Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality of Care Issues
Charles George VA Medical Center
Asheville, North Carolina

Report No. 09-01657-187 **August 5, 2009**

VA Office of Inspector General
Washington, DC 20420

Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections (OHI) reviewed allegations of poor quality of care, delay in services, and erroneous documentation at the Charles George VA Medical Center (the medical center). The complainant alleged that as a result of these issues, he has suffered financial hardship. The complainant stated that medical center staff did not adequately respond to his concerns.

We did not substantiate the allegations of poor quality of care, delay in services, or inadequate communication, and we could not adequately evaluate allegations of financial hardship. We did confirm that a provider erroneously documented that the patient suffered "chest pain" during an outpatient visit; however, actions were taken to remedy the condition. We made no recommendations and plan no further actions. The VISN and Medical Center Directors concurred with our findings.

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

TO: Director, VA Mid-Atlantic Health Care Network (10N6)

SUBJECT: Healthcare Inspection – Alleged Quality of Care Issues, Charles George VA Medical Center, Asheville, North Carolina

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) conducted an evaluation in response to a patient's complaints of poor quality of care, delay in services, and erroneous documentation at the Charles George VA Medical Center (the medical center) in Asheville, NC. The patient alleged that as a result of these issues, he has suffered financial hardship. In addition, the patient alleged inadequate communication by medical center staff. The purpose of the review was to determine whether the allegations had merit.

Background

The medical center is a tertiary care facility that provides a broad range of medical and surgical services, and operates 112 hospital beds and 120 Extended Care and Rehabilitation (ECR) beds. The medical center serves veterans in western North Carolina and portions of South Carolina, Tennessee, and Georgia, and also provides outpatient care at one community based outpatient clinic in Franklin, NC. The medical center is under the jurisdiction of Veterans Integrated Service Network (VISN) 6.

In general, prostate cancer screening using prostate-specific antigen (PSA) testing and digital rectal exam (DRE) should begin at age 50.[1] Normal PSA levels are 0–4 ng/mL[2] and anything higher can indicate prostate cancer. The American Cancer Society states that a borderline PSA level between 4 and 10 ng/mL indicates a 25 percent chance of having prostate cancer, and a PSA higher than 10 ng/mL may indicate a 50 percent chance. However, other factors can elevate the PSA including age, prostatitis, or non-cancerous enlargement of the prostate. DRE is performed to identify abnormalities in the size or shape of the prostate. If cancer is suspected, a biopsy will confirm (or refute) the clinical diagnosis.

[1] They should begin earlier for African-American men or men with a family history of prostate cancer.
[2] "ng/mL" is nanograms per milliliter; a nanogram is one-billionth of a gram.

On March 10, 2009, the OIG received a request from Rep. Heath Shuler to evaluate multiple allegations made by the patient. The patient specifically alleged that:

a. Two prostate biopsies resulted in infections that made him very ill and from which he had difficulty recovering. After the second biopsy, he developed an *Escherichia coli (e. coli)* infection that was treated, but the information was not shared [with other providers]. While he eventually received an effective antibiotic treatment, he lost 20 pounds. and is still weak.

b. He waited 4 hours for treatment in the emergency department (ED), and despite being very sick, was sent, unattended, to the Pharmacy to pick up his prescriptions. He was then discharged home.

c. Due to a delay in scheduling hip replacement surgery, the patient was forced to receive the service at a private hospital.

d. A chest x-ray consultation request erroneously reflected that the patient had chest pain.

e. The radiologist's interpretation of the chest x-ray erroneously reflected that the patient had an "enlarged heart."

f. As a result of (a) and (c), the patient has incurred medication co-pay costs and private hospital bills. As a result of (d) and (e), the patient is "uninsurable."

g. The medical center Director and patient advocate have been non-responsive, and the risk manager improperly referred the patient to Regional Counsel for information regarding Tort claim processes.

Scope and Methodology

We learned about some of the patient's concerns through an unofficial source in early February 2009. We conducted a site visit February 9–12 for a previously scheduled and unrelated inspection and followed-up on the patient's complaints during that visit. We interviewed the complainant by phone on February 12, and we interviewed the medical center Director and Chief of Staff on the same date. We reviewed the veteran's medical record, clinical protocols, and medical center and national policies related to Fee Basis payments.

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

Case Summary

The veteran is a non service-connected male in his 70s with Medicare insurance coverage who has been treated at the medical center since 2004. His primary medical history includes degenerative joint disease, hypertension, and chronic prostatitis, with a family history of prostate cancer. In January 2006, a urologist documented that the veteran had an elevated PSA level (8.4 ng/mL in December 2005) and an abnormal DRE.

