Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality of Care and Responsiveness Issues VA Caribbean Healthcare System San Juan, Puerto Rico

Report No. 11-03896-209

June 22, 2012

VA Office of Inspector General
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 a patient's complaints about quality of care and management responsiveness at the San Juan VA Medical Center in San Juan, Puerto Rico. The complainant alleged that improper technique during a cystoscopy procedure in late March 2011, caused him considerable pain and resulted in hospitalization due to infection; that the physician performing the procedure ignored his complaints of pain; and that senior managers were not adequately responsive to his concerns.

We did not substantiate the allegation that improper technique during a cystoscopy procedure caused an infection. Although the patient did develop an infection, this could have been an unavoidable consequence and complication of the cystoscopy procedure he underwent, even if properly performed. Furthermore, we found nothing to indicate that the procedure was performed improperly.

We could neither confirm nor refute the allegation that the resident who performed the cystoscopy procedure ignored the patient's complaints of pain. Anesthetic was utilized, and neither the resident nor any of the other three employees present during the procedure recalled that the patient ever complained of pain. Medical record documentation reflected that the patient tolerated the procedure well. However, events also suggest that the patient was dissatisfied with his procedure as soon thereafter he complained to both the healthcare system's Chief of Urology and the Chief of Staff.

We did not substantiate the allegation that management was unresponsive to the patient's concerns. A review of the case was conducted and the Chief of Staff apologized to the patient. We found that management took acceptable actions to address the patient's concerns. While not one of the complainant's allegations, we found that the informed consent process was not completed according to policy regarding the change in practitioner prior to the procedure.

We recommended that the System Director implement measures to ensure that the informed consent process complies with VHA requirements. The Veterans Integrated Service Network and System Directors concurred with the findings and recommendation and provided acceptable improvement plans. We will follow up on the planned actions until they are completed.

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

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

SUBJECT: Healthcare Inspection – Alleged Quality of Care and Responsiveness Issues, VA Caribbean Healthcare System, San Juan, Puerto Rico

Purpose

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to a complaint regarding the treatment received by a patient at the VA Caribbean Healthcare System (the system) in San Juan, Puerto Rico. The purpose of this review was to determine if allegations regarding quality of care and management responsiveness had merit. Specifically, a complainant alleged that:

- Improper technique during a cystoscopy[1] procedure in late March 2011, caused him considerable pain, and later resulted in hospitalization due to infection.
- The physician who performed the cystoscopy procedure ignored his complaints of pain.
- Senior managers' responses to his concerns were inadequate.

Background

The system includes a tertiary care facility, the San Juan VA Medical Center (VAMC), in San Juan, Puerto Rico, with Community Based Outpatient Clinics in Arecibo, Guayama, and the U.S. Virgin Islands. There are also satellite outpatient clinics located in Mayaguez and Ponce. The system is a teaching hospital with active affiliations with the University of Puerto Rico School of Medicine, Ponce School of Medicine, and the Universidad Central del Caribe Medical Schools. Comprehensive health care is provided through a variety of inpatient and outpatient services, including primary care specialty clinics such as Urology. The system has a designated suite in the operating room to

[1] A diagnostic procedure that involves insertion into the bladder of an instrument called a flexible cystoscope in order to visualize the inside of the urethra and bladder.

perform urology procedures. The system is part of Veterans Integrated Service Network 8.

Scope and Methodology

We interviewed the complainant prior to conducting a site visit on November 29, 2011. During our site visit, we interviewed senior managers, including the Chief of Urology and Chief of Staff. We also interviewed an attending urologist, a senior resident, and two registered nurses (RNs). We conducted a telephone interview with a urology technician on January 10, 2012. We reviewed medical record documentation, system policies, clinical practice guidelines, Infection Control Committee minutes, quality management data, clinical competency files, and the resident's level of competency document.

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.

Case Summary

The patient is a male in his sixties with a history of atrial fibrillation,[2] chronic hepatitis C, high blood pressure, and diabetes mellitus type II.

