Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care Issues
Louis A. Johnson VA Medical Center
Clarksburg, West Virginia

Report No. 09-02950-58 **January 7, 2010**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time, Monday through Friday, excluding Federal holidays

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Executive Summary

The purpose of the review was to determine the validity of allegations regarding quality of care at the Louis A. Johnson VA Medical Center, Clarksburg, West Virginia.

We concluded that there were deficiencies in this patient's care that warranted consideration of institutional disclosure to the family.

We did not substantiate the complainant's allegation that a surgeon failed to inform a patient or his family that resident physicians would be performing surgeries. We substantiated the allegation that dialysis was delayed; however, the medical center now provides in-house dialysis and medical center leaders reported that a nephrologist is now on call at all times. We substantiated the allegation that some of the patient's medical care was improperly documented. The medical record did not support statements made in an addendum to the discharge summary. We did not substantiate the allegation that a late entry into the electronic medical record (EMR) was not marked as such, since entries into the EMR are automatically timed and dated. We did not substantiate allegations that complete medical records were not provided as requested, restraints were improperly used, and a medication was not discontinued despite a possible adverse reaction.

We recommended that management officials evaluate this case with Regional Counsel to determine whether disclosure was managed appropriately.

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

TO: Director, Veterans Integrated Service Network 4 (10N4)

SUBJECT: Healthcare Inspection – Quality of Care Issues, Louis A. Johnson VA Medical Center, Clarksburg, West Virginia

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections received allegations regarding quality of care at the Louis A. Johnson VA Medical Center (the medical center), in Clarksburg, WV. The purpose of the review was to determine whether the allegations had merit.

Background

The medical center, part of Veterans Integrated Service Network (VISN) 4, is a tertiary care facility affiliated with the West Virginia University (WVU) School of Medicine. WVU surgical resident physicians (residents) complete components of their clinical training at the medical center.

The complainant contacted the OIG hotline on July 2, 2009, with multiple allegations regarding the care a patient received in February 2008. Specifically, the allegations were that:

- A surgeon failed to inform a patient or his family that residents would be performing the patient's surgeries.
- Staff failed to address the patient's renal failure promptly, delaying required dialysis.
- There was improper medical record documentation, including a late entry, concerning the patient's care.
- Medical center staff failed to provide requested medical record documentation to the patient's family.

- There was inappropriate use of restraints while the patient was in the intensive care unit (ICU).
- A medication was continued despite evidence of a possible adverse reaction.

Scope and Methodology

The complainant submitted a 15-page document to the OIG. We reviewed the complainant's information, the patient's electronic medical record (EMR), local and VHA policies and procedures, and other pertinent documents. We interviewed the patient's primary care provider and the complainant.

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

Case Summary

The patient had an extensive medical history. His diagnoses included severe peripheral vascular disease with left lower extremity (LLE) claudication (pain with walking, usually due to circulatory problems), diabetes mellitus, coronary artery disease (with a remote myocardial infarction), emphysema, hypertension, and hyperlipidemia. He also had cataracts, osteoarthritis, bursitis (inflammation of the sac surrounding joints), and lumbar radiculopathy (disorder of the nerves in the lower back), gastroesophageal reflux disease, non-alcoholic liver disease, and chronic anxiety. His surgical history included aortofemoral bypass and coronary angioplasty in the 1990s.

At a routine visit to the Primary Care (PC) clinic the patient described one month of worsening headaches (HAs), which he attributed to rosuvastatin, a lipid lowering medication that he had been taking for approximately 6 months. The rosuvastatin dosage was increased from 5 mg to 10 mg daily 4 months prior to this clinic visit. The primary care provider (PCP) discontinued the rosuvastatin and advised the patient to return in 2 weeks for re-evaluation. At the follow-up visit the patient reported that the HAs had decreased significantly. The PCP discussed resuming the rosuvastatin, and the patient and his family agreed to a 2-week trial. The patient was to call the clinic in 2 weeks to report any symptoms or problems and otherwise to return in 3 months. Prior to his scheduled follow-up visit, he was to have laboratory blood work and a computed tomography (CT) scan of the head to evaluate the recent HAs.

Seven weeks after his last clinic visit, the patient presented to the medical center emergency department (ED) complaining of acute pain in his back, left hip, and left buttock, radiating down the left leg. The patient was examined and treated by the ED physician for "pain secondary to trochanteric bursitis." Eleven weeks after the ED visit he was again seen in the PC clinic. He indicated at that time that the HAs had decreased significantly. Because his lipid levels remained elevated, the rosuvastatin dose was again increased to 20 mg daily. The patient was to follow up with his PCP should HAs recur.

