Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Poor Quality of Care in Radiation Therapy
VA Long Beach Healthcare System
Long Beach, California

Report No. 10-03861-119

March 9, 2011

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding radiation therapy (RT) at the VA Long Beach Healthcare System (the facility) in Long Beach, CA. Allegations included:

- Inappropriate care
- Lack of competence of radiation oncologists
- Lack of communication with facility leadership about adverse events
- Hostile work environment

We substantiated the allegation of poor care for 1 of the 10 patients reported and identified deficiencies in medical record documentation for 9 of the 10 patients. We also substantiated that facility leaders were not aware of adverse patient outcomes in RT and found that action was not taken to correct deficiencies identified in peer reviews.

We did not substantiate the allegation that radiation oncologists lacked competence.

We recommended that the VISN Director require that the Facility Director (1) ensures that an external peer review assessment of the treatment provided by radiation oncologists for Patient 1 is performed; (2) evaluates the care of Patient 1 with Regional Counsel for possible disclosure to the patient; (3) ensures that RT medical record documentation complies with VHA policy and ACR guidelines; and (4) ensures that RT patient outcomes are monitored by the Quality Management program and others external to the RT department to oversee the implementation of corrective actions for all adverse patient outcomes.

The VISN and facility Directors agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

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

TO: Director, Veterans Integrated Service Network 22

SUBJECT: Healthcare Inspection – Alleged Poor Quality of Care in Radiation Therapy, VA Long Beach Healthcare System, Long Beach, California

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding poor quality of care in radiation therapy at the VA Long Beach Healthcare System (the facility) in Long Beach, CA.

Background

The OIG Hotline Division received allegations that the facility's Radiation Therapy Service provided inappropriate radiation therapy (RT) care to 10 patients. Allegations included:

- Inappropriate care
- Lack of competence of radiation oncologists
- Lack of communication with facility leadership about adverse events
- Hostile work environment

The facility, part of Veterans Integrated Service Network (VISN) 22, has 231 acute care beds and 91 long-term care beds. It provides primary, secondary, and tertiary care for 183,000 veterans. Affiliations include the University of California at Irvine, the California State University at Long Beach, and the University of Southern California. At the time of our review, RT was provided by full-time radiation oncologists.

RT is used to treat cancer and other abnormal cell growth while protecting normal cells as much as possible. In the most common form of RT, external beam RT, intense radiation from linear accelerators is directed at tumors. With intensity-modulated RT (IMRT), higher doses can be delivered to abnormal tissue while reducing exposure of

adjacent non-target structures, resulting in fewer side effects.[1] The severity of side effects varies depending on the part of the body being treated and whether the patient is also receiving chemotherapy. Common side effects from RT include fatigue, diarrhea, hair loss, and abnormalities of the skin and urinary tract.[2]

With the higher doses of radiation used in IMRT, there is an increased risk of harm to patients. Practice guidelines and documentation requirements aim to maximize patient safety.[3] Examples of documentation requirements include weekly clinical treatment management notes and summaries at the completion of treatment.[4]

Effective quality management (QM) requires an organized, systematic approach to planning, delivering, measuring, and improving health care.[5] Peer review is a key organizational function contributing to quality improvement. In addition to assessments of specific instances of care in response to an adverse patient outcome, peer review encompasses the ongoing evaluation of professional practice.[6]

Scope and Methodology

We conducted a telephone interview with the complainant to clarify the allegations prior to a site visit November 15–16, 2010. We interviewed managers and employees and reviewed pertinent VHA policies and procedures, facility documents, credentialing and privileging (C&P) information, and medical records. We did not address the allegation of a hostile work environment in this report.

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.

Inspection Results

Issue 1: Quality of Care and Competence

We substantiated the allegation of inappropriate RT care for 1 of the 10 subject patients. We also found deficiencies in the documentation of treatment for 9 of the 10 patients.

