Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Quality of Care Issues
VA Medical Center
Birmingham, Alabama

Report No. 07-02106-38 **December 13, 2007**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an evaluation in response to allegations that a cancer patient received inadequate care at the VA Medical Center (the medical center) in Birmingham, Alabama. The complainant alleged that her sister, who has Stage IV ovarian cancer, did not receive appropriate cancer treatment and services from the medical center.

We did not substantiate that medical center providers failed to consult with the patient's University of Alabama (UAB) oncologist regarding her treatment regimen. The medical center's clinical case manager obtained the patient's UAB treatment plan, and the oncology resident discussed the patient's case with her UAB oncologist prior to initiating treatment. We did not substantiate that medical center staff failed to complete necessary laboratory tests, although we did find that there was a delay in forwarding laboratory test results to UAB. The patient still received her chemotherapy treatment as scheduled. We could not confirm or refute the allegations that a nurse did not assure the patient's privacy and that she failed to use sterile technique when initiating treatment on April 10. We determined that nursing procedures, along with the chemotherapy suite's physical layout, promoted visual privacy when needed. In addition, all three oncology nurses were trained and competent in the use of sterile technique.

We did not substantiate the allegation that there was a delay in filling the patient's prescription; she received her medication within 30 minutes of the physician's order. In addition, Pharmacy staff followed protocol when they declined to fill a non-formulary pain medicine. An alternate pain medicine on formulary was provided.

We could not confirm or refute the allegation that some medical center staff were disrespectful, although the patient and complainant perceived this. The medical center's staff followed regulations by denying Fee Basis authorization for the topotecan treatment as it was a chemotherapy treatment available at the medical center. When it became clear that the patient was not satisfied with the medical center's oncology services, arrangements were immediately made for her to resume chemotherapy at UAB. We believe that the medical center took the appropriate actions to ensure the physical and emotional well-being of the patient. We made no recommendations.

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

TO: Director, VA Medical Center, Birmingham, Alabama (521/00)

SUBJECT: Healthcare Inspection – Alleged Quality of Care Issues at the VA Medical Center, Birmingham, Alabama

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an evaluation in response to allegations that a cancer patient received inadequate care at the VA Medical Center (the medical center) in Birmingham, Alabama. The complainant alleged that her sister, who has Stage IV ovarian cancer, did not receive appropriate cancer treatment and services from the medical center. She specifically alleged that medical center providers:

- Did not consult with the patient's private oncologist at the University of Alabama (UAB).
- Did not order necessary laboratory tests.
- Lost important laboratory test results.
- Compromised the patient's privacy.
- Did not use sterile technique when administering chemotherapy.
- Did not fill one prescription in a timely manner, and would not fill another prescription at all.

She also alleged that providers and managers did not show respect for the patient and her family.

The purpose of the review was to determine whether the allegations had merit.

Background

The medical center is a tertiary care facility that is part of Veterans Integrated Service Network (VISN) 7. The medical center has 144 operating beds and provides inpatient and outpatient care, including oncology services, to veterans of Alabama and surrounding states. The medical center operates six Community Based Outpatient Clinics (CBOCs) in northern Alabama.

Fee Basis

The VA Fee Basis Program allows VA to pay for services provided outside a VA medical facility. Fee Basis can pay for virtually any treatment a veteran needs that the VA medical center cannot provide (for example, specialty services not available through VA) or when travel to the medical center would be too difficult for a frail veteran. The approval process for inpatient and outpatient Fee Basis services purchased by the VA is as follows:

- The VA provider requests Fee Basis services for the patient.
- The VA Clinical Coordinator for Contracted Services (CCCS) establishes services with the Fee Basis provider.
- The VA Fee Basis clerk prepares an authorization for payment of services.
- The Fee Basis provider delivers the requested services.
- The Fee Basis provider sends the invoice and appropriate documentation of the service rendered to the VA for payment.
- The VA Fee Basis clerk processes the payment.
- Fee Basis clinical documents are scanned into the patient's VA medical record.

