Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-00467-202

Healthcare Inspection

Substandard Care of a Lupus Patient at the Albany CBOC and Carl Vinson VA Medical Center Dublin, Georgia

July 1, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to complaints about mismanagement of patient care at the Carl Vinson VA Medical Center (the facility), Dublin, GA, and the contractor-operated Albany community based outpatient clinic (CBOC). Because of limitations in the contract, we could not fully evaluate some of the issues that were central to this case.

We did not substantiate the allegation that a patient with systemic lupus erythematosus (lupus) was not promptly treated for a urinary tract infection (UTI) and that the infection contributed to her death. The patient did not have test results consistent with a UTI. We do not know the precise cause of death, but the patient had laboratory evidence consistent with increased lupus activity in the month preceding her death. While facility and contract CBOC providers were aware of the patient's lupus diagnosis, neither acknowledged this significant clinical finding in their progress notes nor consulted a rheumatologist for follow-up.

We could not substantiate that the patient was told that the facility would not pay for further care with a private-sector rheumatologist. We were unable to interview the Albany CBOC providers or their supervisors, but the patient's electronic health record in the 9 months prior to her death did not reflect discussion of the need for reauthorizing Non-VA care. Therefore, we could not say specifically what the patient was *told* about future Non-VA care. Based on medical record documentation, it did not appear that either of the Albany CBOC physician assistants who cared for the patient in 2011–2012 ensured that she received appropriate continuity of rheumatology care.

Responsible facility clinicians and managers did not comply with guidelines for completing peer reviews, and as a result, the peer review of this case did not address the full scope of quality issues contributing to the patient's outcome.

We recommended that the facility develop a system to ensure appropriate follow-up on Non-VA care consults; follow policies for conducting and completing peer reviews; evaluate the VA care provided to this patient and determine the need for possible disclosure; and ensure that an individual patient's clinical complexity is considered when assigning a primary care provider.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 7–11 for the Directors' comments.) We will follow up on the planned actions until they are completed.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to evaluate allegations of patient care mismanagement at the Carl Vinson VA Medical Center (the facility), Dublin, GA, and the Albany community based outpatient clinic (Albany CBOC). The purpose of the review was to determine the merit of the allegations.

Background

The facility is a 34-bed secondary care center located in Dublin, GA, that provides a broad range of inpatient and outpatient medical and mental health services. The facility has five CBOCs located in Albany, Brunswick, Macon, Milledgeville, and Perry, GA. The Albany CBOC, located approximately 98 miles southwest of the facility, is staffed with physicians, nurse practitioners, and physician assistants (PAs) who are employed by a local health maintenance corporation (HMC). These providers deliver primary care and associated services to eligible veterans through a contract between the facility and the HMC.

Systemic lupus erythematosus (lupus) is a chronic, inflammatory, autoimmune disease in which the immune system attacks the body's own organ systems, resulting in inflammation and tissue damage. Lupus can affect multiple organs including the skin, blood vessels, heart, lung, kidneys, and nervous system. The course of the disease is unpredictable, with periods of illness (called *flares*) alternating with periods of quiet inactivity. Lupus patients have characteristic immunologic abnormalities and may have a compromised immune response due to the disease itself and/or the effects of the pharmacologic agents used in treating the condition. Lupus is managed with corticosteroids and other agents that may suppress the body's immune response. There is no cure for lupus and the condition can be fatal. Because it is a chronic and complex disease, lupus requires treatment by, or consultation with, a rheumatologist.[1,2]

Allegations

On September 26, 2013, the OIG received an e-mail from a complainant alleging that a patient:

- Was not promptly treated for a urinary tract infection (UTI),[3] which contributed to her premature death.

[1] http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/lupus.asp, accessed March 31, 2014

[2] A rheumatologist is a specially trained physician with expertise in the diagnosis and medical management of patients with select inflammatory conditions, often autoimmune (such as lupus) affecting the joints, muscle, bone, and various internal organs.

