



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Delay in Cancer Diagnosis and Treatment Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin

To Report Suspected Wrongdoing in VA Programs and Operations

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

E-Mail: yaoighotline@va.gov

Executive Summary

The VA Office of Inspector General conducted an inspection at the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin, after receiving a complaint regarding delays in cancer diagnosis and treatment. The purpose of the inspection was to determine the validity of the allegations.

A complainant alleged that a radiologist failed to identify a pulmonary nodule. The complainant further alleged that a subsequent imaging report provided inaccurate information; also, it was alleged that medical center staff did not inform the patient of the abnormal test result.

We substantiated that there was a delay in cancer diagnosis and treatment because a radiologist failed to identify a pulmonary nodule. In addition, the radiologist who noted the nodule on a subsequent imaging study failed to follow medical center policy for reporting abnormal results; the primary care provider also neglected to follow up on the test. These errors resulted in a 5-month lapse between the identification of the abnormality and initiation of a treatment plan. Thirteen months elapsed from the time the lung abnormality was apparent to the initiation of definitive therapy.

We substantiated that medical center staff initially failed to inform the patient of the adverse event. However, after becoming aware of the abnormal imaging study, the primary physician discussed it with the patient. Medical center managers were unaware that action had not been taken in response to the abnormal test result.

We recommended that medical center managers conduct a formal peer review and root cause analysis of all activities involving the care of the identified patient from the time of the imaging study on which the pertinent abnormality was present. We recommended that staff adhere to Veterans Health Administration and local incident reporting and adverse event disclosure policies and procedures. We also recommended that the senior managers consult Regional Counsel regarding disclosure to the family and explanation of rights.

Management agreed with the findings and recommendations and provided acceptable improvement plans. 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, VA Great Lakes Health Care System (10N12)

SUBJECT: Healthcare Inspection – Alleged Delay in Cancer Diagnosis and Treatment, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections reviewed allegations that providers at the Clement J. Zablocki VA Medical Center (the medical center), Milwaukee, WI, delayed a patient's cancer diagnosis and treatment and that this adverse event was not disclosed to the patient. The purpose of the inspection was to determine the validity of the allegations.

Background

Located in Milwaukee, WI, the medical center is part of Veterans Integrated Service Network (VISN) 12 and provides primary, secondary, and tertiary care. The medical center has 180 acute care, 113 community living center, and 356 domiciliary beds. The medical center has four community based outpatient clinics in Appleton, Cleveland, Green Bay, and Union Grove, WI, and provides services to a veteran population of about 320,000 in southeastern and central Wisconsin.

A complainant alleged that a radiologist failed to identify and report the presence of a left lower lobe (LLL) pulmonary nodule¹ on an abdominal computed tomography (CT) scan, causing a delay in cancer diagnosis. The complainant also alleged that a subsequent imaging report provided inaccurate information, describing the pulmonary abnormality as "new." The complainant further alleged that medical center staff did not inform the patient of the adverse event.

¹ A small mass of cells or tissue which might be a normal part of the body or an abnormal growth such as a tumor.

Scope and Methodology

We conducted a telephone interview with the complainant and conducted a site visit at the medical center. We interviewed radiologists, the patient's primary physician, acting quality manager, risk manager, and other medical center staff. We reviewed the patient's medical record, local clinical and administrative policies, Radiology Service standard operating procedures and quality management data, and Veterans Health Administration (VHA) policies and procedures.

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

Case Summary

This elderly patient had an extensive medical history that included cancer of the larynx and skin, cerebral infarction, hypertension, hypothyroidism, hyperlipidemia, hernias, and eye disorders. The patient's surgical history included:

- Total laryngectomy² (1993)
- Eye lid surgery (1999, 2002, 2008)
- Inguinal and umbilical hernia repair (2008)

The patient had abnormal chest radiographs dating from 1984. Following is a summary of pertinent events in the patient's clinical course, including chest imaging studies.