In March 2006, the veteran underwent a transrectal ultrasound (TRUS) guided biopsy, the results of which reflected adenomatous and fibromuscular hyperplasia (increase in size of prostate, often related to age) and high-grade prostatic intraepithelial neoplasia (PIN).[3] The veteran tolerated the procedure well without complications. The veteran was discharged home with a 5-day supply of ciprofloxacin to prevent infection. The tissue specimen showed no evidence of cancer. The veteran was instructed to return in 4–6 weeks for a repeat biopsy.

In May 2006, the veteran was seen again in Urology Clinic for a repeat biopsy. The veteran told the physician that the last TRUS was difficult to recover from. The physician explained to the veteran that "there is a low risk of progression, although [there is a] likely 30% chance of PCa [prostate cancer] on repeat bx [biopsy], if he wants to wait several months that is reasonable. He agrees and will RTC [return to clinic] with PSA in 3 months."

In August 2006, the veteran returned to Urology Clinic and again expressed that he did not want to undergo another biopsy at that time. As the veteran's PSA declined to 7.7 ng/mL, he was scheduled for a follow-up PSA in February 2007. The medical record reflects that the veteran did not show for this appointment, and he was not seen again at the medical center until October 2007.

In early October 2007, the veteran saw his primary care provider (PCP) for his annual physical examination. The PCP noted that a private-sector ophthalmologist suggested that an eye growth be removed. The PCP ordered laboratory tests (including a PSA); urology, orthopedic, and ophthalmology consultations; an x-ray of the right hip; and an influenza vaccine.

In mid-October, the veteran was seen in Urology Clinic and noted to have an increased PSA (19.9 ng/mL). The physician recommended another biopsy, to which the veteran agreed. On this date, he was also seen in Orthopedic Clinic for evaluation of his right hip.

In the latter part of October 2007, the veteran voluntarily underwent a second TRUS without apparent complication. He was able to void post-procedure and his urine was

[3] Microscopic lesion in the prostate which may be a precursor to cancer.

clear. He was discharged with a 5-day supply of ciprofloxacin and given instructions to contact the clinic if he experienced bloody urine or stool or if he was unable to void. Three days after the TRUS, a urology resident discussed the biopsy results, which were virtually identical to the March 2006 biopsy results, with the veteran. The veteran indicated his reluctance to repeat the biopsy (as is standard practice to confirm the results) because he had experienced fevers and chills after both previous biopsies. The treatment plan documented that the veteran was to return to Urology Clinic for PSA testing in 6 months, and if the PSA level continued to increase, a repeat biopsy would be considered.

The veteran presented to the emergency department in the early afternoon, a week after the second TRUS, reporting that he had had a fever since his biopsy the previous week. He was triaged by a nurse at 27 minutes after arrival; his temperature was 100.1 F and his blood pressure was 130/82. He was placed in an observation room at 13 minutes after triage and had blood drawn 4 minutes later and a portable chest x-ray completed 14 minutes after that. His PSA level was 46 ng/mL and he had an abnormal urinalysis (white blood cells in his urine). The veteran received intravenous (IV) fluids and levofloxacin to treat his infection. The IV was removed at after 3 hours, and he was discharged home with a 14-day supply of levofloxacin, slightly more than 4 hours after his arrival in the.

In mid-December 2007, the veteran presented to the Urology Clinic complaining of urinary frequency, and cloudy and foul-smelling urine. The physician's assistant documented that the veteran had visited the emergency room in October, and a urine culture grew out *e. coli* that was resistant to levofloxacin; however, the veteran had not had his antibiotic switched. A urinalysis completed during this visit showed evidence of infection, and the patient received Bactrim, a sulfa-based antibiotic, to treat this condition.

In early February 2008, the veteran saw his PCP reporting that after taking the antibiotics, he was voiding better and feeling "ok." His PSA was 17.3 ng/mL. The PCP documented the veteran's concern that his insurance premium had increased after the insurance company reviewed his urology reports. The PCP also documented that the veteran had had hip replacement surgery (not at a VA facility) in mid-January 2008.

The patient was seen in Urology Clinic in May 2008 for a follow-up PSA and scheduled to return to clinic in 6 months to repeat the test. His PSA was 13.8 ng/mL at this visit.

In early August 2008, the patient complained to his PCP about an increase in insurance premiums relative to erroneous documentation that he had chest pain and heart problems. The PCP documented that there was no clinical evidence of a cardiac condition and ordered a chest x-ray and electrocardiogram. Three days later the PCP amended his progress note, documenting that the chest x-ray showed the patient was "without cardiopulmonary irregularities."

In October 2008, the patient again saw his PCP and reported that he needed to follow-up on his *e. coli* infection and that he was concerned about his weight loss. The patient's weight was 201 lbs. and his PSA level was 11.3 ng/mL during this visit. At the time of this report, he continued to receive his primary care at the medical center.

Inspection Results

Issue 1: Quality of Care Issues

We did not substantiate the allegations of poor quality of care.

