



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

Office of Healthcare Inspections

Report No. 15-01968-424

Healthcare Inspection

Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation Iowa City VA Health Care System Iowa City, Iowa

July 9, 2015

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:

Telephone: 1-800-488-8244

E-Mail: vaoighotline@va.gov

Web site: www.va.gov/oig

Contents

	Page
Executive Summary	i
Purpose	1
Background	1
Scope and Methodology	4
Case Summary	5
Inspection Results	7
Issue 1	7
Issue 2	13
Conclusions	15
Recommendations	16
Appendixes	
A. Interim Under Secretary for Health Comments	17
B. VISN Acting Director Comments	18
C. System Director Comments	19
D. OIG Contact and Staff Acknowledgments	22
E. Report Distribution	23

Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations at the Iowa City VA Health Care System, Iowa City, IA. The complainant contacted the VA OIG, the Office of the Secretary of Veterans Affairs, and Senator Charles E. Grassley alleging that the facility provided poor quality of care; failed to comply with the Veterans' Access, Choice, and Accountability Act of 2014 (Public Law 113-146); and refused to pay for a lung transplant outside of the VA.

We did not substantiate the allegation that the patient received poor care during a summer 2014 admission to the facility. We could not substantiate whether or not family members were told the patient had pneumonia but did determine that the patient and family members understood that the patient had received antibiotics for "an infection."

We did not substantiate the allegation that the patient received inadequate treatment for her worsening respiratory condition between summer and fall of 2014. Rather, clinicians determined that the patient's lung transplant evaluation should be prioritized in light of the rapid progression of her interstitial lung disease and aggressively pursued testing needed to determine whether or not the patient could receive a lung transplant. We further noted that the radiologist's report from a late summer 2014 computed tomography scan did not conclude that the patient had radiographic findings suggestive of pneumonia.

We substantiated that while an inpatient in fall 2014, physicians did not properly address the patient's multiple episodes of oxygen desaturation because providers did not investigate potentially reversible causes of the patient's deteriorating respiratory status.

We did not substantiate that the facility failed to appropriately train floor nurses on the oxygen equipment in the patient's room but noted that floor nurses had limited experience using some of that equipment.

We substantiated that the patient sustained an acute kidney injury during the course of her fall 2014 hospitalization but did not conclude this resulted from poor quality of care or that this disqualified her from receiving a lung transplant.

We did not substantiate the allegation that the facility failed to appropriately address concerns regarding the patient's care when brought to the attention of the patient advocate and the Chief of Staff.

We did not substantiate that the facility failed to comply with the Veterans Access, Choice, and Accountability Act because the patient did not receive her Choice Card or that the facility refused to pay for the patient's lung transplant at an outside hospital, forcing her to travel to a VA facility out of state to receive the transplant. Instead, we determined that in fall 2014, the facility authorized a lung transplant at the outside hospital, but the hospital would not accept the patient because the hospital stated

Veterans Health Administration (VHA) reimbursement does not cover the cost of organ acquisition.

We recommended that the Interim Under Secretary for Health review how VHA compensates non-VA facilities for lung transplantation to ensure that reimbursement is appropriate for the services performed. We further recommended that the facility perform a focused professional practice evaluation of care provided by the attending physicians providing care during the patient's fall 2014 hospitalization.

Comments

The Interim Under Secretary for Health, Veterans Integrated Service Network Acting Director, and Facility Director concurred with our recommendations and provided an acceptable action plan. (See Appendixes A–C, pages 17–21 for the Interim Under Secretary for Health and Directors' comments.) We will follow up on the planned actions until they are completed.



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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection of the Iowa City VA Health Care System (facility), Iowa City, IA to assess the merit of allegations made by a complainant to Senator Charles E. Grassley, the VA Secretary, and the OIG regarding poor quality of care; failure to comply with the Veterans' Access, Choice, and Accountability Act of 2014 (VACAA); and refusal to pay for a lung transplant outside of the VA.

Background

The facility consists of a tertiary care university-affiliated teaching hospital with 83 acute medical, surgical, and psychiatric beds, including 10 beds in the Intensive Care Unit (ICU). The facility provides specialty services including kidney and pancreas transplants. Outpatient care is provided at the parent facility and 10 community based outpatient clinics (CBOCs), 7 in Iowa and 3 in Illinois. The facility is part of Veterans Integrated Service Network (VISN) 23 and serves veterans in 33 counties in eastern Iowa, 16 counties in western Illinois, and 1 county in northern Missouri.

