



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Delay in Treatment Louis Stokes VA Medical Center Cleveland, Ohio

Report Suspected Wrongdoing in VA Programs and Operations:
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(Hotline Information: <http://www.va.gov/oig/hotline/default.asp>)

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding a patient's care at the Louis Stokes VA Medical Center (the facility). A complainant alleged that biopsy technique and delay in treatment contributed to enlargement of a cutaneous squamous cell carcinoma (CSCC) lesion, affecting the patient's prognosis and necessitating extensive surgical treatment and follow-up.

We did not substantiate that the biopsy technique used to obtain a tissue sample for diagnosis contributed to a CSCC lesion enlargement.

We substantiated that a delay in scheduling the patient's Dermatology Clinic appointment at the facility occurred. This delay was related to the facility's clinic scheduling and consult tracking processes. However, based on reviews of CSCC clinical practice guidelines and current medical literature, we did not substantiate that the delay affected the patient's prognosis or necessitated more extensive surgical treatment and follow-up.

Although there was a delay in scheduling the appointment for facility dermatologist examination, we found that referrals and subsequent treatment were timely.

We found that facility policies and procedures did not ensure adherence to Veterans Health Administration (VHA) requirements in these areas: (1) outlining procedures for contacting patients to schedule an appointment, (2) scheduling consults within the timeframe established by VHA, and (3) defining timeliness of response from Dermatology Service regarding consult requests.

We recommended that the Facility Director strengthen local policies to include all VHA required elements regarding procedures for contacting patients to schedule appointments. In addition, we recommended that the Facility Director strengthen processes for clinic scheduling and consult tracking and monitor timeliness of outpatient scheduling for adherence with VHA timeliness requirements.

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan.



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

TO: Director, VA Healthcare System of Ohio (10N10)

SUBJECT: Healthcare Inspection – Delay in Treatment, Louis Stokes VA Medical Center, Cleveland, Ohio

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections reviewed allegations of a delay in treatment of skin cancer at the Louis Stokes VA Medical Center (the facility) in Cleveland, OH. The purpose of the review was to determine whether the allegations had merit.

Background

Louis Stokes VA Medical Center

The facility is part of Veterans Integrated Service Network (VISN) 10 and has 262 inpatient beds, 160 Community Living Center beds, 8 Compensated Work Therapy Transitional Housing beds and 225 domiciliary beds. The facility provides a broad range of inpatient and outpatient health care services including medical, surgical, mental health, geriatric, and rehabilitation services. Outpatient services are provided in a variety of settings, including Community Based Outpatient Clinics (CBOC). The facility serves approximately 104,000 veterans in a primary service area that includes 24 counties in Northeast Ohio.

A complainant reported allegations that skin cancer treatment was delayed for a patient and that the delay contributed to a change in prognosis, causing the need for more extensive surgical treatment and follow-up. The patient further alleged that the technique used to obtain a biopsy specimen may have contributed to mismanagement of his case.

Cutaneous Squamous Cell Cancer

Skin cancer (melanoma and non-melanoma) is the most commonly diagnosed malignancy in the United States. More than one million new cases of non-melanoma

skin cancers are reported in the U.S. each year.¹ Basal cell and cutaneous squamous cell carcinomas are the most common types of non-melanoma skin cancers. Cutaneous squamous cell carcinoma (CSCC) is less common than basal cell carcinoma, accounting for approximately 20 percent of non-melanoma skin cancers. CSCC primarily occurs on sun-exposed areas of the head, neck, and hands.²

The appearance of CSCC varies depending on its location and type. However, appearance alone does not indicate invasiveness (the ability to enter and move through tissue).³ Some lesions appear as scaly patches, while the more invasive, poorly differentiated, lesions may have ulceration, bleeding, and areas of necrosis (dead cells). Most lesions are asymptomatic, but invasive lesions may cause pain or itching. Further, lesions typically extend beneath the skin surface; thus the lesion size cannot be determined by visual inspection alone.

Suspicious skin lesions are biopsied for diagnosis. Biopsies are obtained by removing all or part of the lesion for microscopic examination of the cells (histology) in order to confirm the diagnosis of cancer and cancer type. Biopsies are obtained using local anesthetic with a blade (shave or excision technique) or a punch device. A trained practitioner can perform the procedure in an outpatient office setting.

Once the diagnosis is confirmed, treatment approach is determined by whether the lesion is extensive or local.⁴ Extensive lesions are suspected of involving deep structures such as nerve, lymph node, or bone. Extensive lesions are considered likely to metastasize (spread to other areas), and require further assessment to determine the extent of the lesion.