In mid-April 2009, the patient had a urology consultation due to laboratory results that reflected microhematuria[3] and abnormal cells in the urine. Two months later, a cystoscopy procedure was performed. Findings included a large prostate gland and a papillary lesion[4] in the bladder. In early September, a cystourethroscopy[5] with a transurethral resection of the bladder (TURB)[6] was performed. The patient's papillary bladder tumor, which was less than 1 centimeter in length, was resected completely. There was no evidence of urethral stricture or masses, no evidence of additional bladder masses, and there was no active bleeding after the procedure. A nursing progress note documented administration of the antibiotic ciprofloxacin 400 milligrams (mg) intravenously (IV) during the procedure. The patient was discharged to home several hours later with a Foley catheter[7] in place, oral antibiotics (ciprofloxacin 500 mg every 12 hours for 14 days), and pain medication (acetaminophen with codeine 30 mg every6 hours or as needed). A subsequent pathology report classified the resected tumor as

[2] A type of irregular heart rhythm.
[3] Red blood cells in the urine visible only with the aid of a microscope.
[4] A tumor projecting into the inside space of the bladder).
[5] A procedure that involves insertion of an instrument through the urethra in order to view the inside of the urethra and bladder.
[6] TURB is a surgical procedure used to remove tissue samples and/or tumors via a resectoscope that is passed through the urethra.
[7] A small, flexible tube that is inserted into the urethra to the bladder to drain and collect urine.

urothelial carcinoma[8] according to the urologist notes, and dysplastic cells consistent with urothelial neoplasm according to the surgical pathology report.

Two weeks later, the patient attended a follow-up urology appointment. The medical record note indicated that the Foley catheter was in place and there was no evidence of fever or blood in the urine. The urologist ordered prophylactic antibiotics (ciprofloxacin 500 mg every 12 hours) for 5 more days. Five days later, the patient presented to the system's Emergency Department and was treated for fever and urinary tract infection. He was sent home with oral antibiotics for 14 additional days (ciprofloxacin 500 mg every 12 hours).

In early December, the patient had a follow up cystoscopy. Medical record notes indicated that he tolerated the procedure well and there was no evidence of tumor recurrence. An oral antibiotic (nitrofurantoin 100 mg) was administered as a single dose following the procedure.

The patient had two follow-up cystoscopies in May and September 2010. The post procedure notes for both cystoscopies reflected no recurrence of bladder tumor, and also document an obstructive prostate.

In late March 2011, the patient presented to the Urology Clinic for a follow-up cystoscopy. He complained of occasional urinary incontinence and urgency. However, he had no complaints of fever, or abdominal or bladder pain. A progress note indicated that the patient had continued with oral finasteride to treat his prostate enlargement and that an oral antibiotic (nitrofurantoin) was given at the time of the cystoscopy procedure. It was documented that the patient tolerated the procedure well and that there was "mild prostate obstruction" and "no evidence of bladder tumoral lesions."

Three days later, the patient presented to the system's Emergency Department and complained of fever, chills, bloody urine, and left testicular pain and swelling. A progress note documented that he received an intravenous antibiotic (levofloxacin 750 mg), a Foley catheter was inserted, and blood analysis and urine cultures were ordered. The documentation for the laboratory blood results indicated an elevation of the patient's white blood cells (12.7×10^3 cells/mm^3), and the presence of *Escherichia coli* (*E coli*)[9] in the urine. The patient was diagnosed with epididymo-orchitis[10]and was admitted to an internal medicine unit for treatment. A nursing note indicated that he received intravenous antibiotics (gentamicin 430 mg to infuse over 30 minutes every 24 hours) during the hospitalization.

[8] A type of cancer that typically occurs in the urinary system.
[9] *E coli* is a common bacterium normally found in the human intestine, that often causes infections of other organ systems including urinary tract infections.
[10]Epididymo-orchitis is an inflammation of the testicle(s) and the spermatic duct which is characterized by fever, pain, and swelling.

The patient's Foley catheter was removed on hospital day 2. On hospital day 3, a progress note reflected a decrease of the white blood cell count (from 12.7 to 8.4 x 10^3 cells/mm^3) and the patient was discharged home on oral antibiotics (ciprofloxacin 500 mg every 12 hours for a month) and pain medication (acetaminophen with codeine 30 mg every 6 hours, or as needed).