Chemotherapy

Chemotherapy is a treatment that uses drugs to kill cancer cells. Treatment protocols vary depending on the type of cancer. Protocols often entail weekly treatments (called a chemotherapy cycle) followed by a few weeks of no treatment. Prior to each chemotherapy treatment, specific laboratory tests are completed to monitor the patient's tolerance.

Scope and Methodology

We conducted a site visit June 25–26, 2007. We interviewed medical center and UAB clinical care providers, administrative staff, and other staff knowledgeable about the

patient's care. Prior to our visit, we interviewed the complainant, the patient, and VISN 7 staff. We reviewed relevant medical center and VA policies, patient medical records, quality management documents, and other medical center documentation pertinent to the allegations. We also inspected the chemotherapy suite and observed chemotherapy administration practices.

This review was performed in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Summary of Events

The patient is a 49-year-old female Iraq war veteran diagnosed with metastatic ovarian cancer while serving in the U.S. Army in 2005. During 2005–2006, the patient underwent a total abdominal hysterectomy and several cycles of chemotherapy at UAB. Due to illness, the patient was unable to work and maintain her civilian medical insurance benefits. Anticipating that her private insurance would expire in 6 months, she enrolled for care at the VA medical center in April 2006. She was seen at the medical center on April 25, 2006, for an initial screening appointment with a primary care nurse and was seen on August 24 by her VA primary care physician. While enrolling in various VA clinics, she continued to receive chemotherapy at UAB.

On October 25, the medical center's Chief of Oncology evaluated the patient to prepare for her transfer of care from UAB to the VA. Upon evaluating the patient's treatment plan from UAB, the oncologist determined that the medical center did not have the expertise to provide the specialized intraperitoneal[1] chemotherapy the patient was receiving at UAB. Therefore, the oncologist requested Fee Basis approval for the patient to complete her remaining intraperitoneal chemotherapy treatment at UAB. On November 7, Fee Basis services were authorized for UAB to provide the final intraperitoneal chemotherapy treatment. Fee Basis services were again authorized in February and March 2007 for the patient to receive mammogram screenings, follow-up studies, laboratory testing, and a 3-day hospitalization at UAB.

In April 2007, the patient's UAB oncologist requested Fee Basis authorization for additional chemotherapy treatment cycles to be administered at UAB. The medical center's oncologist reviewed the request and determined that the planned topotecan[2] treatment was standard chemotherapy available at the medical center and denied Fee Basis treatment.

The patient and complainant expressed dissatisfaction about the Fee Basis denial and noted their concern about transferring the patient's oncology care from UAB to VA. The Patient Advocate met with the patient and encouraged her to "give the medical center a

[1] Within the lining of the abdomen.
[2] A type of chemotherapy drug.

chance." The patient received one chemotherapy treatment at the medical center on April 10. While there were no apparent concerns expressed by the patient during her treatment, the patient, complainant, and other family members complained to the Patient Advocate shortly thereafter about the Fee Basis denial, as well as privacy and quality of care issues related to her April 10 treatment.

The medical center Director and the Patient Advocate met with the patient and determined that to promote her overall physical and emotional health, she should return to UAB for chemotherapy treatments. The medical center Director authorized the patient's Fee Basis treatment to be resumed at UAB. On April 16, the patient had laboratory tests completed at the Oxford CBOC, and on April 18, the patient received her next chemotherapy treatment at UAB.

As a result of the medical center Director's decision, Fee Basis staff revised the original authorization to cover all "cancer-related treatments" from November 7, 2006, through September 30, 2007.

Inspection Results

Consultation. We did not substantiate the allegation that medical center providers did not consult with the patient's UAB oncologist regarding her treatment regimen.

In preparation for the patient's eventual transfer of care to the medical center, the CCCS obtained a copy of the patient's UAB treatment plan in October 2006. Based on this document, the VA Chief of Oncology determined that the medical center could not provide the specialized intraperitoneal chemotherapy the patient was receiving at the time. Fee Basis was approved for the patient to continue her treatments at UAB. When UAB requested a new Fee Basis authorization in April 2007 for a new cycle of chemotherapy, the CCCS obtained a copy of the patient's current UAB treatment plan and appropriate medical records. The Chief of Oncology determined the medical center would be able to provide the prescribed topotecan treatments; thus, the Fee Basis request was denied in accordance with VA regulations.