Interstitial Lung Disease. Interstitial lung disease (ILD) describes a group of lung diseases that inflame or scar the lungs. The inflammation and scarring make it difficult to get enough oxygen into the blood stream.¹ ILD encompasses more than 100 different disorders, generally grouped into exposure-related ILD, genetic disorders, ILD resulting from a systemic disease, or ILD of unknown cause. ILD of unknown cause is more common than exposure-related or occupational ILD.

Chronic silicosis is an exposure-related ILD that results from inhaled silica particles. Occupations that commonly entail exposure to silica include mining, tunneling, sandblasting, and foundry work, but can also include individuals who work on dental implants. The impact of scarring in the lungs for patients with exposure to silica varies widely, with some patients having few if any symptoms and others developing widespread scarring, or fibrosis, which can progress even in the absence of continued exposure. No proven medical therapy exists for silicosis other than eliminating future exposure, medications to reduce symptoms related to mucus production or obstructive airway disease. Pulmonary rehabilitation may improve a patient's functional status, but many patients will require lung transplantation for continued survival.²

Veterans Health Administration Transplantation Services. The Veterans Health Administration (VHA) has provided transplantation services since 1962. In calendar year 2014, 2,308 veterans were referred for transplant evaluation, and 516 veterans

¹ Oxygenation in the blood stream is measured by the use of a pulse oximeter. This device measures the oxygen saturation in blood. Generally, an oxygen saturation greater than 90% is considered adequate.

² Paoletti, Timothy P. and M. Whelan. "Lung transplantation for interstitial lung disease." Current Respiratory Care Reports vol. 3, issue 3, September 2014, pp. 96–102.

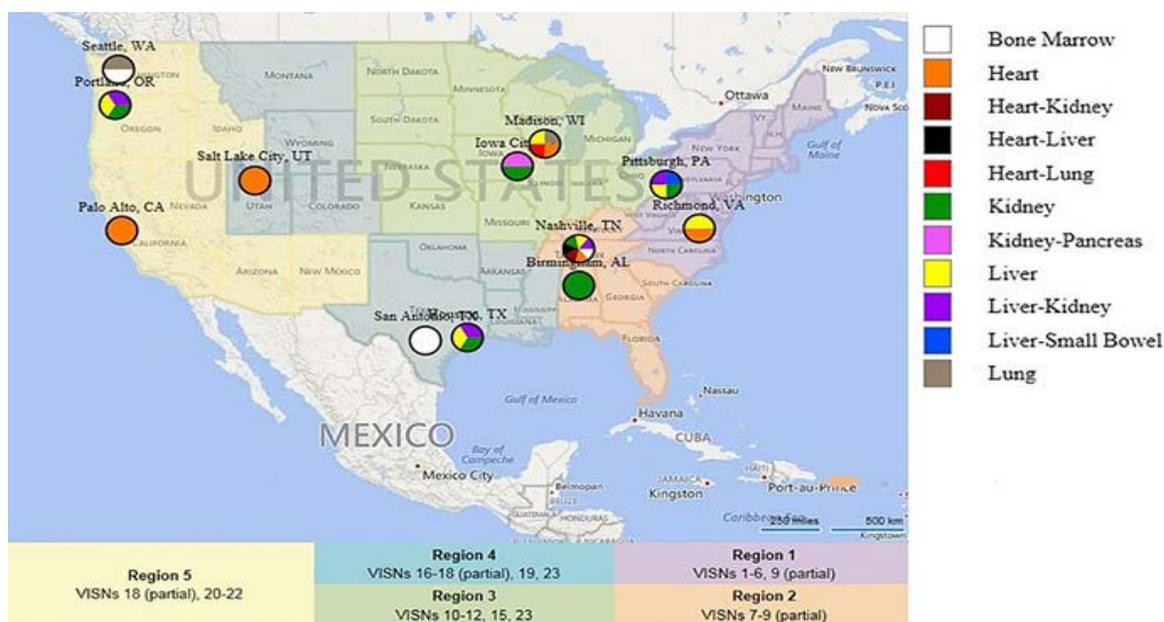
had solid organ or bone marrow transplantation at an approved VA transplant center (VATC).

