



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 14-00875-325

Healthcare Inspection

Delay in Care of a Lung Cancer Patient Phoenix VA Health Care System Phoenix, Arizona

September 30, 2016

Washington, DC 20420

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Executive Summary

At the request of Senator Jeff Flake, the VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the merit of allegations regarding a delay in treating a patient diagnosed with lung cancer at the Phoenix VA Health Care System, Phoenix, AZ. Specifically, allegations included the following:

- A delay between diagnosis and treatment of the patient's lung cancer that resulted in the patient's death
- A delay in identifying and treating symptoms of metastasis to the brain
- Failure to communicate the patient's status post craniotomy¹ to the patient and family
- Failure to adequately manage the patient's pain

We substantiated a delay between the diagnosis of the lung cancer and treatment. We could not determine whether this delay impacted the final outcome. We substantiated a delay in identification of symptoms of cancer metastasis. We did not substantiate a delay in treatment once brain metastasis was discovered. We identified lack of patient education and primary care provider involvement in the coordination of subsequent cancer-related specialty appointments as factors contributing to delays in care.

We did not substantiate the allegation that following his craniotomy there was a failure to communicate the patient's status to the patient and family. Documentation in the electronic health record (EHR) demonstrated that the patient and his family received accurate information regarding his status and the plan to transition the patient to a non-VA nursing home and place him in hospice. We did not substantiate a failure to adequately manage the patient's pain. We found documentation of the patient's comfort and pain management monitoring, decisions, and education in the EHR.

We identified several additional issues during our review. The patient's risk for depression was not fully assessed following the new diagnosis of lung cancer. Evidence within the EHR supports that the system providers were aware of the results on non-VA testing; however, non-VA medical records were not consistently available in the EHR, including a positron emission tomography scan that was essential in the diagnosis and staging of the patient's cancer. Service agreements, which are used to define work flow rules and support continuity of care when making patient referrals between clinical services, were not active for the oncology and neurology services at the time of our review in 2015. We discovered examples of consults placed during the course of the patient's treatment with routine urgency even though the clinical expectation and actual need was for a more urgent response.

We made seven recommendations to strengthen care coordination, patient education, depression screening, documentation, and consult management.

¹ A craniotomy is the surgical removal of part of the bone from the skull to expose the brain.

Comments

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendations and provided acceptable action plans. (See Appendixes A and B, pages 16–22, for the Directors’ comments.) Based on action plans already completed we consider Recommendation 1 closed. We will follow up on the planned actions for all other recommendations until they are completed.



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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Senator Jeff Flake to determine the merit of allegations regarding a delay in treating a patient diagnosed with lung cancer at the Phoenix VA Health Care System (system), Phoenix, AZ.

Background

The system, comprised of the Carl T. Hayden Veterans Affairs Medical Center and seven outpatient clinics, provides acute medical, surgical, and psychiatric inpatient care as well as rehabilitation medicine. The system has the full spectrum of medical specialties.

The Carl T. Hayden Veterans Affairs Medical Center has 129 inpatient medicine beds (including 10 Medical Intensive Care Unit beds and 10 Surgical Intensive Care Unit beds), 48 inpatient mental health beds, 20 Substance and Alcohol Abuse Rehabilitation Treatment beds (via contract), and 102 nursing home beds.

Lung Cancer

Lung cancer is a disease in which malignant cells² form in the tissues of the lung. Lung cancer is the leading cause of cancer mortality in the United States for both men and women. In 2013, 212,284 people in the United States were diagnosed with lung cancer and it accounted for 156,176 deaths.³

A variety of risk factors may contribute to an individual developing lung cancer. These include age, tobacco smoking, and contact with cancer-causing agents, such as asbestos. Among risk factors, smoking cigarettes, pipes, or cigars is associated with the highest risk of lung cancer. If a person stops smoking, the risk decreases over time.

Symptoms of lung cancer include chest discomfort or pain, a cough that does not go away, trouble breathing, wheezing, blood in sputum, hoarseness, loss of appetite, weight loss for no known reason, feeling very tired, trouble swallowing, and swelling in the face and/or veins in the neck.

Tests

The various methods a physician might employ to detect, diagnose, and stage lung cancer include:

- Pulmonary Function Tests (PFTs), which is a group of tests that measure how well the lungs take in and release air and how well they move gases, such as

² Malignant cells are abnormal cells that divide without control and can invade nearby tissue.

³ Centers for Disease Control and Prevention, Lung Cancer Statistics, <http://www.cdc.gov/cancer/lung/statistics/> (retrieved on July 28, 2016).

oxygen, throughout the body. These tests are performed to diagnose certain types of lung disease (such as, asthma, bronchitis, and emphysema), find the cause of shortness of breath, check lung function before surgery, assess the effect of medication, and measure progress in disease treatment.

- Imaging tests, such as chest x-rays, computed tomography (CT) scans,⁴ positron emission tomography (PET) scans,⁵ and magnetic resonance imaging (MRI) tests,⁶ that are used to help determine if a mass might be cancer based on features of the mass and abnormal lung tissue. These tests are often repeated to look for an increase in mass size or density over time.
- A biopsy, which is a procedure to remove tissue or fluid from the body to test it for cancer. A biopsy is important in the process of planning which treatment is best suited for the specific type of cancer.
 - A standard bronchoscopy⁷ allows the doctor to look at a patient's airway (throat, larynx, trachea, and lungs) and collect samples of tissue to test for cancerous cells.
 - A mediastinoscopy with biopsy is performed by inserting a scope into the space in the chest between the lungs (mediastinum). Tissue is taken from any unusual growth or lymph nodes.