Following total laryngectomy, the patient completed radiation treatment and received outpatient care at the medical center. Physicians ordered chest x-rays each year from 1993 through 1997. Chest x-rays completed in 1993 and 1994 showed densities in the left lung fields; x-rays completed in 1995 and 1996 showed chronic pulmonary disease; and the x-ray completed in 1997 showed fibro-atelectatic³ changes. In May 1999, a radiologist identified pulmonary fibrotic changes on a chest x-ray and reported that the chest was otherwise stable and free of active disease.

Chest x-rays completed in 2000, 2001, and 2002 show scarring in both lungs, density in the LLL, and left lung calcifications, respectively. The following year a radiologist noted left pleural calcification with no evidence of active pulmonary disease.

A CT in 2004 indicated multifocal calcified pleural plaques related to asbestos exposure, with no pulmonary nodules noted. A May 2006 chest x-ray showed patchy densities in the left lung base. The radiologist noted tiny densities throughout both lung fields and that a pleural calcification or plaque could not be ruled out. The August 2007 chest x-ray

² Surgical removal of the structure of muscle and cartilage that contains the vocal cords.

³ Scarring or thickening of the lung and collapse of airways.

revealed stable left pleuroparenchymal⁴ scarring with unchanged bilateral apical fibrotic changes, but a September chest x-ray showed a small opacity in the left lung base in addition to overlying calcified pleural plaques. The x-ray also indicated minimal atelectasis⁵ of the left lung base.

In December 2007, a physician admitted the patient to the medical center with gastrointestinal bleeding and ordered a chest x-ray prior to colonoscopy.⁶ The chest x-ray showed stable left pleural calcification and CT of the abdomen was interpreted as showing calcified pleural plaques in the lower hemithorax.⁷ Physicians diagnosed severe diverticulosis⁸ as the cause of the gastrointestinal bleeding. The patient's condition improved and he was discharged home.

In March 2008 the patient reported to the medical center for preoperative evaluation prior to inguinal and umbilical hernia surgery. A chest x-ray showed a round opacity in the left base that appeared more pronounced than in August 2007. The radiologist also described calcified pleural plaques at the left lung base. The primary physician and radiologist discussed the results and scheduled a follow-up positron emission tomography (PET) scan.⁹

On an April 2008 PET scan, the radiologist identified a new LLL pulmonary nodule with no regional lymph node involvement or distant metastasis. Ten days later, a general surgeon informed the patient of the nodule and suggested that it might be malignant. The surgeon also informed the patient that additional studies might be required. However, the patient decided to proceed with surgical repair of the hernias as scheduled. The patient's condition remained stable after surgery, and he was discharged home. During a routine follow-up appointment in early May, a radiation oncologist documented that "the patient had done well" and there was no evidence of disease recurrence for 15 years. In late May, a medical resident documented that the patient had been doing "well" since the repair of the hernias and noted that the patient's lungs were clear with good inspirations with "no wheezes, rales, or ronchi." However, the medical resident did not document knowledge of or discussion with the patient regarding the April 2008 abnormal chest PET scan.

In July, the patient reported to the medical center for outpatient clinic appointments. On a July chest x-ray, a radiologist found no significant change in the rounded opacity in the left lung base; this radiologist selected the March chest x-ray and the April chest PET scan for comparison.

⁴ Anatomical element essential for proper functioning of the membrane of the lungs.

⁵ Collapse.

⁶ Diagnostic procedure that uses a scope for visualization of the colon.

⁷ One side of the chest.

⁸ Abnormal bulging (out pouching) of tissue in the bowel.

⁹ Imaging technique which produces a 3-dimensional image or picture of functional processes in the body.

In September 2008, the patient reported to the medical center for an outpatient clinic visit. At that time, a medical resident and the primary physician ordered a chest CT scan and submitted a consultation request to the Cardiothoracic Surgery Service.

In October 2008, the patient underwent left eyelid surgery. A chest CT scan performed November 3 revealed that the LLL pulmonary nodule had increased in size since the prior two studies and that there were new abnormal lymph nodes. Bronchoscopy showed no definitive evidence of malignancy, but a CT guided needle biopsy was positive for squamous cell cancer.

