Administrative Closure
Alleged Failure to Diagnose Renal Cancer
Charles George VA Medical Center
Asheville, North Carolina
MCI# 2010-00369-HI-0233

Background

We reviewed allegations of poor care, including delay in diagnosis of renal cancer, for a veteran at the Charles George VA Medical Center, Asheville, NC..

The medical center is an acute care facility and operates a separate Community Living Center (CLC). The center provides a full range of patient care services for a veteran population of approximately 99,000 within the VA Mid-Atlantic Health Care Network (VISN 6).

The veteran presented the Emergency Department (ED) in May 2009 with complaints of flank pain. After a computed tomography (CT) scan and liver biopsy he was diagnosed with metastatic renal cancer. His medical history included hypertension, diabetes mellitus, osteoarthritis (status post bilateral knee replacement), and anemia (colonoscopy showed diverticulitis and internal hemorrhoids). After diagnosis, the veteran was treated by an oncologist in the local community and was later admitted to the CLC for palliative care. He died on (b)(3):38 U.S.C. 5701 2009.

During our interview with the complainant, the following additional allegations of substandard care were raised:

- The veteran complained about blood in his urine for more than 1 year, yet providers failed to diagnose renal cancer.
- Providers failed to investigate chronic anemia, which would have led to the renal cancer diagnosis.
- Primary care providers did not provide proper continuity of care.
- The patient's leg was broken during knee replacement surgery, and this was not discovered until after the first post-operative physical therapy appointment.
- The CLC was understaffed, which resulted in substandard care and an unintended discharge of the patient from the CLC.
- While in the CLC the patient suffered a fall, yet no physician or mid-level provider visited him until after he died.

Scope and Methodology

We conducted an onsite inspection March 22–25, 2010, and reviewed pertinent documents which included Veterans Health Administration (VHA) and medical center policies and procedures, committee minutes, quality management documents, and the patient's medical

record. We conducted interviews of relevant clinical staff. We also interviewed the veteran's spouse and daughter.

Chronology of Care

September 2004: The veteran's initial visit to the medical center primary care clinic was for treatment of bilateral knee pain. He had diabetes mellitus, hyperlipidemia, tobacco abuse, and gastrointestinal reflux disease. No genitourinary issues were documented. He was referred to ophthalmology for an eye exam, to cardiology for an electrocardiogram (EKG), to patient education for diabetes care. He was also given fecal occult blood cards and a home blood pressure monitor.

November 2004: The veteran sought care for a callus on his left foot, plantar surface. The veteran would continue to be seen for minor foot care issues over the next 5 years – calluses and trimming of toenails. He also provided the Primary Care provider with results of a colonoscopy from 2001, which showed small hyperplastic polyps and mild sigmoid diverticulosis. In addition, he was taking cholesterol-lowering drugs.

February 2005: The veteran was seen for an annual physical examination. He complained of neck pain, bilateral knee pain, and increased hemorrhoid bleeding after bowel movements.

April 2005: In a primary care visit, the veteran again complained of blood in his stools. The provider examined the abdomen and rectum, noting no organomegaly, no distension, no masses, no external hemorrhoids, no bleeding, and a normal prostate. The provider recommended Sitz baths, stool softeners, and hemorrhoid pads, with follow-up in 2 weeks if the bleeding persisted, for possible colonoscopy.

September 2005: At his annual physical, the veteran complained of continued hemorrhoid and left knee problems. Again, his abdomen was palpated with no findings.

November 2005: The veteran began having problems seeing his computer screen. On exam, no diabetic retinopathy was detected. He was advised to return to the clinic in 2 years for another dilated fundus exam.

March 2006: After falling and twisting his left knee, the veteran was seen in primary care. His abdomen was examined, and again there were no findings. His knee was not tender or swollen.

April 2006: The veteran presented to the ED with fever, dysuria, and nocturia. The record specifically notes "no back pain or hematuria." On physical exam, his abdomen and testicles were normal. Urine tests did not reveal any hematuria - "Urine c/s [culture and sensitivity] neg." The EKG revealed sinus tachycardia. A urinary tract infection was diagnosed.