During this visit, the PCP examined the patient's lower extremities and noted that pulses were present. The PCP's impression was that the basis for the back and leg pain was multi-factorial, with contributing causes including bursitis and compromised circulation.

Two weeks later the patient made an unscheduled visit to the PC clinic with complaints of continued left leg pain. These symptoms led to an arteriogram (a radiologic test using dye to visualize arteries) the next day. The arteriogram showed severe occlusive vascular disease in the LLE and the PCP discussed the situation with a vascular surgeon. The surgeon felt that urgent treatment was not necessary because the patient was not having pain at rest. However, an expected 3-week absence of vascular surgery at the medical center led the PCP to refer the patient to the VA Pittsburgh Healthcare System (Pittsburgh HCS) Vascular Surgery Service. An appointment was scheduled at the Pittsburgh HCS in approximately 3 weeks, but 1 week prior to that appointment the patient was seen routinely by his PCP. The PCP noted that the patient did not complain of HA, but had evidence of worsening LLE circulation.

When the patient was evaluated at the Pittsburgh HCS, a vascular surgeon recommended conservative measures, including initiation of cilostazol.[1] The surgeon's opinion was that the patient did not have "… limb threatening ischemia at this time," and that the trial of cilostazol "for a few months" should be undertaken.

A vascular surgeon at the Clarksburg medical center subsequently evaluated the patient 1 week later and requested a CT scan of the abdomen and pelvis "for any kind of repair done on his aortoiliac on the left side and examine for a potential aortic aneurysm." The scan identified a thrombotic occlusion (clot) of the patient's previous aortoiliac graft. The vascular surgeon recommended that the patient undergo a surgical intervention, most likely an aortoiliac bypass graft, on the LLE as soon as possible. However, the patient requested that surgical intervention not be scheduled for 3 months, until after the first of the new year, due to "personal reasons." The patient was seen for pre-operative teaching in early January 2008 and aortoiliac and/or aortofemoral bypass surgery was scheduled for the following month.

On the scheduled day, the patient had left aortofemoral bypass surgery at 8:00 a.m., and was admitted to the ICU post-operatively. The initial ICU nursing assessment reflected that the patient had severe pain in his right leg and that pulses were not palpable or detected by Doppler[2] in either leg. At 6:45 p.m. the same day, the patient was again taken to the operating room, this time for emergent removal of a clot in the right lower extremity (RLE), and for right aortoiliac and left femoral bypass procedures. The patient returned to the ICU at 1:45 a.m., with a breathing tube in place, and remained on mechanical ventilation. The patient also now required restraints to prevent accidental dislodgement of tubes.

[1] Medication shown to increase walking distance by improving blood flow in the legs.
[2] A Doppler ultrasound test uses reflected sound waves to evaluate blood as it flows through a blood vessel.

The EMR shows that, during the night, the patient had increased pain and worsening circulation in his right leg, and it was felt by the surgical team that the patient had developed compartment syndrome.[3] Also noted was that the patient had decreased urine output along with rising levels of creatinine. Blood tests early the next morning showed anemia, an elevated white blood cell count, and decreased platelets.

On the patient's second hospital day, the patient's spouse was contacted by telephone to obtain consent on behalf of the patient for emergency surgery to relieve pressure in the right lower leg. The patient's daughter was also contacted by telephone, and she agreed with the plan to take the patient back to surgery. A right lower leg fasciotomy (a surgical incision to relieve pressure) was performed at 7:30 a.m., and the patient returned to the ICU at approximately 9 a.m.

The patient's condition continued to deteriorate despite administration of medications to lower the potassium level and increase renal function. A consult was placed for nephrology at 11:39 a.m. When a central line was replaced at around 2:30 p.m., excessive bleeding was noted at the site, and blood was noted in the patient's nasogastric tube.

The surgical resident advised at 4:12 p.m. that the patient needed dialysis for the treatment of the hyperkalemia (elevated potassium levels) and anuria (absence of urine). The patient's EMR reflected that dialysis was not available at the medical center, nor was a nephrologist available at this time. The resident recommended that the patient be transferred to a facility with dialysis capabilities. The surgical resident's examination at this time also revealed that the "LLE has dopplerable DP/PT[4] and RLE has dopplerable DP and both feet are warm," which indicated there was still blood supply to the lower limbs. Heparin (a blood thinning medication) was discontinued, and transfusions of fresh frozen plasma (a blood product to promote clotting) were given at 5:40 p.m.

After the Pittsburgh HCS was found to be unable to accommodate the patient, he was transferred to Mercy Medical Center (Mercy) in Pittsburgh, PA at 7:00 p.m., via a private transport company.

