Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-00853-100

Healthcare Inspection

Alleged Adverse Outcomes and Access Issues in Diagnostic Imaging Services North Florida/South Georgia Veterans Health System Gainesville, Florida

March 20, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to complaints about diagnostic imaging services at the North Florida/South Georgia Veterans Health System, Gainesville and Lake City, FL (system).

We substantiated that some patients with documented contrast media (contrast) allergies received contrast for Computed Tomography (CT) exams; however, the system had processes in place to address potential adverse effects of contrast administration. We did not substantiate that patient deaths occurred as a result of contrast administration.

We substantiated that ureteral stent placements were performed in the Gainesville cystoscopy clinic without general anesthesia; however, we found that other appropriate measures were taken to provide pain control. Further, we did not substantiate that the clinic setting was chosen so that urology resident physicians could perform a required number of stent placements for professional education.

We substantiated that a staff member in the Lake City campus CT department was absent for a protracted period and that the system did not replace/maintain staff levels using alternative measures. However, we did not substantiate that the reduced staffing resulted in a backlog of patients.

We did not substantiate that a pre-procedure marking was incorrect or that a patient's bowel was perforated. The pre-procedure marking was verified by a radiologist, and an autopsy showed no gross perforation of the bowel.

We did not substantiate that the system lacked after-hours radiologist support for CT technologists at the Lake City campus. Offsite radiologists were available to technologists after hours from the Gainesville campus and through the National Tele-radiology Program.

We did not substantiate that the CT scanner at the Lake City campus was beyond its useful life and broke down weekly. The scanner had been serviced by the manufacturer with an up-time rate greater than 98 percent. A new scanner has recently been installed in accordance with a routine replacement schedule.

We made no recommendations.

Comments

The Veterans Integrated Service Network and System Directors concurred with the report. (See Appendixes A and B, pages 11–12, for the Directors' comments.) No further action is required.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection in response to complaints about diagnostic imaging services at the North Florida/South Georgia Veterans Health System, Gainesville, and Lake City, FL (system). The OIG was contacted by a confidential complainant who alleged that patients received inappropriate treatment that resulted in death or harm and that there was poor oversight of the Diagnostic Imaging Service (DIS). During that investigation, the OIG hotline received a second confidential complaint regarding DIS. The purpose of the review was to determine whether the allegations had merit.

Background

The system consists of two campuses; one located in Gainesville, FL, and the other in Lake City, FL, and is part of Veterans Integrated Service Network (VISN) 8, the VA Sunshine Healthcare Network. The system has 687 beds with 3 large multi-specialty outpatient clinics, 7 community based outpatient clinics, and a rural health outpatient clinic. A full range of primary, secondary, and tertiary care services is offered to more than 125,263 veterans from 50 counties.

The Chief of DIS is located at the Gainesville campus and is responsible for the overall management of the service. The Associate Chief of DIS and a DIS Technologist Supervisor are located at the Lake City campus. They supervise radiologists and technologists who provide General Radiology, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and Ultrasound (US) services. After normal business hours, the Lake City campus is staffed with one CT technologist until midnight. After midnight and on weekends, a CT technologist is on call.

The Chief of Urology is located at the Gainesville campus, is responsible for the overall management of the urology service, and directly supervises all urology attending physicians. The attending physicians supervise the residents. The Lake City campus is staffed with a urologist, and no residents are assigned.

Contrast Media

Contrast media (contrast) are used to improve pictures of the inside of the body produced by x-ray, CT, MRI, and US. By improving the visibility of specific organs, blood vessels, or tissues, contrast helps physicians diagnose the presence of medical conditions and the extent of disease or injury. When the test is finished, the kidneys and liver eliminate the contrast from the body.

