Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care and Patient Safety Issues
Martinsburg VA Medical Center
Martinsburg, West Virginia

Report No. 07-02191-147 **June 18, 2007**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections reviewed allegations regarding substandard care of a patient who was admitted to the Martinsburg VA Medical Center (the medical center) on March 24, 2007, and died the following day.

On March 30, 2007, the Veterans Health Administration's Office of the Medical Inspector received a telephone call from someone at the medical center, reporting that there had been an unnecessary death at the medical center. The Under Secretary for Health was notified at around 4:00 p.m., and later that day, he contacted the OIG.

It was alleged that:

- The patient's condition did not warrant an emergency intubation.
- The intubation was performed without the presence of an anesthesiologist.
- The intubation was performed without sedation and/or anesthesia.
- Staff were not familiar with airway emergency equipment and supplies available in the Intensive Care Unit (ICU).
- The Difficult Airway Cart was ill equipped.

Following our review, we concluded that the surgeon made a reasoned decision to proceed with an urgent intubation. However, the rationale for that intervention was not apparent to the ICU nurses and may have led to the concerns expressed in this allegation. The patient did not receive sedation before the nasal intubation attempt. However, it was the clinical judgment of the surgeon that the patient needed his airway expeditiously secured and that sedation would be inappropriate. Such a judgment is well within the range of sound clinical practice. Overall, medical and nursing staff were not familiar with the specific medical emergency equipment and medications available in the ICU. This lack of familiarity was a source of confusion and may have contributed to the inability to establish an airway. The ICU Difficult Airway Cart was not adequately equipped. While individual descriptions of many events varied, staff consistently reported that the scene in the patient's ICU room was chaotic and that no one appeared to be in charge. Staff reported that while clinicians were trying to assist the patient, they did not appear to be working in a coordinated fashion. Independent of outcome, the overall effort to secure an airway was inadequate.

We recommended that emergency airway instrument trays and Difficult Airway Carts be consistently equipped throughout the medical center; that physician and nursing staff be knowledgeable about what is on the emergency airway trays and the Difficult Airway Carts and be properly trained to use the equipment; and that the OIG receive copies of all quality of care and administrative reviews, including medical center corrective action plans, for all recommendations that concern this case.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Veterans Integrated Service Network (10N5)

SUBJECT: Healthcare Inspection – Quality of Care and Patient Safety Issues, Martinsburg VA Medical Center, Martinsburg, West Virginia

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections reviewed allegations regarding substandard care of a patient who was admitted to the Martinsburg VA Medical Center (the medical center) on March 24, 2007, and died the following day.

Background

The medical center provides a broad range of inpatient and outpatient health care services. Outpatient care is also provided at six community based outpatient clinics located in Hagerstown and Cumberland, MD; Stephens City and Harrisonburg, VA; and Franklin and Petersburg, WV. The medical center is part of Veterans Integrated Service Network (VISN) 5 and serves a veteran population of about 129,000 in a primary service area that includes 23 counties in West Virginia, Maryland, Virginia, and Pennsylvania. The medical center provides medical, surgical, mental health, geriatric, and rehabilitation services and rehabilitation domiciliary care. The medical center is affiliated with the West Virginia University School of Medicine, the West Virginia University School of Dentistry, and the George Washington University School of Medicine, as well as the West Virginia School of Osteopathic Medicine.

On March 30, 2007, the Veterans Health Administration's Office of the Medical Inspector (OMI) received a telephone call from a caller identified only as a "patient advocate" at the medical center, reporting that there had been an unnecessary death at the medical center. The caller did not leave her name or the patient's name. On Friday, April 6, the OMI received a telephone call (at approximately 3:00 p.m.) from a medical center intensive care unit (ICU) nurse, reporting that a patient died as a result of an unnecessary procedure. The nurse faxed five "Reports of Contact," one written by herself, three from other ICU nurses, and one from a respiratory therapist. The Medical

Inspector immediately notified and provided the faxed documents to the Acting Principle DeputyUnder Secretary for Health. The Under Secretary for Health was notified at around 4:00 p.m., and in turn, contacted the Inspector General for the Department of Veterans Affairs.

The complainants alleged that:

- The patient's condition did not warrant an emergency intubation.
- The intubation was performed without the presence of an anesthesiologist.
- The intubation was performed without sedation and/or anesthesia.
- Staff were not familiar with airway emergency equipment and supplies available in the ICU.
- The Difficult Airway Cart was ill equipped.