According to the follow-up EMR notes, the patient's abdomen was found to be "firm, large and distended" on admission to Mercy. Documentation in the EMR also reflects that the patient was having symptoms of hypotensive shock, and had an ischemic left colon. Hemodialysis was initiated on the day of transfer to Mercy, and continued for 8 days. On the following day, the patient had an anterior resection of the transverse colon with a colostomy. Full life support measures, including mechanical ventilation and dialysis, were maintained at the request of the patient's family.

[3] An acute problem following injury, surgery or repetitive and extensive muscle use, in which increased pressure (usually caused by inflammation) within a confined space in the body impairs blood supply. Without prompt surgical treatment, it may lead to nerve damage and muscle death.
[4] DP and PT are common abbreviations for the dorsalis pedis and posterior tibial pulses in the feet.

One week after surgery, the patient had significant respiratory distress and increased lower extremity edema. The attending physician at Mercy advised the patient's family that the patient's prognosis was "poor," and recommended that dialysis and mechanical ventilation be discontinued and the patient be transferred to the inpatient hospice unit. The patient was removed from mechanical ventilation and, with permission from the family, was made a "DNR."[5] The patient died the next day.

Inspection Results

Issue 1: Informed Consent

We did not substantiate the allegation that the patient's family was not informed that surgical residents would be performing the patient's surgeries. A review of the informed consent forms signed by the patient or his family prior to his surgeries showed that a resident surgeon and supervising surgeon were identified by name and title. By signing an informed consent form, a signer indicates an understanding of the procedure and the medical personnel who will be performing it.

Issue 2: Delay in Dialysis

We substantiated the allegation that there was a delay in addressing the patient's renal failure and providing the dialysis he needed. The patient had three surgical interventions within 24 hours, and his condition rapidly deteriorated following the first surgery. He had bleeding from his nasogastric tube and intravenous sites, worsening laboratory results, and no urine output. A consult to nephrology, placed at 11:39 a.m. on the second hospital day following the third surgery, received no response. At 4:12 p.m. the surgical resident recorded, "Dialysis not done at our hospital, neither is there a nephrologist today. This patient needs to be transferred to a facility with dialysis capabilities." The Pittsburgh HCS was unable to accept the patient and the transfer was delayed until arrangements could be made with Mercy hospital in Pittsburgh. Following this event, the medical center reported that dialysis is now done on site, with a nephrologist on call at all times. Therefore, we made no recommendations.

Issue 3: Medical Record Documentation

We substantiated the allegation that some of the patient's medical care was improperly documented. The complainant alleged that inaccurate information was entered into the medical record by the supervising surgeon. The supervising surgeon's addendum to the discharge summary stated, "There was no evidence of ... abdominal compartment syndrome and [the patient] had no clinical or laboratory evidence of acute abdomen." The EMR did not contain any documentation or test results to support the supervising surgeon's statement in the addendum. The statement also contradicts documentation of

[5] DNR is the standard abbreviation for "Do Not Resuscitate," which means that resuscitation should not be attempted if a person suffers cardiac or respiratory arrest.

the patient's condition upon arrival to Mercy. According to the EMR, the patient had a distended abdomen on arrival, and had to undergo an exploratory laparotomy for an ischemic bowel. We also found that the EMR did not reflect sufficient involvement of the supervising surgeon in the critical hours post-operatively.

Furthermore, we noted discrepancies in the nursing and physician notes regarding the presence or absence of pulses in the patient's legs. We recognize that assessment of pulses is subjective and dynamic, and we were unable to confirm the accuracy of these observations.

According to information provided to us, the medical center conducted appropriate peer reviews regarding the patient's care. Medical center leaders also told us that they contacted the patient's family by letter in an effort to discuss the patient's care. The patient's family told us they did not receive this letter.

We did not substantiate the allegation that there were entries added to the patient's EMR that were not marked as a "late entry." Review of the EMR shows that the surgical resident entered a discharge summary on the day the patient was transferred to the private hospital in Pittsburgh. The surgical resident signed, and the supervising surgeon cosigned, the discharge summary 13 days later. The supervising surgeon entered an addendum to the discharge summary 8 months later. The time and date an entry is made into the EMR cannot be altered or changed, so to mark a note as a "late entry" is not necessary.

Issue 4: Release of Information

We did not substantiate the allegation that the medical center failed to provide complete medical record documentation to the patient's family. The complainant made multiple requests for medical records, twice using the forms required by local policy, once by phone, and once by fax. When the appropriate forms were used, the medical records were provided to the complainant. A review of documentation of the records sent to the complainant revealed that all existing medical records for the specific dates of care requested were provided.