[3] A UTI is an infection in any part of the urinary system—kidneys, ureter, bladder, or urethra. http://www.mayoclinic.com/health/urinary-tract-infection/DS00286, accessed December 9, 2013.

- Was told that the facility would not pay for the further services of a private-sector rheumatologist.

Although not an allegation, we also evaluated selected aspects of the facility's internal review of the case.

Scope and Methodology

We conducted a site visit to the facility December 11–12, 2013. We interviewed the complainant and reviewed the patient's electronic health record (EHR); relevant Veterans Health Administration (VHA) and facility policies, directives, and handbooks; patient advocate reports; quality management documents; and a physician assistant's scope of practice. During our site visit, we interviewed the Chief of Staff, Chief of Non-VA Care Services, Chief of Pharmacy, and Chief of Pathology and Laboratory Medicine Service. We also interviewed nursing staff, patient representatives, and the Director of Primary Care. We interviewed, via telephone, the patient's former private-sector rheumatologist.

Because a portion of the patient's care was at the Albany CBOC, we attempted to interview Albany CBOC staff and review their policies and practices. However, the contract between the facility and the HMC did not contain a provision requiring the contracted staff to talk with us or allow us to review their records. The contractor, based on advice of counsel, would not allow us to access the facility to review records or interview staff and we had no statutory authority to compel compliance with our request for interviews. Because of these limitations, we could not fully evaluate some of the issues that were central to this case.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Case Summary

In 2006, a private-sector rheumatologist diagnosed a female patient in her 30s with lupus and started her on a regimen of anti-inflammatory, immunosuppressive medications. The private-sector rheumatologist told us that he evaluated the patient at 3–6 month intervals from 2006 through 2010. The facility authorized these visits because rheumatology care was not reasonably available to this patient within the VA system.[4]

The patient's last visit with the private-sector rheumatologist occurred in February 2011, when her condition was described as "stable," with no change to her treatment plan. The patient did not keep a follow-up appointment in May, and she cancelled a subsequent appointment scheduled for August 16.

According to the EHR, the patient's assigned primary care provider at the Albany clinic, a physician assistant (PA-1), evaluated her for sinus congestion in late August 2011. During this visit, PA-1 referenced the patient's diagnosis of lupus, commenting that she was "…seeing a local rheumatologist. She states she is currently doing well, but needs another referral." PA-1's plan included "lupus/new referral," but the EHR does not reflect that a rheumatology referral was made that day or on a subsequent day.

A second physician assistant, PA-2, saw the patient at the Albany CBOC in May 2012, for a routine visit to assess chronic health issues, including lupus. During this visit, PA-2 described the lupus condition as "stable," though laboratory data obtained that day revealed worsening anemia and the presence of proteinuria.[5] We found no further reference to the patient's lupus or need for a rheumatology referral. According to PA-2's plan of care, he/she advised the patient to return to the Albany CBOC in 1 year.

In early June 2012, the patient attended a follow-up visit in the Women's Health (WH) Clinic at the facility. The WH provider ordered a urinalysis, which revealed abnormalities of increasing proteinuria and 28 red blood cells not menstrual-related.[6] The WH provider judged the urine profile as "showing some infection" and ordered antibiotics for the patient with delivery to the patient's home. We found no mention of increasing lupus activity or need for rheumatologic care. Four days later, the patient died at home. The next-of-kin declined an autopsy.

[4] The facility could not produce the invoices back to these dates due to a change in recordkeeping systems; however, facility staff confirmed that the patient had previously been authorized for private-sector rheumatology care.
[5] Proteinuria occurs when protein molecules in the circulating blood spill into the urine; proteinuria may indicate inflammation or structural damage in the kidneys, which allows "leakage" into the urine.
[6] Normal urine contains 0-2 red blood cells per high-powered field under a microscope. The finding of 28 red blood cells unassociated with menstruation in a patient with lupus raises the specter of lupus actively affecting the kidney.