Non-Small Cell Lung Cancer

The two main types of lung cancer are non-small cell lung cancer (NSCLC) and small cell lung cancer. Small cell lung cancer, also called oat cell cancer, makes up about 10–15 percent of lung cancers. NSCLC is the most common type of lung cancer making up about 85 percent of cases. Types of NSCLC, named for the type of cells found in the cancer, include squamous cell carcinoma,⁸ large cell carcinoma,⁹ adenocarcinoma,¹⁰ and other¹¹ less common types. A rare type of NSCLC,

⁴ A CT scan combines a series of x-ray images taken from different angles and uses computer processing to create cross-sectional images, or slices, of the bones, blood vessels and soft tissues inside the body.

⁵ A PET scan is an imaging test that uses radioactive drug to show how the body's tissues and organs are functioning. The drug is injected, swallowed, or inhaled and it collects in areas of the body that have higher levels of chemical activity, which often corresponds to areas of disease. On a PET scan, these areas show up as bright spots.

⁶ An MRI uses a magnetic field and radio waves to create detailed images of your body. When you lie in the machine, the magnetic field temporarily realigns hydrogen atoms in your body. Radio waves cause the aligned atoms to produce very faint signals which are used to create cross-sectional MRI images, like slices of bread.

⁷ A bronchoscopy involves a scope that has a light, camera, and open channel. The light and camera allow the doctor to guide a tube down the patient's nose or mouth. A small brush, needle, or tongs can also be inserted into the open channel to collect samples.

⁸ Squamous cell carcinoma is a common form of skin cancer that develops in the thin, flat squamous cells that make up the outer layer of the skin.

⁹ Large cell carcinoma describes a type of cancer in which the abnormal cells are particularly large.

¹⁰ Adenocarcinoma is the most common type of NSCLC and forms in the mucus-secreting glands (for example, salivary glands on the tongue, goblet cells in the lungs, et cetera) throughout the body.

adenosquamous carcinoma,¹² typically has a worse prognosis than any other lung cancers.

An individual's prognosis depends on many factors. Some of those factors include the size of the tumor and whether it is in the lung only or has spread to other parts of the body, the type of lung cancer, whether there is coughing or trouble breathing, and the patient's general health.

Metastasis

Metastasis is the spread of cancer to another part of the body. Cancer cells break away from where they began in the primary tumor and travel through the lymphatic system or blood. The tumor that results from the metastasis is the same type of cancer as the primary tumor. The secondary tumor may form in nearby sites, such as another lobe of the lung, or in distant sites, such as the brain. Metastatic disease to the brain is common for lung cancer and occurs in approximately 36 percent of patients with NSCLC.¹³ An MRI of the head with contrast¹⁴ is the preferred imaging study for the diagnosis of brain metastasis.

Staging

Cancer staging is the process of determining how much cancer is in the body and where it is located. Staging also describes the severity of the cancer based on the original location of the tumor and evidence of spread in the body. Understanding the stage of the cancer is important in planning the appropriate treatment. The different stages of NSCLC are the occult (hidden) stage, stage 0, stage I, stage IIA, stage IIB, stage IIIA, stage IIIB, and stage IV. Higher stage numbers are indicative of a more extensive disease process. Stage IV, the highest stage, indicates that the cancer has spread to distant tissues or organs. The tumor, where the tumor is found, and whether the cancer has spread to any lymph nodes¹⁵ and/or other parts of the body determines the tumor stage. Cancer is often staged twice. The first staging is done before treatment and is called the clinical stage, and the second is done after surgery and is called the pathological stage.

Survival rates are based on the stage of the cancer at the time of diagnosis and are often used by doctors as a standard way of discussing a person's prognosis. The following survival rates were published in 2007 and calculated from the National Cancer

¹¹ Other types of NSCLC include pleomorphic, carcinoid tumor, salivary gland carcinoma, and unclassified carcinoma.

¹² Adenosquamous carcinoma is a type of cancer that contains two types of cells: squamous cells and gland-like cells.

¹³ Radiology, Vol 242, Issue 3. *Clinical Predictors of Metastatic Disease to the Brain from Non-Small Cell Lung Carcinoma; Primary Tumor Size, Cell Type, and Lymph Node Metastasis*, March 2007.

¹⁴ Contrast is a dye used during an MRI that is injected into the body, often through an intravenous line into a vein in your hand or arm, in order to enhance the appearance of certain details on the MRI scan.

¹⁵ Lymph nodes are small, bean-shaped masses of tissue scattered along the lymphatic system that act as filters and immune monitors, removing fluids, bacteria, or cancer cells that travel through the lymphatic system.

Institute's Surveillance, Epidemiology, and End Results database, based on people who were diagnosed with NSCLC between 1998 and 2000.¹⁶

Table 1. 5-Year Observed Survival Rate for NSCLC¹⁷

Stage	5-year Observed Survival Rate
IA	49%
IB	45%
IIA	30%
IIB	31%
IIIA	14%
IIIB	5%
IV	1%

Source: American Cancer Society

Treatment Types

The most common types of cancer treatment include surgery to remove the cancer, radiation, chemotherapy, and targeted drug therapy. The recommendation for which treatment approach to apply may differ from one stage of cancer to another.