Issue 5: Use of Restraints

We did not substantiate the allegation that restraints were used inappropriately. The complainant alleged that there was no indication for use of wrist restraints and that the family was not notified regarding the use of restraints. It is further alleged that consent was not obtained for use of restraints and there was not a physician order for restraints. According to local policy, a registered nurse can initiate restraints without physician orders, following an established protocol. Restraints were necessary to prevent accidental removal of the patient's breathing tube.

Issue 6: Continuation of Medication

We did not substantiate the allegation that a medication was continued despite evidence of a possible adverse reaction. The patient's PCP prescribed rosuvastatin because elevated lipid levels persisted on the maximum dose of simvastatin. The dose was gradually increased, and approximately 4 months later, the patient complained of HAs. The medication was discontinued and after 2 weeks his HAs were substantially improved. Because the PCP felt the medication was best for the patient, he advised another trial of treatment and the patient and his family agreed. The patient had no further complaint of HAs at subsequent clinic visits.

Conclusions

We concluded that there were deficiencies in this patient's care that warranted consideration of institutional disclosure to the family.

We did not substantiate the complainant's allegation that surgical residents performed surgery without the family's knowledge. The informed consent forms signed by the patient or his family identified a resident and supervising surgeon. We substantiated the allegation that dialysis was delayed; however, the medical center now provides in-house dialysis and medical center leaders reported that a nephrologist is now on call at all times. We substantiated the allegation that some of the patient's medical care was improperly documented. The supervising surgeon's addendum to the discharge summary did not reflect the patient's actual condition at the time of transfer. We did not substantiate the allegation that a late entry into the EMR was not marked as such, since entries into the EMR are automatically timed and dated. We did not substantiate the allegation that complete medical records were not provided as requested. Medical records were provided as directed by local policy. We did not substantiate the allegation that restraints were improperly used. Local policy was followed in the initiation and maintenance of restraints for patient safety. We did not substantiate the allegation that a medication was not discontinued despite a possible adverse reaction.

Recommendations

Recommendation 1. We recommended that the VISN Director requires that the Medical Center Director reviews this case with Regional Counsel to determine whether disclosure was managed appropriately.

Comments

The VISN and Medical Center Directors concurred with our conclusions and recommendation (See Appendixes A and B, pages 9–11, for the full text of their comments).

(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: December 7, 2009

From: Director, Veterans Integrated Service Network 4 (10N4)

Subject: **Healthcare Inspection – Quality of Care Issues, Louis A. Johnson VA Medical Center, Clarksburg, West Virginia**

To: Associate Director, St. Petersburg Office of Healthcare Inspections (54SP)

1. I have reviewed this OIG Hotline report and the response from the Director of the Clarksburg VAMC.

2. I concur with the response and look forward to closure of this issue.

(original signed by:)

MICHAEL E. MORELAND

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: December 7, 2009

From: Director, Louis A. Johnson VA Medical Center

Subject: **Healthcare Inspection – Quality of Care Issues, Louis A. Johnson VA Medical Center, Clarksburg, West Virginia**

To: Director, Veterans Integrated Service Network 4 (10N4)

1. I have reviewed the draft OIG report and have included my response in the attached Director's Comments.

2. Please contact me if you have any questions or comments.

(original signed by:)

WILLIAM E. COX

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

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director requires that the Medical Center Director reviews this case with Regional Counsel to determine whether disclosure was managed appropriately.

Concur

The Clarksburg Medical Center Director appreciates the fair and accurate review of the issues raised by the complainant. Further, we concur with the recommendation related to discussion of institutional disclosure.

The issue of disclosure was discussed locally soon after the February episode of care for the patient and the decision was made to table the decision pending the outcome of review activity. The review activity extended into the spring and summer of 2008. On April 13, 2008 the Clarksburg VAMC Patient Advocate was notified by the complainant that she had hired an attorney to pursue legal action. On April 14, 2008 the Clarksburg Chief, Quality & Risk Management spoke to the complainant, provided contact information for VA Regional Counsel, and mailed a letter containing FAQs related to financial compensation after an injury. Subsequent to these interactions with the complainant, the Clarksburg VAMC anticipated tort activity and did not disclose.

On November 19, 2009, Clarksburg briefed VA Regional Counsel about the patient's episode of care. The consensus decision from this briefing was to disclose at an institutional level. The factors influencing this decision were the results of the review activity surrounding the patient's clinical care and the absence of anticipated tort activity. This briefing included the VA Regional Counsel, Medical Center Director, Chief of Staff, and Chief, Quality & Risk Management.

On December 8, 2009 an institutional disclosure meeting occurred at the Clarksburg VAMC. Attending the disclosure was [ ].

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Carol Torczon, Associate Director St. Petersburg Office of Healthcare Inspections 727-395-2415
Acknowledgments	Darlene Conde-Nadeau Jerome Herbers, M.D.

Appendix D

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