Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality of Care Issues
VA Salt Lake City Health Care System
Salt Lake City, Utah

Report No. 09-02589-54 **December 28, 2009**

VA Office of Inspector General
Washington, DC 20420

Executive Summary

The purpose of the review was to determine the validity of allegations regarding quality of care at the VA Salt Lake City Health Care System (the system). The complainant alleged:

- Lack of collaboration, inappropriate vascular care, and deaths.
- Unwarranted amputations.
- Inappropriate management of vein patients.

We substantiated poor collaboration between Interventional Radiology and Vascular Surgery for two of the four patients; however, we concluded that this did not directly contribute to their deaths. We concluded that the system took appropriate actions to review the quality of care and make system improvements prior to and during our review of the allegations, including conducting institutional disclosures in two of the four cases. However, we determined that the system needed to refer Patient Case 2 to Regional Counsel for guidance. We did not substantiate the occurrence of unwarranted amputations or inappropriate management of vein patients.

We recommended that the Veterans Integrated Service (VISN) Director ensure that the System Director refers Patient Case 2 to Regional Counsel to determine whether the system has an obligation to report the providers to the NPDB. The VISN and System Directors agreed with the findings and recommendation. Since the system had already addressed the issue identified in the recommendation, we consider this recommendation closed.

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

TO: Director, Veterans Integrated Service Network 19

SUBJECT: Healthcare Inspection – Alleged Quality of Care Issues, VA Salt Lake City Health Care System, Salt Lake City, Utah

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections received allegations regarding quality of care at the VA Salt Lake City Health Care System (the system). The purpose of this review was to determine whether the allegations had merit.

Background

The system, part of Veterans Integrated Service Network (VISN) 19, provides primary and secondary medical, surgical, neurological, psychiatric, and rehabilitative care for veterans in Salt Lake City and the surrounding areas. It is a specialty referral center for VISN 19 and is affiliated with the University of Utah School of Medicine (the university).

A complainant alleged that four veteran patients died from inappropriate vascular care at the system. The complainant attributed these fatal outcomes to the lack of collaboration between vascular surgery (VS) and interventional radiology (IR) physicians. The complainant also alleged unwarranted amputations and inappropriate management of vein patients at the system.

Patients requiring vascular care are managed by VS or IR, two separate clinical services at the system. IR is a sub-specialty of radiology which performs minimally invasive procedures[1] using imaging (x-ray) guidance, and both IR physicians and vascular surgeons have clinical privileges to perform endovascular procedures at the system. Technological advances in this area have brought about major changes in vascular disease management as these clinicians guide tiny catheters and miniature instruments,

[1] A minimally invasive procedure is any procedure (surgical or otherwise) that is less invasive than open surgery used for the same purpose.

such as stents,[2] through blood vessels to treat diseases without surgery (also known as endovascular interventional procedures).

Tension between IR and VS began in July 2008 when the university initiated the VS fellowship at the system with the purpose of increasing VS access and training in endovascular procedures. In July 2009, the IR Chief resigned from the system and the university. All patients requiring endovascular procedures at the system are now managed exclusively by VS while those needing non-vascular interventional procedures are managed by IR. With these changes and numerous process improvements, system managers report that tensions have resolved between IR and VS.

Scope and Methodology

We conducted an oversight evaluation through interviews and document reviews. We interviewed the complainant on July 16, 2009, and a key system senior leader on multiple occasions. We reviewed pertinent medical records, official emails, VHA policies and procedures, and system documents, including policies, meeting minutes, and various related reports.

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

Inspection Results

Issue 1: Lack of Collaboration, Inappropriate Vascular Care, and Deaths

Case Review Patient 1

The patient, a man in his fifties, had a history of peripheral vascular disease and left femoral arterial bypass graft in 2006. In March 2007, an ultrasound showed that the graft was completely occluded with no flow through the graft. In August 2007, the provider told the patient that a second surgery had a very high risk of failure and that this would not be attempted.