In early January 2009, an oncologist documented that the patient was not a candidate for surgery or chemotherapy because of “advanced age and performance status,” and referred the patient to Radiation Oncology. In mid January, a radiation oncologist discussed a treatment plan with the patient and early in February the patient was admitted to the Palliative Care Unit to begin radiation therapy, 5 days per week, for 34 treatments.

In mid March, during the course of radiation therapy, the patient developed a cough with phlegm.¹⁰ The physician ordered a chest x-ray for possible pneumonia. The chest x-ray indicated that the known left retrocardiac opacity appeared stable.

The patient received his last radiation treatment in late March and was discharged home the next day. An oncologist reported that the patient tolerated all treatments “well.” Throughout April the patient reported to the medical center for outpatient appointments and imaging procedures. Although the patient’s clinical course remained uneventful, he died at home in early May 2009.

Inspection Results

Issue 1: Delay in Cancer Diagnosis and Treatment

We substantiated that there was a delay in cancer diagnosis and treatment.

Failure to Identify Lung Nodule

A radiologist failed to identify a LLL pulmonary nodule on abdominal CT scan. In December 2007, a physician ordered an abdominal CT to evaluate an inguinal hernia prior to colonoscopy. The interpreting radiologist described calcified pleural plaques. Upon notification of an OIG review, the same radiologist revisited the abdominal CT scan and acknowledged the presence of the LLL pulmonary nodule. In addition, the radiologist requested that a colleague assess the same radiograph.

Unlike VHA’s 3-tier peer review rating levels, the medical center’s peer review form included 4 tiers for reviewer interpretation:

¹⁰ Thick mucus secreted by the walls of the respiratory passages.

1. Interpretation acceptable; reviewer comfortable with the interpretation.
2. Interpretation varies slightly, but not unexpected; reviewer still comfortable with interpretation.
3. Interpretation varies moderately; reviewer uncomfortable with interpretation, which might adversely affect patient condition.
4. Interpretation varies significantly; reviewer very uncomfortable with interpretation, which probably would adversely affect patient condition.

Levels 2–4 include subsections to allow the reviewer to submit additional comments. The supervisory radiologist reported that the medical center form for peer review follows guidelines of the American College of Radiology (ACR). The ACR scoring for peer review includes the following levels:

1. Concur with interpretation.
2. Discrepancy in interpretation/not ordinarily expected to be made (understandable miss).
3. Discrepancy in interpretation/should be made most of the time.
4. Discrepancy in interpretation/should be made almost every time (misinterpretation of findings).

The ACR recommends that peer review scores of 3 and 4 be sent for internal arbitration, for example, review by the Chair or Medical Director or Quality Assurance Committee. The supervisory radiologist reported that he did not inform medical center managers of the peer review or the reviewer's interpretation of the December 2007 abdominal CT scan.

During the onsite interviews, a supervisory radiologist reported that the Radiology Service recently instituted a quality improvement program that requires a second reading of randomly selected radiographs.

Failure to Follow Up and Failure to Notify

The primary physician did not follow up on an abnormal chest PET scan. On the April 2008 PET scan, a radiologist identified a new LLL pulmonary nodule. Medical center policy requires that if a radiograph reveals a significant new abnormality, the radiologist must contact the ordering (referring) physician immediately and submit an electronic notification. Medical center policy also requires that unexpected radiologic findings or those requiring immediate medical attention be directly communicated (personally or by telephone) to the referring physician or surrogate. The communication must be

documented in the radiology report with the date, time, and name of the person who received the results. The supervisory radiologist reported that the radiologist who identified the pulmonary nodule on the April 2008 chest PET scan did not submit an electronic view alert. The primary physician did not remember receiving a telephone call or an electronic view alert regarding the abnormal finding. Additionally, we did not find documentation that the referring physician received a telephone call or an electronic view alert regarding the abnormal finding.