Allegations

In 2014, the OIG Hotline Division received a request from Senator Jeff Flake to review a complaint alleging the system provided poor quality of care to a patient. Specifically, allegations included the following:

- A delay between diagnosis and treatment of the patient's lung cancer that resulted in the patient's death.
- A delay in identifying and treating symptoms of metastasis to the brain.
- Failure to communicate the patient's status post craniotomy¹⁸ to the patient and family.
- Failure to adequately manage the patient's pain.

¹⁶ American Cancer Society, <http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-survival-rates> (retrieved on December 15, 2015).

¹⁷ Ibid.

¹⁸ A craniotomy is the surgical removal of part of the bone from the skull to expose the brain.

We referred the allegations to the system for review and comment. After reviewing the system's response to the allegations, we were not satisfied and elected to conduct an inspection.

Scope and Methodology

The scope of our inspection was the review of the system's processes related to the provision of care for a single patient. The inspection was conducted from late March 2015 to July 2015.

We interviewed the complainant to clarify allegations. We reviewed relevant Veterans Health Administration (VHA) and system policies and procedures, quality management documents, the patient's VA electronic health record (EHR) and non-VA medical records, cancer guidelines and articles from the medical literature, as well as other pertinent documents. We conducted a site visit April 22–23, 2015. We interviewed clinical staff, consult management staff, case management staff, and system leaders.

In the absence of current VA/VHA policy, we considered previous guidance to be in effect until superseded by an updated or re-certified Directive, Handbook, or other policy document on the same or similar issue(s).

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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 was in his 50s with a history of chronic obstructive pulmonary disease,¹⁹ tobacco use, and other conditions when he presented to his primary care provider (PCP) in 2010 for a routine appointment (Day 0). At that appointment, during which the patient's smoking history and complaints of chest congestion were discussed, a chest x-ray was ordered and completed the same day. The x-ray revealed a large mass in the lung that was not present on previous chest x-rays, and the PCP referred the patient to a pulmonologist. A CT scan was ordered and completed 13 days later. The radiologist who reviewed the CT scan noted a lung mass with an adjacent soft tissue mass. A few enlarged para-aortic lymph nodes were also present. A bronchoscopy was performed on Day 22, and a few days later, the pathology of the mass was reported as NSCLC. A PET scan completed by a non-VA provider on Day 34 supported this diagnosis.²⁰

The system pulmonologist referred the patient to the Thoracic Surgery Service, and a thoracic surgeon evaluated him approximately 3 weeks after the PET scan was completed (Day 53). Based on the pathology and size of the tumor, the plan was to proceed with a mediastinoscopy with the intent of then pursuing a lobectomy (the surgical removal of a lobe of an organ such as the thyroid gland, lung, or liver). The thoracic surgeon documented the need for an evaluation by Cardiology Service staff, as well as PFTs prior to surgery to determine if the patient had medical conditions that would make it unsafe to perform surgery. An echocardiogram²¹ was completed on Day 57; PFTs were completed on Day 60; an exercise treadmill test was performed on Day 68; and, an evaluation by a cardiologist occurred on Day 69. After examining the patient and reviewing the test results, the cardiologist determined that he was an appropriate candidate for surgery.

After the evaluation by the cardiologist, there is no documented evidence that any further steps are taken to schedule the patient for a mediastinoscopy. The next entry in the EHR is a procedure note for an epidermoid cyst²² removal previously identified and originally treated with antibiotics. The note suggests the procedure occurred without complications. The surgeon who removed the cyst documented that the patient believed he was having a lymph node biopsy in preparation for lung surgery and not surgical removal of an epidermoid cyst. The surgeon documented a plan to communicate with Thoracic Surgery Service and the patient's PCP regarding the treatment plan, including a mediastinoscopy, for staging of the patient's lung cancer.

¹⁹ Chronic obstructive pulmonary disease is a lung disease characterized by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible.

²⁰ Although the results of a 2010 PET scan were not available in the EHR, the information was known by one provider and was reflected in a note when he referred the patient to the Thoracic Surgery Service.

²¹ An echocardiogram is a diagnostic test which uses ultrasound waves to make images of the heart chambers, valves and surrounding structures. It can measure cardiac output and is a sensitive test for fluid around the heart. It can also be used to detect abnormal anatomy or infections of the heart valves.

²² An epidermoid cyst is a non-cancerous small bump beneath the skin. It is typically slow growing and often painless but should be removed if painful, ruptured, or infected.

That same day, the thoracic surgeon cosigned a note indicating that regardless of the mediastinal node biopsy results, the patient would need a lobectomy due to the risk of hemoptysis. The patient was scheduled and attended a follow-up appointment with Thoracic Surgery Service on Day 130 to discuss the planning and necessary pre-operative preparation for a lobectomy.

On Day 146, a mediastinoscopy with biopsy was performed and the sampled nodes were analyzed and found to be negative for malignancy. Following the mediastinoscopy, the cancer stage was amended to stage IIB NSCLC. One week later, the patient underwent a lobectomy, and although there were no major complications during the surgery, it was discovered that the tumor had invaded the chest wall. The pathology results reported the tumor to be adenosquamous carcinoma. During the timeframe of these procedures, opioids were prescribed to help the patient with pain management.