Inspection Results

Issue 1: Quality of Care

UTI

We did not substantiate the allegation that the patient was not promptly treated for a UTI and that the infection contributed to her death. Urinalyses conducted in May and June 2012 (4 days prior to the patient's death) were both negative for the presence of significant "nitrite"[7] and "leukocyte esterase."[8] Neither urine profile was suggestive of, or consistent with, a UTI.

The WH provider prescribed antibiotics when test results were not consistent with an infection. The WH provider had retired at the time of our visit and was unavailable for interview.

Lupus Flare

Without an autopsy, the precise cause of the patient's death remains uncertain. During the course of our review, however, we found that the patient had clinical signs consistent with increased lupus activity in the month preceding her death. The patient developed a significant anemia in May 2012, and urinalysis results showed progressive protein leakage and an increasing number of red blood cells. These findings are highly suggestive of lupus activity with kidney involvement, especially in a patient with a known diagnosis of lupus.

While both PA-2 and the WH provider were aware of the patient's lupus diagnosis, neither acknowledged this significant clinical finding in their progress notes nor consulted a rheumatologist for follow-up care.

Issue 2: Access to Non-VA Care

We could not substantiate that the patient was told that the facility would not pay for further care with a private-sector rheumatologist. Non-VA Care is a program that allows VA facilities to preauthorize and pay for specialty services that are not reasonably available through a VA health care system.[9] In this case, the facility had authorized the patient to see a private-sector rheumatologist near her home for several years.

We were unable to interview the Albany CBOC providers or their supervisors, but the patient's EHR in the 9-months prior to her death did not reflect discussion of the need for reauthorizing Non-VA care. Therefore, we could not say specifically what the patient was *told* about future Non-VA care. Facility staff confirmed that, in general, patients

[7] Urine nitrite is a screening test to detect a substance present in the urine of many patients with the common bacteria causing UTIs.
[8] Leukocyte esterase is a screening test to detect white blood cells in urine and is usually positive in bacterial UTIs. A negative leukocyte esterase test indicates that a UTI is unlikely.
[9] http://www.nonvacare.va.gov/, accessed January 3, 2014.

requiring specialty care should receive the care within the VA health care system whenever possible. Staff also stated that the facility Director had issued a "blanket approval" allowing this patient to receive Non-VA rheumatology care. We found no documented evidence of this approval.

While we could not determine what information the patient received about future Non-VA care, it did not appear (based on EHR documentation) that PA-1 or PA-2 at the Albany CBOC ensured that she received appropriate, ongoing rheumatology care. Because lupus is chronic, complex, and unpredictable, the frequency of rheumatology visits should be determined by a rheumatologist. PAs generally do not have the specialty training needed to manage lupus-related conditions independently.

Issue 3: Adequacy of Internal Quality Review

While not an allegation, during the course of our review we found responsible clinicians and managers did not adequately consider the scope of quality issues contributing to the patient's adverse outcome.

Peer review for quality improvement includes all protected clinical reviews of patient care by an individual clinician that are performed for the purpose of improving the quality of health care. Peer review findings and results are generally confidential and may not be disclosed.[10] However, the *process* by which the facility peer-reviewed the VA care delivered in this case may be discussed in this report.

The facility did not follow VHA Directive 2008-004, *Peer Review for Quality Management*, which requires the peer reviewer to evaluate quality and/or resource issues related to care using the 11 "Aspects for Review of Care." The aspects of care relevant to this case include:

- Lack of recognition and/or communication of critical clues to the patient's condition during a period of clinical deterioration.
- Abnormal results of diagnostic tests not addressed.

Reportedly, the peer reviewer was asked to evaluate a narrowly focused issue that did not include the above aspects of care. The peer reviewer did as requested but did not consider or address the question of what may have contributed to the patient's unexpected death 4 days after a WH appointment.