May 2006: On a follow-up visit, the veteran complained of nocturia and right groin discomfort. On exam it was noted "slightly tender right groin though area seems normal on exam. No inguinal hernias or adenopathy there, somewhat tender right lumbar area."

September 2006: The veteran's annual history and physical showed no complaints of abdominal pain, hemorrhoid irritation, dysuria, hematuria, or nocturia. The provider recommended x-ray of both knees and right hip and an evaluation by orthopedics.

October 2006: An orthopedic provider examined the veteran and scheduled him for knee surgery.

July 2007: The veteran underwent left total knee replacement for osteoarthritis. He had acute blood loss after the procedure and received infusions of packed red blood cells (PBRC).

September 2007: At a primary care visit for diabetes follow-up, the patient had no abdominal pain, dyspepsia, hemorrhoid irritation, dysuria, or hematuria. The veteran did describe nocturia.

April 2008: The veteran had a right total knee replacement. At some point intra-operatively, he suffered a non-displaced medial condyle fracture. He again required transfusion of PBRCs due to acute blood loss. Physicians discussed the iatrogenic injury with the veteran, who spent the next two months in the Extended Care and Rehabilitation Center at the medical center.

October 2008: Once again the veteran presented to the ED, this time with complaints of swelling in his lower extremities. A provider diagnosed dependent edema, hypertension, chronic nonproductive cough secondary to angiotensin converting enzyme inhibitor medication, osteoarthritis status post knee replacements, and anemia (based on hemoglobin drop from a September value of 12.4 to 10.3). The ED provider recommended a follow-up visit with Primary Care to further evaluate anemia. At the Primary Care visit, the veteran denied any palpitations, dizziness, pallor, hematuria, melena, or rectal bleeding. The provider recommended colonoscopy and possible esophagogastroduodenoscopy (EGD).

November 2008: A colonoscopy and EGD was performed with the following findings, respectively: scattered pancolonic diverticulosis, no polyps or masses identified, moderate internal hemorrhoids; and small, less than 1 centimeter, salmon-colored mucosa that extended above the z-line – probable Barrett's esophagus.

December 2009: In a follow-up appointment with orthopedics, the veteran noted that he was doing remarkably well and the provider noted that he was in great shape for his age. He also had capsule endoscopy, wherein several benign lymphangiectasia and an area of mild mucosal erythema in the mid-jejunum were noted; these findings were not considered medically significant.

March 2009: The veteran was seen in Primary Care to review the capsule endoscopy results and follow up on his medical conditions. He made no complaints about abdominal pain, change in bowel habits, or dysuria. The provider assessed iron deficiency anemia and recommended continued iron replacement therapy.

May 2009: The veteran presented to the ED the first week of May with complaints of right upper abdomen pain radiating to his right side that worsened with cough and touch. He denied any urinary symptoms and no masses were felt on palpation. The ED provider ordered abdominal series x-rays and laboratory tests. The x-rays revealed no abnormality and the urine test did not detect any blood. The veteran returned the next day for a CT scan, which revealed an 8 x 5 x 8 cm left renal mass "most likely due to renal cell carcinoma." The veteran was referred to a private oncologist for treatment. At the end of May, the veteran was admitted through the ED with complaints of fever, shortness of breath, and cough; and was hospitalized for 2 days.

June 2009: The veteran was admitted to the medical center for 5 days due to dehydration, bladder outlet obstruction, and pain. He had not tolerated well the morphine prescribed by his private oncologist. His medications were adjusted and the obstruction treated. He was referred for continued palliative care in the Hospice unit of the CLC.

July 2009: The veteran received chemotherapy in the Oncology Clinic and was found to be anemic. Two units of PRBCs were ordered; however, the transfusion could not take place in the oncology clinic so the veteran was admitted to a general medicine unit to complete the transfusion. Upon completion of the transfusion, he returned to the CLC.