Adverse reactions to contrast range from mild to severe and can appear up to 7 days after contrast administration. Examples of adverse reactions include rash; itching; sudden swelling of the mouth or throat, which may restrict breathing; and residual kidney damage after the contrast is excreted from the body. VHA requires that patients are screened for prior allergic reactions, kidney failure, or other risk factors during the

consent process.[1] Patients at risk for an allergic or adverse reaction to contrast are not precluded from receiving it. Medications, including steroids or antihistamines, can be given to prevent or decrease adverse effects before the contrast is administered.

Liver Disease Evaluation by Ultrasound

Cirrhosis occurs in the later stages of liver disease, where liver fibrosis has resulted in widespread scarring of normal liver tissue. Symptoms may not develop for years and are often nonspecific (for example, anorexia, fatigue, and weight loss). Late manifestations include portal hypertension (increased pressure in liver blood vessels) and ascites (abnormal accumulation of fluid in the peritoneal cavity causing swelling of the abdomen).

Pain and discomfort caused by ascites can be relieved by paracentesis, a procedure that can also assist with diagnosis. Paracentesis is performed by inserting a needle through the abdominal wall to remove ascitic fluid. Prior to the procedure, an ultrasound may be done to identify the best areas in the abdomen for fluid removal. Once identified, the area is marked on the skin with a pen, a needle is inserted at the mark, and after withdrawal, the fluid is sent to a laboratory for analysis and cultures.

Air is not normally present in the abdominal cavity but may enter the abdominal cavity during puncture of the abdominal wall for paracentesis. Air may also enter the abdomen from the bowel if it is punctured or traumatized.

Spontaneous bacterial peritonitis is an infection of ascitic fluid caused by bacteria crossing from the bowel into systemic circulation causing an infection that has a significant mortality rate.

Ureteral Stent Placement

Urine is normally carried from the kidneys to the bladder via a pair of long narrow tubes called ureters (each kidney is connected to one ureter). A ureter may become obstructed as a result of a number of conditions including kidney stones, tumors, or blood clots. A ureteral stent is a small flexible tube placed in the ureter to restore the flow of urine from the kidney to the bladder or to an external collection system.

Resident physicians in training can perform ureteral stent placements under supervision of attending physicians. Resident training programs are accredited by the Accreditation Council for Graduate Medical Education (ACGME). ACGME establishes standards for medical residents regarding the types of procedures residents must perform and minimum requirements for those procedures.

[1] VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009.

CT Scanner Useful Life Expectancy

VA has developed criteria for determining the life expectancy[2] of equipment it purchases. A category stock number (CSN) is assigned to equipment with life expectancy of greater than 2 years.

VA requires facilities to use the Automated Engineering Management System /Medical Equipment Reporting System (AEMS/MERS) to manage equipment with a CSN throughout its life expectancy.

To leverage its buying power, VA has established the National Acquisition Center (NAC) to procure high cost medical equipment. Requests are submitted through the VISN.

Allegations

Specifically, the complainants alleged that:

- Patients with documented contrast media allergies received contrast for CT exams resulting in patient deaths.
- Radiologists failed to review CT exam orders.
- The system lacked policies regarding contrast administration.
- A pre-procedure marking was incorrect, causing a physician to perforate a patient's bowel during paracentesis, resulting in the patient's death.
- Ureteral stent placements were performed in the cystoscopy clinic at the Gainesville campus without general anesthesia.
- The clinic setting was selected for ureteral stent placements to support urology resident physician training requirements.
- The system lacked radiologist support for CT technologists after hours.
- The CT scanner at the Lake City campus was beyond its useful life and broke down weekly.
- While a CT staff member was absent for a protracted period, the system did not replace/maintain staff levels using alternative measures, resulting in a backlog of patients.

Both complainants made additional allegations regarding human resources and equal employment opportunity issues that were beyond the scope of our review.

[2] In this context, life expectancy refers to the normal operating life of an asset in terms of usefulness to the owner. *VA Financial Policy* Volume V, Chapter 9, October 2013.

