Department of Veterans Affairs

Office of Inspector General

Healthcare Inspection

Alleged Inappropriate Treatment
Oklahoma City VA Medical Center
Oklahoma City, Oklahoma

Report No. 06-00689-38 **December 8, 2006**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The Office Of Inspector General reviewed allegations of inappropriate treatment in the Cardiac Intensive Care Unit (CICU) at the Oklahoma City VA Medical Center (medical center), Oklahoma City, OK. The purpose of the inspection was to determine the validity of allegations of inappropriate treatment concerning a patient admitted to the CICU in November 2005 with uncontrolled diabetes. He became septic (infected) and was placed on a ventilator. His condition deteriorated and several physicians and nurses performed an emergency amputation of his right lower leg at his CICU bedside. Several employee complainants alleged that performing the amputation in the CICU was inappropriate, several staff declined to be involved, it was performed without an anesthesiologist, and the patient was not receiving adequate pain management.

We did not substantiate the allegations. We concluded that performing the emergency amputation in the CICU was not unreasonable or clinically inappropriate. The patient had necrotizing fasciitis, a potentially fatal medical emergency associated with systemic toxicity and shock, which necessitated timely and aggressive management. The patient was critically ill, his hemodynamic stability was tenuous, and the surgical team felt that moving the patient from CICU to the operating room was precarious. An anesthesiologist was present during the entire procedure and monitored the appropriateness of the patient's sedation. CICU staff assisted with the procedure as needed.

However, we concluded that the patient had previously called the facility's Telcare program and reported pain and swelling in his right lower leg. Telcare is a component of primary care that provides 24-hour telephone triage and health care advice. A primary care nurse attempted to call the patient 2 days later, and the line was busy. Later that day the patient's wife brought him to the emergency room. We did not find documentation of earlier attempts to contact the patient.

We recommended the Veterans Integrated Service Network (VISN) and Medical Center Directors take actions to review the Telcare triage and response process to ensure that calls are appropriately prioritized and followed in an efficient and timely manner. The VISN and Medical Center Director agreed with the findings and provided acceptable improvement plans. We will follow up until all action plans have been completed.

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

TO: Director, Veterans Integrated Service Network (10N16)

SUBJECT: Healthcare Inspection – Alleged Inappropriate Treatment, Oklahoma City VA Medical Center, Oklahoma City, Oklahoma

Purpose

The Department of Veterans Affairs, Office Of Inspector General (OIG), Office of Healthcare Inspections (OHI) reviewed allegations of inappropriate treatment in the Cardiac Intensive Care Unit (CICU) at the Oklahoma City VA Medical Center (the medical center), Oklahoma City, OK. The purpose of the inspection was to determine the validity of the allegations.

Background

Several anonymous employees alleged inappropriate treatment of a patient at the medical center. The patient was admitted to the CICU on November 18, 2005, with uncontrolled diabetes. He became septic (infected) and was placed on a ventilator. His condition deteriorated, and several physicians and nurses performed an emergency amputation of his right lower leg at his CICU bedside.

The complainants alleged that:

- Performing the amputation in the CICU was inappropriate.
- Several staff declined to be involved in the surgery.
- The surgery was performed without the benefit of an anesthesiologist, because the patient was deemed unconscious and probably would not feel pain.
- The patient was not receiving adequate pain management.

On the day of the surgery, the CICU nurse manager provided Nursing Service with a Report of Contact regarding this issue and on December 14, the facility conducted a Peer Review of this case.

Scope and Methodology

We visited the facility on January 17–19, 2006. We interviewed medical staff and nursing staff from the primary care clinic (PCC), emergency room (ER), CICU, and operating room (OR) involved in this case. We reviewed medical records, local policies and procedures pertinent to the case, patient complaints, and quality management documents. We also conducted a general inspection of the CICU on the second floor to assess the distance from the patient's bedside to the OR suite on the fourth floor.

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

Case Review

The patient was a 73-year-old male with a history of diabetes mellitus, congestive heart failure, coronary artery disease, two myocardial infarctions, hypercholesterolemia, hypertension, peripheral vascular disease, and venous insufficiency.

