



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Credentialing, Privileging, and Infection Control Practices

VA Western New York Healthcare System, Buffalo, New York

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Executive Summary

The purpose of the inspection was to determine the validity of anonymous allegations that a board certified surgeon at the Western New York Healthcare System, Buffalo division, performed lung surgeries without appropriate credentials and privileges. The complainant further alleged that the surgeon's "hygiene practices were not met."

We did not substantiate the allegations. We concluded that the surgeon had appropriate credentials and privileges for the surgeries performed. We also concluded that when surgical procedures involving the lungs were necessary, a surgeon who was appropriately credentialed and privileged either assisted with or performed those procedures. Additionally, we concluded that the surgeon followed established pre-operative prophylactic antibiotic protocols, appropriately consulted Infectious Disease clinicians, and had an excellent clean wound infection rate. We made no recommendations.



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

TO: Director, VA Healthcare Network Upstate New York (10N2)

SUBJECT: Healthcare Inspection – Credentialing, Privileging, and Infection Control Practices, VA Western New York Healthcare System, Buffalo New York

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) reviewed allegations regarding credentialing, privileging, and infection control practices at Western New York Healthcare System (the system), Buffalo division, Buffalo NY. The purpose of this inspection was to determine the validity of the allegations.

Background

The system consists of two divisions, located in Buffalo and Batavia, NY. The Buffalo division provides medical, surgical, mental health, and long-term care services through a full range of inpatient and outpatient programs. It is the main referral center for cardiac surgery for Central and Western New York and Northern Pennsylvania. The Batavia division provides services for long-term care, post-traumatic stress disorder, and primary care. The system is academically affiliated with the State University of New York at Buffalo School of Medicine and Biomedical Sciences.

An anonymous complainant alleged that several patients died because a specific surgeon performed lung surgeries that the surgeon was not credentialed and privileged to perform. The complainant specifically identified three patients who allegedly suffered complications and died after undergoing surgical procedures performed by the surgeon. The complainant further alleged that the surgeon's "hygiene practices were not met." Because we were unable to identify and interview the complainant, we interpreted the second allegation to mean that the surgeon's infection control practices were inadequate resulting in increased wound infection rates.

Scope and Methodology

We reviewed the provider's credentialing and privileging documents, mortality data, and wound infection rates. We reviewed the medical records of the three patients identified in the complaint and six other patients who expired after undergoing surgeries performed by the surgeon over an 18-month period of time. The system provided us the names of the additional patients. We also reviewed VA Continuous Improvement in Cardiac Surgery Program (CICSP)¹ data and evaluated results of reviews of the provider's care conducted through the system's internal processes.

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

Case Summaries

Patient 1

This 62-year-old patient had a medical history that included high cholesterol, hypertension, and cervical spinal disease. The patient also had a history of suffering a heart attack. In 2004, the patient underwent coronary artery stenting² at a community hospital outside of the Buffalo area. The stenting was unsuccessful and the patient proceeded to a 2-vessel coronary artery bypass surgery with placement of an internal defibrillator.³ The patient continued to do poorly and underwent a heart transplant evaluation. However, the patient's cardiac function improved, a transplant procedure became unnecessary, and the patient was discharged from the community hospital to home.

Over the next 3 years, the medical record shows that tests indicated progressive deterioration of the patient's aortic valve.⁴ In April 2007, clinicians diagnosed the patient with severe to critical aortic stenosis⁵ and referred the patient to the Buffalo division for evaluation. The surgeon examined the patient and recommended replacement of the aortic valve. The patient agreed and was admitted to the Buffalo division for surgery in December 2007.

¹ CICSP data contains a comparative analysis of all the VA medical centers performing cardiac surgery.

² A stent is a small tubular device that is inserted into an obstructed blood vessel after the obstructed area is opened by the inflation of a balloon. The stent holds the blood vessel open after the balloon is deflated and withdrawn.

³ A defibrillator is a device that delivers an electrical charge to the heart muscle in order to terminate abnormal heart rates and rhythms.

⁴ The aorta is the very large blood vessel that delivers blood from the heart to the rest of the body. It begins at the aortic valve, which is one of four valves in the heart, and courses through the chest into the abdomen where it divides into two large vessels that continue on into the lower extremities.

⁵ Hardening and narrowing of the aortic valve resulting in decreased blood flow from the heart.

Anesthesia staff categorized the patient pre-operatively as having moderate to severe systemic disease that increased the patient's surgical risk and assigned an American Society of Anesthesiologists (ASA) risk score of 3 to 4.⁶ Prior to surgery, clinicians administered prophylactic intravenous antibiotics per established surgical protocol to reduce the risk of surgical infection. During the sternotomy,⁷ lung tissue that was adherent to the chest wall was injured requiring the resection of multiple lung blebs.⁸ At the end of surgery, the patient could not be weaned from the cardiopulmonary bypass machine, and the surgeon inserted an intraaortic balloon pump to assist with the forward flow of blood from the heart. The chest incision was closed but had to be reopened when the patient's heart stopped. Cardiac massage was successful, but the surgeon decided to leave the chest incision open for 24–48 hours. The patient was transferred to the Intensive Care Unit (ICU) with orders for postoperative antibiotics. However, the following morning the patient destabilized and suffered a cardiopulmonary arrest. Resuscitative efforts were unsuccessful.