We found no documentation that physicians initiated a treatment plan to follow up on the abnormal PET scan until late September, when the patient reported to the medical center for an outpatient clinic appointment. At that time, physicians consulted the Cardiothoracic Surgery Service and ordered a chest CT. The chest CT was completed in early November, and the patient underwent diagnostic procedures during November and December until the mid December pathology report described squamous cell lung cancer.

Issue 2: Inaccurate information on Imaging Report

We substantiated that an imaging report subsequent to the December 2007 abdominal CT scan included inaccurate information. In mid-March 2008, a pre-operative chest x-ray showed calcified pleural plaques at the left base. The primary physician ordered a chest PET scan for additional evaluation of the x-ray report.

In April 2008, a second radiologist noted a “new” LLL pulmonary nodule on a chest PET scan. The radiologist did not reference the December 2007, abdominal CT scan.

During our onsite interview, the radiologist reported selecting similar radiographs for comparison reviews. The radiologist selected three previous chest reports for comparison radiographs for the April 1, 2008, chest PET scan. The radiologist did not select the December 2007, abdominal CT scan for comparison. However, the same radiologist interpreted the November chest CT scan and selected the December 2007 abdominal CT scan for comparison.

Issue 3: Failure to Disclose

We substantiated that medical center staff failed to disclose the adverse event to the patient. Medical center policy defines an adverse event as an untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility. This policy also defines examples of adverse events that warrant disclosure. These include:

- Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team.
- Adverse events that necessitate a change in the patient’s care.

- Adverse events with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small.

VHA¹¹ and local adverse event disclosure policies require forthright and empathetic discussion of clinically significant facts between treating clinicians and or other VHA personnel and patients and their representatives about the occurrence of an adverse event that resulted in patient harm, or could result in harm in the foreseeable future. There was no evidence to support that managers were aware of the delay in cancer diagnosis or subsequent 5-month delay in formulating a treatment plan as an adverse event. Consequently, this information was not disclosed to the patient or family.

Conclusions

We substantiated that there was a delay in cancer diagnosis and treatment because a radiologist failed to identify a lung nodule on a December 2007 abdominal CT scan. A different radiologist noted the nodule on an April imaging study but failed to notify the referring physician as required by medical center policy. In addition, the referring primary care provider neglected to follow up on the test. These errors resulted in a 5-month lapse between the identification of the abnormality and initiation of a treatment plan. Thirteen months elapsed from the time the lung abnormality was apparent (December 2007) to the initiation of definitive therapy (February 2009).

We substantiated that an imaging report subsequent to the December 2007 abdominal CT scan included inaccurate information. The report of the April 2008 chest PET scan, described a “new” pulmonary nodule which in fact was present on the December 2007 abdominal CT scan.

We substantiated that medical center staff failed to disclose the delays in diagnosis to the patient. However, the primary physician discussed the abnormal chest PET finding with the patient in September 2008. Medical center managers were unaware of the delay in diagnosis and results of radiology peer review.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Medical Center Director requires a formal peer review and Root Cause Analysis of all activities involving care of the identified patient from December 2007 to May 2009.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that staff adhere to VHA and local incident reporting and adverse event disclosure policies and procedures.

¹¹ VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

Recommendation 3. We recommended that the VISN Director ensure that the Medical Center Director consults Regional Counsel regarding disclosure to the family and explanation of rights.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations and provided acceptable corrective actions. (See Appendixes A and B, pages 9–12, for the full text of the Directors’ comments.) We will follow up on the planned actions until they are complete.

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: October 8, 2009

From: Director, Clement J. Zablocki VA Medical Center,
Milwaukee, Wisconsin (695/00)

Subject: **Healthcare Inspection – Alleged Delay in Cancer Diagnosis and
Treatment, Clement J. Zablocki VA Medical Center,
Milwaukee, Wisconsin**

Thru: Director, Management Review Service (10B5)

To: Director, Chicago and Kansas City Offices of Healthcare
Inspections (54CH/KC)

I have reviewed and concur with the attached response from
the Milwaukee VAMC regarding the above referenced
healthcare inspection. Thank you.