Approximately 4 weeks after the lobectomy, Oncology Service staff evaluated the patient and made arrangements for him to receive chemotherapy at the system and radiation at a non-VA facility. A follow-up PET scan and bone scan completed approximately 12 months and 15 months respectively after the initial discovery of the lung mass showed no evidence of metastasis.²³

The patient discussed with his PCP concerns of poor memory and loss of appetite 1 year after the lobectomy. He requested assistance in discontinuing all pain medications and was subsequently referred to and enrolled in a Buprenorphine Clinic. This clinic provides prescription medication to relieve the symptoms of opiate withdrawal such as restlessness, anxiety, and nausea.

Over the next 3 months, and on three separate occasions, neurological deficits were documented in the patient's EHR. One provider noted that the patient's "demeanor is distant, ambulation is unusual." A second provider documented a plan to refer the patient to neurology; however, the EHR does not include a neurology consult for this time frame. A third provider, who noted that the patient had left-sided weakness in his arm, face, and leg, placed a neurology consult. A neurologist evaluated the patient 2 weeks later. The neurologist's evaluation described the patient as exhibiting new symptoms of changes in nerve, spinal cord, or brain functioning affecting the left side of his body, and an MRI was ordered. The MRI confirmed a large frontal lobe mass in the brain, as well as a smaller left mass in the brain, both suggestive of metastatic lung cancer.

The patient was transferred for a neurosurgical evaluation, a service not available at the system, to a non-VA hospital and had a craniotomy with tumor resection.²⁴ The patient transferred back to the system about 2 weeks later. An Inpatient Palliative Care Consult was placed, and during the Palliative Care meeting, the social worker documented that

²³ The PET scans performed were from the neck down and did not evaluate the brain for metastasis.

²⁴ Tumor resection is the surgical removal of the tumor.

the patient's terminal status was discussed with the patient and family and a hospice consult was submitted.

A few days later, the patient transferred to a non-VA nursing home and was admitted to hospice. About 2 weeks after admission to the nursing home, the patient transferred back to the system where he was seen in the Emergency Department (ED) due to sudden onset of pain in his left leg and possible left lower extremity thrombosis.²⁵ An exam found cooler skin temperature, a lack of palpable pulses, and tenderness of the left leg which indicated the presence of a lower extremity thrombosis. In conjunction with the patient's family, and in consideration of the patient's recent medical history and "terminal" prognosis, the decision was made to limit treatment to the management of the patient's pain. The patient died a few days later.

Inspection Results

Issue 1: Delay Between Diagnosis of Lung Cancer and Treatment that Resulted in the Patient's Death

We substantiated a delay between the diagnosis of lung cancer and the surgical removal of the lung tumor. From the date that the lung mass was discovered, the patient had an initial appointment with a thoracic surgeon after 53 days, a second appointment with the same surgeon after 130 days, a biopsy for cancer staging after 146 days, and surgical removal of the lung mass after 153 days. Considering that all required diagnostic and pre-operative evaluations were completed at day 69, a mediastinoscopy should have been scheduled at that time. Contributing factors to the delay included care coordination and lack of patient/family education.

Although the delay in treatment of this patient's lung cancer placed him at high risk for a hemorrhagic event, based on the size of the tumor at the time of diagnosis, the staging at the time of diagnosis, and the aggressiveness of the disease confirmed on tissue biopsy, we could not determine whether this delay impacted the final outcome.

Care Coordination

VHA requires that each patient receiving primary care have a single PCP.²⁶ The PCP is responsible for offering education to patients about their diseases; coordinating with specialty services; and screening for substance abuse, anxiety, and depression. Although it is silent on the method of communication to be used, VHA Directive, *Primary Care Standards*, requires that specialty consultation services staff communicate with the assigned PCP regarding results of specialty evaluations and treatment plans.²⁷

²⁵ Thrombosis is the formation or presence of a blood clot in a blood vessel. The presence of the clot blocks the flow of blood in the blood vessel.

²⁶ VHA Directive 2006-031, *Primary Care Standards*, May 27, 2006 was replaced by VHA Directive 2012-011, *Primary Care Standards*, April 11, 2012, and has the same requirements.

²⁷ Ibid.

On Day 0, the patient's PCP notified him that chest x-ray results revealed a lung mass. The PCP made the initial referral to the pulmonologist and was electronically notified of the pulmonologist's recommendation for bronchoscopy with biopsy. The PCP was not electronically notified via a view alert, by being made a co-signer, or set up to sign as "receipt acknowledged" for other cancer-related appointments and/or consults. As a result, the PCP was not involved with coordinating subsequent specialty appointments.

Over the next 4-months, the patient had appointments in multiple clinics and the ED for non-lung cancer related medical care. During interviews, we learned that the patient's PCP was not notified of many of the patient's non-cancer related visits. A family member stated that at multiple appointments, he asked the patient's providers about the treatment plan for the patient's cancer but was not given a clear answer.

According to a family member, when the patient was in the Surgery Clinic for removal of an epidermoid cyst the patient and family were under the impression that the "surgery" was to be the surgery to manage his lung cancer diagnosis. When it became clear that the procedure to remove the epidermoid cyst was unrelated to the cancer, the family member became very angry and demanded to speak to someone who could "tell him what was going on." The surgeon performing the excision took the family member to a private room and made a phone call, presumably to a staff member within the Department of Thoracic Surgery to discuss the patient's case.