On Tuesday, November 15, 2005, the patient called Telcare (a component of primary care that provides 24-hour telephone triage and health care advice) and reported that his right ankle was so swollen he was not able to put on his shoe. The patient had a several month history of ongoing difficulties with intermittent leg edema (swelling). He reported that pain started the night before and that his present pain score was 5 on a scale of 1 to 10. He requested a clinic appointment as soon as possible. Telcare relayed the patient's concerns to the nurse working with the patient's primary care physician. The primary care physician was on leave on November 16. On November 17, the primary care nurse followed up on the message from Telcare and called the patient's home, but the line was busy.

On November 17, 2005, at 2:15 p.m., the patient's wife brought him to the ER with complaints of right lower extremity (RLE) pain. The ER physician inserted an intravenous line, and ordered blood tests, x-rays of the leg, and a surgical consultation. The nurse noted that the patient's RLE had significant edema with multiple weeping blisters. The patient's vital signs were: blood pressure 99/42 millimeters of mercury (mm/hg), pulse 91 beats per minute (BPM), oral temperature 98.3 degrees Fahrenheit (°F), and respirations 20.

A 5:01 p.m. nurse's note states that blood cultures were collected and sent to the lab and electrocardiogram (EKG) and portable chest x-ray were performed.

At 5:47 p.m., the patient's blood test results included: glucose 383 (normal 70–110) milligrams per deciliter (mg/dL), blood urea nitrogen 73 mg/dL (normal 6–24), creatinine

3.7 mg/dL (normal .6–1.3), and white blood count (WBC) 6.7 microliters (µL) (normal 4.5–10.9).

At 6:21 p.m., the patient's vital signs were: blood pressure 89/56, pulse 130, temperature 100.6° F, and respirations 20.

At 8:28 p.m., the ER clinician inserted a left femoral triple lumen catheter (intravenous line inserted in a main vessel) for fluid resuscitation.

An 8:59 p.m. surgical consultant note states that the patient had "…2+ edema of the RLE, with erythema half way up to his knee, he has warmth to the touch. He also has multiple serous filled bulla (blisters) which go half way up to the knee. They are very superficial…the overlying skin appears white. He has no crepitus[1] to palpitation. His compartments feel soft, and he has no pain with passive motion." The surgery consultant noted, "…necrotizing fasciitis (tissue death) doubted," and recommended starting Vancomycin® (a broad spectrum antibiotic), now, and "…repeat exams of lower extremity q2hrs, if cellulitis/bulla worsen, please call immediately." The surgical consultant also documented that "x-rays of RLE show a streaky appearance to the soft tissue likely due to edema. Clinically the patient has no crepitus. Assessment: 73 year old with blisters and cellulitis[2] of the RLE." The x-rays were later reviewed with the radiology resident whose interpretation was that the "…strandy areas are more consistent with woody edema and no gas is seen."

The patient's respiratory status declined and, at 9:45 p.m., the ER clinician sedated him for intubation and a breathing tube was successfully inserted into his airway for mechanical ventilation. He was placed on morphine for pain control and Ativan® for sedation while on mechanical ventilation. The patient continued to receive intravenous (IV) fluid boluses and IV antibiotics as recommended by general surgery as well as the antibiotic medications Zosyn® and Cleocin Phosphate®.

The patient's vital signs remained unstable and clinicians initiated vasopressors (norephinephrine, dobutamine, and dopamine) to support his blood pressure and heart function. The patient's blood laboratory values revealed acute renal failure and WBC count of 17. The patient was treated with the antibiotic Xigris® and with hydrocortisone. His serum glucose was elevated and he was placed on an insulin drip.

His chest x-ray revealed a small amount of consolidation (an accumulation of fluid in the lung) in his left lower lobe and the EKG indicated tachycardia (an accelerated heart rate) with possible lateral infarction (an area of tissue death in the heart muscle).

[1] *Crepitus* is a crinkly or crackling feeling that indicates gas in the tissues.
[2] *Cellulitis* is a spreading infection of the skin.

At 10:02 p.m., records show the patient had the following vital signs: blood pressure 88/47, pulse 125, oral temperature 101.2 °F, and respirations 16 (assisted by mechanical ventilation).

On November 18, at 2:47 a.m., the patient remained in a critical condition and was transferred to the CICU. The patient remained in a hypotensive state, receiving fluid boluses and vasopressor support to maintain his blood pressure. Ventilator settings were adjusted to maintain blood oxygen concentration in the mid to upper 90 percent.