In March 2008, the patient presented to VS clinic with worsening left lower leg pain. Because he was a poor surgical candidate, IR clinicians placed a stent for recanulization of his left iliac external artery. The IR procedure on August 6, 2008, was uneventful, and the patient stayed overnight in observation status.[3]

On August 7 at 0315, within 12 hours of the procedure, the patient showed signs of distress and the nurses notified the IR resident physician (resident) on call. Because IR

[2] A stent is a small tubular device that is inserted into an obstructed blood vessel after the obstructed area is opened.
[3] Observation status is designated for outpatients requiring observation, preparatory, and/or recovery services for a period of less than 24 hours.

has no admitting privileges at the system, the IR resident contacted the surgery resident on call to admit the patient to the surgical intensive care unit (SICU) for more appropriate monitoring and care. The surgery resident stated that the IR resident would have to contact the university's VS resident on call.

Concurrently, the medical ICU resident evaluated the patient at Nursing's request and the patient transferred to the SICU. The patient was intubated soon thereafter and at approximately 0400 went into cardiac arrest.

Following resuscitation, the patient was then taken to the IR suite for emergent angiography (x-ray of the blood vessels), which showed a sizeable leak in the left external iliac artery. The IR attending physician placed a stent as a temporary measure to stop the bleeding.

At 1034, the patient underwent evacuation of an intra-abdominal hematoma and vascular surgical repairs. Surgeons terminated further aggressive surgical intervention when necrotic (dead) colon and small bowel were noted. The patient had profound anuria,[4] hypotension, hypothermia, and rigor mortis in the legs. Comfort measures were initiated. The patient expired at 1400 in the SICU (within 24 hours of the IR procedure).

Findings Patient 1

We partially substantiated the allegation that poor collaboration between IR and surgery services occurred. However, we did not substantiate the allegation that this contributed to the patient's death.

Miscommunication and the lack of a cohesive team approach between the IR and surgery residents were noted in the first 5 hours following onset of the patient's deterioration. On initial contact, the IR resident, who had no admitting privileges, failed to communicate the urgency of the situation to the VS resident and did not seem to be aware that IR had to request a consultation from VS in order to secure assistance with the patient. The IR staff was not aware of this expectation.

Following this incident, system managers took several corrective actions.

- The Chief of Staff placed a moratorium on all IR and VS procedures from August 8 through August 21 until collaborative practice between IR and VS could be re-established. During the moratorium, 15 IR procedures were referred out to the university on a fee basis.

- The system conducted peer reviews and completed root cause analysis appropriately and followed through with actions to improve processes and care.

[4] Lack of urine output, usually indicating renal failure.

- An administrative board of investigation evaluated whether communications between the residents resulted in the patient's death and concluded that the professional communications between IR and VS residents did not directly cause the fatal outcome for this patient.

- System managers disclosed[5] the event to the patient's sister on August 25, 2009.

With the various levels of reviews and actions above, we noted system managers' efforts to improve care processes and promote collaborative practice for the past 12 months. This included the preliminary development of service agreements between IR and VS as well as attempts to standardize endovascular privileges for the system and the university. Additionally, the facility established a standardized protocol allowing nursing staff to transfer patients to a higher level of care. The system states that this is a work in progress. We concluded that all improvement efforts have been thoroughly pursued and made no recommendations.

Case Review Patient 2

The patient, a man in his 70s, presented to the system for progressive worsening of left lower leg pain due to poor circulation. IR angiogram and intervention performed on October 22, 2008, was uneventful. However, in less than 15 hours, left foot pulses were absent by Doppler (equipment used to evaluate blood flow by sound waves), and the foot was cool and clammy with poor refill time.

On October 23 at 1738, the IR resident assessed the patient and concluded that the patient did not have limb-threatening ischemia (insufficient supply of blood due to a blocked artery) and recommended monitoring for signs of improvement. The VS attending and resident also examined the patient that night, noting absence of signals in the left foot and the back side of the leg at the knee joint. They recommended surgical intervention.

The following day, ultrasound testing showed a clotted left superficial femoral artery, and IR initiated thrombolytic (blood clot-dissolving) therapy at 1900. However, about 9 hours later, the patient showed signs of abdominal bleeding. The computerized tomography (CT) scan was negative.

On October 25, a repeat angiogram showed the clot to be smaller. Thrombolytic therapy continued. That night, VS noted progressive bilateral clinical ischemia, and the patient underwent emergent surgery to include extensive vascular surgery on the right leg as well as a left above the knee amputation.