PCP involvement could have assisted the patient to prioritize his health care appointments; decreased confusion; and improved communication between the patient, family, and health care team.

Patient Education

System policy states that patient and family education be documented in the EHR.²⁸ The policy also requires health care staff to assess learning needs, barriers, abilities, and readiness to learn. Health care staff are required to provide the patient with education on his/her illness, the plan for care, treatment, and all services to be provided.

A review of the patient's EHR demonstrated a lack of evidence that a thorough learning assessment was completed. Prior to the patient's lung surgery, documented evidence of a comprehensive assessment of his ability to understand the cancer diagnosis, the connection between smoking and lung cancer, or the impact of continued smoking on his prognosis and the quality of life was absent from the EHR.²⁹

Patient and family education, along with a thorough learning assessment, could have enabled the patient to better advocate for himself when there was confusion about medical appointments or a perceived delay.

²⁸ Phoenix VA Health Care System Policy Memorandum No. NUR 118-09, *Patient and Family Education*, July 1, 2009.

²⁹ The National Comprehensive Care Network recognizes that being addicted to nicotine is one of the hardest addictions to stop. The stress of lung cancer may make it harder or easier, depending on the patient. Quitting is particularly important since smoking can limit how well cancer treatment works.

Issue 2: Delay in Identifying and Treating Symptoms of Metastasis to the Brain

We substantiated that a delay in identifying the symptoms of cancer metastasis in the brain occurred. We did not substantiate a delay in treatment once the metastasis was discovered.

Fifty days elapsed between the first documentation in the EHR of changes in the patient's neurological assessment to medical testing for the purpose of ruling out brain metastasis. The patient discussed concerns of poor memory and loss of appetite with his PCP about 1 year after his lung surgery. Over the next 3 months, the patient had seven documented outpatient appointments. Multiple providers documented that the patient had slow responses to questions, upper extremity tremors, limping, and left sided weakness in face, arm, and leg. A family member told one of the providers that the patient had exhibited periods of confusion and eye twitching for several months. According to the family member, the explanation given for these symptoms was "likely related to the previous chemotherapy treatments." The provider documented his concern that these new neurologic changes may be suggestive of a cerebrovascular accident,³⁰ transient ischemic attack,³¹ or Parkinson's disease and initiated a consult to neurology.³² The provider gave routine priority to the neurology consultation, and the patient was seen 14 days later.³³

Once the brain metastasis was identified, the treatment plan was decided and acted upon within a day.

Issue 3: Failure To Communicate the Patient's Status Post Craniotomy

We did not substantiate that providers failed to communicate the patient's terminal status post craniotomy to the patient and family.

VHA details requirements for patient education, including at the time of discharge.³⁴ Delivery of health education services is the responsibility of each clinical discipline or service line providing patient care and must be coordinated to ensure consistency of content. The ultimate goal of health education is to enable patients to make competent health care decisions.

System policy states that patients and/or surrogates should be informed about the reasons, alternatives, and/or anticipated need for continued care, treatment, and services following discharge or transfer to another organization or level of care.³⁵ When

³⁰ A cerebrovascular accident is a rapidly developing stroke of brain tissue persisting for longer than 24 hours.

³¹ A transient ischemic attack is like a stroke, producing similar symptoms, but usually lasting only a few minutes and causing no permanent damage.

³² Parkinson's disease affects the nerve cells in the brain that produce dopamine. Parkinson's disease symptoms include muscle rigidity, tremors, and changes in speech and gait.

³³ VHA Directive 2008-056, *Consult Policy*, September 16, 2008.

³⁴ VHA Handbook 1120.04, *Veterans Health Education and Information Core Program Requirements*, July 29, 2009. This VHA Handbook expired July 2014 and has not yet been updated.

³⁵ Phoenix VA Health Care System Policy Memorandum No. COS 11-72, *Continuing Care Including Hand-off Communications*, January 1, 2010.

continuing care services are indicated, the patient/family are to be educated about appropriate options available to them and should be involved in the decision-making process.

Documentation in the EHR demonstrated that the patient and his family received accurate information regarding his status and the plan to transition the patient to a non-VA nursing home and place him in hospice following the patient's transfer back to the system after his craniotomy. A Hospice Care Consult was also submitted at that time.

Issue 4: Failure To Adequately Manage the Patient's Pain

We did not substantiate that the patient's pain was inadequately managed. Pain associated with the patient's cancer was monitored closely by his providers, and information related to the medication and dosage decisions was documented in the EHR.

VHA recognizes pain as a national priority with an overall objective of developing an approach to pain management that reduces pain and suffering and improves quality of life for veterans experiencing acute and chronic pain associated with a wide range of injuries and illnesses, including terminal illness.³⁶ VHA requires that a timely and appropriate comprehensive pain assessment is performed, a pain treatment plan is developed and implemented, and reassessment of the effectiveness for the plan is completed.³⁷ Each of these parameters must be documented in the EHR. In addition, patient and family education and participation in decision-making should be included in the treatment plan. The ultimate goal is to provide for an approach to pain management that emphasizes optimal pain control, improved function, and quality of life.

The patient's oncologist told us that the type of lung cancer the patient had generally requires significant amounts of medication to ensure patient comfort. Pain management was initiated early in the patient's cancer treatment. When the patient determined that he was ready to stop taking pain medications due to his concern of overuse and reliance, along with episodes of eye twitching, falls, and inability to manage his daily activities, he was started in a Buprenorphine group. While the patient's pain was treated and the care and related education were documented in the EHR, a family member told us that the family was never given a clear explanation as to whether the medication was the cause of the patient's strange behaviors reported to providers.