Other allegations concerning unprofessional behavior and inappropriate administrative actions were either not substantiated or are being reviewed by medical center managers; therefore, they are not discussed in this report.

Scope and Methodology

The OIG made site visits to the medical center April 9–13, 2007, and on April 17, 2007. We interviewed clinicians involved in the pre-procedure, procedure, and/or post-procedure care of this patient. We also reviewed the patient's medical records, quality management documents, and credentialing and privileging documents.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Case Review

The patient, a 51-year-old male with a complex medical history, including severe chronic obstructive pulmonary disease (COPD), right heart failure with pulmonary hypertension and secondary polycythemia (increased red blood cells), congestive heart failure, sleep apnea, hypertension, and peptic ulcer disease, presented to the medical center emergency room (ER) on the afternoon of March 24, 2007. The patient complained of poor appetite, a 10-day history of shortness of breath, and productive cough. Earlier that day, he had a nosebleed. On physical examination, the ER physician noted a rapid heart rate and abnormal respiratory sounds. The patient was admitted to a medical ward with a presumptive diagnosis of congestive heart failure exacerbation.

Shortly after admission, the patient was evaluated by the hospitalist physician on-call, whose physical examination noted poor air entry bilaterally and coughing on deep breathing. The hospitalist's assessment was exacerbation of COPD and congestive heart failure. The patient was placed on intravenous antibiotics, steroids, and the diuretic furosemide. The physician ordered oxygen via nasal cannula and aerosolized nebulization of albuterol (a medication used for bronchodilation) every 4 hours, and the patient was placed on a cardiac telemetry monitor.

Later that evening, a nurse notified the medical officer of the day (MOD) that the patient was restless and had an oxygen saturation of 91 percent on 4 liters of oxygen. The patient was given 60 milligrams (mg) of furosemide at 9:54 p.m.. Shortly before midnight, a nurse contacted the MOD and received an additional order for furosemide. On March 25 at 3:00 a.m., the patient was noted to be pleasant and was found smoking in his room.

On March 25, at approximately 9:30 a.m., the patient came to the nurses' station describing shortness of breath. His oxygen saturation was in the mid-80's, and his heart rate was in the 140's. He was taken back to his room, and the hospitalist was notified. Oxygen was increased to 5 liters per minute, and an additional dose of furosemide was given.

The hospitalist examined the patient and noted that he was short of breath, in distress, and unable to lie down. An EKG, a chest radiograph, and an arterial blood gas test were ordered. The hospitalist planned to order abdominal scans when the patient was more stable in order to evaluate increasing liver enzyme and bilirubin levels.

A physician's assistant (PA) found the patient difficult to understand because he was "gurgling" as he spoke. She noted that the patient was in acute respiratory distress. In addition, she described his pharynx as swollen and erythematous with pooling of secretions, and documented that "the airway appears compromised."

After examining the patient, the PA reported that she called the hospitalist, who noted that the airway was compromised due to tonsillar enlargement. The hospitalist also described the patient as short of breath and breathing rapidly. The hospitalist spoke with the intensive care physician (intensivist) regarding transfer to the ICU and ordered additional doses of steroids and antibiotic.

The intensivist reported that he examined the patient prior to the patient's transfer to the ICU, and noted that the oropharyngeal exam was limited due to the patient's shortness of breath. However, he observed swelling of the lips, erythema and swelling of the tonsillar fossa, and possible stridor (high pitched respiratory sound suggestive of obstruction).

The hospitalist asked a surgeon to examine the patient. At 12:40 p.m., the surgeon documented in the medical record that the patient had stridorous breathing, and swelling

of the pharynx. The surgeon recommended giving a large dose of steroids, securing the airway, and requesting that an otolaryngologist (surgical specialist with expertise in ear, nose, and throat disorders) evaluate the patient that day. However, he was told that an otolaryngologist was not available on an urgent basis.

The intensivist asked for anesthesiology and surgical consultation to manage the patient's airway. The anesthesiologist favored a "wait and see" approach. He reported that the patient's respiratory rate was not elevated, his oxygen saturation was in the mid-high 90's, he was not wheezing, and he was not displaying labored respiratory effort. The anesthesiologist reported that he did not feel the airway was obstructed and felt this was an elective rather than emergent situation.