Treatment options for local lesions are determined by their risk for recurrence. Factors affecting recurrence risk include location, size, clinical features, and histology. Any one high-risk feature places the patient in the high-risk category. Specific high risk features include (1) size larger than 2 centimeters (cm), (2) location on the 'mask areas' of the face, or on or around the ear, (3) clinical conditions affecting the immune system, prior radiation, or chronic inflammation at the site of the lesion and (4) cell histology reporting poorly differentiated cells (versus well-differentiated) and cell layer greater than 2 millimeters in depth.

¹ Dean, N. R., L. Sweeny, et al. (2011). "Outcomes of Recurrent Head and Neck Cutaneous Squamous Cell Carcinoma." *Journal of Skin Cancer* 2011.

² Alam, M. and D. Ratner (2001). "Cutaneous squamous-cell carcinoma." *N Engl J Med* 344(13): 975-983.

³ Cherpelis, B. S., C. Marcusen, et al. (2002). "Prognostic factors for metastasis in squamous cell carcinoma of the skin." *Dermatologic Surgery: Official Publication For American Society For Dermatologic Surgery [Et Al.]* 28(3): 268-273.

⁴ National Comprehensive Cancer Network Guidelines™ Version 1.2012 Squamous Cell Skin Cancers. Retrieved from http://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

High-risk CSCC requires aggressive treatment to increase the likelihood of cure. The primary surgical treatment of choice for local, high-risk CSCC is Mohs surgery. Radiation therapy may be indicated if the lesion cannot be removed completely, if there is evidence of deep structural involvement, or the patient is not a surgical candidate.⁵

Mohs Surgery

Mohs surgery is an outpatient procedure performed under local anesthesia by a dermatologist, plastic surgeon, or other specially trained physician. It is the surgical treatment of choice because of its high cure rate and ability to minimize the amount of tissue removed. The surgeon removes the lesion in a series of thin layers, best visualized as scraping out the lesion in the form of a bowl. The ‘bottom’ margin of the bowl represents the portion of the lesion in contact with the patient’s deeper skin tissue. For evaluation, each layer is ‘flattened out’, sectioned, and diagramed into a pie-like grid. The surgeon microscopically examines the entire ‘bottom’ surface for evidence of cancer cells. If cancer cells are found, the precise location is noted on the diagram, and the surgeon removes another layer of skin from the corresponding area. The process is repeated until all margins are clear of residual cancer cells.

Mohs surgery is preferred because it allows examination of the entire lesion’s peripheral margin, whereas standard surgical excision allows for evaluation of less than 1 percent of the margin. Because of its comprehensive process, Mohs surgery is associated with a 5-year cure rate of approximately 97 percent for primary CSCC.⁶

Thirty to 50 percent of patients with a non-melanoma skin cancer develop another skin cancer within 5 years. Therefore, life-long skin cancer screening is essential, as well as patient education about sun protection and regular self-examination of the skin. Guidelines recommend postoperative follow-up every 3 to 6 months for 2 years, then every 6 to 12 months for 3 years, then annually for life.⁷

Literature guidelines do not specify a timeframe for the diagnosis and treatment of CSCC. In general, early diagnosis and definitive treatment provide the best opportunity for cure. Clinical guidelines recommend prompt treatment for high risk lesions or certain clinical conditions.^{8,9} Few studies have evaluated the impact of treatment delay for non-

⁵ Ibid.

⁶ Leibovitch, I., S. C. Huilgol, et al. (2005). "Cutaneous squamous cell carcinoma treated with Mohs micrographic surgery in Australia I. Experience over 10 years." *J Am Acad Dermatol* 53(2): 253-260.

⁷ National Comprehensive Cancer Network Guidelines™ Version 1.2012 Squamous Cell Skin Cancers. Retrieved from http://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

⁸ Alam, M. and D. Ratner (2001). "Cutaneous squamous-cell carcinoma." *N Engl J Med* 344(13): 975-983.

⁹ National Comprehensive Cancer Network Guidelines™ Version 1.2012 Squamous Cell Skin Cancers. Retrieved from http://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

melanoma cancers; however, an association between time to treatment and lesion size was seen when treatment delay was greater than one year.¹⁰

Scope and Methodology

We conducted a site visit February 21–22, 2012. We interviewed the complainant, the patient, and facility leadership, physicians, clinicians, and support staff. We reviewed the patient's VA and private clinic medical records, facility quality management documents and policies, Veterans Health Administration (VHA) policies, and Dermatology Service records. We also reviewed current CSCC literature and clinical practice guidelines. In addition, we interviewed non-VA staff who provided fee-based care for the patient.