At 10:32 a.m., an infectious disease (ID) consultant evaluated the patient and determined that sepsis[3] and necrotizing fasciitis[4] were a possibility and concluded that the patient's acute renal and respiratory failure were due to sepsis. The consultant advised antibiotic adjustments, fascia biopsies to assess the health of the deeper tissues, and noted, "if the biopsies were questionable and the blood pressure remained difficult to control emergent amputation might be indicated to save the patient's life."

Documentation shows that the patient's systolic blood pressure decreased to the 60–70's. The surgical resident and the surgical attending discussed the need for a biopsy to isolate the source of infection and assess the viability of the patient's leg. The surgical resident obtained an informed consent from the patient's wife for a biopsy of the patient's infected RLE. The medication Xigris® was discontinued because of its blood thinning effect. The surgical resident performed the fascia biopsies, which were sent to pathology. At 12:00 p.m., the patient was hypotensive. He developed supraventricular tachycardia and was treated with digoxin to lower his heart rate. An echocardiogram done earlier that day showed markedly decreased left ventricular systolic function, an ejection fraction estimated in the range of 25–30 percent and akinesis of the entire posterior wall. Preliminary results of the biopsy were indicative of necrotizing fasciitis.

A Report of Contact documents that the surgical clinicians planned to perform a right above the knee amputation (AKA) at the patient's bedside. They informed the CICU nurse manager who informed the Specialty Care Associate Chief of Nursing Service (ACNS) about the surgical plan. The ACNS contacted the OR nurse manager to discuss the plan.

At 2:01 p.m., the surgical resident obtained an informed consent from the patient's wife to perform a right AKA. The surgical clinicians agreed to perform the right AKA in the CICU as the patient's systolic blood pressure was in the 60's while receiving vasopressor support; he was totally obtunded[5] (not alert, with decreased sensation) and was on

[3] *Sepsis* is commonly called a "blood stream infection"; it can be a life threatening, calling for urgent care.
[4] *Necrotizing fasciitis* is a dangerous infection of soft-tissue that starts in the subcutaneous tissue (just below the skin) and spreads along the flat layers of fibrous tissue that separate different layers of tissue (fascial planes). The death rate is up to 40 percent.
5 *Obtunded* means mentally dulled; from the Latin *obtundere*, to blunt.

mechanical ventilation. They believed it would pose a greater risk to transport the patient to the OR.

At approximately 2:15 p.m., the OR team arrived and proceeded to prepare the patient and the CICU room for surgery. Records show the surgical resident injected Xylocaine® (a local anesthetic) to the surgical site before performing the amputation. An incision was made over the anterior surface. Once the femur was encountered, the patient did begin to "squirm" and more local anesthetic was injected into the deeper tissues. They also administered Versed® for sedation. The surgical resident irrigated the site copiously and dressed the surgical site with moist sterile gauze. The procedure took approximately 15–20 minutes and was performed without any complications. The patient remained in critical condition, requiring increasing doses of vasopressors for hypotension.

On November 19, the patient's blood glucose was 159 mg/dL, and he continued to be on an insulin drip. The dobutamine drip was stopped overnight when the patient's blood pressure improved. He was non-responsive to painful stimuli and remained on the ventilator in an unstable condition. Documentation shows there were plans to wean the patient off the ventilator. The patient's WBC decreased to 9.8/µL and he continued on antibiotics as suggested by ID consultant. The patient's urinary status improved. The attending surgeon documented the patient's wound appeared to be "doing okay." He also documented plans to revise the surgical site when the patient became stable.

The patient's condition gradually showed improvement, and he required less oxygen on mechanical ventilation, he no longer required vasopressors and his WBC count initially normalized. Blood cultures had grown *Morganella Morganii*[6] and he remained on intravenous antibiotics. A repeat blood culture from November 19 was without growth. On November 23, the patient's blood glucose was 123 mg/dL and his renal function continued to recover. His chest x-ray showed better lung expansion with bilateral lobe infiltrates. His wound was noted to be clean and without signs of infection. On November 25, the patient was taken to the OR for formalization and incision and drainage of his right AKA.