However, the surgeon felt that it was clear that the patient had worsening upper respiratory tract obstruction and that he required urgent intubation. He and the intensivist decided to intubate the patient then, in light of the potential dire consequences if the patient's airway were to become more obstructed later that evening.

The surgeon and anesthesiologist spoke with the patient in the presence of an ICU nurse to obtain consent for intubation and potential tracheostomy. The surgeon then attempted to perform nasal intubation. The patient began to bleed from the nose and mouth and the nasal intubation attempt was abandoned.

The anesthesiologist, who had left to obtain supplies, returned to the ICU. The patient's oxygen saturation decreased during or shortly after the nasal intubation attempt. The anesthesiologist and intensivist then attempted oral intubation but were not successful. The patient's respiratory status continued to worsen and an emergent tracheotomy was attempted. During ongoing efforts to secure an airway, the patient went into cardiopulmonary arrest. Resuscitation efforts continued from 4:55 p.m. to 6:05 p.m. but were ineffective, and the patient died.

Findings

Issue 1: The patient's condition did not warrant an emergency intubation.

We did not substantiate this allegation.

The patient was examined by a PA, a hospitalist, an intensivist, and a surgeon. All agreed that the patient's airway was compromised and at risk for complete obstruction. The patient was transferred to the ICU. An anesthesiologist was consulted, and he examined the patient. It was his opinion that the patient's condition was serious but stable, and he recommended a "wait-and-see" approach. However, it was the opinion of the intensivist and the surgeon that the patient's airway needed to be secured that afternoon.

The patient was admitted to the ICU on a Sunday in the mid-afternoon. The surgeon and the intensivist were concerned that if they did not secure the patient's airway soon, it would progress to total obstruction and require emergency surgery. However, the medical center does not have in-house coverage for surgery, the operating room, or anesthesia during the evening and night tours of duty; and total obstruction would require immediate surgery for the patient to survive.

Upon admission to the ICU, the surgeon, intensivist, and some nurses described the patient as having difficulty breathing with stridor, garbled speech, and drooling. Some ICU nurses described the patient as comfortable and in no apparent respiratory distress. The anesthesiologist appreciated the surgeon's and the intensivist's concerns but felt that the patient was stable. He did not feel that there was a need for emergent intervention.

There was a marked discrepancy in the perceptions of the patient's condition among the clinical staff. The surgeon made a reasoned decision to proceed with urgent intubation; however, the rationale for that intervention was not apparent to the ICU nurses and may have led to the concerns expressed in this allegation.

Issue 2: The procedure was performed without the presence of an anesthesiologist.

We substantiated that the surgeon attempted nasal intubation without assistance from an anesthesiologist or respiratory therapist. However, nasal intubation is a valid method for use outside of operating rooms.

The surgeon recalled asking the intensivist and the anesthesiologist if they would mind if he tried a nasal intubation. He told us that when he did not receive a negative response, he assumed they were assenting, or at least not objecting. The intensivist did not recall this request and told us that he was attending to another patient on the unit. The anesthesiologist told us that he left the area to get medications and supplies and was surprised when he returned to the ICU and discovered that, in his absence, the surgeon had attempted nasal intubation.

The surgeon told us that he had performed several nasal intubations during his career and felt comfortable performing this procedure on this patient in the ICU setting. He told us that, from his experience, he did not anticipate needing assistance from an anesthesiologist or respiratory therapist. The surgeon was under the impression that the intensivist and anesthesiologist where just outside the patient's room at the nurses' station.

In contrast to intubation for congestive heart failure, sepsis, or other non-airway related indications, clinicians attempting intubation in the context of a difficult airway should fully consider the potential for difficult intubation and the possibility of clinical decompensation. In addition, each attempt at intubation can potentially produce or

aggravate airway integrity and thereby complicate subsequent attempts. In this scenario, one would want to optimize the personnel, the understanding of expected roles, and the equipment available for the procedure. While securing an airway in this patient did appear indicated and urgent, it was not emergent. We therefore question the surgeon's decision to proceed with intubation without insisting on the presence of the anesthesiologist, intensivist, and optimal equipment and supplies prior to initiation of the attempt. In addition, it was unfortunate that the anesthesiologist's departure from the ICU to retrieve airway related equipment from the operating room was either not communicated to or not heard by the surgeon. Non-surgical airway management usually falls under the prerogative of anesthesiologists. Although the anesthesiologist, in his clinical judgment, initially favored a "wait and see" approach, once it was decided to secure the patient's airway, the anesthesiologist would be expected to lead the airway management process. The intensivist was the attending physician for the patient and agreed with the urgent need for intubation. However, he chose to attend to other patient care responsibilities on the unit, leaving the immediate decision about intubation with the surgeon.