The medical center oncology resident who evaluated the patient in clinic on April 10, 2007, told us that she contacted the UAB oncologist who agreed with her plan to order laboratory tests and imaging studies prior to administering chemotherapy. The patient's UAB oncologist confirmed that medical center staff consulted him regarding the patient's care.

Laboratory Tests. We did not substantiate the allegation that medical center staff failed to order necessary laboratory tests. The complainant alleged that on April 16, 2007, laboratory evaluation for the patient consisted only of testing for CA125[3] and did not

[3] A tumor marker used in the management of suspected or established ovarian cancer.

include a complete blood count (CBC) and a comprehensive metabolic panel (CMP). Our record review revealed that a CBC, CMP, and CA125 were all completed as ordered on April 16.

Laboratory Results. We did not substantiate the allegation that providers lost laboratory test results that were needed prior to chemotherapy. However, there was a delay in forwarding the patient's laboratory test results to UAB. The patient had blood drawn for laboratory tests at the Oxford CBOC because it was near her home. The patient expected the CBOC to fax the laboratory test results to her UAB oncologist for his review prior to her next chemotherapy treatment on April 18. On April 18, the laboratory results (from the April 16 laboratory tests) had not arrived at her UAB physician's office. The patient notified the CBOC and signed another authorization to release the laboratory test results. CBOC staff verbally confirmed the laboratory test results to UAB, and the patient received her chemotherapy treatment as scheduled on April 18. We found no evidence that the problem recurred.

Privacy. We could not confirm or refute the allegation that staff in the chemotherapy suite compromised the patient's privacy. The patient and the responsible nurse described events differently.

The complainant and patient alleged that a nurse did not close the privacy curtain before she accessed the patient's Port-a-Cath®[4] (located in the patient's upper left chest). They alleged that as a result, the patient's left breast was exposed in front of male patients.

The oncology nurse told us that in preparation for the chemotherapy treatment, the patient exposed her Port-a-Cath® before the curtains were drawn, but that her breast was not visible. The nurse told us that she drew the curtains closed for privacy while initiating the chemotherapy treatment and then opened the curtains so that the patient could talk to the other veterans receiving chemotherapy. Staff told us that the patient did not express any complaints and noted that she was knitting and talking with the other patients.

While we could not say with certainty what happened on the day in question, we noted that the chemotherapy suite is designed to allow for patient privacy but also promotes patient socialization. The suite contained six chairs and a stretcher, each separated by privacy curtains. The oncology nurse told us that their routine practice is to close privacy curtains when accessing a patient's Port-a-Cath® and then open the curtains to allow conversation among the patients.

Sterile Technique. We could not substantiate the allegation that the nurse did not use sterile technique when starting the patient's chemotherapy treatment. Sterile technique is a process used to exclude microorganisms from the infusion site.

[4] A Port-a-Cath® is the brand name of a common type of central venous access device.

We could not determine exactly what occurred on April 10. However, during our visit we observed an oncology nurse using sterile technique as required by medical center policy. The chemotherapy suite has three nurses who administer chemotherapy. We reviewed all three oncology nurses' competency folders and found each had received appropriate annual training, and all were competent to perform their duties as validated by a supervisor.

Pharmacy Timeliness and Responsiveness. We did not substantiate the allegation that pharmacists did not fill a prescription in a timely manner on April 10, 2006. The complainant alleged that the patient's anti-nausea prescription was not filled until 5:00 p.m. During the patient's chemotherapy treatment, the physician entered the order for anti-nausea medication at 4:21 p.m., and the prescription was filled by the pharmacy at 4:51 p.m. Pharmacy Service performance improvement documents showed that for the period October 2006–June 2007, the average time to fill an outpatient prescription was 20 minutes.