Two weeks later, the patient attended a Urology Clinic follow-up appointment. A progress note indicated that he had "no complaints; the infection was resolved," and he was referred back to his primary care physician with a recommendation to return for urology follow-up in 1 year.

Inspection Results

Issue 1: Alleged Improper Technique

We did not substantiate the allegation that improper technique during a cystoscopy procedure in March 2011, caused the patient considerable pain and resulted in hospitalization due to infection.

During a telephone interview, the patient stated that this was the first time he had a painful cystoscopy although he had several cystoscopies in the past. His earlier procedures had been performed by an attending urologist. In the case of this procedure, the attending urologist completed the informed consent on that day, but became unavailable at the time of the procedure. Instead, a urology resident performed the cystoscopy. The patient told us he felt pain at least three or four times while the physician was "poking his bladder." The patient also said that no anesthesia (including local anesthetic) was used during the procedure. We interviewed all staff who participated in the patient's procedure that day (the resident, an RN in orientation, the circulating RN, and the urology technician), and they each told us that the correct protocols were followed (including the application of a topical anesthetic), and that nothing out of the ordinary occurred. The surgical documentation package verified that the urology technician applied lidocaine 2 percent (topical anesthetic) 5 minutes prior to the procedure.

The patient also stated that when he consented to the procedure that morning, the attending urologist discussed with him possible complications that could result from the procedure, such as blood in the urine or infection. The circulating RN who assisted the resident during the procedure told us the patient asked him some questions related to the cleanliness of the equipment when he was first brought into the procedure room. The RN told us he explained the procedures for reprocessing the equipment and showed the patient the sealed package containing the clean cystoscope.

We reviewed data on the reprocessing of cystoscopes for FY 2011, and validated that the cystoscope used for this procedure was appropriately disinfected. We attempted to review recorded images from the procedure, but were told that the system does not store images for cystoscopy procedures.

We asked an external consultant who is a highly experienced urologist to review the patient's medical record. He informed us that urinary tract infections (UTIs) occur about 1 percent of the time after instrumentation of the bladder in procedures such as cystoscopy, and that epididymo-orchitis is a known complication of both UTIs and cystoscopy. He also stated that because the urine culture from early April revealed *E.Coli* that was sensitive to nearly all of the antibiotics included in concurrent sensitivity tests (including the nitrofurantoin that the patient was given), it is likely that this organism was not hospital-acquired, but more likely a community-acquired bacterium. Our consultant concluded that if the local infection rate after cystoscopies is low and there are not multiple complaints against the providers, it would appear that this complaint may be more patient specific and not represent a system problem.

The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases states that anyone with an abnormality of the urinary tract that obstructs the flow of urine (such as an enlarged prostate) is at risk for UTIs, and that a diabetic patient is more likely to get UTIs.[11] The patient's medical record reflected that he has diabetes and an enlarged prostate, factors that both predispose him to UTIs.

The urology consultant also found that the procedure appeared to have been performed correctly. He stated that while the patient may have felt that the surgeon was poking at his bladder, the documented time of the procedure was only 5 minutes and it is important for the surgeon to inspect the entire surface of the bladder wall to ensure that there is no tumor recurrence. This requires moving the scope around the bladder which can be uncomfortable. He concluded that if there is not a pattern of complaints against the resident, it would appear the technique that was performed with the cystoscopy was appropriate.

We reviewed the resident physician's level of competency document and validated that he had clinical privileges to perform the procedure without direct supervision. The resident told us that he had performed approximately 1,000 cystoscopies during the past 6 years. In addition, senior managers told us that they had not received any other complaints related to the care provided by this resident.

[11] Accessed at http://kidney.niddk.nih.gov/kudiseases/pubs/utiadult/index.aspx on January 13, 2012.

The patient was admitted to the hospital 3 days following the procedure due to infection but was successfully treated with antibiotics until the infection was resolved. We do not deny that he perceived his procedure to be painful. However, we do not attribute his perception of pain or the infection to improper technique.