Issue 3: Nasal intubation was performed without sedation and/or anesthesia.

We partially substantiated this allegation. The patient was not sedated prior to the attempted intubation, but the surgeon did lubricate the endotracheal tube with a local anesthetic gel. While literature supports that topical anesthesia is important, as is an appropriate amount of sedation, it is not a requirement.

The patient did not receive a sedative prior to or during the attempted nasal intubation. The surgeon told us that he did not sedate the patient because he was concerned about possible respiratory depression. However, he stated that he liberally greased the tube with viscous lidocaine, a topical anesthetic. When it was apparent that oral intubation would be attempted, the anesthesiologist ordered 5 mg. of versed (a sedative).

The anesthesiologist told us that nasal vasoconstrictors are usually administered prior to nasal intubation. A vasoconstrictor agent is used to widen the nasal passage and decrease the risk of bleeding. The surgeon reported that in preparation for the intubation, he asked for a vasoconstrictor, but no one responded to his request.

The patient did not receive sedation before the nasal intubation attempt. However, it was the clinical judgment of the surgeon that the patient needed his airway expeditiously secured and that sedation would be inappropriate. Such a judgment is well within the range of sound clinical practice.

Issue 4: Staff were not familiar with airway emergency equipment and supplies available in the ICU.

We substantiated this allegation.

The ICU clinical staff alleged that the surgeon was unable to use available equipment and supplies. For example, when the surgeon called for a cricoid cannulation tray, he allegedly stated that the equipment he received was not familiar to him and, therefore, was not useable. However, the surgeon told us that there was not a cricoid cannula on the tray, nor did the tray include the right number of clamps or needles, a trachea spreader, a tracheotomy attachment bag, or acceptable suture material. Staff accounts varied even as to what type of tray was provided, some stating that it was a tracheotomy tray while others stated that it was a thoracotomy tray.

We were not able to determine if the available equipment was adequate or appropriate for use by the surgeon for this procedure. We were unable to discern what equipment was actually provided.

The intensivist and ICU nurses told us that the equipment was available and that the surgeon had ample time prior to the attempted intubation to review the tracheotomy tray check list. The surgeon told us that in retrospect, he should have checked the list. However, at the time he attempted the procedure, he thought that the nasal intubation would be successful and a tracheostomy would not be needed.

Overall, medical and nursing staff were not familiar with the specific medical emergency equipment and medications available in the ICU. This lack of familiarity was a source of confusion, which adversely affected patient care.

Issue 5: The ICU Difficult Airway Cart was not adequately equipped.

We substantiated this allegation.

The operating room staff told us that the equipment available on the Difficult Airway Cart in the ICU does not have the same equipment as on the Difficult Airway Cart in the operating room. For example, the ICU Difficult Airway Cart does not include fiberoptic intubation equipment or a cricothyrotomy tray.

An American Society of Anesthesiology Task Force suggested that Difficult Airway Carts should include the following:

1. Rigid laryngoscope blades of alternate design and size from those that are routinely used.
2. Endotracheal tubes of assorted sizes.

3. Endotracheal tube guides.
4. Fiberoptic intubation equipment.
5. Retrograde intubation equipment.
6. At least one device suitable for emergency nonsurgical airway ventilation.
7. Equipment suitable for emergency surgical airway access (e.g., cricothyrotomy).
8. An exhaled carbon dioxide detector.

We concluded that the ICU and operating room Difficult Airway Carts did not contain the same equipment.

Other Issues

Coordination of Care Issues

We identified deficiencies in communication and in coordination of treatment throughout this patient's short ICU stay. While, in general, there was agreement among the physician staff that there was a need to secure the patient's airway, an actual plan of when and how to secure his airway was not clearly defined and communicated among the physicians. Further, the rationale for elective intubation was apparently not well communicated with the ICU nursing staff. In addition, we did not find evidence of an inclusive discussion regarding preparation for performing a possible tracheostomy in this ICU.

