Healthcare Inspection

Quality of Care Issues
St. Louis VA Medical Center
St. Louis, Missouri

and

Minneapolis VA Health Care System
Minneapolis, Minnesota
To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding quality of care at the St. Louis VA Medical Center, John Cochran Division, St. Louis, MO (St. Louis VA). A patient alleged that the St. Louis VA surgically removed his bladder and created a neobladder (a bladder using a portion of intestine) in 2007 without his consent. He also alleged that the St. Louis VA did not provide pain medication after the surgery.

We did not substantiate that the St. Louis VA removed the patient’s bladder or that pain management was inappropriate.

During our review, we identified aspects of care warranting improvement. A Minneapolis VA Health Care System radiologist incorrectly documented that a bladder seen on a September 2009 ultrasound was a neobladder, and staff at the St. Louis VA did not consistently document pain assessments as required by local policy.

We recommended that the Minneapolis VA Health Care System Director of Radiology and Chief of Staff correct the medical record and disclose to the patient the facts surrounding the incorrect 2009 ultrasound report. We also recommended that St. Louis VA staff document patient pain assessments as required.

The VISN and Medical Center Directors agreed with the findings and recommendations. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.
TO: Director, VA Heartland Network (10N15)
       Director, VA Midwest Health Care Network (10N23)

SUBJECT: Healthcare Inspection – Quality of Care Issues, St. Louis VA Medical Center, St. Louis, Missouri, and Minneapolis VA Health Care System, Minneapolis, Minnesota

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to determine the validity of allegations regarding the quality of care provided to a complainant (patient) at the St. Louis VA Medical Center, John Cochran Division, in St. Louis, MO (St. Louis VA).

Background

The patient received care at the St. Louis VA and at the Minneapolis VA Health Care System (Minneapolis VA) in Minneapolis, MN.

The St. Louis VA is a two-division, tertiary care facility in Veterans Integrated Service Network (VISN) 15. The John Cochran Division is located in downtown St. Louis, MO. It has 136 acute care beds and provides acute medical and surgical programs with a wide range of specialty care. The Minneapolis VA is a tertiary care facility in VISN 23 that provides a broad range of inpatient and outpatient health care services. It has 279 hospital beds and 80 extended care beds.

The patient alleged that the St. Louis VA removed his bladder and created a neobladder, an operation that creates a bladder using a portion of the intestines, in 2007 without his consent. He also alleged that the St. Louis VA did not provide pain medication following the surgery.
**Scope and Methodology**

We reviewed the patient’s VA and private facility medical records. We also reviewed quality management documents and patient care policies. We requested that the Minneapolis VA Chief of Radiology and another VA radiology consultant evaluate a 2009 pelvic ultrasound performed at the Minneapolis VA. We conducted telephone interviews with the patient, the Minneapolis VA Chief of Radiology, and a VA consultant radiologist.

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 is male in his 60s who was diagnosed with bladder cancer in December 2005 at the St. Louis VA following a cystoscopy and bladder biopsy. The cystoscopy revealed a large bladder with folds and pockets. The biopsy results showed an early bladder cancer, which had not gone into the bladder’s muscle layer.

In February 2006, an urologist at the St. Louis VA performed a cystoscopy to remove the tumor and to inject an anti-cancer drug into the patient’s bladder. In August 2006, a bladder biopsy indicated some cancer remained, so the patient received a 6-week course of Bacillus Calmette-Guerin (BCG) treatment. He had a total of 12 cystoscopies at the St. Louis VA for treatment and follow-up evaluations, and experienced no further recurrence of bladder cancer after receiving the BCG treatment in 2006.

During 2009, the patient relocated to Minneapolis. In August 2009, the patient had a pelvic ultrasound at the Minneapolis VA to evaluate his kidneys. The medical history section of that ultrasound report noted cystectomy and neobladder. The radiologist’s evaluation noted, in part, that a neobladder was visualized. In September 2009, a cystoscopy performed at the Minneapolis VA showed a large bladder with folds.

**Inspection Results**

**Issue 1: Bladder Removal and Neobladder Creation**

We did not substantiate the patient’s allegation that the St. Louis VA surgically removed his bladder and created a neobladder without his consent.