The peer reviewer told us that during the record review of the case, he/she recognized the abnormal laboratory value showing proteinuria. However, he/she did not comment on this clinical finding (which suggested a lupus flare) or the fact that it went unaddressed. When the scopes of peer reviews do not include or consider the relevant aspects of care as defined in VHA and local policies, facility leaders and risk managers cannot be assured that peer review results are informative and credible.

[10] http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2250, Accessed April 8, 2014.

Conclusions

Due to limitations in the contract between the facility and the Albany CBOC contractor, we could not fully evaluate some of the issues central to this case.

We did not substantiate that the patient was not promptly treated for a UTI, which contributed to her premature death. The patient's test results were not consistent with a UTI. The patient's most recent laboratory results revealed worsening anemia and urinalysis findings of significant proteinuria. These results suggest an increase in lupus disease activity with kidney involvement. While both the primary care and WH providers were aware of the patient's lupus diagnosis, neither followed-up on the abnormal laboratory values nor consulted a specialist. The precise cause of death remains uncertain.

Because the services at the CBOC were provided by a contractor, not VA personnel, CBOC staff were not obligated to talk to us, and we could not compel them to do so. Therefore, we could not determine what the patient was *told* about future Non-VA care with a private-sector rheumatologist. We did not find evidence of Non-VA care referrals or authorizations in the 9 months prior to her death. Based on EHR documentation, it did not appear that either of the Albany CBOC PAs who cared for the patient in 2011–2012 ensured that she received appropriate, ongoing rheumatology care.

Although not an allegation, responsible clinicians and managers did not comply with guidelines for completing peer reviews, and as a result, the peer review of this case did not address the full scope of quality issues contributing to the patient's outcome.

Recommendations

1. We recommended that the Facility Director develop a system to ensure appropriate follow-up on Non-VA care consults.

2. We recommended that the Facility Director ensure that managers and peer reviewers follow policies for conducting and completing peer reviews.

3. We recommended that the Facility Director evaluate the VA care provided to the patient summarized in this report and confer with Regional Counsel regarding the need for possible disclosure.

4. We recommended that the Facility Director and the Chief of Staff ensure that an individual patient's clinical complexity is considered when assigning a primary care provider.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: June 2, 2014

From: Director, Veterans Integrated Service Network (10N7)

Subj: **Draft Report**—Healthcare Inspection—Mismanagement of Patient Care, Carl Vinson VA Medical Center, Dublin, Georgia

To: Director, Atlanta Office of Healthcare Inspections (54AT)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the subject Draft Report and Dublin's related action plans. I concur with their action plans and will ensure that VISN oversight is provided to monitor and support the timely completion of these actions.

2. Thanks and again we appreciate your partnership as we work to improve the quality of care provided to Veterans at the Dublin VA Medical Center and its CBOCs. If there are any questions, contact Dr. Robin Hindsman at 678-924-5723.

Charles E. Sepich, FACHE

Appendix B

Facility Director Comments

Department of
Veterans Affairs

Memorandum

Date: May 23, 2014

From: Director, Carl Vinson VA Medical Center (557/00)

Subj: **Draft Report**— Healthcare Inspection – Mismanagement of Patient Care, Carl Vinson VA Medical Center, Dublin, GA

To: Director, Veterans Integrated Service Network (10N7)

1. I concur with the attached facility draft responses to the recommendations. I provided information to clarify Issue 2, lines 2-4, page 3.

2. If you have any additional questions or concerns, please contact Jahmel Yates, Quality Manager at 478-272-1210 ext. 2446.

John S. Goldman

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

The facility would like to clarify the following:

Issue 2, lines 2–4, page 3, Access to Non-VA Care: Staff also stated that the facility Director had issued a "blanket approval" allowing this patient to receive Non-VA rheumatology care. We found no documented evidence of this approval.