VHA Directive 2012-018, *Solid Organ and Bone Marrow Transplantation*, July 9, 2012, provides policy for ensuring patients' access to solid organ and bone marrow transplantation, post-transplantation health care, as well as providing guidance to VA facilities regarding the responsibilities of the National Surgery Office in oversight and funding of the VHA Transplant Program.

Beginning in 2011, the VA National Surgery Office substantially modified the transplant referral process between the referring VA medical facility staff and the VATC staff with the goal of streamlining patients' access to transplant services and reducing wait times. To expedite case reviews, enhancements included implementation of an electronic transplant referral process that distinguishes stable from emergency referrals based on the patient's immediate health care needs.

VATCs are located across the country (see Figure 1). Lung transplants are provided at VA facilities in Madison, WI and Seattle, WA. VHA policy provides reimbursement to the veteran and a support person for all transplant-related round-trip travel costs to the VATC for the pre-transplant evaluation, transplant episode, and post-transplant follow-up.

Figure 1 Locations of VA Transplant Centers



Source: <http://www.va.gov/health/services/transplant/>

The Scientific Registry of Transplant Recipients³ lists 70 non-VA hospitals with lung transplant centers having at least one case since July, 2011. The University of Iowa Hospital and Clinics, Iowa City, Iowa is the only facility providing this service in the State of Iowa.

Non-VA Funding for Transplantation Services. Funding sources that help cover the cost of lung transplants for veterans and non-veterans include private health insurance, Medicare, Medicaid, and Tricare. In 1995, Medicare issued a national coverage decision authorizing payment for lung transplantation when centers performing the transplant procedure met certain criteria. Lung transplants paid for by Medicare are covered using Medicare Part A (Hospital Insurance), Medicare Part B (Medical Insurance), and Medicare Part D (Prescription Drug Plan). Hospitals generally receive reimbursement through Medicare Part A, while professional services of individual practitioners, as well as laboratory services and certain medications, are generally covered under Medicare Part B. Medicare enrollees pay 20 percent of the Medicare-approved amount for doctors' services. Most outpatient medications are covered under Part D.

Allegations

On December 10, 2014, the VA OIG Hotline Division referred a complaint alleging poor quality of care for a single patient at the Iowa City VA Health Care System to the OIG's Office of Healthcare Inspections. The same complainant also contacted the Office of the Secretary of Veterans Affairs and Senator Charles E. Grassley.

The complainant alleged that the facility provided poor quality of care to the patient from summer 2014 through fall 2014. Specifically, the complainant alleged:

- The patient received inappropriate treatment during a summer 2014 admission to the facility, and physicians failed to communicate the diagnosis of pneumonia to the patient or the patient's family members.
- Between summer and fall 2014, the patient received inadequate treatment for her worsening respiratory condition.
- During a fall 2014 hospitalization, the patient received poor quality of care. Specifically, the patient's multiple episodes of oxygen desaturation⁴ were not appropriately addressed by physicians, and nurses working on the medical floor were not properly trained to use the oxygen equipment in the patient's room.

³ The Scientific Registry of Transplant Recipients (SRTR) is a group that supports ongoing evaluation of the status of solid organ transplantation in the United States. It is administered by the Chronic Disease Research Group of the Minneapolis Medical Research Foundation with oversight and funding from the Health Resources and Services Administration.

⁴ Oxygen desaturation refers to when the oxygen saturation drops below 90 percent. Oxygen saturations less than this are considered too low to adequately oxygenate the body's organs.

- As a result of poor care during the patient's fall 2014 hospitalization, the patient experienced a loss of kidney function, which may disqualify her from receiving a lung transplant.
- The facility did not appropriately address concerns regarding the patient's care when the complainant raised them with the patient advocate and the Chief of Staff.

The complainant further alleged that the facility did not comply with VACAA because:

- The patient had not received a Choice Card, and
- The facility refused to pay for the patient's lung transplant at a private hospital but instead is forcing the patient to travel to a VA facility out of state to receive the transplant.

Scope and Methodology

The scope of our inspection was the review of the facility's processes related to the provision of care for a single patient. The inspection was conducted from January 20, 2015, through March 27, 2015.