[5] In an institutional disclosure, the patient(s) or personal representative(s) are invited to meet with the facility leaders. During this meeting, an apology is made, and information about compensation and procedure available to request compensation is provided, when appropriate.

On October 26, the patient, now on a ventilator, was transferred to the university as the right foot was cold and mottled with no dopplerable pulses. The patient expired within 24 hours of transfer.

Findings Patient 2

We substantiated the allegation that less than optimal care management of this patient occurred with the lack of collaboration between VS and IR as a contributing factor. The system managers responded appropriately and referred this case for an external review.

The results of this external review were presented to the responsible IR and VS physicians and discussed at the system's peer review committee. Actions taken complied with VHA policy related to the peer review process.

On August 28, 2009, system managers made several attempts to perform institutional disclosure of this adverse event to the patient's son. However, these attempts were unsuccessful as phone calls were not returned and certified letters were sent back without signature. Actions to improve care processes, promote collaborative practice, and disclose the adverse events were carried out since the patient's death. However, we determined that system managers should refer this case to Regional Counsel to determine if the system has an obligation to report the providers to the National Practitioner Data Bank (NPDB).

Case Review Patient 3

The patient, a man in his 80s with a history of end stage renal disease and major artery surgery for both legs 20 years ago, complained of increasing umbilical pain. In 2007, he had an ultrasound that showed a 4 cm aneurysm. On February 25, 2009, the patient presented to the emergency department (ED) with a pulsatile mass. The CT scan showed a large abdominal aortic aneurysm (5.5 – 6 cm).

The ED physician consulted both IR and VS. IR stated that they could manage the patient in a less invasive manner, while VS felt that traditional open surgical repair was the best approach. On February 26, the patient underwent uneventful open surgery but suffered a post-operative heart attack 2 days later. The patient became progressively weaker and did not want to eat even though labs and vital signs were within normal limits. On March 6, after a long discussion with his family and physicians, the patient wished no further treatment and chose to be discharged home with palliative care. However, the patient's condition declined rapidly, and he expired at 2210 before further discharge arrangements could be made.

Findings Patient 3

We did not substantiate the allegation of inappropriate management of the patient by VS. The patient suffered a post-operative heart attack, which is a known risk due to the

patient's age and co-morbidities. It is unclear whether the heart attack affected the patient's decision to withdraw care as it is documented in the medical record that he had been considering this even before surgery. We determined that the care provided was consistent with community standards.

Case Review Patient 4

The patient, a man in his 60s with coronary artery disease, had a history of coronary artery bypass graft, peripheral vascular disease, and glomerulonephritis.[6] On May 9, 2009, the patient presented with fevers and graft-threatening narrowing in his left femoral-peroneal bypass graft. VS and infectious disease physicians initiated an antibiotic regimen for the aneurysm[7] and pneumonia after admission. The patient repeatedly declined any imaging or invasive procedures. On May 26, the patient finally agreed to an MRI and CT scan of the abdomen, which showed a large peri-aortic lesion and development of a large aneurysm, respectively.

Documentation shows that medicine and VS physicians made several attempts to gain the patient's consent for surgery. On May 28, the patient finally agreed to the surgery. The VS attending discussed the case with a vascular surgeon at the Denver VA Health Care System, and both surgeons agreed that it would be best to transfer the patient to the university. The surgeons felt that the patient's need for bypass during urgent repair of his large abdominal aneurysm exceeded the capabilities of both VA systems. Immediate transfer to the university took place but surgery was not performed as the patient expired of a ruptured aneurysm 2 days later.

Findings Patient 4

We did not substantiate inappropriate management of the patient. The patient resisted diagnostic testing and delayed surgical intervention for days. We determined that the care provided was consistent with community standards.

Issue 2: Unwarranted Amputations

Complainant alleged that the system had a higher occurrence of unwarranted amputations performed by VS after July 2008.

Findings

VS performed 22 amputations in FY 2009, compared with 10 and 6 amputations during FY 2007 and FY 2008, respectively. A review of the 22 amputations during FY 2009 did

[6] A kidney disease that is caused by inflammation of the internal kidney structures which help filter waste and fluids from the blood.