Patient 2

This 83-year-old patient was evaluated in September 2007 by the system's surgical team for a large aortic aneurysm⁹ discovered during a work up of an abdominal aneurysm. The patient's previous medical history included hypertension, high cholesterol, obesity, remote tobacco use, chronic bronchitis, diverticulosis, and oral cavity cancer. Medical record documentation shows that the surgeon informed the patient that there was a high risk for rupture of the aortic aneurysm, but that surgery to repair the aneurysm also carried a high risk of morbidity (20 per cent) and mortality (20 per cent). After thinking it over for several weeks, the patient decided to proceed with the surgery and underwent extensive pre-operative evaluation, including cardiac catheterization, carotid artery evaluation, peripheral vascular tests, and pulmonary function tests.

The patient was admitted to the Buffalo division for surgery. Anesthesia staff assigned the patient an ASA risk score of 4. At the time of admission, a provider ordered three doses of an antibiotic for a potential bladder infection. A urine culture was subsequently negative. Per protocol, prophylactic intravenous antibiotics were administered just prior to and during surgery to reduce the risk of surgical infection.

Surgery involved the use of an aortic arch graft because of displacement and significant disease of the patient's blood vessels that branched from the aorta at its arch. It was

⁶ The ASA has devised a physical status classification system for patients undergoing anesthesia based on a 1 to 5 scale. ASA 1 patients have the lowest risk for complications and ASA 5 patients carry the highest risk. ASA 3 patients are those with severe systemic disease(s). ASA 4 patients are those with severe systemic disease that is a constant threat to life.

⁷ Division of the sternal bone.

⁸ Lung tissue consists of small balloon-like sacs where air exchange takes place. A bleb is an abnormally enlarged balloon-like sac.

⁹ A weakening in the wall of the blood vessel resulting in an outpouching or dilatation of the vessel.

necessary to administer several units of various blood components during surgery. The patient was successfully weaned from a cardiopulmonary bypass machine on the second attempt and transferred to the ICU in stable condition.

The next morning, the patient had low blood pressure readings and an abnormal chest x-ray. The physician ordered a bedside test of the heart structures, which showed good heart muscle function but severe blood volume deficits and a large left-sided pleural effusion.¹⁰ The patient was returned to surgery. Large blood clots were present in both the right and left chest, but the surgeon found no active source of bleeding. The surgeon irrigated the chest with an antibiotic solution, inserted chest tubes to facilitate drainage, and closed the incision. The patient returned to the ICU in stable condition; however, over the next few hours, the patient's respiratory condition deteriorated and clinicians diagnosed the patient with rapidly progressing Acute Respiratory Distress Syndrome (ARDS).¹¹ The patient developed a low heart rate and cardiac arrest in the early morning hours on postoperative day 1 and could not be resuscitated.

Patient 3

This 72-year-old patient had a medical history that included diabetes mellitus, peripheral vascular disease, high blood pressure, high cholesterol, shortness of breath, osteoarthritis, and glaucoma. The patient had a cardiac catheterization performed in March 2008 at another VA facility that showed severe coronary artery disease and significant mitral valve disease. The cardiologist from that facility referred the patient to the Buffalo division for urgent surgery.

Medical record documentation shows that during transfer by ambulance to Buffalo, the patient developed chest discomfort, nausea, and vomiting. Upon arrival at Buffalo, the patient's cardiac biomarkers were elevated (indicative of a heart attack) and the blood pressure was unstable. Documentation also shows that the anesthesiologist gave the patient an ASA risk level score of 4 because of the extent of cardiac disease, the patient's recent heart attack, and overall medical instability. While arrangements were made for surgery by the surgical team, the cardiology team placed an intraaortic balloon pump to assist circulation.

The patient underwent a 3-vessel coronary artery bypass surgery and replacement of the mitral valve. Per protocol, prophylactic antibiotics were started prior to surgery to reduce the risk of infection and were continued for 48 hours post-operatively. The balloon pump and ventilator were discontinued on the third post-operative day. Soon thereafter, the

¹⁰ A small potential space exists between the lung and the wall of the pleural cavity. A pleural effusion is fluid that accumulates in the potential space.

¹¹ ARDS is characterized by increased resistance of lung tissue (stiff lungs) and increased oxygen needs with poor ventilation.

patient developed a low-grade fever and an increased white blood cell count signifying a potential infection.

Laboratory tests showed evidence of two infectious organisms in the patient's sputum and one in the patient's urine. The surgeon consulted the Infectious Disease (ID) team who identified multiple possible sources for infection. They recommended triple antibiotic therapy.