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1. A cystoscopy is a medical procedure during which a physician inserts a tube through the urethra and into the bladder to visually inspect the bladder and take tissue samples (biopsy).
2. Bacillus Calmette-Guerin is a treatment for bladder cancer. Bacillus bacteria are injected into the bladder to stimulate a local immune reaction against the cancerous cells.
3. A cystectomy is the surgical removal of the urinary bladder.
Between December 2005 and September 2009, the patient had thirteen cystoscopies; every report noted the presence of the patient’s bladder. The most recent cystoscopy, done in September 2009 at the Minneapolis VA, showed a large capacity bladder with folds.

Surgical removal of the bladder and the creation of a neobladder is major abdominal surgery requiring hospitalization and a lengthy recovery period. The patient had not been hospitalized overnight within the VA health care system, and he told us he had not had bladder surgery at a private hospital. A large abdominal scar would have been present as a result of the surgery. In September 2009, a private physician examined the patient and documented that the patient did not have an abdominal scar that might indicate major abdominal surgery.

Based on the patient’s cystoscopy reports, medical history, and an independent private physician’s physical examination, we determined the patient did not have surgery to remove his bladder.

**Issue 2: Pain Management**

We did not substantiate the allegation that the patient’s pain management was inappropriate after the removal of his bladder because we determined that the patient did not have surgery to remove his bladder.

**Issue 3: Other Issues Identified**

During our review, we identified aspects of care warranting improvement.

**Pelvic Ultrasound**

In August 2009, a Minneapolis VA radiologist incorrectly noted that a neobladder was seen on an ultrasound image.

In August 2010, the Minneapolis VA Chief of Radiology and a VA radiology consultant reviewed the patient’s medical record, the August 2009 pelvic ultrasound, and a September 2009 cystoscopy report. Both radiologists agreed that the ultrasound images did not display a neobladder, and the cystoscopy confirmed the presence of a large bladder with folds and pockets.

The Minneapolis VA Chief of Radiology theorized that the original radiologist, under the mistaken belief that the patient’s medical history included a cystectomy and neobladder creation, and upon viewing a large bladder with folds and pockets, incorrectly documented observing a neobladder.

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Pain Assessment Documentation

The St. Louis VA did not consistently document pain assessments as required by local policy.

The local policy directed staff to assess and document pain at any clinic visit where vital signs are completed. The St. Louis VA did not document pain assessments for 5 of 12 cystoscopies when pain assessments should have been documented.

Conclusions

We did not substantiate the allegation that the St Louis VA surgically removed the patient’s bladder without his consent. Because the patient’s bladder was not removed, we did not substantiate that pain management was inappropriate.

We did identify aspects of care that warranted improvement. A Minneapolis VA radiologist incorrectly documented that a bladder seen on an August 2009 ultrasound image was a neobladder, and staff at the St. Louis VA did not consistently document pain assessments as required by local policy.

Recommendations

Recommendation 1. We recommended that the Minneapolis VA Director of Radiology and the Chief of Staff correct the medical record and disclose to the patient the facts surrounding the incorrect 2009 ultrasound radiology report.

Recommendation 2. We recommended that St. Louis VA staff document patient pain assessments as required by local policy.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations (see Appendixes A and B, pages 5–9, for the Director’s comments). The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for Healthcare Inspections
Date: September 23, 2010

From: Director, VA Heartland Network (10N15)

Subject: Healthcare Inspection – Quality of Care Issues, St. Louis VA Medical Center, St. Louis, Missouri, and Minneapolis VA Health Care System, Minneapolis, Minnesota

To: Director, Denver Office of Healthcare Inspections (54DV)

Thru: Director, Management Review Service (10B5)

1. Attached please find St. Louis VA Medical Center, St. Louis, MO response to the Healthcare Inspection Quality of Care Issues draft report.

2. I have reviewed the comments provided by the Medical Center Director and concur with the responses and proposed action plans to the recommendations outlined in the report.