We found marked discrepancies in staff accounts of what occurred during this patient's ICU stay. Each of the many staff we interviewed offered a different description and interpretation of the events that occurred. A few examples follow:

- Some staff reported that, during the tracheostomy, arterial blood spurted onto the ceiling and window. Other staff reported that a large amount of venous blood flowed from the incision. Yet others described the flow as normal for that procedure.
- Staff reports of the time spent by the surgeon attempting to perform the tracheostomy ranged from just a few minutes to 1.5 hours.
- Some staff reported that the anesthesiologist attempted oral intubation once or twice. Other staff reported that he tried multiple times, even during the tracheostomy attempt. Some staff reported the intensivist also attempted oral intubation, yet others did not recall his attempts. The intensivist himself told us that he made two attempts prior to the tracheostomy.

While individual descriptions of many events varied, staff consistently reported that the scene in the patient's ICU room was chaotic and that no one appeared to be in charge.

Staff reported that while clinicians were trying to assist the patient, they did not appear to be working in a coordinated fashion. Independent of outcome, the overall effort to secure an airway was inadequate.

Recommendations

We recommended that the VISN Director require the Acting Medical Center Director to:

1. Ensure emergency airway instrument trays and Difficult Airway Carts are consistently equipped throughout the medical center.

2. Ensure that staff are knowledgeable about what is on the emergency airway trays and the Difficult Airway Carts and are properly trained to use the equipment.

3. Ensure that the OIG receives copies of all quality of care and administrative reviews, including medical center corrective action plans, for all recommendations that concern this case.

VISN and Acting Medical Center Directors' Comments

The VISN and Acting Medical Center Directors concurred with our recommendations and have taken action to identify needed supplies and instruments to ensure consistency in the Difficult Intubation Airway cart, and develop training protocols on the use of emergency equipment. Upon completion of two administrative investigations, a root cause analysis, and three peer reviews, the findings with corrective action plans and timelines will be sent to the OIG.

Assistant Inspector General for Healthcare Inspections Comments

The VISN Director and Acting Medical Center Director concurred with our recommendations and submitted an acceptable improvement plan. We will follow up until all actions have been implemented.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 23, 2007

From: Network Director (10N5)

Subject: Healthcare Inspection Quality of Care Issues, Martinsburg VAMC

To: VA Office of Inspector General

1. The attached memorandum submitted from the Martinsburg VAMC provides clarification and concurrence of recommendations on the above subject.

2. I have reviewed and concurred with the attached response.

3. If there are any questions, please contact Dr. Archna Sharma, Quality Management Officer, at 410-691-1142.

(original signed by Jeffrey H. Kam for:)

SANFORD M. GARFUNKEL, FACHE

Attachment

Appendix B

Acting Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 22, 2007

From: Acting Medical Center Director, VA Medical Center Martinsburg, WV (613/00)

Subject: V05-550 OIG Response

To: Network Director (10N5) VA Capitol Health Care Network

1. Upon review of the draft report, all facts were documented correctly with the exception of paragraph 2. Under case review, where it was documented "On May 25, 2007, at 3:00 a.m., the patient was noted to be pleasant and smoking in his room," the correct date is March 25, 2007.

a. Recommendation 1 – Concur

The facility has assigned the Chief, Anesthesia Service, and Chief of SPD to identify needed supplies and instruments to ensure consistency in the Difficult Intubation Airway Cart, and has requested the purchase of these items be expedited. Estimated completion date is July 13, 2007.

b. Recommendation 2 – Concur

The Root Cause Analysis team has preliminary recommendations which concur with this finding, and training protocols will be developed. Estimated completion of training is July 13, 2007.

c. Recommendation 3 – Concur

Upon completion of the two Administrative Investigations, the RCA, and three Peer Reviews, the findings will be sent to the OIG with corrective action plans and time lines. All reports are to be completed by May 31, 2007, with corrective actions completed or implemented by July 13, 2007.

2. If further information is needed, please contact Linda J. Morris, M.D., Chief of Staff, at 304-263-0811, extension 4009.

(original signed by:)

PEDRO E. GARCIA, MHSA

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Patricia Christ, Director Program Management and Special Projects Office of Healthcare Inspections 202-565-8301
Acknowledgments	Michael Shepherd, M.D.

Appendix D

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