October 2009: Chemotherapy was initiated, but was stopped at the veteran's request after he experienced mouth blisters. His wife and daughter visited him daily. He fell while using the toilet and was taken to the ED for examination and treatment, and fractures were ruled out. After this he was confined to his bed. He was examined by a physician assistant and a physician after his return to the CLC and a Foley catheter was placed. Opiate dosages were increased and the patient had some confusion and hallucinations. The veteran was in a "Do Not Resuscitate" status. The veteran continued to deteriorate and became unresponsive. His wife was with him at his bedside when he died.

Issues

Delay in the diagnosis of renal cancer:

We did not substantiate this allegation. The complainant contended that the veteran reported blood in his urine for at least a year prior to diagnosis and that the reporting of blood in the stool should have led to a medical work-up to rule out kidney problems and renal cancer. Our review of the medical record and interviews with relevant staff members did not reveal that the veteran complained of blood in his urine, nor do any of the urine tests which specifically looked

for hematuria support this allegation. Rather, the veteran had complained of blood in his stools and medical staff had taken appropriate steps to identify causes.

Renal cancer is traditionally described as presenting with hematuria, flank pain, and a flank mass. However, the complete triad is rarely found in renal cancer patients. (Grabstald, *CA Cancer J Clin 1966; 16: 102-110)* Forty percent of patients may present with gross hematuria and up to 80 percent may experience hematuria during the course of their disease. Half of patients present with flank pain or a palpable mass.

In 1996, 30,600 new cases of renal cell carcinoma were reported with 12,000 deaths. (Sokoloff, *CA Cancer j Clin 1996: 46: 284-302)* The classic triad was seen in only 10 percent of patients, and generally only those with advanced disease. In current practice, renal cancer is most often detected during routine imaging studies, referred to by physicians as "incidentalomas."

In a third of diagnosed patients, the cancer has already metastasized and the five-year survival rate is about 20 percent. (Sokoloff) The 9th Edition of *Campbell-Walsh Urology* notes that in the time since the publication of the Grabstald and Sokoloff studies, there has developed a greater understanding of the many "distinct subtypes" of renal cell carcinoma and the unique genetic basis and tumor biology. (Wein: *Campbell-Walsh Urology: Chapter 47; Renal Tumors, Section XII-Neoplasms of the Upper Urinary Tract. (9th Ed., 2007).* Renal cell cancer accounts for almost 3 percent of adult malignant neoplasms, and is the most lethal of the urologic cancers, with 40 percent of patients dying from the cancer. The incidence rate cited by *Campbell-Walsh* is 8.9 cases per 100,000 population per year (31,000 new cases each year in the United States, and 11,900 deaths), with a male-to-female predominance of 3:2; diagnosis is typically at 60 to 80 years of life. Tobacco use is a known risk factor.

"Because of the sequestered location of the kidney within the retroperitoneum, many renal masses remain asymptomatic and nonpalpable until they are advanced. With the pervasive use of noninvasive imaging for the evaluation of a variety of nonspecific symptom complexes, more than 50 percent of renal cell carcinomas are now detected incidentally." (Campbell-Walsh) The classic triad of flank pain, gross hematuria, and palpable abdominal mass is now rarely found.

Compbell-Walsh lists systemic syndromes associated with renal cell carcinoma (See Table 47-9). The most frequent syndromes are as follows.

Syndrome	Percentage
Elevated erythrocyte sedimentation rate	55.6
Hypertension	37.5
Anemia	36.3
Cachexia, weight loss	34.5
Pyrexia	17.2
Abnormal liver function	14.4

While the conditions cited in the table are associated with renal cancer, their presence alone would not necessarily lead to a diagnosis of renal cancer. The veteran described in this report did have hypertension and anemia.

The veteran was Stage IV at diagnosis, with cancer spread to other organs of his body. *Campbell-Walsh* cites survival rates from several studies (see Tables 47-13 and 47-14), with 5-year survival ranging from 2 to 20 percent. "Systemic metastases portends particularly poor prognosis for renal cancer, with a 1-year survival rate of less than 50 percent, a 5-year survival rate of 5 to 30 percent, and a 10-year survival rate of 0 to 5 percent." *(Campbell-Walsh)*

We did not find evidence that the veteran complained of hematuria. We did find evidence that providers inquired about hematuria and even conducted specific tests that would reveal it. From our review of medical records, laboratory tests, and witness interviews, we conclude that reasonable efforts were made to treat the veteran's many conditions and that an earlier diagnosis of renal cancer could not be expected.