The complainant also alleged that the medical center Pharmacy would not fill a prescription for OxyContin® (a pain medication prescribed by her oncologist at UAB) because the medication was not on the medical center's formulary.[5] The patient was allegedly told that her UAB physician should prescribe another medication for pain. Pharmacy staff confirmed that OxyContin® is not on the medical center's formulary, which complies with VISN 7 policy. The patient returned to the medical center on May 9 with a prescription for morphine, which was on formulary, and the prescription was filled. Medical center pharmacists followed policy related to non-formulary medication requests and the patient received appropriate medication for pain.

Interactions with Staff. We could not confirm or refute the allegation that some medical center staff did not treat the patient or her family with respect. The complainant alleged that one of the medical center's oncology residents and the medical center Director made disrespectful comments to the patient, and that the Patient Advocate and a social worker did not return her telephone calls and/or respond to e-mail messages.

The complainant stated that on April 10, the oncology resident that cared for her sister at the medical center had a "sarcastic and hateful attitude." The oncology resident confirmed that her encounter with the patient was somewhat tense. She told us that she had difficulty assessing the patient because the patient's family members kept interrupting with questions and demands. At one point, the oncology resident asked a nurse to be present for the remainder of the assessment because of the strained communication with family members.

[5] A list of approved medications that may be dispensed by the medical center's pharmacy.

The medical center Director confirmed that he discussed services with the patient in the presence of the Patient Advocate, but denied making any disrespectful comments. He stated that it was immediately apparent to him that the patient and complainant would not be satisfied with the medical center providing the patient's chemotherapy. He told us that for the patient's physical and emotional health, he promptly reauthorized Fee Basis payment so that she could return to UAB for chemotherapy treatments. The medical center Director and Patient Advocate reported that the patient appeared satisfied with the medical center Director's decision to reauthorize Fee Basis services at UAB.

The Patient Advocate told us that she had multiple contacts with the patient which she perceived as positive. She reported that she had only one early encounter with the complainant about establishing her sister's benefits, and that the problem was resolved. She reported that to her knowledge, she had responded to all of the patient's telephone calls. She denied ever receiving telephone calls or e-mails from the complainant.

We found no documented evidence that a social worker was involved in this case, nor did we find evidence that any medical center social worker spoke with, or was otherwise contacted by, the complainant or patient.

Conclusion

We did not substantiate that medical center providers failed to consult with the patient's UAB oncologist regarding her treatment regimen. The medical center's CCCS obtained the patient's UAB treatment plan, and the oncology resident discussed the patient's case with her UAB oncologist prior to initiating treatment. We did not substantiate that medical center staff failed to complete necessary laboratory tests. Although we did find that there was a delay in forwarding laboratory test results to UAB on one occasion, the patient received her chemotherapy treatment as scheduled. We could not confirm or refute the allegations that a nurse did not assure the patient's privacy and that she failed to use sterile technique. We determined that nursing procedures, along with the chemotherapy suite's physical layout, promoted visual privacy when needed. In addition, all three oncology nurses were trained and competent in the use of sterile technique.

We did not substantiate the allegation that there was a delay in filling the patient's prescription; she received her medication within 30 minutes of the physician's order. In addition, Pharmacy staff followed protocol when they declined to fill a non-formulary pain medicine; an alternate pain medicine was provided.

We could not confirm or refute the allegation that some medical center staff were disrespectful. The medical center's staff followed regulations by denying Fee Basis authorization for the topotecan treatment because it was a chemotherapy treatment available at the medical center. When it became clear that the patient was not satisfied with the medical center's oncology services, arrangements were immediately made for her to resume chemotherapy at UAB. We believe that the medical center took the

appropriate actions to ensure the physical and emotional well-being of the patient. We made no recommendations.

Comments

The VISN and Medical Center Directors agreed with our findings. No follow-up actions are planned.

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

Appendix A

OIG Contact and Staff Acknowledgments

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Contributors	Annette Robinson, Healthcare Inspector Jerome Herbers, M.D.

Appendix B

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