We found documentation in the EHR regarding the ED physician's assessment and pain management decision for the day the patient presented to the ED complaining of sudden and extreme pain in his lower left leg. Following consideration of the patient's health status and medical history, the ED physician determined that management of pain by hospice was the best course of treatment.

³⁶ VHA Directive 2009-053, *Pain Management* October 28, 2009. This VHA Directive expired October 31, 2014 and has not yet been updated.

³⁷ Ibid.

We found evidence that staff interacted with the patient's family when they were present at appointments. However, we are unable to assess the quality of staff communications or patient/family understanding of the information presented. The family's confusion over the adequacy of pain management may be due, in part, to the number of providers involved in treating this patient. While it is not uncommon for cancer patients to be seen by various residents and specialists, it presents an additional challenge in the management of a patient with complex and changing medical needs.

Issue 5: Other Findings

During the course of our review, we found that the patient's risk for depression was not fully assessed following the new diagnosis of lung cancer. We also found that non-VA medical records were not consistently available in the patient's VA EHR as required. Finally, although the clinical expectation and actual need for specialty consultation was urgent, consults placed during the course of the patient's treatment were consistently designated routine.

Depression Screening

Depression is a disabling syndrome that affects 15–25 percent of cancer patients.³⁸ "The prevalence of major depressive disorders in the US population aged 18 years and older has been estimated at 5 percent and it is one of the most commonly encountered conditions in primary care, but up to 50 percent of cases go unrecognized."³⁹ Throughout VHA, the PCP is responsible for screening for depression. A validated depression screening tool is to be completed at least annually or more frequently based on the patients existing or newly identified risk factors.

In the absence of communications from specialty consultation staff to the PCP, there was a missed opportunity for the PCP to assess the patient for depression in the presence of the new and potentially life threatening diagnosis of lung cancer. We found no evidence of documentation that education on the signs and symptoms of depression was provided to the patient and/or family or that the patient was referred for any additional support services.

Documentation of Non-VA Care

During our review, we found evidence that non-VA medical records, resulting from VA provider referrals, were not available in the patient's VA EHR.

Non-VA medical records are vital in understanding a patient's overall health status and care. Gaps in non-VA documentation, such as those found in this case, put a patient at risk and make continuity of care between various providers and specialties more difficult

³⁸ Depression for health professionals. National Cancer Institute website. <http://www.cancer.gov/about-cancer/coping/feelings/depression-hp-pdq>. Accessed on 03/02/2016.

³⁹ Saver BG, Van-Nguyen V, Keppel G, & Doescher MP. (2007). A Qualitative Study of Depression in Primary Care: Missed Opportunities for Diagnosis and Education. *Journal of the American Board of Family Medicine*, January–February 2007 Vol. 20: Page 1.

to achieve. Copies of clinical documentation submitted by non-VA medical care providers and other reports (such as laboratory and radiology records) should be available in the EHR.

We discovered several examples of non-VA care reports that had not been scanned and made available in the EHR. The report of the first PET scan, which was essential in the staging of the patient's NSCLC, was missing from the EHR. Although evidence within the EHR supports that the system oncologist was aware of the results at the time the PET scan was completed, system staff did not retrieve the written report until it was requested by the OIG.

The patient underwent chemotherapy and radiation following his lung surgery. The chemotherapy was provided at the system, and the radiation component was provided at a non-VA facility. Although the social worker documented information about the travel arrangements made for the patient to get to his radiation therapy, none of the non-VA radiation treatment records were included in the patient's EHR.

Consult Management and Scheduling

According to VHA consult policy, "a clear and solid consult process is vital to good patient care."⁴⁰ Requests for consultation from a specialist are made using electronic consults in the EHR and can be scheduled, completed, cancelled, or discontinued. If a provider is added as a 'signer' on the consult and a change is made to the consult status, he/she will receive a "view alert" notifying him/her of the status change. When a consult is submitted, the requesting provider must designate the urgency of the request based on how quickly the provider needs a response from the specialist. Urgent care, which is to be provided on an expedient basis, is care for an acute medical or psychiatric illness or for minor injuries for which there is a pressing need for treatment to manage pain or to prevent deterioration of a condition where delay might impair recovery.⁴¹

Written service agreements are a mechanism used to define work flow rules and support continuity of care when making patient referrals. Service agreements can be created between two or more services that refer patients to one another and typically include the timeframe expected for a response based on the designated urgency. Ideally, this document is developed based on discussion and consensus between the involved services ensuring that providers have the same expectation regarding the standard of care that is to be provided.⁴² VHA requires that the Director ensure the effective use of service agreements, well-designed communication processes, and effective electronic templates are in place in order to reduce the need for additional review of consults prior to scheduling.⁴³

⁴⁰ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008. This Directive expired on September 30, 2013 and has not yet been updated.

⁴¹ PVAHCS Scheduling Policy Memorandum No. HAS 136-83, August 19, 2011.

⁴² VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008.

⁴³ Ibid.

At the time of these events, the system had no active system service agreements for the oncology and neurology services. In July 2015, the system still had not put agreements in place for these services. We reviewed examples of consults placed during the course of the patient's treatment that were designated with a routine urgency even though the providers reported the clinical expectation and need was for a more urgent response.

