Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality of Care Issues
Ralph H. Johnson VA Medical Center
Charleston, South Carolina

Report No. 09-02538-30 **November 30, 2009**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time, Monday through Friday, excluding Federal holidays

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Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections reviewed the validity of allegations regarding inpatient and end of life care at the Ralph H. Johnson VA Medical Center in Charleston, SC. At the request of Congressman Henry E. Brown Jr., we reviewed allegations from the widow of a deceased veteran that:

- The medical record contained inaccuracies and did not account for the last 20 minutes of the patient's life.
- The nursing staff placed the patient's walker out of reach and did not help him eat.
- The patient was kept "doped up" causing intestinal blockage.
- The patient's advanced directives were not followed and the complainant's wishes were disregarded even though she was the medical power of attorney.
- The patient's isolation room was filthy.

We did not substantiate any of the allegations. The medical record discrepancies contained inaccuracies; however, they were not relevant to the care provided. We determined that medical record documentation appropriately reflected the circumstances that took place in the final events of the patient's life. Due to the patient's medical condition, he was at risk for falls. Staff told us that if the walker was out of the patient's reach, it was done for patient safety as a reminder to call for assistance. The patient was unable to tolerate foods or liquids. Nutritional consumption by mouth was monitored and found to be insufficient and total parenteral nutrition was ordered for the duration of the hospitalization. The patient was receiving intravenous pain control. However, a surgery consultant noted that the partial small bowel obstruction (SBO) was secondary to adhesions versus recurrent cancer. An infectious disease consultant also noted that the SBO was likely due to tumor burden. An environment of care inspection of unit 4BN found the rooms to be clean, orderly, and free of biohazard waste on the floors.

The patient was medically complex with advanced stage transitional cell carcinoma that had metastasized to the lungs/rib. He was able to make his own decisions and wished to be resuscitated only if it had a reasonable chance of making him better. Physicians felt that due to his multi-organ system failure, widely metastatic cancer without prospect for further treatment, SBO without prospect for operative cure, and asystole, the patient's situation was medically futile regardless of code status. The patient and his wife endured a long and difficult struggle with his metastatic cancer. We concluded that the patient received appropriate care. Because we did not substantiate any of the allegations, we made no recommendations.

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

TO: Director, VA Southeast Network (10N7)

SUBJECT: Healthcare Inspection – Alleged Quality of Care Issues, Ralph H. Johnson Medical Center, Charleston, South Carolina

Purpose

At the request of Congressman Henry E. Brown Jr., Ranking Member of the U.S. House of Representatives, Committee on Veterans' Affairs, Subcommittee on Health, the VA Office of Inspector General, Office of Healthcare Inspections, conducted an inspection to determine the validity of allegations regarding the inpatient and end of life care of a patient at the Ralph H. Johnson VA Medical Center (the medical center) Charleston, SC.

Background

The medical center is a tertiary care facility that provides a broad range of inpatient and outpatient health care services. The medical center is affiliated with the Medical University of South Carolina and provides training for 82 full-time equivalent resident physicians, as well as training for other disciplines including Nursing, Psychology, Dietetics, Medical Technology, and Allied Health. It is part of Veterans Integrated Services Network (VISN) 7 and serves veterans throughout South Carolina and part of Georgia. The medical center has 75 hospital beds and 20 nursing home beds and is the parent facility for community based outpatient clinics in Beaufort, Goose Creek, Myrtle Beach, South Carolina and Savannah, Georgia.

We reviewed allegations from the widow (the complainant) of a deceased veteran (the patient) that her husband received poor care while an inpatient at the medical center in March 2009, which led to premature death. The complainant alleged that:

- The medical record contained inaccuracies and did not account for the last 20 minutes of the patient's life.
- The nursing staff placed the patient's walker out of reach and did not help him eat.
- The patient was kept "doped up" causing intestinal blockage.

- The patient's wishes regarding advanced directives were not followed and staff disregarded the complainant's wishes although she was the patient's medical power of attorney.
- The patient's isolation room was filthy.

Scope and Methodology

We interviewed the complainant by telephone on June 19 and 23, 2009, and conducted a site visit June 28 through July 1. We interviewed physicians, nurses, senior managers, a social worker, chaplain, quality manager, and other staff knowledgeable about the patient's care. We reviewed documents, policies and procedures, incident reports, and the patient's medical records. In addition, we conducted an unannounced environment of care inspection of Unit 4BN at the medical center. The complainant expressed an additional allegation regarding VA benefits which was outside the scope of our review. A contact number for VA Benefits was given to the complainant.

