Specialties, the American Board of Medical Specialties, and the American Osteopathic Association.
80 Rapid sequence intubation is the preferred method of intubation in the Emergency Department because it results in rapid unconsciousness and paralysis, which is important in reducing the risk of vomiting and aspiration in patients who have not been fasting.
81 For this report, when discussing urgent or emergent intubation within the parameters of OOORAM, the OIG uses the term “provider” to include all individuals who have been trained and certified as competent to perform OOORAM.
vocal cords.  

The provider identifies the vocal cords, which are located in the middle of the larynx, and passes an ETT with a stylet through the vocal cords and into the trachea. (See Figures 2 and 3.) The provider then removes the stylet, confirms that the ETT is in the trachea, and secures the ETT to the patient to prevent dislodgement. The two most common complications during intubation are oral trauma during the procedure and misplacement of the ETT into the esophagus.

Emergency airway management and intubations are often performed under chaotic and uncertain environments with providers making split second decisions on critically ill patients, often with minimal information. One study reviewed over 17,000 Emergency Department intubations attempted by Emergency Department physicians, Emergency Department physician trainees, and anesthesiologists, and found that approximately 88 percent of intubations were successful in the first attempt.

**Video Laryngoscope**

The video laryngoscope is a relatively new invention. Research has shown that its use has improved rates of successful first attempts, particularly for patients with difficult airways. As a result, VHA has required the availability of video laryngoscopes in all facilities. The video laryngoscope available to facility staff was a GlideScope®. The design of the GlideScope® is not without complications. If the scope is inserted too deep, it can move the larynx forward (anteriorly), causing a steeper angle for intubation. The GlideScope® rigid stylet has an acute angle (with a 70 degree angulation and a width that is longer than the width of the trachea), so it does not fit into the trachea like a traditional, more malleable stylet. Experienced providers have developed tips and techniques to overcome some of these design issues, including pulling the scope back to improve visualization and pulling the stylet out a little bit to decrease the angle.

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82 The larynx is a tube made of cartilage that forms the beginning of the respiratory tree. It spans between the base of the tongue to the trachea and closes to prevent food or liquid from entering the lungs during swallowing.

83 The trachea, also known as the windpipe, carries air through the neck and upper chest. It is in front of the esophagus and is made up of 15 to 20 stacked C-shaped rings of cartilage that extend from the larynx to the thorax.


86 VHA Directive 2012-032.

of trajectory before advancing the ETT.\footnote{Levitan, “Video Laryngoscope.”} The manufacturer’s instruction indicates that providers not only look at the video laryngoscope monitor but also obtain a direct visualization of the patient’s mouth when introducing the scope to avoid injury.

The GlideScope® includes a video camera inserted into a plastic blade.\footnote{“Blade” is the term used to describe the section of the guide piece that assists insertion of the ET tube in a traditional two-piece laryngoscope.} (See Figure 1.) The provider (and others) are able to watch the video monitor as the blade approaches the anatomical landmarks for intubation. The manufacturer also makes a stylet specific to the GlideScope® which needs to be inserted into an ETT to provide the proper angle and rigidity to traverse the airway. (See Figures 2 and 3.)

![Figure 1. GlideScope®](image)

\textit{Source: VA Vendor Portal}

\footnote{The portal was accessed on September 12, 2018.}
Health Information Management and Health Records

VHA Handbook 1907.01 requires that provider documentation for a patient encounter include the recording of pertinent facts, findings, health history and the results of any tests or treatments. The scope of documentation in the electronic health record (EHR) “needs to reflect accurate and clinically-relevant statements.” Appropriate EHR communication assists other providers in their delivery of care to the patient and needs to contain accurate and relevant information. VHA Handbook 1907.01 outlines that “[t]he [COS], or designee, has ultimate oversight responsibility for timeliness, accuracy, and completion; however, the author of the

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91 The portal was accessed on September 12, 2018.
93 VHA 1907.01, Health Information Management and Health Records, March 9, 2015.
entry is responsible for completing, authenticating, and correcting any health record deficiencies within the time frame defined by facility policy or medical staff bylaws.”