Issue 2: Resident's Responsiveness

We could not definitively confirm or refute the allegation that the resident who performed the cystoscopy procedure ignored the patient's complaints of pain. The patient told us he complained of pain at least three or four times during the cystoscopy and that his pain was so severe that at one point he "almost came up to a sitting position." However, neither the resident nor any of the other three employees in the room during the procedure remembered hearing the patient complain of pain. Two of the employees were on the other side of the curtain from the patient, but stated they did not hear the patient say anything about pain or produce any vocalizations indicating he was in pain. The employee assisting the resident during the procedure was closer and could see the patient the entire time. He also stated that he neither saw nor heard any evidence that the patient was in pain. Medical record documentation stated that the patient tolerated the procedure well. There was no documentation that he complained of pain.

The patient also told us that the resident said nothing at all to him before or during the procedure. The patient had not been informed prior to the procedure that the resident would be performing the procedure in place of the attending urologist. The resident and the other employees told us that the patient asked many questions (including several about the cleanliness and disinfection of the equipment) prior to the start of the procedure. The resident told the patient that he would answer any questions after the procedure. The patient told us that after the procedure, one of the employees who assisted told him that he could complain. He told us he could not remember which employee said this to him.

The RN in orientation informed us that after the procedure, the urology technician told her he took the patient to the Chief of Urology's office so he could complain about the resident's manner during the procedure. However, the urology technician denied that he took the patient to complain. He told us that he escorted the patient to the resident's office as he does with every patient post-procedure because it is part of their usual process. He stated that the purpose was to allow the physician to answer patients' questions and explain the findings of the procedure to them.

Due to the conflicting information we received about whether or not the patient reported pain during the procedure and whether or not he was taken afterward to the Chief of Urology's office to complain, we could neither confirm nor refute the allegation that the resident was unresponsive to the patient's complaints of pain. The medical record

reflected that the patient tolerated the procedure well. The patient was not expecting this resident to perform the procedure, and that the resident did not answer the patient's questions prior to the procedure but told him he would do this following the procedure. Some of the employees we interviewed told us that the resident's manner and way of speaking was sometimes perceived to be overly assertive.

Issue 3: Management Responsiveness

We did not substantiate the allegation that management was unresponsive when the patient discussed his concerns with them. The patient told us that 3 days after he was discharged from the hospital, he complained to the Chief of Urology about the resident's bedside manner during the cystoscopy. He also told us he reported his concerns to the Chief of Staff.

The Chief of Urology confirmed that the patient spoke with him but said that the patient did not complain about pain during the procedure or about the infection, but only spoke about the resident's attitude. The Chief of Staff confirmed that he spoke with the patient, who told him he felt that the resident had "abused him." The Chief of Staff referred the case to the Chief of Surgery for review.

We verified that the Surgery Service had conducted an internal case review, including verification that the cystoscope had been properly reprocessed. This review concluded that the patient received appropriate care until his symptoms were resolved and that although a competent resident performed the procedure, he could be more "sensitive to patients' complaints."

The Chief of Staff told us that he met with the patient a second time, reported on actions taken, and apologized to the patient. Because the case was reviewed and the patient received an apology, we feel that management was adequately responsive to this patient's concerns.

Issue 4: Informed Consent

While not one of the patient's allegations, we found that the informed consent process for the cystoscopy procedure in late March 2011 was not completed according to policy. Local policy and VHA policy[12] require identification of the practitioner performing a procedure, as well as any other practitioner responsible for supervision. In addition, VHA policy[13] requires that if a different practitioner is substituted for the practitioner responsible for conducting the procedure, his/her name and signature must be added to the consent form, or a progress note must be placed in the patient's medical record to indicate all changes to the treatment plan, as well as patient agreement.

[12] VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures, August14, 2009.*
[13] Ibid

The patient told us that his regular attending urologist met with him prior to the procedure in late March 2011 and discussed the risks of the procedure with him. At that time, the patient also signed the informed consent document. This urologist's name and signature were on the informed consent document as the provider conducting the procedure. However, prior to the procedure, the attending urologist asked the resident to perform the procedure because he had to leave the facility. The patient told us that he was never informed that another physician had been assigned to perform his procedure. In addition, the resident's name and signature were not added to the consent form and no documentation of this change in plan was found in the patient's medical record.