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

Case Summary

The patient was a male veteran in his early 60s, who was diagnosed with advanced stage transitional cell carcinoma of the bladder (bladder cancer) with metastases[1] to the lungs/rib with recurring malignant effusions[2] in the area of the right iliopsoas[3] muscle. The patient's medical history also included diverticulitis, hypertension, hyperlipidemia, anemia, chronic obstructive pulmonary disease, chronic kidney disease, peripheral vascular disease, occlusion and stenosis of carotid arteries for which he underwent carotid endarterectomy surgery complicated by a post-operative hematoma. Additional history included a deep venous thrombosis for which a Greenfield filter was placed. Prior to his last hospitalization in March 2009, the patient's chronic pain was generally managed with prescribed morphine administered through a patient controlled analgesia (PCA) device.

In 1992, at a non-VA facility, the patient was diagnosed with localized bladder cancer, for which he underwent local excision along with intravesicular[4] chemotherapy. He experienced multiple local recurrences treated in a similar fashion. At a non-VA facility in 1999, the patient underwent surgery to remove the bladder, prostate, right kidney, and appendix followed by bladder reconstruction.

[1] Metastases are cancer growths that originate from a primary site in the body and travel and grow in other sites.
[2] An effusion is an accumulation of fluid.
[3] The iliopsoas is a very strong muscle set that starts at the lower back and inserts into the thigh bone (femur).
[4] Intravesicular refers to chemotherapy delivered directly into the bladder.

In September 2006, a chest x-ray performed during the pre-operative evaluation for carotid endarterectomy surgery showed pulmonary lesions. Multiple bilateral pulmonary nodules were seen on a computerized tomography (CT) scan of the chest and a biopsy revealed that the bladder cancer had metastasized to the lungs.

The patient was evaluated by the hematology and oncology service in November 2006. At the time, the hematology oncology consultant discussed the diagnosis, prognosis, and treatment options with the patient and his wife. The consultant noted that his disease was incurable, since it was metastatic and typically an aggressive cancer. Due to his poor renal function he was not a candidate for systemic chemotherapy. The consultant recommended starting palliative chemotherapy and noted, "We hope and pray he will do well and that we can maximize his quality of life…His prognosis is quite poor."

Palliative chemotherapy was discontinued in December due to side effects, including worsening kidney function, confusion, fatigue, orthostasis, and anemia. A CT scan in March 2007 revealed interval development of several new pulmonary nodules with increase in size and density of previously identified nodules and a new bone lesion involving the sixth rib. In May 2007 an oncology consultant reviewed the clinical situation with the patient and his wife. The consultant felt that re-trying chemotherapy would be too risky. The consultant offered hospice care to the patient, which he and his wife declined. The consultant also discussed consideration of palliative radiation therapy if pain from the rib lesion became an issue.

At a follow-up visit in October 2007, the patient reported feeling easily fatigued with shortness of breath on exertion, along with right groin pain. An oncology consultant offered hospice to control symptoms. The patient agreed but requested re-imaging to assess his disease progression. The consultant ordered a CT scan of the chest and also a magnetic resonance imaging (MRI) study of the abdomen and pelvis. A CT scan done in late November showed resolution of almost all lung nodules, with a single nodule present in the superior segment of the right lower lobe; resolution of a small pericardial effusion noted on prior imaging; but continued presence of a mixed sclerotic and lytic lesion of the sixth rib. The patient had subsequently declined hospice care.

The MRI study of the abdomen and pelvis revealed a large fluid collection in the region of the right iliopsoas muscle. A CT scan of the abdomen showed abnormality of the right iliopsoas extending from hip to mid-abdomen retroperitoneum, thought most likely due to an enlarged bursa with secondary compression of local venous structures. He was referred to vascular surgery and orthopedics for consultation. The orthopedic consultant felt that bursitis was the likely etiology; however, given the patient's history of metastatic disease, follow-up imaging in 6 months was recommended.

The right hip pain continued and in May 2008, the patient was admitted for drainage of the fluid in the region of the right iliopsoas. Cytology of the drained fluid was positive for bladder cancer recurrence manifesting as an effusion. As the patient was

experiencing significant pain in the area, palliative treatment with radiation therapy (XRT) was discussed, and the patient was referred to radiation oncology where he underwent palliative XRT from late June to late July. Subsequent to this time period, the patient had several hospitalizations during which CT guided drainage of the iliopsoas effusion was performed with temporary relief.