We did not substantiate the allegation that radiation oncologists lacked competence. The C&P folders and profiles of the radiation oncologists complied with VHA policy. In

[1] American College of Radiology. *Practice Guidelines for Intensity-Modulated Radiation Therapy (IMRT)*, 2007.
[2] U.S. National Institutes of Health, National Cancer Institute, "*Radiation Therapy Side Effects*."
[3] American College of Radiology, *Practice Guidelines for Radiation Oncology*, rev. 2009.
[4] American College of Radiology, *Practice Guideline for Communication: Radiation Oncology*, rev. 2009.
[5] VHA Directive 2009-023, *Quality Management System*, September 11, 2009.
[6] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

addition, peer reviews for ongoing professional practice evaluations were appropriately documented.

Patient 1

Case Review. A patient was diagnosed with squamous cell carcinoma of the right tonsil with metastasis to retropharyngeal lymph nodes. He underwent IMRT and 3D conformal RT in May and June 2010. During and after IMRT, concerns included sore throat, hoarse voice, and moderate erythema of the skin involving breakdown on both sides of the neck.

IMRT treatments were suspended in early June to avoid further skin breakdown. The treatment plan was modified without new scan images, and the patient was started on 3D conformal RT 5 days later with minimal documentation explaining the treatment change. Although the patient's condition subsequently improved, at 3 months after treatment, he continued to have dry mouth and was unable to tolerate solid foods.

Case Findings. We substantiated the allegation that this patient received inappropriate care during the course of RT. The radiation prescription did not spare the parotid gland on the side opposite the tumor, and the patient was not referred for Speech Pathology consultation after experiencing swallowing difficulties.[7] Additionally, progress notes required during treatment were not entered, and the treatment summary lacked details about treatment dates, patient response, and radiation dose.

Patient 2

Case Review. A patient with a past history of prostatectomy and hormone therapy[8] underwent IMRT for prostate cancer in late 2009 and early 2010. The patient had urinary frequency, dysuria, and diarrhea during and after RT. He underwent cystoscopies in September 2009, May 2010, and July 2010. Radiation urethritis[9] was diagnosed, and the patient was treated with hyperbaric oxygen (HBO) therapy. A total of 30 treatments were administered prior to resolution of symptoms.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and the side effects anticipated. However, treatment documentation had discrepancies with respect to cumulative dose and type of treatment given.

[7] American College of Radiology, *Practice Guideline for Radiation Oncology*, rev. 2009.
[8] Treatment to stop testosterone from being released in order to manage the growth of remaining prostate cancer cells.
[9] Inflammation of the canal through which urine is discharged from the bladder.

Patient 3

Case Review. A patient underwent IMRT for prostate cancer during February—April 2009. Approximately 1 month after initiation of hormone therapy in early September, an oncologist noted that although progression of the cancer had halted, the patient had developed diarrhea, dysuria, and urinary frequency. The patient continues to receive hormone therapy at the facility.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, treatment documentation had discrepancies with respect to radiation doses and dates of treatment.

Patient 4

Case Review. A patient with oropharyngeal squamous cell cancer underwent a positron emission tomography scan that showed a large metabolically active pharyngeal mass. He had chemotherapy & concurrent IMRT to the head and neck area during March—May 2010. The patient experienced mucositis[10] and mild erythema (redness) on the neck. During the course of treatment, the patient required blood transfusions.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, there was no required treatment summary describing the patient's response to IMRT or resolution of symptoms.

Patient 5

Case Review. A patient was diagnosed with low grade prostate cancer. He underwent IMRT treatment under research protocol during July—September 2009. The patient developed urinary frequency, nocturia, dysuria, and rectal irritation. During follow-up visits, side effects were noted to have subsided.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, we found a change in the prescribed dose prior to initiation of treatment and noted the lack of documentation of this change and of the type of treatment delivered.