The surgeon followed the ID team's recommendations and the patient initially improved. The patient was transferred out of ICU to telemetry¹² about two weeks after the initial surgery. However, the patient's white blood cell count began to elevate again. The ID team was re-consulted to adjust the patient's antibiotics. The ID team recommended a computed tomography scan¹³ of the chest, which showed a pleural effusion and possible empyema.¹⁴

The surgeon consulted a second surgeon who was credentialed and privileged to perform lung surgery. The second surgeon placed a chest tube into the area of the pleural effusion. When the chest tube was not effective in draining the fluid, the second surgeon returned the patient to surgery where lung surgery was performed to remove the abnormal pleural fluid and tissue in an effort to improve lung function and to prevent re-accumulation of fluid.

The ID team, continued to make recommendations and the surgeon continued to manage the patient after the second surgeon performed the lung surgery. In the beginning of April, the patient had an episode of a very rapid heart rate and suffered a cardiopulmonary arrest. Defibrillation was successful; the patient initially stabilized but had difficulty regaining strength and grew depressed. Other complications in April included the development of diarrhea, a pressure ulcer, and the placement of a feeding tube. A rehabilitation medicine specialist evaluated the patient, but the patient was too debilitated to tolerate intensive rehabilitation. Physical therapy was started to improve the patient's endurance. Upon return from a physical therapy session, the patient suffered another cardiopulmonary arrest and could not be resuscitated.

Inspection Results

Issue 1: Appropriate Credentials and Privileges.

We did not substantiate the allegation that the surgeon was not properly credentialed and privileged to perform the surgeries on the patients described in the case summaries. We found that the surgeon was board certified in the appropriate specialty and was privileged

¹² A unit with the capability of ambulatory cardiac monitoring using portable monitoring devices.

¹³ An imaging method that generates a three-dimensional image.

¹⁴ An empyema is a loculated, infected collection of fluid in the pleural space.

by the system to perform a variety of surgeries in the surgeon's area of expertise, including heart valve surgery, aortic aneurysm repair, and coronary bypass surgeries. Patient 1 underwent heart valve surgery, patient 2 underwent aortic aneurysm repair, and patient 3 underwent heart valve and coronary artery bypass surgery. Patients 2 and 3 also required lung surgeries that the subject surgeon was not privileged to perform. Medical record documentation shows that a surgeon who was privileged to perform lung surgeries assisted in the surgery of Patient 2 and was the attending surgeon for Patient 3.

We reviewed the records of six additional patients who had procedures performed by the surgeon and found that the surgeon was privileged to perform all the procedures. We also found that the three patients identified in the complaint and the additional six patients all had complex co-morbidities increasing their risk for surgical complications and mortality. According to CICSP data that we reviewed, the surgeon's mean mortality rate, while higher than the national average, was actually lower than the expected rate once it was risk adjusted.

Issue 2: Infection Control Practices.

We did not substantiate the allegation that the surgeon had poor infection control practices. For the three patients cited in the complaint, documentation showed that clinicians administered prophylactic antibiotics per established protocols. For the additional six patients reviewed, there was documentation to support that clinicians followed prophylactic antibiotic protocols. Additionally, we reviewed wound infection data for surgeries performed between July 2006 and July 2008. The data showed that of 356 total surgeries performed during that time period, the surgeon performed 198 and had a clean wound infection rate of 0 percent.

Conclusions

We concluded that the surgeon had appropriate credentials and privileges for the surgeries performed. We also concluded that when surgical procedures involving the lungs were necessary, a surgeon who was appropriately credentialed and privileged either assisted with or performed those procedures. Additionally, we concluded that the surgeon followed established pre-operative prophylactic antibiotic protocols, appropriately consulted ID clinicians, and had an excellent clean wound infection rate. We made no recommendations.

OIG Comments

The VISN and Healthcare System Directors agreed with the findings and conclusions. (See Appendixes A and B, pages 8–9, for the Directors’ comments.)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: December 3, 2008

From: Network Director, VA Healthcare Network Upstate New York (10N2)

Subject: **Healthcare Inspection – Credentialing, Privileging and Infection Control Practices, VA Western New York Healthcare System, Buffalo, NY**

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

I concur with the findings, including no recommendations.

(original signed by:)

STEPHEN L. LEMONS, Ed.D.

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: December 3, 2008

From: Interim Director, VA Western New York Healthcare System
(528/00)

Subject: **Healthcare Inspection – Credentialing, Privileging and Infection Control Practices, VA Western New York Healthcare System, Buffalo, NY**

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

1. Thank you for the opportunity to review the draft report on the Healthcare Inspection of VA Western New York Healthcare System (528).
2. I have reviewed the document and concur with the findings.

(original signed by:)

JAMES P. CODY

OIG Contact and Staff Acknowledgments

OIG Contact	Katherine Owens, MSN Director, Regional Office of Healthcare Inspections (603) 222-5871
Acknowledgments	Kathy Gudgell, BSN

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