Providers failed to investigate chronic anemia, which would have lead to renal cancer diagnosis:

We did not substantiate this allegation. Review of the veteran's hemoglobin and hematocrit levels indicate a general decline in values starting in 2006. Significant drops in these levels can be attributed to hemorrhoidal and post-operative bleeding. By July 2009, both the hemoglobin and hematocrit measurements (while still on the low end of the spectrum) had risen to their highest levels in almost 6 months. *Campbell-Walsh* notes that a third of renal cancer patients are anemic. While this association is observed in cancer patients, it is also associated with many other conditions; alone it would not lead a reasonable provider to attempt to rule out renal cancer or to include it as a differential diagnosis.

Primary Care providers ordered appropriate tests and recommended appropriate initial treatments for complaints of blood in stools. When the veteran presented to the ED in October 2008 providers observed a significant drop in hemoglobin and made appropriate referrals.

Primary care providers did not provide proper continuity of care:

We did not substantiate this allegation. The veteran saw a number of physicians in the primary care setting over the course of 5 years. We interviewed several of the providers who were still at the medical center and we interviewed the Chief of Primary Care. While standard of care and continuity of care were maintained with changes in primary providers, the physician-patient relationship may have deteriorated over time. The complainant stated, "how can a doctor treat a patient when the doctor only talks to the computer?" Clearly, the complainant

(b)(6)

The patient's leg was broken during knee replacement surgery, and this was not discovered until after first physical therapy appointment:

We substantiated this allegation. We interviewed the attending surgeon responsible for the conduct of the surgery and we reviewed medical records and quality management documents. Such a fracture is a known, yet remote, risk of the surgery and was discovered in post-operative x-rays. The case was discussed in the Surgery Department's Morbidity and Mortality (M&M) meeting and, in accordance with VHA policy, the injury was disclosed and discussed with the veteran and his wife in 2008.

The CLC was understaffed, which resulted in substandard care and an unintended discharge of the patient from the CLC:

We did not substantiate this allegation. Our review found that CLC staffing was reasonable for the number and acuity of patients. This particular instance of discharge was administratively recorded in the medical record to account for the veteran's transfusion of 2 units of PRBCs post-chemotherapy and his presence on a medical unit to complete the transfusion. Upon completion of the transfusion, the record shows a discharge from the hospital and return to the CLC.

While in the CLC, the patient suffered a fall, yet no physician or mid-level provider visited him until after he died:

We did not substantiate this allegation. The veteran was immediately examined by a physician in the ED after his fall.

The practice in the CLC is that all patients receive constant monitoring and treatment from the nursing staff. Patients with more critical health issues are examined by a physician assistant and, if necessary, referred to a physician. The medical record shows that the veteran was examined by a physician assistant after his fall and that his case was discussed at an interdisciplinary team meeting which included physicians.

<u>Conclusion</u>

While on-site, we discussed the case and our preliminary findings with the medical center leadership and the Director, who offered to meet and discuss the case with the complainant. We extended that offer to the complainant, but (b)(6) declined.

This veteran did not manifest the classic signs of renal cancer. Medical records do not contain reference to a patient complaint of blood in urine, but there are numerous references to blood in stools. The patient was referred for Gastroenterology (GI) consultation and underwent upper and lower endoscopy, plus capsule endoscopy. There was worsening of anemia over time, with marked drops after knee replacement surgery. A post-operative M&M was

completed for the intra-operative fracture of the medial femoral condyle and the attending surgeon discussed the case with patient and spouse.

After review of the medical records, quality assurance documents, relevant medical literature, and after conducting interviews with involved staff and medical center leadership, we have administratively closed this inspection.

/s/

RANDALL G. SNOW, J.D.
Director, Washington DC Region
Office of Healthcare Inspections

/s/

BRUCE BARNES
Health Systems Specialist
Washington DC Region
Office of Healthcare Inspections