The patient was improving on the ventilator but was unable to be extubated. On December 9, the surgeon performed a tracheotomy and replaced the breathing tube with a tracheostomy tube.

In January 2006, the patient's condition gradually deteriorated, and he developed recurrent sepsis resulting in septic shock, an overwhelming blood infection. He continued to deteriorate, and he expired on January 25. The patient's wife requested an autopsy to determine the cause of his death. The autopsy report revealed multi-system organ failure secondary to sepsis as the cause of death.

[6] *Morganella Morganii* is a bacteria of the family *Enterobacteriaceae*, which causes secondary infections of blood, respiratory tract, and wounds.

Results

Issue 1 Inappropriate Treatment

We did not substantiate the allegation that the patient received inappropriate treatment in the CICU.

Tissue biopsies of the patient's RLE confirmed a diagnosis of necrotizing fasciitis, a fast spreading, potentially fatal infection. The surgical clinicians performed the AKA in an attempt to isolate the patient's infection and prevent it from entering the blood stream. The surgical clinicians told us that due to the patient's critical condition the procedure was performed in the CICU. The patient was intubated, in respiratory and renal failure, and on multiple intravenous antibiotics. In addition, the patient was on combination vasopressor medications for hemodynamic instability secondary to septic shock whose source was the RLE cellulitis (suspected fasciitis). The surgeon considered the options and reported that in his clinical judgment, the time it would take to transport the patient to the OR would have jeopardized patient care and survival. He noted "... we will do this at the bedside as the patient's pressure is in the 60s while on norephinephrine and dopamine, he is totally obtunded and on the ventilator. I think it would be more dangerous and offer few additional aids to transport him up two flights of stairs than just to do the procedure here." The Acting Chief of Staff approved the need to perform the procedure in the CICU and remained at the bedside to monitor the patient. In addition, a surgical resident spoke with the patient's wife, who gave permission to proceed with the planned procedure.

Issue 2 Staff Declined To Be Involved in the Surgery

We did not substantiate the allegation that staff declined to be involved in the surgery at the bedside.

The CICU nurse manager assisted during the surgical procedure, and the Specialty Care ACNS was present and observed the procedure. Other CICU staff assisted with the surgery as needed. The nurse manager stated she had no knowledge of staff refusing to be involved in the case.

We did find that the surgeon had asked the nurse assigned to the patient that day to administer Versed®. The nurse expressed not feeling comfortable administering the medication due to the patient's low blood pressure. The surgeon accepted her concerns and administered the medication himself.

Issue 3 Surgery Performed Without an Anesthesiologist

We did not substantiate the allegation that the surgery was performed without the benefit of an anesthesiologist.

An anesthesiologist was present in the CICU during the procedure. The anesthesiologist was reluctant to move the patient to the OR and agreed with the decision to perform the surgery in the CICU. He did not believe the patient would tolerate additional sedation due to his critical condition. The anesthesiologist observed that the patient was obtunded and believed that further sedation beyond the Versed® and local anesthetic was not necessary or prudent. A nurse manager present in the room reported that she did not notice any signs of pain from the patient.

Issue 4 Inadequate Pain Management

We did not substantiate the allegation that the patient had not received adequate pain management.

According to the patient's medical records, physicians ordered morphine and fentanyl patches to be administered routinely, as needed, and stat (immediately) to control the patient's pain. Nursing medication administration records show that the patient received morphine and/or fentanyl on a regular basis.

Issue 5 Response from Telcare

While not a formal allegation, we had concerns regarding the clinical response to the patient's concerns when he called Telcare on November 15 and reported pain and swelling in his RLE. We did not find evidence that staff had responded to the Telcare patient call until the morning of November 17. Records show the primary care nurse had called the patient, but his line was busy. The patient subsequently presented to the ER that afternoon. The primary care nurse and the PCC provider could not remember if they had followed up on the Telcare patient call earlier.

Conclusion

We did not substantiate the complainant's allegations. We concluded that performing the emergency amputation in the CICU was not unreasonable or clinically inappropriate. Necrotizing fasciitis is a potentially fatal medical emergency associated with systemic toxicity and shock, which necessitates timely and aggressive management. The patient was critically ill, his hemodynamic stability was tenuous, and the surgical team felt that moving the patient from CICU to the OR was precarious. An anesthesiologist was present during the entire procedure and monitored the appropriateness of the patient's sedation. CICU staff assisted with the procedure as needed.