We interviewed the complainant to clarify allegations. We reviewed relevant VHA and facility policies and procedures, quality management documents, the patient's VA electronic health record (EHR) and non-VA medical records, as well as other pertinent documents. We conducted a site visit March 10–11, 2015. We interviewed the patient, clinical staff, facility leadership, patient advocate staff, business office staff, and staff from the University of Iowa knowledgeable about funding processes for solid organ transplantations.

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 is a service-connected veteran who worked as a dental technician for several years in the military. As a dental technician, the patient had been exposed to silica and developed ILD almost 10 years ago. While the patient's EHR does not document the histologic type of ILD, a lung biopsy at the time of diagnosis demonstrated fibrosis and honeycombing without granulomas or lymphocytic infiltration.

The patient presented to the facility for admission in summer 2014, after being transferred from an outside hospital's Emergency Department (ED). At the time of presentation to the facility, the patient was in her mid 50s with a history of pulmonary fibrosis, gastroesophageal reflux disease, and sleep apnea. The patient complained of one episode of epigastric pain the night before admission that lasted less than 30 minutes and resolved on its own as well as significantly increased shortness of breath for approximately 2 weeks. The patient also described some mildly increased shortness of breath for some months prior to the summer ED visit. Laboratory evaluations completed in the outside ED suggested that the patient could have a pulmonary embolism.

Because the patient had a severe allergy to contrast dye, which increased the risk of performing a computed tomography (CT) scan to determine whether the patient had a pulmonary embolism, the facility pulmonologist considered obtaining a V/Q scan instead of a CT scan.⁵ However, because of the patient's underlying lung disease, the pulmonologist did not believe the V/Q scan would be helpful in diagnosing a pulmonary embolism. He further noted that a lower extremity ultrasound was not available at the facility on that day. The patient did receive a chest x-ray, which the radiologist read as consistent with ILD, but noted that a pneumonia at the left lung base "was not excluded." Pleural spaces did not contain fluid, although some interstitial edema was noted on the x-ray.

Overall, the pulmonologist felt that the likelihood of the patient having a pulmonary embolism was very low. Instead, he believed the cause of the patient's condition was worsening pulmonary fibrosis and a possible pneumonia. Specifically, the pulmonologist documented that "the chest x-ray and history are consistent with pneumonia, although certainly not specific."

The pulmonologist recommended that the patient be discharged on 10 days of antibiotics (moxifloxacin) and follow up with the pulmonologist. In the interim, the patient's home oxygen was increased to 4 liters per nasal cannula with activity and 2 liters at rest. The patient had not previously required oxygen at rest. The discharge summary for the summer hospital admission listed "progressive worsening of chronic lung disease" as the patient's principal diagnosis. It did not indicate the patient had pneumonia.

⁵ V/Q scan: A lung ventilation/perfusion scan is a test used to determine how well air moves and blood flows in the lungs.

Facility staff called the patient 2 days after discharge and recorded that the patient's condition was "improved." When the patient returned to the pulmonologist, approximately 2 weeks after discharge, the pulmonologist noted that the antibiotics had not improved the patient's symptoms. He further noted a significant decline in the patient's lung function, which he attributed to worsening pulmonary fibrosis and scheduled a repeat CT scan of the chest without contrast, an echocardiogram, and arranged for a lung transplant evaluation. The patient received two phone calls within a week from the transplant coordinator.

In late summer, the patient received the CT scan of the chest, which described worsening pulmonary fibrosis, but did not identify a pneumonia. Approximately 10 days later, the patient had a negative cardiac stress test. Thereafter, the patient received multiple appointments and additional tests to further evaluate whether the patient could benefit from a lung transplant. This workup included right and left heart catheterizations and carotid ultrasound studies. The right heart catheterization identified moderate pulmonary hypertension.

In early fall, a VA Staff Physician Assessment for Transplant Candidates done at the facility documented that the transplant coordinator and pulmonologist did not believe any contraindication existed to lung transplant.

About 3 weeks later, the patient returned to the facility's ED with complaints of increasing shortness of breath for the past 3 days. On arrival, the patient was on 4 liters of oxygen but had oxygen saturations of only 47–51 percent. The patient was placed on BiPAP,⁶ started on intravenous antibiotics for a possible pneumonia, and transferred to the ICU.