Conclusions

We substantiated a delay between the diagnosis of the lung cancer and treatment; however, we could not determine whether this delay impacted the final outcome. We substantiated a delay in identification of symptoms of cancer metastasis; however, we did not substantiate a delay in treatment once the brain metastasis was discovered. We identified lack of patient education and PCP involvement in the coordination of subsequent cancer-related specialty appointments as factors contributing to delays in care.

We did not substantiate the allegation that following his craniotomy there was a failure to communicate the patient's status to the patient and family. Documentation in the EHR demonstrated that the patient and his family received accurate information regarding his status and the plan to transition him to a non-VA nursing home and place him in hospice.

We did not substantiate a failure to adequately manage the patient's pain. The patient's comfort and pain management monitoring, decisions, and education were documented in the EHR.

We identified several additional issues during our review. The patient's risk for depression was not fully assessed following the new diagnosis of lung cancer. Non-VA medical records were not consistently available in the EHR, including a PET scan that was essential in the diagnosis and staging of the patient's cancer. Service agreements were not active for the oncology and neurology services, and at the time of our review, the system had not put agreements in place for those services. We discovered examples of consults placed during the course of the patient's treatment that were designated with routine urgency even though the clinical expectation and actual need was for a more urgent response.

Recommendations

Recommendation 1. We recommended that the System Director ensure that primary care providers are notified of specialty evaluations and treatment plans so they can be involved in care coordination.

Recommendation 2. We recommended that the System Director ensure that staff assesses patient learning needs, barriers, abilities and readiness to learn, and that related education is provided as required by local policy, and monitor for compliance.

Recommendation 3. We recommended that the System Director ensure that all patients are annually screened for depression, or more frequently as indicated by existing or newly identified risks, and that system manager's monitor for compliance.

Recommendation 4. We recommended that the System Director ensure that documentation from non-VA clinical care, including radiology reports, are obtained and available in the electronic health record for review in a timely and consistent manner.

Recommendation 5. We recommended that the System Director ensure that system staff place consults with urgency based on the needed response time.

Recommendation 6. We recommended that the System Director review facility service agreements and care coordination in order to better care for patients with complex diseases that require multi-specialty intervention.

Recommendation 7. We recommended that the System Director review this case and consult with the Office of Chief Counsel (formerly Regional Counsel) regarding the care provided and take action if appropriate.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: September 16, 2016

From: Network Director, VA Southwest Health Care Network (10N18)

Subj: Healthcare Inspection—Delay in Care of a Lung Cancer Patient, Phoenix VA Health Care System, Phoenix, Arizona

To: Director, Seattle Office of Healthcare Inspections (54SE)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the findings and recommendations in the OIG report entitled, "Healthcare Inspection-Delay in Care of a Lung Cancer Patient, Phoenix VA Health Care System, Phoenix, Arizona."
2. If you have any questions or concerns, please contact Terri Elsholz, Acting VISN 18 Quality Management Officer, at 480-397-2782.


MARIE L. WELDON, FACHE
Network Director, VISN22

System Director Comments

**Department of
Veterans Affairs**

Memorandum

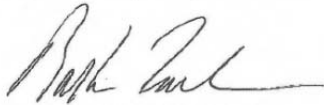
Date: September 16, 2016

From: Interim Director, Phoenix VA Health Care System (644/00)

Subj: Healthcare Inspection—Delay in Care of a Lung Cancer Patient,
Phoenix VA Health Care System, Phoenix, Arizona

To: Acting Network Director, VA Southwest Health Care
Network (10N18)

1. Attached you will find the facility response to Recommendations 1-7 for OIG Draft Report Delay in Care of a Lung Cancer Patient, Phoenix VA Health Care System, transmitted on December 22, 2015.
2. If you have any questions regarding this matter, please contact Jill Friend, Acting Chief of Quality, Safety, and Improvement Service, at (602) 277-5551, extension 6362.



BARBARA FALLEN, FACHE

//es//

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the System Director ensure that primary care providers are notified of specialty evaluations and treatment plans so they can be involved in care coordination.

Concur

Target date for completion: Completed

System response: Specialty providers will add the primary care provider (PCP) as an additional signer on notes pertaining to their patients, including consults sent to other specialty areas. The specialty consult note will include what the specialists will follow and take primary responsibility for and what the PCP is expected to follow and do. If there is disagreement, then the specialist must have a direct conversation with the PCP. If agreement is not reached then, the Section Chiefs/Service Chiefs will be involved. When the specialist believes the PCP can take over care, the specialist will write a formal note to inform the PCP regarding the transfer of care. PCP's will view all consultant notes on their patients.

Primary care providers (PCP's) are automatically notified when a specialty service takes action on a consult. Consult actions include completion, cancellation, and discontinuation. Specialty providers "alert" PCP's electronically when high-risk findings are identified by the Specialist. The Phoenix VA Health Care System developed a "Self-Alert" which allows PCPs to track the progress of patients through their clinical work-ups. This Self-Alert provides an opportunity for all members of the Primary Care Team to assist with coordination of management of complex medical conditions.

Recommendation 2. We recommended that the System Director ensure that staff assesses patient learning needs, barriers, abilities and readiness to learn, and that related education is provided as required by local policy and monitor for compliance.