Complaint (a): The patient alleged that two prostate biopsies completed at the medical center resulted in infections that made him very ill and from which he had difficulty recovering. The patient stated that he was diagnosed with *e-coli* after the second biopsy, but that he was not treated and the results were not shared.

The patient had TRUS-guided biopsies in March 2006, and October 2007; he received standard antibiotic therapy to prevent infection after both procedures. After the first biopsy, the medical record consistently reflects the patient's reluctance to undergo a repeat biopsy because of his lengthy recovery period. However, the patient did not seek treatment at the medical center, so it is unclear what complications were delaying his recovery.

Three days after the second biopsy, the urology resident contacted the patient to discuss the biopsy results. The veteran indicated his reluctance to repeat the biopsy because he had experienced fevers and chills after both previous biopsies. The resident told the veteran that fevers after a biopsy are sometimes caused by a ciprofloxacin-resistant bacteria. The veteran stated that he was unsure how high his [current] fevers were, and the resident encouraged him to go to the medical center's emergency department (ED) if the fevers persisted or worsened.

The patient sought treatment for fever and chills at the medical center's ED a week after the second biopsy in late October 2007. Subsequent laboratory results reflected that the patient did have an *e. coli* infection. The patient was treated in the ED with IV levofloxacin and discharged home with a 14-day supply of these oral antibiotics. The patient's medical record, which was available to all clinical practitioners, appropriately reflected the laboratory results and treatment provided.

The patient's next documented contact with the medical center was in mid-December 2007 when he was seen in Urology Clinic. The progress note confirms the *e. coli* infection, which was apparently resistant to levofloxacin. However, we found no evidence that the patient told anyone between the end of October and mid-December that his symptoms were not improving. In fact, the Urology Clinic note documented that the

patient did not [seek to] have his antibiotic changed. The Urology Clinic provider prescribed a sulfa-based antibiotic which effectively treated the infection.

We concluded that while the patient did experience difficulties recovering from both biopsies, and did require treatment for a post-procedure infection after the second biopsy, medical center clinical practitioners met community standards of practice. The patient received appropriate pre- and post-biopsy treatment, education, and instructions. When the patient presented to the ED in late October 2007, the ED physician ordered a broad-spectrum antibiotic which could reasonably be expected to treat the patient's infection. As the patient did not seek treatment for continuing symptoms, clinical providers had no way of knowing that his *e-coli* was also resistant to levofloxacin. When the problem was identified, a change in antibiotics effectively treated his condition. For the roughly 3-year period from December 2005–October 2008, the patient (who is not a small person) lost about 17 pounds; however, we could not attribute this weight loss specifically to the biopsies, infection, or recoveries. Many factors could have influenced the patient's weight loss.

Complaint (b): He waited 4 hours for treatment in the ED, and despite being very sick, was sent to the pharmacy to pick up his medications. He was then discharged home.

The patient spent approximately 4 hours in the ED in late October 2007. He signed in early in the afternoon and was triaged by a nurse less than half an hour later. Over the next several hours, he was placed in an ED bed, had laboratory work and a chest x-ray completed, was evaluated by a physician, and received IV fluids and antibiotics. He was discharged approximately 4 hours after arrival and was given a prescription for oral antibiotics to be continued at home. The nurse documented, "Pt [patient] waiting for a ride home. Resting with his eyes closed…."

We concluded that the patient was triaged and treated promptly in the ED. As he would not have met criteria for hospital admission, he was appropriately discharged to his home. Standard practice at many medical centers is for patients to pick up their own medications at the pharmacy after discharge, so this expectation did not deviate from community standards of care.

Issue 2: Delay in Services

Complaint (c): We did not substantiate the allegation that due to a delay in scheduling hip replacement surgery, the patient was forced to receive the service at a private hospital. During an October 2007 primary care appointment, the PCP documented that the veteran requested an evaluation of his right hip because a private-sector orthopedist suggested the need for an injection or hip replacement. The patient was evaluated in Orthopedic Clinic 2 weeks later. The x-rays reflected "multiple cystic changes in the femoral head consistent with osteonecrosis," and the physical examination revealed decreased range of motion. The orthopedist suggested a total hip replacement

and advised the veteran that he would be placed on a waiting list for the procedure. The progress note shows that the veteran requested the surgery be completed around Christmas 2007; however, the orthopedist advised that the scheduling clerks would let him know when he could be scheduled for the procedure.

We spoke with the Surgery Service scheduler who told us that while she did not remember speaking with this patient, she would, in fact, have told him that he could not be scheduled for hip replacement surgery for about 3–4 months. The scheduler told us that the medical center conducts a high volume of hip replacement surgeries on service-connected veterans, and as such, non service-connected veterans with non-emergent medical needs (like the complainant) are frequently placed on waiting lists. We found that the scheduler's actions conformed to VA guidelines.