We found that the medical record lacked documentation of both identification of the practitioner performing the procedure and the patient's agreement with this change in plan.

Conclusions

We did not substantiate the allegation that improper technique during a cystoscopy procedure in late March 2011 caused the patient considerable pain and resulted in hospitalization due to infection. Although the patient did develop an infection, this could have been an unavoidable consequence and complication of the cystoscopy procedure he underwent, even if properly performed. The patient had several factors that predisposed him to urinary tract infections. We found nothing to indicate that the procedure was performed improperly.

We could neither confirm nor refute the allegation that the resident who performed the March 2011 cystoscopy procedure ignored the patient's complaint of pain. Anesthetic was utilized, and neither the resident nor any of the other three employees present during the procedure recalled the patient complaining of pain. Medical record documentation reflected that the patient tolerated the procedure well. However, the patient was clearly unhappy with some aspect(s) of the procedure as he lodged complaints with the Chief of Urology and the Chief of Staff.

We did not substantiate the allegation that management was unresponsive to the patient's concerns. A review of the case was conducted and the Chief of Staff apologized to the patient. We found that management took acceptable actions to address the patient's concerns.

We found that the informed consent process was not completed according to policy regarding a change in practitioner prior to the procedure.

Recommendation

Recommendation 1. We recommended that the System Director implement measures to ensure that the informed consent process complies with VHA requirements.

Comments

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendation and provided acceptable improvement plans. (See Appendixes A and B, pages 10-12, for the full text of the Directors' comments.) We will follow up on the planned actions until they are completed.

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 6, 2012

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

Subject: **Healthcare Inspection – Alleged Quality of Care and Responsiveness Issues, VA Caribbean Healthcare System, San Juan, PR**

To: Director, Bay Pines Office of Healthcare Inspections (54SP)

Thru: Director, Management Review Service (10A4A4)

1. I have reviewed and concur with the VA Caribbean Healthcare System, San Juan, Puerto Rico draft inspection report (San Juan – Draft Response to HL Draft Report 2011-03896-HI-0249).

2. Appropriate action has been initiated and/or completed as detailed in the attached report.

Nevin M. Weaver

Nevin M. Weaver, FACHE
Director, VA Sunshine Healthcare Network (10N8)

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 31, 2012

From: Director, VA Caribbean Healthcare System (672/00)

Subject: **Healthcare Inspection – Alleged Quality of Care and Responsiveness Issues, VA Caribbean Healthcare System, San Juan, PR**

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

1. Attached is the VACHS response to the above-mentioned OIG Draft Report Healthcare Inspection Project Number: 2011-03896-HI-0249.

2. Appropriate actions have been initiated.

3. If additional information is needed, please contact Ms. Lavell Velez, Quality Manager at telephone number 787-641-7582, extension 18313.

Sincerely,

WANDA MIMS, MBA
Director, VA Caribbean Healthcare System (672/00)

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 System Director implement measures to ensure that the informed consent process complies with VHA requirements.

Concur **Target Completion Date: August 31, 2012**

Facility's Response:

A. Reinforce informed consent process as per CM 136-10-27 to clinical services and residency programs at their service staff meetings.

B. Health Information Management Service will perform monthly random spot checks of electronic consents to verify the appropriateness of the completion of the consent form. The review must ensure that the consent form contains identification by name and profession the practitioner who has primary responsibility for the relevant aspect of the patient's care. Also identify by name and profession any other individuals responsible for authorizing or performing the treatment or procedure. And when applicable practitioner is substituted, ensure that they advise the patient if another practitioner will need to be substituted for any of those named. If the need for a substitution is known prior to initiating a treatment or procedure that requires signature consent, the patient must be informed of the change and this discussion and the patient's assent must be documented in the patient's electronic health record. Their findings will be reported to service chiefs for educational purposes and data aggregates will be reported to the Medical Record Review Committee for trending.

Status: Pending

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Christa Sisterhen, MCD, Project Leader Alice Morales-Rullan, MSN, CNS, Team Leader Alan Mallinger, MD Wm. Eli Lawson, Program Support Assistant

Appendix D

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