In the ICU, the patient initially did well and was weaned off BiPAP. The patient still required high flow oxygen and had episodes of desaturation when getting up to go to the restroom. On hospital day 3, a follow-up chest x-ray demonstrated findings consistent with either infection or increased fluid in the lungs (interstitial edema).

On hospital day 5, the patient's physician transferred her from the ICU to a medical floor. Between hospital day 5 and 11, EHR notes document that the patient had multiple episodes of desaturation when attempting to go to the bathroom. Each of these episodes resolved with administration of higher flow oxygen and rest. On hospital day 7, a respiratory therapist documented that the patient needed 50 percent oxygen by aerosol face mask to keep oxygen saturations 93–96 percent. On hospital day 8, documentation reflected that the patient was on 40–60 percent oxygen by face mask, but requirements stabilized at 60 percent. However, later in the day, staff called the rapid response team because the patient's oxygen saturations dropped into the 60s after the patient got up to go to the bathroom. Staff stabilized her oxygen saturation

⁶ BiPAP refers to a device that provides noninvasive ventilation through a face mask. BiPAPs are used to help keep the lungs open.

using an Ambu bag⁷ and 100 percent oxygen. Thereafter, the patient received 80 percent oxygen by face mask. On hospital day 9, the resident's note indicated that the patient's oxygen saturations were dropping even if the oxygen was turned up to 95 percent prior to exertion. Nursing notes documented another episode of desaturation on hospital day 10.

On hospital day 11, the patient desaturated and did not respond to higher flow oxygen or initiation of BiPAP. The patient's physician ordered a portable chest x-ray, the first chest x-ray performed since hospital day 3, which demonstrated worsening bilateral diffuse lung space opacities, consistent with bilateral pneumonia or pulmonary edema (fluid in the lungs). The patient was intubated, transferred back to the ICU, and subsequently transferred to an outside hospital at the family's request.

At the outside hospital, providers determined that the patient's deterioration in respiratory status resulted from increased fluid in the lungs secondary to a stiffening of the heart muscle. The patient responded to diuretics and was discharged home almost a month after her initial admission to the facility

Inspection Results

Issue 1: Alleged Poor Quality of Care

Allegation: The patient received inappropriate treatment during a summer 2014 admission to the facility, and physicians failed to communicate the diagnosis of pneumonia to the patient or patient's family.

We did not substantiate the allegation that the patient received poor care during a summer 2014 admission to the facility. Further, we could not substantiate whether or not family members were told the patient had pneumonia but determined that the patient and family members understood that the patient had received antibiotics for "an infection."

While an outside hospital transferred the patient to the facility because a blood test suggested a possible pulmonary embolism, the patient's history was more consistent with pneumonia or an upper respiratory infection with worsening of her ILD. Both an internal medicine physician and a pulmonologist saw the patient and believed treatment for a respiratory infection was more appropriate. Both physicians considered further evaluation of a possible pulmonary embolism but concluded that additional testing would not be appropriate. The patient's history of an allergy to contrast dye made her a poor candidate for a CT scan of the chest with contrast dye and a V/Q scan would not be helpful in determining whether or not the patient had a pulmonary embolism because the patient's underlying lung disease would cause the scan to be read as abnormal whether or not the patient had a pulmonary embolism.

⁷ Ambu bag: A valve mask typically attached to oxygen and a bag, which is squeezed to force oxygen into a patient's lungs. This type of mask is used for artificial ventilation when a patient cannot breathe on his/her own.

Often, a pulmonary embolism starts as a blood clot in a deep vein within the leg, which breaks free and moves through the circulation to the lung. Therefore, another way to test for a likely pulmonary embolism is to look for residual clot in a patient's legs with ultrasound. The EHR documents that a lower extremity ultrasound was not available when the patient presented to the facility. The Chief of Radiology and a vascular lab technician both informed us that lower extremity ultrasounds were performed in the vascular lab, not in radiology, and were only available during certain hours. The vascular lab is staffed by two technicians from 8:00 a.m. to 4:30 p.m. Monday through Friday. While we found that the lower extremity ultrasound was not available, physicians reasonably determined based on the patient's history and clinical condition that the patient had pneumonia and worsening ILD and that additional evaluations for a pulmonary embolism were not necessary.