It appears that the patient became frustrated with the surgery delay and underwent total hip replacement surgery in mid-January 2008 at a private-sector hospital. We found no evidence that the patient advised anyone at the medical center of his intent do this or sought prior approval for VA payment for this procedure.

Issue 3: Erroneous Documentation

Complaint (d): We substantiated the allegation that a chest x-ray request erroneously reflected that the patient had chest pain. In late October 2007, the patient visited the medical center's ED complaining of fever and chills after a prostate biopsy the previous week. The ED physician requested a chest x-ray and documented "chest pain" in the clinical history section. However, the ED physician documented in his assessment that the patient did not have a cough, shortness of breath, or chest pain.

As we could not determine any clear reason why a chest x-ray was ordered based on the patient's presenting symptoms, we concluded that the ED physician may have confused this patient with another ED patient with chest pain who was being treated at the same time.

Complaint (e): We confirmed that the radiologist's interpretation of the October 2007 chest x-ray did reflect that the patient's heart was "mildly enlarged;" however, the report also documented that there was no evidence of pulmonary edema or other acute lung abnormalities. Because the patient also had no physical symptoms such as chest pain or shortness of breath, the radiologist's interpretation does not completely correlate with the other clinical findings. Nevertheless, we could not say with certainty that this was an erroneous interpretation. A chest x-ray completed in August 2008 showed no evidence of "cardiopulmonary irregularities."

Issue 4: Financial Hardship

Complaint (f): We did not substantiate the allegation that as a result of (a) and (c), the patient has incurred medication co-pay costs and private hospitable bills. We were unable to evaluate the allegation that as a result of (d) and (e), the patient is "uninsurable."

As discussed above, medical center practitioners met standards of care relative to the prostate biopsies and took reasonable measures to prevent infection. Unfortunately, infections cannot always be predicted or prevented, as occurred in this case. As a non service-connected veteran, the patient was required to pay $8.00 per 30-day supply of medication.

In addition, we found no evidence that the patient was forced to receive hip replacement surgery at a private-sector hospital, thus incurring responsibility for the balance of this bill. The orthopedist clearly advised the patient during his October 2007 appointment that he would be placed on a waiting list. Because the patient's condition was not emergent, schedulers accurately advised him that it could be several months before he could be scheduled for surgery at the medical center. It appears that the patient was frustrated by this answer and arranged for surgery to be conducted at a private-sector hospital in January 2008, the cost of which was primarily covered by Medicare. We found no evidence that the patient notified anyone at the medical center of his intention to receive the surgery in the private-sector or secure preauthorization for said surgery; in fact, the first reference we found in the medical record appeared in a February 2008 PCP progress note.

In early February 2009, the COS documented that she had met with the patient on two previous occasions and had recently received angry correspondence from him. She met with him regarding a $1,000 balance owed to the private-sector hospital for costs not covered by Medicare related to his hip replacement. The COS documented that "…we have explained to him about required preauthorization not being in the chart and the fact that Medicare has already paid making it difficult to now pay. I told him that VA cannot legally be second payor, but that there was likely a way that we can help."

VA policy states that "non-VA hospital and medical care services may be authorized at VA expense for certain eligible veterans when VA facilities are not feasibly available AND the urgency of the veteran's medical condition is such that it prohibits immediate movement to the nearest VA medical center." As the patient's situation did not meet either criterion, the case was referred to the Centralized Fee Unit at the Salem VA Medical Center for consideration as an "unauthorized claim."

As indicated previously, we were unable to evaluate the allegation that the patient is now "uninsurable" because of erroneous documentation.

The PCP's progress note from February 2008 reflects that the patient voiced concerns about an increase in insurance premiums related to a urology report. No apparent action was taken to address that concern. In August 2008, the PCP documented that the patient complained of increased insurance rates related to erroneous documentation of heart problems. In response, it appears that the PCP ordered a chest x-ray which confirmed his clinical impression that the patient did not suffer from a heart condition. It is unknown whether the patient provided this information to his insurance company or what he may have been told about adjustments to his premiums.

Issue 5: Inadequate Communication

Complaint (g): We did not substantiate the allegation that medical center staff did not appropriately or adequately respond to the patient's complaints. The medical record documents multiple efforts to discuss and address the patient's concerns. As the patient remained dissatisfied, we found that the risk manager's decision to refer the patient to Regional Counsel to explore the Tort claim process was reasonable.

Conclusions

We did not substantiate the allegations of poor quality of care, delay in services, or inadequate communication, and we could not adequately evaluate allegations of financial hardship. We did confirm the allegation of erroneous documentation; however, actions were taken to remedy the condition. We made no recommendations and plan no further action. The VISN and Medical Center Directors concurred with our findings.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
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Appendix A

OIG Contact and Staff Acknowledgments

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Acknowledgments	Susan Zarter

Appendix B

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