The facility Director did not issue a "blanket approval" allowing this patient to receive Non-VA rheumatology care. He indicated on numerous occasions that Veterans residing in the Brunswick and Albany CBOC catchment areas are authorized for Non-VA care due to the distance to the nearest VA facility if it is determined the care is clinically appropriate and medically necessary.

OIG Recommendations

Recommendation 1. We recommended that the Facility Director develop a system to ensure appropriate follow-up on Non-VA care consults.

Concur

Target date for completion: August 30, 2014

Facility response: In September 2013, Dublin VAMC implemented the Non-VA Care Coordination (NVCC) process following national guidelines. There is a designated NVCC physician who provides oversight and, in collaboration with the NVCC nurses, reviews and determines the appropriateness of NVCC consults. Special emphasis is placed on high risk, urgent, and stat consult follow-up. NVCC administrative staff monitor scheduled consults on a daily basis. The referring provider receives alerts for every edit made to the consult. Current performance improvement initiatives include increasing clinical and administrative NVCC staff, as well as improving relationships with community partners.

Action – Dublin's NVCC leads will provide training to Albany CBOC clinical staff to ensure that they are aware of the process for submitting a NVCC Consult request and how to track such requests to ensure that they have been processed by NVCC. The goal is to create a continuous care process for Veterans who are receiving care in Dublin's Contract CBOCs.

Recommendation 2. We recommended that the Facility Director ensure that managers and peer reviewers follow policies for conducting and completing peer reviews.

Concur

Target date for completion: September 30, 2014

Facility response: In December 2013, we reviewed the local Peer Review Policy for congruence with VHA Directive 2010-025, Peer Review for Quality Management. The local policy was found to include all required components. The Chief of Staff chairs the Peer Review Committee and actively provides oversight of the peer review process.

In March 2014, the peer review documentation form was revised to specifically instruct the reviewer to check all aspects of care that may be applicable in cases identified as Level-2 or Level-3.

Protected peer review education is provided to all clinical health care professionals and to new staff. Peer Review Committee members and Peer Reviewers are required to complete initial training prior to assuming their roles and every two years thereafter.

Action – Dublin's Risk Manager will conduct a performance monitor to track the quality of peer reviews submitted to the PRC. This monitor will track the accuracy and completion of the PR form, the accuracy and completeness of the PR scope, and the comprehensiveness documentation provided by the peer reviewer on the form related to the identified levels and scope of the peer review. This monitor will be submitted to the PRC for review and action of all substandard peer reviews.

Recommendation 3. We recommended that the Facility Director evaluate the VA care provided to the patient summarized in this report and confer with Regional Counsel regarding the need for possible disclosure.

Concur

Target date for completion: July 15, 2014

Facility response: We have discussed further with Regional Counsel and the VISN and are moving forward with the process to provide an Institutional Disclosure as appropriate.

Recommendation 4. We recommended that the Facility Director and the Chief of Staff ensure that an individual patient's clinical complexity is considered when assigning a primary care provider.

Concur

Target date for completion: September 30, 2014

Facility response: We have a process in place to facilitate co-managed care for Veterans receiving care with Non-VA specialists, in accordance with VHA Directive 2009-038, VHA National Dual Care Policy. Veterans with a chronic disease, such as lupus, may be managed by a mid-level provider. The provider should ensure that the Veteran is receiving the appropriate specialty treatment periodically and whenever acutely necessary. Mid-level providers function under the auspices of a medical

director, who is a physician. Complex cases are routinely discussed with the supervising physician and referred as needed.

Action – Dublin will conduct clinical reviews of Albany's mid-level provider's panels containing Veterans with clinical complex diagnosis and work within the Contract to ensure that veterans are provided appropriate clinical care oversight by an Attending Physician.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Joanne Wasko, LCSW, Team Leader Victoria Coates, LICSW, MBA Thomas Jamieson, MD

Appendix D

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