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

The patient, a man in his early 70's, had a prior history of several skin cancer diagnoses and treatments since about age 50. He received his routine care at a primary care clinic in a CBOC located approximately 100 miles from the facility and traveled to the facility for specialty care when necessary.

In 1994, he was diagnosed with his first skin cancer, a well-differentiated squamous cell carcinoma on the forehead, which was surgically excised. All together, he had four lesions (three squamous cell and one basal cell) surgically removed between 2000 and 2005.

In 2006, a VA dermatologist referred the patient for Mohs surgery at a nearby private sector dermatology clinic, as the procedure was not available at the facility. A private dermatologist removed a well-differentiated CSCC from his temple. His Primary Care Provider (PCP) referred him to the facility Dermatology Clinic for follow-up skin cancer screening in 2008 and again in 2010 and 2011, but the patient declined due to the driving distance.

In August 2011, the patient reported a new lesion behind his ear during a routine visit. His CBOC PCP described the visible portion of the lesion as measuring 1 cm in diameter without bleeding or discharge and referred him the same day to the CBOC procedure clinic for a biopsy. Nineteen days later the lesion was biopsied by another CBOC provider and the laboratory at the facility received the biopsy specimen the following day. The pathology report was available 3 days after the biopsy and diagnosed well-

¹⁰ Eide, M. J., M. A. Weinstock, et al. (2005). "Relationship of treatment delay with surgical defect size from keratinocyte carcinoma (basal cell carcinoma and squamous cell carcinoma of the skin)." *The Journal of Investigative Dermatology* 124(2): 308-314.

differentiated CSCC with cells extending into the specimen margin. The biopsy specimen measured 1.2 x 1.0 x 0.3 cm. The provider called the patient and notified him of the results 13 days after receiving the diagnosis. That same day the provider referred the patient to the facility Dermatology Clinic.

The patient was seen in the facility Dermatology Clinic 56 days after his biopsy. At that visit, the dermatologist estimated the lesion as 1.6 cm in diameter with 2 cm of surrounding erythema (redness). Based on the lesion size and location, the dermatologist recommended Mohs surgery for removal of the lesion and submitted a fee-basis consult for Mohs surgery during the clinic visit. The provider told the patient that if he did not receive confirmation of a surgery appointment within 4 weeks to call the facility Dermatology Clinic. In addition, the patient was told to call the facility Dermatology Clinic if he had any changes in the lesion or had other concerns.

In late November, the patient began to have pain with intermittent bleeding and discharge from the lesion. He contacted his primary care clinic in early January, and was given an appointment for the next day in the urgent visit clinic. A provider examined the lesion and described it as measuring 2.5 x 3 cm with tenderness, erythema, and necrotic areas. There was no drainage and no evidence of infection. Noting that the patient was scheduled for fee-based surgery in 3 weeks, the provider advised him to call the private clinic to ask for an earlier surgery date. The patient called and was told the surgery could not be rescheduled to an earlier date.

The Mohs surgery was performed in late January 2012, 124 days after diagnosis. The surgical pathology indicated a poorly differentiated CSCC lesion measuring 4.2 cm x 4.2 cm x 2 cm deep. The surgeon performed frequent follow-up to observe the area for cancer recurrence and advised that if the lesion recurred, the patient might need further treatment with radiation and/or chemotherapy. He followed the patient routinely, and at the time of our inspection, the surgical wound was healing well without evidence of recurrence.

Inspection Results

Issue 1: Biopsy Technique

We did not substantiate the allegation that the technique for obtaining a tissue sample for diagnosis contributed to the enlargement of the skin lesion. The CBOC provider used shave biopsy technique which was well tolerated by the patient and without complications.

Issue 2: Delays in Referrals

During our inspection, we reviewed events in the patient's care from his initial report of the lesion to treatment. We evaluated timeliness of each event separately to determine its potential contribution to an alleged delay in treatment.

We substantiated a delay in Dermatology Clinic appointment scheduling and consult tracking processes; however, we found that referrals and treatment were timely. We did not substantiate that the delays contributed to a change in prognosis or caused the need for more extensive surgical treatment and follow-up.

Referral to Dermatology

We did not find delays in referral for biopsy or subsequent referral to the facility Dermatology Service. VHA requires that outpatient test results are communicated to patients no later than 14 calendar days from the date on which the results are available to the ordering practitioner and that the practitioner initiate appropriate clinical action.¹¹ The patient's initial evaluation, biopsy, and referral for Dermatology consultation were timely.