At a February 2009 oncology visit, the physician documented presence of a new mass, contiguous with the iliopsoas fluid collection felt to represent local-regional progression of the patient's bladder cancer. The physician noted "he is not a candidate for surgical resection of that, he has already received irradiation in that area, and, he has been intolerant of chemotherapy in the past."

The patient was hospitalized three times in February and March. During the last week of February he presented with lethargy, poor appetite, malaise, shortness of breath, and an elevated white blood cell count. The patient was diagnosed with pneumonia, and the infectious disease consultant started him on an intravenous antibiotic regimen. He was discharged 2 days later, and home health was arranged for continuance of pain control and intravenous antibiotics.

Two days later, the patient was re-admitted to a Methicillan Resistant Staphylococcus Aureas (MRSA)[5] isolation room for worsening pneumonia, with weakness, nausea, vomiting, and shortness of breath. The pulmonary service was consulted, an echocardiogram was obtained to evaluate heart function, and a diuretic was prescribed for fluid overload from possible heart failure. Lower extremity Doppler studies and a ventilation and perfusion scan were also obtained to evaluate for possible pulmonary emboli and the patient was transfused for anemia.

During the first week of hospitalization, the antibiotic regimen was changed. A repeat CT scan showed scattered metastatic lesions and processes in the thorax, and dilated small bowel "and the level of obstruction may well be in the right lower pelvis in relation to the right illiopsoas [*sic* iliopsoas] region mass." As the patient appeared to have a partial small bowel obstruction, a surgical consult was obtained and a nasogastric (NG) tube was inserted for decompression.

By hospital day 10, the patient's respiratory status appeared to be slowly improving. The infectious disease service documented that the patient would likely continue to have recurrent infections due to presence of the underlying cancer. The patient remained weak and had multiple ongoing medical problems. A nutrition consult found his nutritional status to be severely compromised, with ongoing weight loss and inadequate nutritional

[5] A bacterium in the Staphylococcus family that can cause infections in different parts of the body. It is tougher to treat than most strains of bacterium due to resistance to most commonly used antibiotics.

intake. The patient could not tolerate foods, and total parenteral nutrition (TPN)[6] was ordered 3 days later.

On hospital day 10, he completed a course of antibiotics for the pneumonia but continued to have a significant supplemental oxygen requirement. Abdominal symptoms related to the small bowel obstruction (SBO) continued, but the patient was having small bowel movements and he reported that the abdominal discomfort was improving. He declined re-introduction of a NG tube which had fallen out 2 nights earlier.

On hospital day 20, plans for home based primary care services were discussed with the patient and his wife. The next day, he reported feeling "okay" but appeared short of breath, his white blood cell count had increased, though he was afebrile and his oxygen requirement had not reportedly changed. The plan was to follow the patient for signs of infection, initiate a fever work up if his temperature spiked, and transfuse the patient for his anemia.

On the morning of hospital day 22, the patient had increasing somnolence, worsening hypoxia with labored breathing, anasarca,[7] and hypotension. Antibiotics were ordered and started due to concern for possible sepsis.[8] A Medical Intensive Care Unit (MICU) physician evaluated the patient for transfer to the MICU. Levophed® (an intravenous medication used to increase blood pressure in critically ill patients) was also ordered. While arranging transfer, the patient stopped having spontaneous respirations and his pulse was non-palpable. An electrocardiogram (EKG) showed asystole.[9] Physicians at the bedside determined that due to his irreversible multi-organ system failure further intervention was not indicated.

Inspection Results

Issue 1: Medical Record Discrepancies

The complainant alleged that the medical record indicated that the patient had a gallbladder and prostate in one note and no gallbladder or prostate in another. The complainant also alleged that the medical record spoke of an "aunt" when the patient did not have an aunt, and "two" Purple hearts when the patient had one Purple Heart. Providers we interviewed reported the documentation reflected information as provided to them. While these discrepancies exist in the notes, they were not relevant to the care provided.

[6] TPN intravenously supplies the body with all daily nutritional requirements.
[7] This is a general accumulation of serous fluid in various tissues and body cavities.
[8] Sepsis is a condition in which the body is fighting a severe infection that has traveled via the blood stream. It is a potentially life threatening condition in which a patient's immune system's reaction to an infection may injure body tissues remote from the site of infection. Progressive sepsis can affect organ function and lead to septic shock, a sometimes fatal drop in blood pressure.
[9] Asystole indicates cardiac standstill with no cardiac output and no ventricular electrical activity.