**2012 VHA OOORAM Directive**

VHA policy outlines the special skills and competencies that are required during OOORAM. VHA Directive 2012-032 that describes OOORAM provider competencies required to perform urgent or emergent airway management was in effect at the time of the events discussed in this report. A provider deemed competent in airway management was required to be available in the facility 24 hours a day, 7 days a week.

Providers seeking OOORAM privileges had to undergo a three-part competency assessment. Competency assessment included a didactic course with a written test, and a skills demonstration using mannequins or airway task trainers, followed by successful patient intubations using a bag and mask with an oral or nasopharyngeal airway, a laryngeal mask airway, a laryngoscope, and the use of a video laryngoscope.

An alternative to the patient demonstration portion of the procedural skills existed for providers who transferred from another medical facility. The supervisor from the prior facility had to certify the provider’s competency “based on actual successful intubations without complication or as part of a skills assessment” by filling out VA Form 10-0544.

To maintain OOORAM certification, a provider had to successfully complete the didactic program and the skills demonstration on a mannequin or airway task trainer. Additionally, the provider had to either perform one successful intubation in two years, have certification of OOORAM competency from an external facility, or perform live intubations in the presence of the SME or designee.

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94 VHA Directive 2012-032, *Out of Operating Room Airway Management*, October 26, 2012. This directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1157(1), *Out of Operating Room Airway Management*, June 14, 2018, amended September 19, 2018. Urgent airway management is defined as occurring in a patient whose respiratory status is deteriorating and assess to likely require an intervention, and a patient who requires immediate airway support is considered to be emergent.

95VHA Directive 2012-032.

2018 VHA OOORAM Directive

VHA Directive 1157(1), issued in June 2018, amended September 19, 2018, rescinded and replaced the 2012 OOORAM directive. The new directive outlined three levels of competency that defined actions a provider could perform based on training and expertise, and was to be implemented by December 2018:

- Level 1 OOORAM providers perform basic airway management with use of mask ventilation, and insertion of nasal airway, oral airway, and supraglottic devices; after establishing an airway, providers will initiate processes to obtain a higher level of airway expertise.
- Level 2 OOORAM providers are competent with Level 1 and have further training with video laryngoscopy but do not provide medications during intubation.
- Level 3 OOORAM providers are proficient in Levels 1 and 2 airway skills, can order medications for intubation, and have expertise in direct laryngoscopy.

The directive included other changes:

- Reappraisal will be based on focused professional practice evaluation (FPPE), OPPE, or non-privileged competency assessment as per facility policy.
- The facility OOORAM SME must review all airway management notes and associated morbidity, mortality, and complications in a quarterly aggregate review.
- For inpatient care facilities, a Level 2 OOORAM provider must be available during all hours when patient care is provided, and there must be a plan either to call in a Level 3 OOORAM provider or call 9-1-1 if there are no Level 3 providers on staff.

Facility OOORAM Policy

Facility policy outlined provider competencies required to perform airway management in emergent and urgent situations. The COS designated providers who would be responsible for OOORAM. The COS or designated SME was to develop and implement the OOORAM competencies. The Chief of Anesthesia was the facility’s designated SME and responsible for

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98 FPPE is a process whereby the facility evaluates the privilege-specific competence of the provider who does not have documented evidence of competently performing the requested privileges of the facility. It typically occurs at the time of initial appointment to the medical staff, or the granting of new, additional privileges. OPPE is the process whereby the facility has on-going monitoring of privileged providers to confirm the quality of care delivered.

99 Health System Policy Management No. 112-4.

100 Emergency Department providers, respiratory therapists, intensivists, hospitalists, nocturnist, and the Medical Officer of the Day were the OOORAM providers at the facility.
overseeing the competency assessment program. As chief of the service line, the Chief of Anesthesia was responsible for maintaining records of competency.101

**Credentialing and Clinical Privileging**

Credentialing refers to the systematic process of screening and evaluating qualifications to ensure an applicant has the required education, training, experience, and mental and physical health. This process also ensures that the applicant has the skill to fulfill the requirements of the position and to support the requested clinical privileges.102

Clinical privileging is the process by which a provider is permitted by law and the facility to provide medical care services, without supervision or direction, within the scope of the individual’s license. Clinical privileges need to be specific, based on the individual’s clinical competence, recommended by service chiefs and the Medical Staff Executive Committee, and approved by the System Director. Clinical privileges are granted for a period not to exceed two years. Providers must undergo re-privileging prior to the expiration of the held privileges.103

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101 Health System Policy Management No. 112-4.
102 VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was scheduled for recertification by October 31, 2017, and not yet been updated.
103 VHA Handbook 1100.19.
Appendix B: VA Form 10-0544

Privilege and Competency Verification

For transfers in from other VA Medical Centers, competency may be established by certification from the prior VA Medical Center or non-VA facility. The certification must be done by the individual's evaluating superior (e.g. Chief of Anesthesia, Chief of Emergency Medicine, etc.)