Scope and Methodology

We conducted a site visit from July 15–19, 2013. We interviewed the Chief of Staff, Chiefs of Urology and DIS, staff urologists, and all CT technologists assigned to DIS at the Lake City campus. Telephone interviews were also conducted with Quality Management staff and other relevant staff members throughout the review. We reviewed patients' electronic health records, system quality management documents including CT wait times, DIS staff meeting minutes, staff training records, certifications, and staffing schedules. In addition, we reviewed relevant system, VHA, American College of Radiology, and Joint Commission policies; system patient advocate data; and biomedical engineering records. We also interviewed the complainants, one of whom was unable to provide us with specific information concerning the allegations.

Without specific information identifying patients, it was necessary to define a population that may have been at risk or harmed based on the allegations. We used Current Procedural Terminology, a standard listing of descriptive terms and identifying codes for reporting medical services and procedures, to isolate representative groups of patients for the contrast and stent insertion allegations. Date ranges were established based on the allegations, and location of procedure was used to further define the respective populations. We identified 32 patients who underwent procedures consistent with the stent placement allegations and 16 patients who died within 7 days after receiving contrast for a CT exam. We reviewed health records for 100 percent of these patients.

We inspected patient care areas of DIS and urology services at both campuses.

We did not review the allegations regarding human resources or equal employment opportunity.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Inadequate Oversight of CT Imaging Processes

Patients with Contrast Allergies Received Contrast. We substantiated the allegation that some patients with documented contrast allergies received contrast for CT exams; however, we did not substantiate that patient deaths occurred as a result of contrast administration.

The system screened patients for contrast allergy and other risk factors prior to CT exams which used contrast. Local policy required a radiologist to review orders for CT prior to starting the procedure. Issues related to contrast contraindications were to be resolved by the radiologist and the ordering provider, and in most cases the orders were modified and the exams were completed without contrast administration.

When the use of contrast was unavoidable in patients with documented contrast allergies, the system used an approved procedure for pretreatment that included an antihistamine and a steroid to prevent or minimize potential adverse reactions. The approved pretreatment was required to begin 13 hours prior to the CT exam. Emergent exams did not allow time for pretreatment and in these cases, local policy required the ordering provider to consult with a radiologist.

Staff recalled only one instance when contrast was required for an emergent CT exam for a patient with a documented allergy to contrast. A radiologist and the ordering provider reviewed the patient's medical history and determined that the documented reaction did not reflect a true contrast allergy. The CT exam was performed with contrast, the patient did not experience an adverse reaction, and the allergy documentation was corrected in the patient's health record.

Radiologist Review of CT Orders. We did not substantiate allegations that radiologists failed to review CT orders, particularly when they originated from the ED. Local policy required a radiologist to review CT orders and select the appropriate protocol (parameters) for the exam. We found that system leaders had identified issues regarding protocols for CT requests and designated certain radiologists with responsibility for reviewing orders during the daytime shift. Additionally, the Lake City campus had a policy that listed CT exams that could be ordered by the ED or Urgent Care providers and performed without consulting a radiologist because the exam protocols were standardized.

Contrast Administration Policies. We did not substantiate that the system lacked policies regarding contrast administration. We reviewed local policies and during our discussions, most staff recalled receiving information about policies through email notifications or staff meetings and they were aware that printed protocols were available.

Issue 2: Incorrect Pre-Procedure Marking

We did not substantiate the allegation that a pre-procedure marking was incorrect, causing a physician to perforate a patient's bowel during paracentesis and resulting in the patient's death.

The patient, who was in his early seventies, used the VA infrequently for his medical care. In August 2012, he presented with complaints of moderate to severe abdominal pain, distention, and diarrhea for over a month. He stated that eating made the pain worse and he had not eaten for a few days. The patient's blood pressure was low, and he complained of dizziness upon standing. During physical examination, a physician noted significant swelling in his feet and scrotum.

The patient was admitted to the Medical Intensive Care Unit (MICU) at the Lake City campus with a diagnosis of cirrhosis of the liver with ascites and abdominal pain. The patient's medical history included diabetes (type II), hypertension, hyperlipidemia, and anemia.