VICTORIA BRAHM

For in the absence of
JEFFREY A. MURAWSKY, M.D.

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

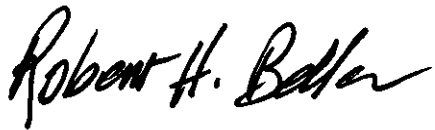
Date: October 8, 2009

From: Director, Clement J. Zablocki VA Medical Center (695/00)

Subject: **Healthcare Inspection – Alleged Delay in Cancer Diagnosis and Treatment, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin**

To: Director, VA Great Lakes Health Care Network (10N12)

I concur with the findings and recommendations in the draft report. The following corrective actions will be taken in response to the recommendations.

A handwritten signature in black ink, reading "Robert H. Beller". The signature is written in a cursive, flowing style.

ROBERT H. BELLER

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 VISN Director ensure that the Medical Center Director requires a formal peer review and Root Cause Analysis of all activities involving care of the identified patient from December 2007 to May 2009.

Concur

Target Completion Date: November 20, 2009

A focused review was performed on the care provided to the identified patient by the staff of the Office of Quality Management and Safety. This focused review triggered initial formal peer reviews by both Hematology/Oncology (on April 29, 2009) and Primary Care (on May 12, 2009). The peer reviews were discussed at the Peer Review Committee meeting on August 3, 2009. As a result of the committee discussion, a memorandum was sent from the Chief of Staff (Chairperson of the Peer Review Committee) to the Medical Imaging Division Manager on August 20 requesting a written review and summary of the identification process for flagging abnormal PET scans. In addition, a formal Medical Imaging peer review on the services provided to the identified patient was requested. This information will be reviewed at the October 5 meeting of the Peer Review Committee. In addition, the Medical Center Director has required a Root Cause Analysis of all activities involving care of the identified patient to be completed no later than November 20.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that staff adhere to VHA and local incident reporting and adverse event disclosure policies and procedures.

Concur

Target Completion Date: November 25, 2009

Specific information, on VHA and local incident reporting and adverse event disclosure policies and procedures, is provided to all new employees by the Office of Quality Management and Safety at New Employee Orientation every 2 weeks and through mandatory annual education for all employees. In addition, the Office of Quality Management and Safety will

provide guidelines for all Division and Program Managers to conduct additional targeted in-service education in all areas on local incident reporting and adverse event disclosure policies and procedures. This additional education will be completed by November 25, 2009.

Recommendation 3. We recommended that the VISN Director ensure that the Medical Center Director consults Regional Counsel regarding disclosure to the family and explanation of rights.

Concur

Target Completion Date: October 22, 2009

Clinical disclosure has already been provided to the identified patient. The Associate Medical Center Director, the Chief of Staff, and the Deputy, Office of Quality Management and Safety met with Regional Counsel on October 7, 2009. Regional Counsel advised Institutional Disclosure with the patient's family. The patient's surviving family member (son) was contacted on October 7. A meeting to provide Institutional Disclosure was scheduled at the family member's convenience on October 22.

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, MN, RN Director, Chicago and Kansas City Offices of Healthcare Inspections (708) 202-2672
Acknowledgments	Reba B. Ransom, MSN, RN Jennifer Reed, RN Jerome E. Herbers, Jr., MD Paula Chapman, CTRS Clarissa Reynolds, LNHA Judy Brown

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Great Lakes Health Care Network (10N12)
Director, Clement J. Zablocki VA Medical Center (695/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Russell D. Feingold, Herb Kohl
U.S. House of Representatives: Tammy Baldwin, Steve Kagen, Ron Kind, Gwen Moore, David R. Obey, Thomas E. Petri, Paul Ryan, F. James Sensenbrenner, Jr.

This report is available at <http://www.va.gov/oig/publications/reports-list.asp>.