Date: 

From VA Credentialing Point of Contact Medical Staff Credentialing Committee

Re: Applicant's Name and Date of Birth

To: Name of Applicant's Supervisor or Chief of Dept. at Losing Facility/Organization Title and Department Street Address City, State, Zip Code

The provider named above has requested clinical privileges for "out-of-operating-room airway management" at our VA Medical Center. Your evaluation of this person's clinical competence with respect to the privileges being requested would be most helpful in our determination of the privileges to be granted.

Please circle "yes" or "no" for each statement. For each "no" answer, please explain in "Comments" section below:

1. Applicant has successfully performed endotracheal intubation on at least one patient in the last two years in your facility.
   □ Yes □ No

2. Applicant has successfully performed bag and mask ventilation utilizing either an oral or nasopharyngeal airway on an unconscious patient in the last two years in your facility.
   □ Yes □ No

3. Applicant has relevant training and clinical experience with the use of alternative methods of intubation such as laryngeal mask airway (LMA), Combitube, bronchoscopy, or other means.
   □ Yes □ No

4. I am not aware of any trends, adverse findings, or information that would preclude applicant from obtaining privileges for "out-of-operating-room airway management".
   □ Yes □ No

Official’s Signature Title Date

Thank you for your time. After signing please scan the signed form and return to me via Outlook e-mail or fax to me at ____________________________.

Sincerely, 

Signature of Medical Staff Credentialing Point of Contact

VA FORM 10-0544
Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: May 8, 2019

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Alleged Deficiencies in Intubation and Out of Operating Room Airway Management Processes at the Colmery-O’Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas

To: Director, Office of Healthcare Inspections (54HL06)
Director, GAO/OIG Accountability Liaison (GOAL) office (VHA 10EG GOAL Action)

1. Please find the initial status response for the Healthcare Inspection—Alleged Deficiencies in Intubation and Out of Operating Room Airway Management Processes at the Colmery-O’Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas.

2. I have reviewed and concur with the facility’s response.

3. Thank you for this opportunity to focus on continuous performance improvement.

4. For Additional questions, please feel free to contact Dawna Bader, Acting 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 D: System Director Comments

Department of Veterans Affairs Memorandum

Date: May 8, 2019

From: Director, VA Eastern Kansas Health Care System—Colmery-O’Neil VA Medical Center (589A5/00)

Subj: Healthcare Inspection—Alleged Deficiencies in Intubation and Out of Operating Room Airway Management Processes at the Colmery-O’Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas

To: Director, VA Heartland Network, (10N15)

1. Thank you for the opportunity to respond to the recommendations in the draft report Healthcare Inspection—Alleged Deficiencies in Intubation and Out of Operating Room Airway Management Processes at the Colmery-O’Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas.

2. I have reviewed the draft report and concur with the recommendations.

3. Corrective action plans have been established with planned completion dates as outlined in the attached report. If additional information is needed please contact my office at 913-682-2000 extension 52008.

(Original signed by:)

RUDY KLOPFER, FACHE, VHA-CM
Director, VA Eastern Kansas Health Care System
Comments to OIG’s Report

Recommendation 1

The VA Eastern Kansas Health Care System Director implements documentation training for facility staff, including the Associate Chief of Staff for Education, and monitors compliance with out of operating room airway management documentation for completeness and accuracy.

Concur.

Target date for completion: August 1, 2019

Director Comments

OOORAM providers and the Associate Chief of Staff for Education were informed about OOORAM documentation requirements. Information on OOORAM is also being shared at the All Medical Staff Meeting. Finally, the process for documenting Out of Operating Room Airway Management (OOORAM) is undergoing revision to force capture of the name of the provider performing the intubation and the total number of intubation attempts. Compliance is being monitored through Cardiopulmonary Resuscitation Committee and is reported monthly to the Medical Executive Board.