Issue 2: End of Life Documentation

We did not substantiate the substance of this allegation.

The complainant alleged that at least 20 minutes in the last hour of the patient's life was unaccounted for in the documentation. The patient's official time of death was 8:10 a.m. Medical record documentation by a nurse signed at 7:38 a.m. (when the note was completed) indicated that his oxygen saturation and blood pressure were low and he was unresponsive. A resident physician's note signed at 8:12 a.m. indicated that the patient had been examined by the resident and the attending physician. Because of their concern for sepsis, antibiotics and a fluid bolus were ordered, and the MICU was contacted for transfer.

The MICU resident's note signed 8:28 a.m. states that the MICU team had been called regarding concern for sepsis. Upon their arrival, antibiotics had already been ordered, the patient had appeared critically ill with distended abdomen, weak peripheral pulses, and significantly low blood pressure. Intravenous fluid was increased to wide open, Levophed® was ordered, and arrangements were being made for transfer to the MICU.

A nursing note signed at 8:13 a.m. stated that the nurse entered the patient's room with another nurse to do shift change and joined a physician already at the bedside. The patient appeared to expire. The attending medicine physician who was down the hall was summoned. An EKG was applied showing asystole.

While the attending physician was writing his note, he was informed by a MICU physician that the patient had stopped breathing and had no pulse. They went to the patient's room "to determine if further intervention was possible."

Issue 3: Nursing Care Issues

We could neither substantiate nor refute the allegation that staff put the patient's walker where he could not reach it. Due to his medical condition, the patient was at risk for falls. Staff told us they could not recall the walker having been placed out of reach. However, they suggested that if the walker was found out of the patient's reach, it would have been done so for patient safety, as a reminder to call for assistance should the patient want to get out of bed.

We did not substantiate the allegation that staff did not help the patient eat. During his hospitalization the patient was unable to tolerate foods or liquids. Diet orders throughout his hospital course fluctuated between nothing by mouth, clear liquids, full liquids, and for 2 days a regular diet (patient request) which he could not tolerate. Consumption by mouth was monitored and found to be insufficient for adequate intake. In mid-March, TPN was ordered for the duration of the hospitalization.

Issue 4: Partial Small Bowel Obstruction

We did not substantiate the allegation that the patient was overmedicated with Dilaudid® (hydromorphone) causing his SBO.

At the time of his last hospitalization in March, he had been on PCA morphine since January 2009. Early in the hospitalization, he was switched from Morphine to Dilaudid® for better pain control and the patient reported significant pain relief with the Dilaudid®.

Four days later, a CT scan of the abdomen was completed to evaluate abdominal symptoms present since admission. The CT report indicated small bowel dilation located in the right lower pelvis near the iliopsoas mass. The surgical service was consulted and a NG tube was placed for treatment of a SBO.

The following day, a nurse documented that the patient's wife was upset with the use of Dilaudid® for pain control. The Dilaudid® was discontinued and morphine was started.

Although pain medication, before and during hospitalization, could have contributed to the patient's constipation, it was the surgery consultant's assessment on hospital day 11, that the patient's abdominal symptoms and the dilated loops of bowel seen on CT scan were due to a SBO secondary to adhesions. An infectious disease consultant noted that the SBO was likely due to tumor burden.

Issue 5: End of Life Care and Medical Power of Attorney

The patient had a General Durable Power of Attorney naming his wife as his healthcare agent "if and when" he was unable to speak for himself. Staff interviews and medical record documentation indicate the patient was capable of making decisions for himself.

The patient's advanced directive regarding code status alternated between full code and Do Not Resuscitate (DNR) during his final hospitalization.

On hospital day1, a resident physician documented,

> …[the patient] is a very sick man with multiple comorbidities which include progressing metastatic bladder cancer. He is severely malnourished and the slightest insults are now sending him to the hospital. During this hospitalization a family meeting should be arranged that involves the patient and his wife, the medical team, palliative care, and case manager and the pts [*sic* patient's] own insight into his illness should be explored. As of now, he remains full code.

On hospital day 5, the patient requested and was given a DNR code status. On hospital day 6, the infectious disease fellow had an extensive discussion with the patient and his wife about his condition and noted "…they are not clear about the resucitation [*sic* resuscitation] wishes and wish to discuss further with his [treatment] team." On the same

day a medicine resident physician documented a disparity in end of life wishes between the patient and his wife.