In addition, the patient's oxygen requirements returned to pre-hospitalization levels, according to the EHR. The patient normally used four liters of oxygen by nasal cannula when walking on a treadmill in Pulmonary Rehabilitation. The patient reported being unable to maintain adequate oxygen saturation on that amount of oxygen for the 2 weeks prior to presentation when she had oxygen saturations in the 70–80 percent range after ambulating. On arrival to the floor, a nurse documented that the patient had oxygen saturations of 95–100 percent on 3 liters of oxygen. A respiratory therapist measured the patient's oxygen saturation while walking and determined that the oxygen saturation remained adequate with ambulation if the patient was placed on four liters of oxygen, the amount of oxygen the patient received at home with ambulation.

A pulmonologist saw the patient and recommended that she be discharged home on a 10-day course of moxifloxacin. We consulted with the Chief of Infectious Diseases at the facility, who informed us that this was an adequate antibiotic choice for the treatment of community-acquired pneumonia based on local antibiotic resistance patterns. The facility's antibiogram also supported the efficacy of antibiotics in this class for community-acquired pneumonia.

While we cannot determine if family members were told that the patient had pneumonia, the EHR documents in a note following the patient's hospital discharge that: "Pt states she was seen in the ER with concerns of pneumonia but was cleared." This suggests that, while the patient understood she had been evaluated for pneumonia, she may not have understood that she had been diagnosed with pneumonia.

Allegation: Between summer and fall 2014, the patient received inadequate treatment for her worsening respiratory condition.

We did not substantiate the allegation that the patient received inadequate treatment for her worsening respiratory condition between summer and fall 2014. Rather, clinicians determined that the patient's lung transplant evaluation should be prioritized in light of the rapid progression of her ILD and aggressively pursued testing needed to determine whether or not the patient could receive a lung transplant.

The pulmonologist evaluated the patient within 2 weeks of the patient's summer hospital discharge. He documented that the patient's oxygen saturations did seem to be dropping with exertion and that this likely reflected a worsening of ILD or possible pulmonary hypertension. He placed a consult requesting that the patient be evaluated for lung transplant and ordered a CT scan of the chest without contrast as well as an echocardiogram of her heart. Two days later, the patient received a telephone call from the transplant coordinator, who asked her to set up a time that the patient and a caregiver could meet to discuss the transplant referral process. The patient and a caregiver met with the transplant coordinator a few days later. In the interim, the transplant coordinator asked the patient's primary care provider to move up the patient's mammogram and pap smear so that it could be completed as part of the transplant evaluation. The pharmacy renewed the patient's prescription for moxifloxacin.

About a month after she first presented to the facility in the summer 2014, the patient received a CT scan of the chest without contrast, which demonstrated worsening of the patient's ILD. The radiologist did not identify a pneumonia on this scan. On the same day, the patient called a pulmonary case manager to report congestion and coughing up phlegm streaked with blood. The case manager informed her that coughing up a small amount of blood was common in patients with a chronic cough. The case manager forwarded the note to the pulmonologist, who signed it.

In late summer, the patient received cardiac stress testing and extensive psychological testing as part of the transplant evaluation. About 2 weeks later, the transplant coordinator contacted the patient to see how she was doing with the multiple appointments. This note does not reflect that the patient was experiencing worsening of her pulmonary symptoms.

The pulmonologist saw the patient again, about 1 week after the transplant coordinator contacted the patient to check with her concerning the multiple appointments. He noted that the patient had pulmonary hypertension, with a pulmonary artery systolic pressure of 60 mmHg (normal range 15–25 mmHg). He also noted increased green sputum production. Right and left heart catheterizations were done that demonstrated moderate pulmonary hypertension but normal coronary arteries. In early fall, the EHR documents that transplant referrals were sent to VA Central Office and to the VA hospital in Madison, WI.

Three weeks later, continuing with the transplant evaluation, the patient presented to the facility for a sleep study. However, her oxygen saturation was low, so pulmonary staff sent her to the ED for further evaluation and treatment.

We did not substantiate the allegation that the facility did not adequately treat the patient's worsening pulmonary status. The only effective treatment for advanced ILD is lung transplantation, which clinicians pursued during this time period. We further noted that the radiologist's report from the CT scan did not conclude that the patient had radiographic findings suggestive of pneumonia.