Referral for Mohs Surgery

We substantiated delays in consult tracking and appointment scheduling in the facility Dermatology Clinic. VHA directives outline the requirements for these processes, which we describe in detail below. We found that the facility policies and procedures did not fully incorporate VHA requirements in these areas: (1) outlining procedures for contacting patients to schedule an appointment, (2) scheduling consults within the timeframe established by VA, and (3) defining timeliness of response from Dermatology consults.

Contacting Patients to Schedule an Appointment

VHA requires facility policies to outline actions to be taken to make patient contact, the number of attempts necessary, and documentation required if patients must be contacted to create an appointment.¹² Facility policies did not comply with VHA requirements.

We found that the scheduler scheduled appointments for three different clinics and rotated days for each clinic's scheduling. Dermatology patients were contacted for clinic appointments at 3-day intervals. Although the scheduler attempted to contact patients by telephone and mail, the facility had no defined process for contacting patients for appointments.

Scheduling Consults within Timeliness Standards

VHA requires that facilities act on consults by either scheduling an appointment within VA's established timeframe or documenting the reason why an appointment is not scheduled.¹³ VHA standards establish the timeframe for patients who must be scheduled

¹¹ VHA Directive 2009-019 *Ordering and Reporting Test Results*, March 24, 2009

¹² VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures*, June 9, 2010

¹³ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008.

for an appointment with a specialist as within 30 days of referral.¹⁴ In addition, facilities are required to establish procedures to track and process consults that are without action within 7 days of the consult request.

VHA also requires use of an electronic wait list (EWL) for patients who cannot be scheduled in target timeframes, including patients with new consult requests waiting for the first scheduled appointment.¹⁵ No other wait list formats (paper, electronic spreadsheets) are to be used for tracking requests for outpatient appointments.

Facility policies and procedures did not incorporate processes to ensure adherence with timeliness standards. The scheduler told us that he received new consult requests twice a week, and tracked his patient wait list with paper copies of the consult requests. There was no prioritization for repeating attempts at contacting patients.

The Dermatology Service used an automated tracking report for performance monitoring and to identify consults requiring follow-up for completion or cancellation. However, based on interviews with facility staff, we found no evidence that this report was used to expedite the scheduling process.

Although the facility documented attempts to contact the patient, it did not make attempts in time to meet required timeframes. We found that 7 days elapsed before the Dermatology consult was approved for scheduling. Nineteen days after the request date, the clinic scheduler documented a second telephone call to the patient, followed by a letter requesting that the patient call for an appointment. The patient received an appointment 22 days after the consult request date, for an appointment with the dermatologist 40 days after referral.

Timeliness of Response from Facility Dermatology Services

VHA recognizes that consult requests are initiated with the clear expectation that a reply will be provided in a timely fashion and requires service agreements for management of the clinical consultation process.¹⁶ A service agreement is a written document developed between services, one of which sends work to the other, and signed by their service chiefs. Service agreements establish the timeframe expected for response from the consultant.

The Primary Care Service requested this Dermatology consult. We found that the facility did not have a service agreement between Primary Care and Dermatology. The consult was completed with recommendations available to the requesting provider 40 days after

¹⁴ VHA Directive 2006-041, *Veterans Health Care Service Standards*, June 27, 2006.

¹⁵ VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures*, June 9, 2010

¹⁶ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008

the request; however, we could not determine timeliness of this response in the absence of facility criteria outlined in a service agreement.

Surgical Treatment of Skin Lesion

We did not substantiate a delay in treatment. The facility dermatologist referred the patient for Mohs surgery, a procedure the facility did not provide. Per VHA policy, if a service cannot be provided in a timely manner due to capability, capacity, or accessibility, the service may, with approval, be provided outside of the VA through fee basis.¹⁷

VHA requires that requests for fee-based care be resolved efficiently, but we found no established requirements for completion of fee-basis consults. Literature guidelines did not recommend a timeframe between the diagnosis and treatment of CSCC.

We found the facility Dermatology Service had an effective process for requesting and tracking their fee-basis consults for Mohs surgery. At referral, facility Dermatology providers instructed patients about the process and timeframe for scheduling by the fee-based provider. We found that the fee-based provider scheduled consult requests timely and had a process for expediting consults labeled as urgent.