[7] An aneurysm is an abnormal bulge in the artery. Normally, the walls of arteries are thick and muscular, allowing them to withstand a large amount of pressure. Occasionally, however, a weak area develops in the wall of an artery. This allows the pressure within the artery to push outwards, creating a bulge or ballooned area called an "aneurysm."

not demonstrate any patterns in patient selection, physician performance concerns, or inappropriate care. Two factors influenced the higher occurrence of amputations: additional physician staffing (five vascular surgeons on staff in FY 2009, as compared to two vascular surgeons in FY 2007 and FY 2008) and an 8.9 percent increase in unique patients at the system. All amputations performed during FY 2009 had a diagnosis of vascular disease; 9 (41 percent) of the 22 cases underwent internal Morbidity and Mortality review and received Level 1[8] designations. Based on these findings, we made no recommendations.

Issue 3: Inappropriate Management of Vein Patients

The complainant alleged inappropriate management of vein patients by VS as evidenced by lack of referrals to IR for laser vein ablation therapy and the presentation of inappropriate patients when referred for IR intervention.

Findings

We did not substantiate inappropriate management of vein patients by VS. On August 29, 2008, the system acquired laser equipment at the cost of $31,625. The new equipment went into service on January 23, 2009, after development of processes to ensure safe operation and quality patient care. Prior to this acquisition, patients requiring vein ablation therapy were referred to the university at the cost of approximately $4,000 per patient.

The IR Chief, who had previous training to perform these procedures, was the only staff with credentials to perform these procedures at the system. The system performed a total of five laser vein ablations before the departure of the IR Chief. The Chief of Radiology was not aware of any inappropriate referrals to IR or the university after the laser was acquired by the system. No laser vein ablation procedures are currently being performed. The plan is for vascular surgeons to acquire privileges to perform these procedures in the future.

Conclusion

Although we substantiated poor collaboration between IR and VS for two of the four patients, we concluded that this did not directly contribute to the fatal outcomes. We determined that two patients received less than optimal vascular care and two patients were managed appropriately. We concluded that the system took appropriate actions to review the quality of care and make system improvements prior to and during OIG's review of the allegations, including conducting institutional disclosures in two of the four cases. Additionally, Regional Counsel needed to determine whether reporting the providers to the NPDB is required for Patient 2.

[8] Most experienced, competent practitioners would have managed the case in a similar manner.

We did not substantiate the occurrence of unwarranted amputations or inappropriate management of vein patients.

Recommendation

We recommended that the VISN Director ensure that the System Director refers Patient Case 2 to Regional Counsel to determine whether the system has an obligation to report the providers to the NPDB.

Comments

The VISN and System Directors agreed with the findings and recommendation and provided acceptable corrective action. (See Appendixes A and B, pages 9–10, for the Directors' comments.) Since the system had already addressed the issue identified in the recommendation, we consider this recommendation closed.

(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: November 19, 2009

From: Director, VA Rocky Mountain Network (10N19)

Subject: Healthcare Inspection – Quality of Care Issues, VA Salt Lake City Health Care System, Salt Lake City, UT

To: Director, Denver and Los Angeles Regional Offices of Healthcare Inspections (54DV/LA)

Thru: Director, Management Review Service (10B5)

Attached is the response from the VA Salt Lake City HCS in response to the Healthcare Inspection – Quality of Care Issues. I have reviewed and concur on their response. If you have any questions, please contact Ms. Susan Curtis, VISN 19 HSS at 303-639-6995.

Glen W. Grippen, FACHE

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: November 3, 2009

From: Director, VA Salt Lake City Health Care System (660/00)

Subject: Healthcare Inspection – Quality of Care Issues, VA Salt Lake City Health Care System, Salt Lake City, Utah

To: Director, Denver and Los Angeles Regional Offices of Healthcare Inspections (54DV/LA)

I concur with the findings and recommendation. On November 2, 2009, I referred Patient Case #2 to VA Regional Counsel in Salt Lake City, Utah for their consideration on VA's obligation to report to the National Practitioner Data Bank.

Steve Young

STEVEN W. YOUNG, FACHE

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Daisy F. Arugay Director, Los Angeles Region Office of Healthcare Inspections (213) 253-5134
	Mary Toy, RN (Team Leader) Jerome Herbers, MD

Appendix D

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