Concur

Target date for completion: December 31, 2016

System response: Nurses in inpatient wards assess patients' learning needs, barriers, abilities, and readiness to learn during their initial assessment. Currently, these tasks are completed annually in the outpatient setting via completion of Barriers to Learning Clinical Reminder. PACT nursing leadership is updating the Barriers to Learning Clinical Reminder to create a more comprehensive outpatient assessment. The new

clinical reminder will include additional assessment information such as family and caregiver support, level of education, ability to read and write, learning preferences, and specific barriers to learning. This reminder will be completed at the beginning of the outpatient visit with a benchmark of 90% completion by December 31, 2016. Education regarding the new elements in the clinical reminder will be provided by PACT nursing leadership. Compliance will be monitored through completion of the Clinical Reminder.

Recommendation 3. We recommended that the System Director ensure that all patients are screened annually for depression, or more frequently as indicated by existing or newly identified risks, and that system managers' monitor for compliance.

Concur

Target date for completion: September 30, 2016

System response: PVAHCS is revising the depression clinical reminder to include patients who have a prior diagnosis of depression. The national Depression Screen Clinical Reminder is not required as a screen for patients with a diagnosis of depression. However, PVAHCS has determined that a screen is necessary to evaluate whether symptoms have returned. Therefore, patients with a diagnosis of depression will no longer be eliminated from completion of the Depression Clinical Reminder. The External Peer Review Coordinator will monitor compliance with completion of the Reminder on a monthly basis and report results to Clinic leadership.

Recommendation 4. We recommended that the System Director ensure that documentation from non-VA clinical care, including radiology reports, are obtained and available in the electronic health record for review in a timely and consistent manner.

Concur

Target date for completion: September 30, 2016

System response: The PVAHCS business rules for non-VA consult closure includes obtaining records from the vendor and uploading to the Veteran's electronic medical record.

PVAHCS is in the process of hiring a Program Support Assistant whose primary responsibility will be to input Radiology reports from non-VA providers. Radiology reports will be uploaded to the electronic medical record upon receipt.

PVAHCS is developing a report to pull information monthly from open consults for which a non-VA appointment has been scheduled. This report will generate a list of Veterans for whom records must be requested when non-VA care is provided. Tri-West uploads records to the communication portal, which PVAHCS then downloads and inserts into the VA medical record. The consult is closed once the records are received from Tri-West.

Recommendation 5. We recommended that the System Director ensure that when system staff place a consult they designate an appropriate urgency based on the needed response time.

Concur

Target date for completion: December 31, 2016

System response: PVAHCS recently created its consult policy so that consults are either “STAT” or “Routine”; this reflects VHA guidance which was implemented on October 21, 2015. STAT consults are seen within six hours; routine consults are seen within 30 days. Requesting providers are required to speak with the consulting provider to discuss the urgency of a STAT consult. Each service is responsible for maintaining and circulating their monthly on call coverage schedule. A link to the specialty provider coverage is on the facility’s main Intranet page.

There is a mandatory alert in CPRS under the CPRS notification for Consult/Request Resolution. After the consultant has completed and closed their notes for the initial consult, the PCP receives notification of this consult so it can be reviewed. If additional notes are written by the consultant, such as follow-up visits, the consultant will add the PCP as an additional signer to review the note.

Informatics will pull all STAT consults that have been discontinued or cancelled by the receiving service and distribute this data to appropriate Service line Chiefs. Service Chiefs will randomly select 10 of these discontinued/cancelled consults for clinical review on a bimonthly basis to determine if the discontinuation/cancellation was due to an inappropriate urgency status. If trends are identified, the Service Chief will be asked to formulate a plan to address non-compliance with providers. These reports will be monitored at the Consult Management Committee meetings.

Recommendation 6. We recommended that the System Director review facility service agreements and care coordination in order to better care for patients with complex diseases that require multi-specialty intervention.

Concur

Target date for completion: December 31, 2016

System response: PVAHCS has been working diligently to create and/or update service agreements throughout the facility. PVAHCS currently has 24 service agreements between Primary Care and the following services in place:

- Allergy
- Audiology
- Cervical Lumbar Spine Surgery
- Chiropractic Clinic
- Dental
- Dermatology
- Emergency Department
- Endocrinology
- ENT (Otolaryngology)
- Eye Clinic
- Gastroenterology
- Infectious Disease
- Nephrology
- Optometry/Ophthalmology
- Orthopedics
- Physical Rehabilitation
- Pain Management Telehealth
- Podiatry
- Pulmonary
- Speech
- Radiology
- Rheumatology
- Urology

Primary Care Nursing has service agreements with the following service lines:

- Mammogram
- NVCC Eye Care
- Podiatry
- Prosthetics
- Radiology

Primary Care Service plans to complete service agreements with the following service lines by the target date provided above.

- Hematology/Oncology
- Cardiology
- Neurology
- General Surgery
- Thoracic Surgery
- Vascular Surgery
- Mental Health
- Hand and Plastics

Recommendation 7. We recommended that the System Director review this case and consult with the Office of Chief Counsel (formerly Regional Counsel) regarding the care provided and take action if appropriate.

Concur

Target date for completion: October 31, 2016

System response: Facility completed initial internal clinical review on October 8, 2014. This clinical review was discussed with Office of Chief Counsel and facility leadership on March 8, 2016 and it was determined that it would be placed in the Protected Peer Review Process and an Institutional Disclosure will be completed.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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