Patient 6

Case Review. A patient underwent IMRT for prostate cancer under research protocol during December—February 2010. Concerns after RT included a skin reaction in the

[10] Painful inflammation and ulceration of the mucous membranes lining the digestive tract.

buttocks area which improved during the course of treatment. The patient also experienced urinary frequency and dysuria which improved with medication 6 months after treatment.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, the prescription was not complete, the isodose was not specified, and the treatment summary was not completed until eight weeks after treatment ended. We also noted that treatment progress notes written by RT residents were not co-signed by an attending physician as required by VHA policy.[11]

Patient 7

Case Review. A patient underwent IMRT under research protocol for prostate cancer during October—December 2009. A cystoscopy[12] performed in July 2010 confirmed the diagnosis of radiation cystitis (inflammation of the urinary bladder). The patient had hematuria (blood in the urine) and required multiple visits to the Emergency Department for bladder irrigation. He did not require blood transfusion, but was treated with HBO and underwent 30 HBO treatments before the hematuria resolved.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, we noted that the radiation oncologist changed the radiation prescription for the patient but did not document the change in the medical record.[13]

Patient 8

Case Review. A diabetic patient with a left above-the-knee amputation required long-term inpatient rehabilitation and wound care beginning in September 2008. In March 2009, he was diagnosed with anal margin squamous cell cancer and underwent surgery. RT was initiated in June 2009 and completed in August 2009.

The patient experienced difficulty with urination which began after the 14th radiation treatment and continued until after the end of RT. In late August 2009, radiation cystitis was diagnosed and confirmed by cystoscopy. Treatment with HBO therapy was not indicated at that time. Residual bladder abnormalities were noted to be slowly improving as of March 2010.

Case Findings. We did not substantiate the allegation of inappropriate RT care. We found that treatment was appropriate and side effects anticipated. However, follow-up

[11] VHA Handbook 1400.1, *Resident Supervision*, July 25, 2007.
[12] Examination of the urinary tract using a lighted instrument.
[13] American College of Radiology. *ACR Practice Guideline for Radiation Oncology*, Rev. 2009.

evaluation of the patient was not completed within 4–6 weeks as required. Discrepancies were also found in the documentation of dates and type of treatment delivered.

Patient 9

Case Review. A patient with head and neck squamous cell cancer required RT and chemotherapy. The patient was admitted with open neck wounds and received the majority of his wound care, RT, and concurrent administration of cetuximab (chemotherapy) in the facility's long-term care unit during June—August 2010.

The neck wounds deteriorated soon after the sixth RT treatment, although it was not documented exactly when the worsening occurred. The patient was subsequently transferred to a private facility for treatment of bleeding arteries in the neck. The patient was transferred back to the facility and RT was resumed.

Supportive wound care and intravenous antibiotics were later required for a neck wound infection. The right neck wounds healed and were considered superficial when the patient was discharged home in late September 2010, 3 months after initiation of RT.

Case Findings. We did not substantiate the allegation of inappropriate RT care. The combination of cetuximab and RT was necessary in the management of this patient's advanced malignancy. However, the combination imparted a high risk of skin complications. Facility staff reported that this case had been reviewed by an interdisciplinary team to determine the appropriateness of reporting to the U.S. Food and Drug Administration. The team concluded that reporting was not necessary for an expected reaction.

Although we did not substantiate poor RT care, we found inadequate documentation of the patient's response to treatment, including the status of neck lesions. In addition, the treatment summary was missing.

Patient 10

Case Review. A patient had metastatic non-small cell lung cancer unresponsive to chemotherapy provided at a private facility. The last dose of chemotherapy was given in June 2010. In July, the patient was found to have a large pericardial effusion, and a pericardial window was placed.