The facility dermatologist initiated the fee-basis referral for Mohs surgery at the time the patient was examined. The fee-based provider received the request and relevant medical records 15 days later, but retained no records of contacting the patient for an appointment. Although the patient recalled receiving an appointment letter, he could not locate it at the time of our inspection. The patient underwent Mohs surgery 10 weeks after fee-basis referral and 17 weeks after lesion diagnosis.

Conclusions

We substantiated that there was a delay in scheduling the appointment for the facility Dermatology Clinic. However, based on reviews of clinical practice guidelines and current CSCC literature, we did not substantiate that the delay affected the patient's prognosis or necessitated more complex surgical treatment and follow-up. Although there was a delay in scheduling the appointment for a Dermatology examination, we found that referrals and treatment were clinically timely.

Recommendation

Recommendation 1. We recommended that the Facility Director strengthen local policies by including all VHA required elements regarding procedures for contacting patients to schedule appointments.

¹⁷ VHA Directive 2008-056 VHA Consult Policy September 16, 2008

Recommendation 2. We recommended that the Facility Director strengthen processes for clinic scheduling and consult tracking and monitor timeliness of outpatient scheduling processes for adherence with Veterans Health Administration timeliness requirements.

Comments

The VISN and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 10-13 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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 10, 2012

From: Director, VA Healthcare System of Ohio (10N10)

Subject: **Healthcare Inspection – Delay in Treatment, Louis Stokes VA Medical Center, Cleveland, OH**

To: Director, Washington DC Office of Healthcare Inspections (54DC)

Thru: Director, Management Review Service (VHA 10AR MRS)

1. Thank you for this thorough review and opportunity to improve our processes.
2. Please see the Cleveland VAMC response to Draft Report of the Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center, Cleveland, Ohio.
3. If you have any questions or need additional information, please contact Jane Johnson, Deputy Quality Management Officer, VISN 10 at (513) 247-4631.

(original signed by:)
Jack G. Hetrick
Network Director

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 3, 2012

From: Director, Louis Stokes VA Medical Center, Cleveland, Ohio
(541/00)

**Subject: Healthcare Inspection – Delay in Treatment, Louis Stokes VA
Medical Center, Cleveland, OH**

To: Director, VA Healthcare System of Ohio (10N10)

1. Please see the Cleveland VAMC response to Draft Report of the Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center, Cleveland, Ohio.
2. If you have any questions or need additional information, please contact Kristen Guadalupe, PhD, RN Chief, Quality Management at (216) 791-3800 extension 3456.

(original signed by:)
Susan M. Fuehrer

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director strengthen local policies by including all VHA required elements regarding procedures for contacting patients to schedule appointments.

Concur

Target Completion Date: 10/31/12

Facility's Response:

Medical Center Policy (MCP) 136-053 Outpatient Scheduling and (MCP) 000-035 Electronic Consult Requests are currently being revised to include all required VHA elements regarding procedures for contacting patient to schedule appointments. The revised policy will outline actions to be taken to make patient contact, including the number of attempts necessary, and the documentation required if patients must be contacted to create an appointment.

Status: Pending

Recommendation 2. We recommended that the Facility Director strengthen processes for clinic scheduling and consult tracking and monitor timeliness of outpatient scheduling processes for adherence with VA timeliness requirements.

Concur

Target Completion Date: 12/01/12

Facility's Response:

Facility leadership reviewed current processes for clinic scheduling, consult tracking, and monitoring of outpatient scheduling processes for adherence with VA timeliness requirements. It is the general practice within the medical center that once a consult is formally accepted staff will initiate an attempt to contact the patient to schedule an appointment. At a minimum two phone call attempts to contact the patient will be made. The unsuccessful phone call attempts will be documented electronically in

CPRS as a comment on the consult. After two unsuccessful phone call attempts, a letter requesting the patient contact the service to schedule an appointment is sent. If the patient does not contact the service within 10 days from the date the letter was sent and it is deemed clinically appropriate, the consult may be discontinued. With regard to specific complaints in the Dermatology Clinic, an assigned daily review of all dermatology consults by the Chief, Dermatology, Senior Resident or Nurse Practitioner is currently in place. A centralized tracking system has been implemented to ensure timely verbal and written communication attempts with each patient. Additionally, there is a daily administrative team huddle to discuss prioritization and appropriate action on new consults. The daily review includes the automated tracking report for performance monitoring and will serve as a 2nd level check to ensure action on all consults within 7 days of the consult request and appointment with specialist within 30 days of referral.

Status: Pending

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Randall Snow, J.D., Project Leader Katharine, Foster, RN, Team Leader Myra Conway, RN Monica Gottlieb, M.D. Natalie Sadow-Colón, MBA, Program Support Assistant

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