The patient was scheduled for a paracentesis. Prior to undergoing the paracentesis, a pre-procedure marking was ordered by a physician. An ultrasound technician performed the marking which was verified by a radiologist.

During the procedure, peritoneal fluid was drained from multiple areas. A total of three liters of slightly clouded, brown fluid was removed. Analysis of the peritoneal fluid showed it contained a very high level of amylase, an indicator of pre-existing bowel injury. The patient tolerated the procedure well and returned to the ward.

Later that afternoon while on the ward, the patient developed increased abdominal pain and worsening low blood pressure. An abdominal CT scan revealed free abdominal air. The patient's blood pressure was stabilized and he was transferred to the MICU at the Gainesville campus in critical condition with a poor prognosis. During the patient's hospitalization, he was placed on antibiotic therapy. Blood transfusions and medications were given in an attempt to control his hypotension. The patient also developed lactic acidosis and respiratory distress which required intubation. He continued to decline and died 3 days after the paracentesis.

An autopsy was performed, and the cause of death was listed as sepsis and acute multi-organ failure on the background of cirrhosis. The pathologist who inspected the bowel told us that he did not identify a perforation associated with the paracentesis . He additionally stated that the patient developed spontaneous bacterial peritonitis, which is common among patients with cirrhosis and ascites and is associated with a significant mortality rate.

Issue 3: Pain Management during Ureteral Stent Placement

Pain Management. We substantiated the allegation that ureteral stent placements were performed in the Gainesville cystoscopy clinic without general anesthesia; however, we found that other appropriate measures were taken to provide pain control. Further, we

did not substantiate that the clinic setting was chosen so that urology resident physicians could perform a required number of stent placements for professional education.

At the Gainesville campus, ureteral stent placements were performed in the cystoscopy clinic without the use of general anesthesia; however, patients received local anesthetic prior to the procedure. Staff told us that additional medication was provided if a patient continued to have discomfort, and if pain persisted, the procedure would be stopped and rescheduled for the operating room. Pain levels were assessed before and after the procedure, either by use of a pain scale or by assessment of the patient's tolerance level for the procedure. None of the patients whose records we reviewed required rescheduling.

Resident Training. We did not substantiate that the clinic setting was selected to support urology resident physician training requirements. System leaders told us they utilized the clinic for stent placements in order to preserve the schedule of surgical cases that required the operating room setting. For example, a patient who presented with a ureteral blockage and needed urgent or emergent stent placement could be treated in the cystoscopy clinic without preempting surgery scheduled in the operating room. Additionally, we found that ACGME had no requirement to record numbers of ureteral stent placements performed.

Issue 4: Radiologist Support at the Lake City Campus

We did not substantiate allegations that the system lacked radiologist support for CT technologists after hours.

DIS offered CT exams 24 hours each day, 7 days each week (24/7). At the Lake City campus, CT technologists were scheduled to work until midnight; from then until 8:00 a.m. they took call on a rotating basis, returning if needed to perform urgent exams. Radiologists were scheduled to work at the Lake City campus until the end of the day shift, after which time the CT technologists were instructed to call radiology resident physicians who were on duty after hours at the Gainesville campus. Staff told us that the resident physicians did not respond to phone calls in a timely manner; however, we could not substantiate that allegation. The system also designated attending radiologists to be available on a rotating basis by telephone as additional support.

To expedite performing urgent or emergent CT exams, the system had a policy in place that specified exams with pre-standardized protocols for use after hours. Although no radiologists were on site at the Lake City campus after hours to read exams, CT exam images could be transmitted to the National Tele-radiology Program where off-site radiologists read the images and returned the results to Lake City.

Issue 5: CT Scanner Life Expectancy

We did not substantiate the allegations that the CT scanner is beyond its useful life and breaks down weekly.

The Lake City campus had one CT scanner which was 8 years old. The predicted VA life expectancy for CT scanners is 10 years. The system contracted with the manufacturer to provide preventive and emergency maintenance. The service contract included a provision requiring the CT scanner to be maintained at a quarterly uptime rate of 98 percent.