Recommendation 2

The VA Eastern Kansas Health Care System Director verifies that facility out of operating room airway management policy and out of operating room airway management providers comply with Veterans Health Administration requirements.

Concur.

Target date for completion: September 1, 2019

Director Comments

VA Eastern Kansas Health Care System (EKHCS) OOORAM HSPM has been updated to reflect VHA Directive 1157(1). Compliance with policy requirements is being monitored through Medical Staff Services. Intubation attempts are documented on the OPPE Form and reviewed by service chiefs. Any concerns are brought forward to the Combined Medicine Committee which reports monthly to Medical Executive Board (MEB).

Recommendation 3

The VA Eastern Kansas Health Care System Director ensures that facility out of operating room airway management staff are trained as required and monitor compliance, including tracking verification of out of operating room airway management competencies.
Concur.
Target date for completion: July 1, 2019

**Director Comments**

The OOORAM competency validation process has been updated to include all required elements. The OOORAM Project Team ensures that all OOORAM providers are compliant with training and competencies, and in collaboration with Quality Management, provide tracking and verification reports to the Combined Medicine Committee. Compliance is also reported monthly to the Medical Executive Board.

**Recommendation 4**

The VA Eastern Kansas Health Care System Director ensures that facility policy and use of Veterans Administration Form 10-0544, *Privilege and Competency Verification*, is consistent with VHA requirements.

Concur.
Target date for completion: August 1, 2019

**Director Comments**

VA Form 10-0544 is being utilized during onboarding consistent with VHA Directive 1157(1). To ensure ongoing compliance, the VetPro process was enhanced to provide a hard stop if the form is incomplete or illegible. Monitoring compliance with use of VA Form 10-0544 occurs through the Professional Standards Board and is reported monthly to Medical Executive Board.

**Recommendation 5**

The VA Eastern Kansas Health Care System Director ensures that facility out of operating room airway management workgroups monitor progress toward implementation of Veterans Health Administration Directive 1157(1), *Out of Operating Room Airway Management*, June 14, 2018, Amended September 19, 2018.

Concur.
Target date for completion: August 7, 2019

**Director Comments**

The OOORAM Project Team has finalized plans and is implementing system improvements to comply with VHA Directive 1157 (1), Out of Operating Room Airway Management, dated June 14, 2018 and amended September 19, 2018. Compliance with the directive and local policy will
be monitored monthly to ensure sustainability. Compliance will be reported monthly through the Combined Medicine Committee to the Medical Executive Board.

**Recommendation 6**

The VA Eastern Kansas Health Care System Director verifies that facility leaders review the VetPro process and ensures all credentialing and privileging files are complete as required by VHA policy and takes action as necessary based on the findings.

Concur.

Target date for completion: June 1, 2019

**Director Comments**

Facility leaders reviewed the VetPro process for ensuring all credentialing and privileging files are complete and implemented validation steps as follows: Medical Staff Services implemented the use of the VetPro credentialing report card that contains information on the completeness of the Credentialing & Privileging Report Card Data and is reviewed weekly by the Chief of Staff Office. Deficiencies related to clinical privileging items are addressed immediately. This new validation process assures that all files are complete. Monthly performance monitoring is communicated through Professional Standards Board to Medical Executive Board at least monthly and more frequently as needed.

**Recommendation 7**

The VA Eastern Kansas Health Care System Director verifies that the Cardiopulmonary Resuscitative Committee analyzes and aggregates data and implements desired changes, as outlined Veterans Health Administration Directive 1177, *Cardiopulmonary Resuscitation*, and monitors compliance.

Concur.

Target date for completion: October 1, 2019

**Director Comments**

The aggregation and trending of data for cardiovascular events is being conducted in the Cardiopulmonary Resuscitative Committee (CPRC). Charts and graphs are updated to include trending. Improvements and outcomes are communicated to MEB and as outlined in Veterans Health Administration Directive 1177, Cardiopulmonary Resuscitation.
# OIG Contact and Staff Acknowledgments

**Contact**

For more information about this report, please contact the Office of Inspector General at (202) 461-4720.

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