Allegation: During a fall 2014 hospitalization, the patient received poor quality of care. Specifically the patient's multiple episodes of oxygen desaturation were not appropriately addressed by physicians, and that nurses working on the medical floor were not properly trained to use the oxygen equipment in the patient's room.

Alleged Failure of Physicians to Appropriately Address the Patient's Oxygen Desaturation. We substantiated that physicians did not properly address the patient's multiple episodes of oxygen desaturation because providers did not investigate potentially reversible causes of the patient's deteriorating respiratory status.

On her first hospital day of the fall admission, while still in the ICU, the patient's chest x-ray demonstrated possible pulmonary edema. The physician gave her a diuretic (a medication that causes increased urination to remove excessive fluid from the body) and reported high urine output after administration of the medication. He also ordered a blood test for congestive heart failure, known as a BNP.⁸ The patient's BNP was 736 pg/ml, a number consistent with, but not diagnostic of, congestive heart failure. Congestive heart failure is a clinical diagnosis, meaning that the diagnosis is based on the patient's symptoms and clinical examination findings, not on the basis of a single laboratory test.

Following diuresis, the patient clinically improved, but the chest x-ray did not change. Therefore, the physician determined that the patient's condition likely resulted from a pneumonia. The patient continued on antibiotics. On hospital day 4, the physician documented that he would consider transferring the patient to the floor when she was on 6 liters of oxygen by nasal cannula.

However, he transferred the patient to the floor the next day. Respiratory notes documented that the patient required 60 percent oxygen by face mask with occasional oxygen by nasal cannula at a rate of 7 liters per minute.

Over the next 5 days, while on a general medicine floor, the EHR documents that the patient had seven episodes of oxygen desaturation severe enough to require respiratory therapists or nurses to use an Ambu bag for ventilation. These episodes resulted from minimal exertion, such as the patient moving from bed to a bedside commode. Despite these episodes, clinicians did not alter medical management or investigate other potential causes of the patient's deteriorating pulmonary status. Orders entered during those 5 days included only routine laboratory orders and one order for an electrocardiogram and ambulatory pulse oximetry (measurement of oxygen saturation while walking).

⁸ BNP refers to brain type natriuretic peptide—a blood test that measures protein secreted in the blood in response to changes in pressure that occur with heart failure. BNP levels below 100 pg/mL indicate no heart failure. BNP levels of 100–300 pg/mL are generally inconclusive; while BNP levels above 300 pg/mL often indicate some degree of heart failure. However, BNP results must be interpreted in light of the patient's overall clinical status.

The patient did not have a chest x-ray or an arterial blood gas⁹ between hospital day 3 and 11 despite increasing needs for oxygen during this time period. Providers did not document consideration of her volume status and whether this could be a contributing factor to her respiratory status. Rather, the EHR documents providers attempted to ready her for discharge home and attributed her condition solely to underlying ILD.

We concluded the patient's providers did not appropriately address the patient's episodes of severe oxygen desaturation.

Alleged Failure to Properly Train Nurses. We did not substantiate that the facility failed to appropriately train floor nurses on the oxygen equipment in the patient's room but noted that floor nurses had limited experience using some of that equipment.

The ICU physician moved this patient to a medical floor, where the patient received continuous monitoring of both telemetry and oxygen saturations. However, on a medical floor, nurses typically are responsible for more patients than in an ICU and have less immediate access to respiratory therapy services.

General medical floor nurses receive training in how to use oxygen equipment. Annual competency training for facility ICU and general medical floor nursing staff included employee demonstration of the ability to provide oxygen therapy using a variety of devices and the identification of resources to use when questions arise related to oxygen therapy. All ICU and general medical floor nursing staff are required to complete Basic Life Support for Healthcare Providers and Advanced Cardiovascular Life Support training every 2 years. Both of these courses include training on bag-valve-mask technique (Ambu bags).

However, training on certain techniques does not necessarily equate to proficiency. Floor nurses involved in the care of this patient confirmed they had limited experience in caring for patients with respiratory needs as severe as this patient. The patient and the patient's family members reported observing incidents where nursing staff did not seem to understand how the oxygen equipment worked, such as failing to hook up the Ambu bag to oxygen and which way to turn the knob to increase or decrease the flow of oxygen. Patients requiring periodic use of an Ambu bag are not common on the medical floors

The patient's family also reported that nursing staff did not consistently increase the patient's oxygen flow prior to exertion, such as the patient getting out of bed to use a bedside commode. The EHR documents instances of nursing staff increasing the patient's oxygen flow prior to the patient getting up or exerting herself. However, nursing staff informed us that at times, the patient would get up on her own, which did not allow them to increase her oxygen sufficiently to prevent episodes of desaturation.