(Original signed by:)
James R. Floyd, FACHE
Network Director, VISN 15
St. Louis VA Medical Center Director Comments

Department of Veterans Affairs

Memorandum

Date: September 20, 2010

From: Director, St. Louis VA Medical Center (657/00)

Subject: Healthcare Inspection – Quality of Care Issues, St. Louis VA Medical Center, St. Louis, Missouri, and Minneapolis VA Health Care System, Minneapolis, Minnesota

To: Director, VA Heartland Network (10N23)

The Medical Center concurs with the recommendation. The Medical Center Standard Operating Procedure 11-102, Pain Management, has been reviewed and found to be compliant with both Joint Commission and VHA guidance on pain assessment.

The existing Urology Clinic intake process was reviewed, and staff was not routinely assessing vital signs prior to outpatient cystoscopy procedures. Surgery, Nursing, and Health Administration staff in this clinic met and modified the patient intake process to include a nursing assessment of patient vital signs, to include pain, prior to outpatient cystoscopy. The process change, effective September 19, 2010, will be monitored monthly by the Surgery Quality Improvement Specialist with reporting to the Associate Chief Nurse for Specialty Care and the Chief of Surgery Service.

(Original signed by:)
Rima Ann O. Nelson, RN, MPHHAS
Acting Medical Center Director
Visn 23 Director Comments

Department of Veterans Affairs Memorandum

Date: September 20, 2010

From: Director, VA Midwest Health Care Network (10N23)

Subject: Healthcare Inspection – Quality of Care Issues, St. Louis VA Medical Center, St. Louis, Missouri, and Minneapolis VA Health Care System, Minneapolis, Minnesota

To: Director, Denver Office of Healthcare Inspections (54DV)

Thru: Director, Management Review Service (10B5)

I have reviewed the attached Healthcare Inspection and concur with the finding and recommendation presented in the report. Actions taken as a result of this recommendation are currently underway. Thank you for the opportunity to review the report and provide comments.

(original signed by:)
Janet P. Murphy, MBA
Network Director, VISN 23
Minneapolis VA Health Care System
Director Comments

Department of Veterans Affairs Memorandum

Date: September 20, 2010

From: Director, Minneapolis VA Health Care System (618/00)

Subject: Healthcare Inspection – Quality of Care Issues, St. Louis VA Medical Center, St. Louis, Missouri, and Minneapolis VA Health Care System, Minneapolis, Minnesota

To: Director, VA Midwest Health Care Network (10N23)

We have reviewed and concur with the finding and recommendation presented in the Health Inspection. Minneapolis VA follow up actions are partially complete, with full completion and documentation of the same targeted for October 15, 2010. The work of the inspection team is appreciated.

(original signed by:)
Steven P. Kleinglass
Minneapolis VA Health Care System Director
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 Minneapolis VA Director of Radiology and the Chief of Staff correct the medical record and disclose to the patient the facts surrounding the incorrect 2009 ultrasound radiology report.

Concur  Target Date of Completion:  October 15, 2010

Facility’s Response:  Actions planned, not yet complete. Veteran medical record to be corrected along with communication to the veteran is planned.

Status:  To be completed on October 15, 2010.

Recommendation 2. We recommended that St. Louis VA staff document patient pain assessments as required by local policy.

Concur  Target Date of Completion:  September 19, 2010

Facility’s Response:  The Medical Center Standard Operating Procedure 11-102, Pain Management, has been reviewed and found to be compliant with both Joint Commission and VHA guidance on pain assessment.

The existing Urology Clinic intake process was reviewed, and staff was not routinely assessing vital signs prior to outpatient cystoscopy procedures. Surgery, Nursing, and Health Administration staff in this clinic met and modified the patient intake process to include a nursing assessment of patient vital signs, to include pain, prior to outpatient cystoscopy. The process change, effective September 19, 2010, will be monitored monthly by the Surgery Quality Improvement Specialist with reporting to the Associate Chief Nurse for Specialty Care and the Chief of Surgery Service.

Status:  Completed on September 19, 2010.
# OIG Contact and Staff Acknowledgments

| OIG Contact                  | Virginia L. Solana, RN, MA  
|                             | Director, Denver Office of Healthcare Inspections  
|                             | (303) 270-6500  
| Acknowledgments             | Barry Simon, DMV, Team Leader  
|                             | Laura Dulcie, BSEE  
|                             | Stephanie Hensel, JD, MPA, BSN  
|                             | Michael Shepherd, MD |
Quality of Care Issues at the St. Louis VA Medical Center and Minneapolis VA Health Care System.

Appendix F

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