Biomedical engineers told us that the CT scanner had recurring issues in the 1st quarter of FY 2013, which caused 16 hours of downtime. Prior to that time, the uptime report for FY2012–2013 showed the CT scanner uptime rate was 100 percent. The uptime rate dropped to 98 percent during the time of the recurring issues. At the time of our inspection, the scanner uptime rate was 99 percent.

The process to replace the scanner was initiated 2 years ago with the VHA's National Acquisition Center. The new scanner has been installed and is operational.

Issue 6: CT Technologist Staffing Issues

We substantiated that while a staff member was absent for a protracted period, the system did not replace/maintain staff levels using alternative measures. However, we did not substantiate that the reduced staffing resulted in a backlog of patients.

Four CT technicians worked in DIS. One was detailed outside of the department for 8 months, leaving the 3 remaining CT technologists to provide 24/7 service. Two technologists were assigned to the day shift, and one worked from 4:00 p.m. until midnight. The daytime technologists took call on a rotating basis after midnight and on weekends. No additional staffing plan was implemented to provide support when CT technologists needed to use planned or unplanned leave.

During our onsite visit the detailed staff member had returned and was being reintegrated into the staffing schedule.

We reviewed Outpatient Imaging Procedure Wait Time Reports and did not substantiate that patient wait times increased during the period the staff member was detailed.

Conclusions

We substantiated the allegation that some patients with documented contrast allergies received contrast for CT exams; however, the system had processes in place to address potential adverse effects of contrast administration. We did not substantiate that patient deaths occurred as a result of contrast administration.

We substantiated the allegation that ureteral stent placements were performed in the Gainesville cystoscopy clinic without general anesthesia; however, we found that the other appropriate measures were taken to provide pain control. Further, we did not substantiate that the clinic setting was chosen so that urology resident physicians could perform a required number of stent placements for professional education.

We substantiated that there was reduced staffing for a protracted period in the CT department and that the system did not replace/maintain staff levels using alternative measures. However, we did not substantiate that the reduced staffing resulted in a backlog of patients.

We did not substantiate the allegations that the pre-procedure marking used to guide needle insertion for a paracentesis was incorrect, that the patient's bowel was perforated, or that these actions were associated with the patient's death. The pre-procedure marking was verified by a radiologist and autopsy showed no gross perforation of the bowel.

We did not substantiate allegations that the system lacked radiologist support for CT technologists after hours at the Lake City campus. Offsite radiologists were available to technologists after hours from the Gainesville campus and through the National Tele-radiology Program.

We did not substantiate the allegations that the CT scanner was beyond its useful life and broke down weekly. The scanner was serviced by the manufacturer and maintained in accordance with the service contract. A new scanner has been installed and is operational.

We made no recommendations.

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 14, 2014

From: Director, VA Sunshine Healthcare Network

Subject: **Healthcare Inspection –** Alleged Adverse Outcomes and Access Issues in Diagnostic Imaging Services, North Florida/South Georgia Veterans Health System, Gainesville and Lake City, FL

To: Director, Washington DC Office of Healthcare Inspections (54DC)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

I have reviewed and concur with the conclusion of no findings or recommendations based on this report.

Thank you for the opportunity to add comments however no additional comments are requested.

Joleen Clark

Joleen Clark, MBA, FACHE

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 10, 2014

From: System Director

Subject: **Healthcare Inspection –** Alleged Adverse Outcomes and Access Issues in Diagnostic Imaging Services, North Florida/South Georgia Veterans Health System, Gainesville and Lake City, FL

To: Director, VA Sunshine Healthcare Network (10N8)

1. Thank you for the opportunity to review and provide comments to this report.

2. I have reviewed and concur with the finding of no recommendations presented by the Office of Healthcare Inspections.

(original signed by:)

Thomas Wisnieski, MPA, FACHE

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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