We also concluded that the patient called Telcare on November 15 and reported pain and swelling in his RLE. A primary care nurse attempted to call the patient on November 17, and the line was busy. We did not find documentation of attempts to contact the patient on November 15–16.

Recommendations

We recommend the VISN Director ensure the Medical Center Director takes action to:

1. Review the Telcare triage and response process to ensure that calls are appropriately prioritized and followed in an efficient and timely manner.

Comments

The VISN Director and Medical Center Director concurred with the findings and recommendations of this inspection and presented acceptable improvement plans. We will follow up until all action plans have been completed.

(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: September 8, 2006

From: VISN Director

Subject: **Healthcare Inspection – Alleged Inappropriate Treatment, Oklahoma City VA Medical Center, Oklahoma City, Oklahoma**

To: Department of Veterans Affairs Office of Inspector General (OIG) - Office of Health Care Inspection

1. The South Central VA Health Care Network (VISN16) has reviewed the response from the Oklahoma City VA Medical Center regarding the subject Draft Report–Healthcare Inspection–Alleged Inappropriate Treatment–Project Number: 2006-00689-HI-0214.

2. Electronic Word Document copies of the responses from the Medical Center Director (00-635) and the Network Director (1 ON16) are being forwarded for your review. The Target Completion Date is October 2, 2006

3. If you have any questions, please contact Donna DeLise, Chief, Office of Performance and Quality at the Oklahoma City VAMC at 405.270.5194.

(original signed by:)

Robert Lynch, M.D.

VISN Director's Comments to Office of Inspector General's Report

The following VISN Director's comments are submitted in response to the recommendation in the Office of Inspector General's Report:

OIG Recommendation

Recommendation 1. We recommend the VISN Director ensure the Medical Center Director takes action to: review the Telcare triage and response process to ensure that calls are appropriately prioritized and followed in an efficient and timely manner.

Concur **Target Completion Date:** 10/2/2006

The network Director concurs with the OIG recommendations. The Network Director will continually monitor progress on completion of the outstanding OIG Recommendation as part of the network quarterly performance report.

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 8, 2006

From: Medical Center Director

Subject: **Healthcare Inspection – Alleged Inappropriate Treatment, Oklahoma City VA Medical Center, Oklahoma City, Oklahoma**

To: Department of Veterans Affairs Office of Inspector General's (OIG)-Office of Health Care Inspection

1. We appreciate the opportunity to work with the Office of Inspector General and provide a response on this issue.

2. I concur with the findings and recommendations. The importance of this review is acknowledged as we continually strive to provide the best possible care to our Veterans. The specific actions taken for the recommendations are on the following page.

3. If you have any questions, please contact Donna DeLise, Chief, Office of Performance and Quality at (405)270-5194.

(original signed by:)

DAVID P. WOOD, MHA, FACHE

Medical Center Director

Medical Center Director's Comments to Office of Inspector General's Report

The following Medical Center Director's comments are submitted in response to the recommendation in the Office of Inspector General's Report:

OIG Recommendation

Recommendation 1. We recommend the VISN Director ensure the Medical Center Director takes action to: review the Telcare triage and response process to ensure that calls are appropriately prioritized and followed in an efficient and timely manner.

Concur **Target Completion Date:** 10/2/2006

1. The Telcare triage and response process was reviewed and the following changes will be implemented:

a. Primary Care Nursing staff will be required to address all view alerts from telcare prior to the end of their tour of duty. A random review will be completed weekly to monitor compliance. The review will be completed utilizing a computer generated report which identifies the date the view alert was initiated, to whom it was sent, when the alert was acknowledged, and any additional signers. In addition, CPRS will be reviewed for the specific corresponding documentation.

b. Documentation will be completed in CPRS any time staff communicates telcare alerts with a provider or other health care staff. A random review will be completed on a monthly basis to monitor compliance.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Marilyn Walls, Healthcare Inspector Dallas Regional Office of Healthcare Inspections (214) – 253-3335
Acknowledgments	Linda DeLong, Director Karen Moore, Associate Director Wilma Reyes Michael Shepherd, M.D. George Wesley, M.D.

Appendix D

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