On hospital day 7, the attending physician documented in the medical record, "Patient has rescinded his DNR at the request of his wife. The patient clearly has decision making capacity and wishes to be DNR … Wife is not present this AM so I will try to visit with her sometime today. We will consider an ethics consult Monday."

On hospital day 9, the attending physician reviewed the patient's current medical situation and code status with the patient and his wife,

> I brought up the subject of DNR since [patient] had expressed his wish to be DNR to me previously but had recently recinded [*sic* rescinded] the DNR at the request of the wife. This was my first opportunity to have the discussion with the wife present. I told them that I felt that if he was found unresponsive with either lack of respirations or lack of pulse that there would be no chance that resucitation [*sic* resuscitation] would change the prognosis and that he would never leave the hospital… The pt [*sic* patient] states that he and his wife's wishes are one and the same…He stated that he wanted everything done as long as it had a reasonable chance at making him better…He chose his words carefully at which time the wife stated that 'he is not DNR and that is it'…Once [the wife] left [the patient] asked that certain parts of his care be unrevealed to his wife specificly [*sic* specifically] the dilaudid PCA. We recently went up on the dose which helped his pain appreciably. I told the pt from now on that we would talk with him, alone, prior to sharing any of his medical information with his wife.

On hospital day 11, an Ethics Committee consultation was documented. The committee concluded that the patient was a capable decision maker at the time and the treatment team should continue to reinforce the patient's abilities to make his own health care decisions.

On the morning of hospital day 22, the patient was minimally responsive to stimulus with labored breathing, diffuse ronchi, anasarca, multi-organ system failure, possible sepsis, and low blood pressure. The patient became unresponsive, stopped breathing, and had no palpable pulse. The cardiac monitor revealed asystole. As per Advanced Cardiac Life Support protocol, asystole is not a shockable rhythm; therefore, cardioversion was not indicated.

The patient's treating physicians determined that due to his multi-organ system failure, metastatic cancer without prospect for further treatment, SBO without prospect for operative cure, and asystole, the patient's situation was medically futile irregardless of code status. Although the patient was full code status, the physicians involved reported

that they did not feel that aggressive intervention with medication or intubation would have been medically indicated or fruitful.

Issue 6: Environment of Care

We did not substantiate or refute the allegation that the condition of the patient's isolation room was filthy. The patient's isolation room was located on Unit 4BN across from the nurses' station and nurse manager's office. This unit had been recently renovated and reopened in September 2008. The complainant brought her cleanliness concerns to the attention of the Associate Director. The Associate Director told us that after receiving this complaint, unannounced inspections of the patient's room were initiated to monitor for room cleanliness. During our site visit, we conducted an unannounced environment of care inspection of unit 4BN and found the rooms to be clean, orderly, and free of biohazard waste on the floors.

Conclusions

The patient and his wife endured a long and difficult struggle with his metastatic cancer. We concluded that the patient received appropriate care. We did not substantiate the complainant's allegations. We made no recommendations.

Comments

The VISN and medical center Directors concurred with our findings and we made no recommendations (see Appendixes A–B, pages 10–11 for the full text of their comments).

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 26, 2009

From: Director, VA Southeast Network (10N7)

Subject: **Healthcare Inspection – Alleged Quality of Care Issues at the Ralph H. Johnson VA Medical Center, Charleston, SC**

To: Assistant Inspector General for Healthcare Inspections

I fully concur with the findings of this report.

(original signed by:)

Lawrence A. Biro

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: 10/15/09

From: Acting Director, Ralph H. Johnson VA Medical Center (534/00)

Subject: **Healthcare Inspection – Alleged Quality of Care Issues at the Ralph H. Johnson VA Medical Center, Charleston, SC**

To: Director, VA Southeast Network (10N7)

1. I have reviewed the draft report of the Inspector General's Healthcare Inspection regarding alleged Quality of Care Issues at the Ralph H. Johnson VA Medical Center. We concur with the findings.

2. I appreciate the opportunity for this review as a continuing process to improve the care to our veterans.

(original signed by:)

John S. Goldman

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Virginia L. Solana, RN, MA, Director Denver and Los Angeles Offices of Healthcare Inspections (303) 270-6500
Acknowledgments	Clarissa B. Reynolds, CNHA, Team Leader Wilma I. Reyes, MD Laura L. Dulcie, BSEE Michael L. Shepherd, MD

Appendix D

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