The patient was transferred to the facility in mid-July 2010 for RT. He was seen by the radiation oncologist on the day of admission, but treatment was not initiated because the patient was unable to lie flat. The plan was to initiate second-line chemotherapy, with RT to be attempted again if and when appropriate. Chemotherapy infusions were initiated but stopped due to the patient's shortness of breath. RT was never contacted

again for re-evaluation. The patient's condition continued to deteriorate, and he expired in mid-August 2010 after electing palliative (end-of-life) care.

Case Findings. We did not substantiate the allegation of inappropriate RT care. The patient had very advanced disease and could not tolerate the positioning requirements for RT. There was no further request for RT, and the patient expired after choosing palliative care.

Issue 2: Communication with Facility Leadership

We substantiated the allegation that senior leaders were not aware of RT patient outcomes. VHA expects that "peer review done for quality management fosters a responsive environment where issues are identified, acted upon proactively, and in ways that continually contribute to the best possible outcomes and strong organizational performance".[14] Facility staff confirmed that RT peer reviews had been performed. However, results had not been communicated to facility leadership nor was action taken to correct deficiencies identified in peer reviews.

During our onsite visit, facility staff provided evidence of plans for a new "Radiation Therapy and Oncology Quality Management Committee" which would focus on clinical care monitors such as unplanned interruptions during treatment, unusual, severe, early, or late complications of treatment, and unexpected deaths during RT care. The committee is to meet quarterly and report to the Medical Executive Council. Staff also provided a 2010 charter for a Comprehensive Cancer Program which is expected to work in concert with the committee and assume responsibility for the "continuous overview of the quality of cancer care, evaluate its safety and long-term results, and assure timely reporting to the [facility] Executive Leadership Board".

Conclusions

We substantiated the allegation of poor care for 1 of the 10 patients reported and found deficiencies in the medical record documentation for 9 of the 10 patients. We also substantiated that facility leaders were not aware of patient outcomes in RT nor was action taken to correct deficiencies identified in peer reviews.

We did not substantiate the allegation that radiation oncologists lacked competence. The C&P folders and profiles of the radiation oncologists complied with VHA policy. Peer reviews for ongoing professional practice evaluations were appropriately documented.

[14] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

Recommendations

Recommendation 1. We recommend that the VISN Director require that the Facility Director ensures that an external peer review assessment of the treatment provided by radiation oncologists for Patient 1 is performed.

Recommendation 2. We recommend that the VISN Director require that the Facility Director evaluates the care of Patient 1 with Regional Counsel for possible disclosure to the patient.

Recommendation 3. We recommend that the VISN Director require that the Facility Director ensures that RT medical record documentation complies with VHA policy and ACR guidelines.

Recommendation 4. We recommend that the VISN Director require that the Facility Director ensures that RT patient outcomes are monitored by the Quality Management program and others external to the RT department to oversee the implementation of corrective actions for all adverse patient outcomes.

Comments

The VISN and facility Directors agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

(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: February 14, 2011

From: Director, Veterans Integrated Service Network 22

Subject: Healthcare Inspection – Alleged Radiation Therapy Quality of Care Issues, VA Long Beach Healthcare System, Long Beach, CA

To: Associate Director, Los Angeles Regional Office of Healthcare Inspections (54LA)

Thru: Director, Management Review Service (10B5)

1. VISN 22 is in concurrence with VA Long Beach Medical Center Director's comments to the four recommendations.

2. If you should have any questions, please contact VISN 22 Quality Management Officer, Kathy Bucher, at 562-826-5963.

(original signed by:)

Barbara Fallen,
Acting Network Director

Department of Veterans Affairs **Memorandum**

Date: February 14, 2011

From: Director, VA Long Beach Healthcare System (600/00)

Subject: Healthcare Inspection – Alleged Radiation Therapy Quality of Care Issues, VA Long Beach Healthcare System, Long Beach, CA

To: Associate Director, Los Angeles Regional Office of Healthcare Inspections (54LA)

1. Attached is the response to the Long Beach Hotline Draft Report, Alleged Poor Quality of Care in Radiation Therapy. We have provided a narrative to the four recommendations in the Office of Inspector General's (OIG) report.

2. If you have questions or require additional information, please contact Nancy Downey, Quality Manager, at (562) 826-5249.

(original signed by:)

Isabel Duff, MS
Director

Attachment

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

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

OIG Recommendation

Recommendation 1. We recommend that the VISN Director require that the Facility Director ensures that an external peer review assessment of the treatment provided by radiation oncologists for Patient 1 is performed.

Concur **Target Completion Date: February 4, 2011**

Facility's Response:

On Friday, February 4, 2011, the Facility's Risk Manager submitted a request to VISN 22 for an external peer review to be conducted by Lumetra, the VA contractor for external peer reviews. In the event Lumetra's services are unavailable, the case will be referred to the Radiation Therapy Service at VA Greater Los Angeles Healthcare System. Upon completion, the findings of the external peer review will be discussed by the Protected Peer Review Committee and action recommended to the appropriate entities, including the Facility Director.

Status: Closed

Recommendation 2. We recommend that the VISN Director require that the Facility Director evaluates the care of Patient 1 with Regional Counsel for possible disclosure to the patient.

Concur **Target Completion Date: February 7, 2011**

Facility's Response:

On Monday, February 7, 2011, the case was referred to Regional Counsel for review. The determination of disclosure will be made by the Facility Director in consultation with Regional Counsel after completion of the external peer review.

Status: Closed

Recommendation 3. We recommend that the VISN Director require that the Facility Director ensures that RT medical record documentation complies with VHA policy and ACR guidelines.

Concur **Target Completion Date: August 18, 2011**

Facility's Response:

The Radiation Therapy Quality Management Committee developed and implemented a Clinical Quality Plan detailing quality assurance and oversight activities for the Radiation Therapy Service. The action plan includes documentation improvement and monitoring. Specifically, it addresses the ongoing review of medical record documentation to ensure compliance with the VHA and ACR guidelines. The Radiation Therapy Nurse audits the medical records daily to ensure progress notes, treatment summaries, radiation doses, and treatment modifications are completed within 7 days after the last radiation therapy treatment. Documentation discrepancies are addressed in the weekly chart round meetings. The Radiation Therapy Chief reports medical record quality assurance aggregate data to the Radiation Therapy Quality Management Committee on a monthly basis and will continue to do so until 95% documentation compliance is sustained for a period of 6 months.

Status: Open

Recommendation 4. We recommend that the VISN Director require that the Facility Director ensures that Radiation Therapy (RT) patient outcomes are monitored by the Quality Management program and others external to the RT department to oversee the implementation of corrective actions for all adverse patient outcomes.

Concur **Target Completion Date: August 18, 2011**

Facility's Response:

Patient outcomes related to the delivery of radiation therapy are collected using clinical monitors. The Radiation Therapy Quality Management Committee provides a summary of all adverse clinical outcomes, which include, but are not limited to, skin breakdown, hematuria/radiation cystitis, and unexpected treatment interruptions, to the Medical Executive

Committee quarterly. The report includes an analysis and summary of clinical monitors, unexpected complications, and adverse outcomes. This report, further assessment and recommendations are also reported to Executive Leadership & Quality Board (chaired by the Medical Center Director), where this information is further reviewed, and analyzed quarterly. To further ensure patient safety and quality of care, a corrective action plan is required within 10 days for all deficiencies identified. The Radiation Therapy Administrative Officer (currently an Acting is in place) ensures timely completion of the corrective actions. The Chief of Diagnostic & Molecular Medicine Healthcare Group reviews outcome data quarterly, and will implement Focused Professional Practice Evaluation when there is a concern regarding a practitioner's ability to provide safe, high quality patient care.

Status: Open

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Mary Toy, RN, Associate Director Los Angeles Regional Office of Healthcare Inspections
	Jerome Herbers, MD Simonette Reyes, RN

Appendix C

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