⁹ An arterial blood gas is a blood test that measures the amount of oxygen and carbon dioxide in the blood stream. It is more accurate, and provides more information, than an oxygen saturation measured through a pulse oximeter.

While the patient and family's recollection of these episodes differed from documentation in the EHR and the recollection of floor nurses, we did determine that two floor nurses involved in this patient's care felt uncomfortable caring for this patient on a general medical floor. Both stated that a patient who required use of an Ambu bag to recover her oxygen saturations had a greater need for care than patients typically handled on the general medical floor.

Allegation: As a result of poor care during the patient's fall 2014 hospitalization, the patient experienced a loss of kidney function which may disqualify her from receiving a lung transplant.

We substantiated that the patient sustained an acute kidney injury during the course of her fall 2014 hospitalization but did not conclude this resulted from poor quality of care because the patient had multiple reasons for a decline in her kidney function apart from deficiencies in the quality of care. We also did not determine that her decline in kidney function disqualified her from receiving a lung transplant.

The patient received laboratory tests regularly that monitored her kidney function during her hospitalization at the facility. Her creatinine remained normal until hospital day 10, when it increased from .66 to 1.4 mg/dl (normal range .5–1.0 mg/dl).

The patient also had regular blood tests to check the level of vancomycin in the blood. These blood tests demonstrated elevated levels of vancomycin in the blood. The patient's trough levels (the lowest level of medicine in the blood) of vancomycin ranged from 16.7 to 29.3 ug/ml (normal 6.0 to 15 ug/ml) for the 7 days during which she received vancomycin. Vancomycin trough levels greater than 20 ug/ml can be associated with kidney injury.

We did not find evidence that clinicians altered the patient's dose of vancomycin in response to these elevated levels. However, because the patient had multiple reasons for acute kidney injury, including an underlying infection and episodes of hypoxemia, we could not conclusively determine that the acute kidney injury resulted from elevated levels of vancomycin.

The facility transferred the patient at her family's request to a non-VA hospital on hospital day 12. On arrival to the outside hospital, the patient had a creatinine of 1.9 mg/dl. She had a low blood pressure (86/46 mmHg), which can also cause acute kidney injury. Notes from the outside hospital suggest that medications given following intubation may have resulted in the low blood pressure and kidney injury. This is a recognized effect of certain medications given following intubation.

After providers changed the patient's medications, the patient's blood pressure improved. The outside facility determined that her respiratory failure resulted from volume overload, and gave her diuretics. This resulted in a rapid improvement in her respiratory status, and she was successfully extubated and discharged from the outside hospital two weeks after transfer. She had several follow-up appointments at the outside facility. About 10 days after discharge, the non-VA facility evaluated her for lung

transplant, noted that her renal function had normalized, and found that she met criteria to be listed for a lung transplantation procedure.

While we substantiated that the patient sustained an acute kidney injury during her hospitalization, we did not substantiate this was the result of poor care as there are many potential causes for this patient to have developed acute kidney injury. However, clinicians missed opportunities to alter vancomycin dosing in the setting of elevated blood levels, which would have reduced the patient's risk of developing acute kidney injury.

Allegation: The facility did not appropriately address concerns regarding the patient's care when the complainant raised them with the patient advocate and the Chief of Staff.

We did not substantiate the allegation that the facility failed to appropriately address concerns regarding the patient's care when brought to the attention of the patient advocate and the Chief of Staff. Four contacts on behalf of the patient were entered in the Patient Advocate Tracking System between fall 2014 and winter 2015. The first contact outlined concerns expressed by the family regarding the inpatient care provided to the patient and the desire to have the patient transferred to a non-VA hospital.

Interviews with staff, and review of facility documentation of the reported concerns, align with those expressed by the complainant. Onsite documentation provided evidence of actions taken by the facility to study the concerns brought to the staff's attention and the patient's timely transfer to a non-VA hospital, as requested. The physician who had been caring for the patient called the complainant to provide information in response to her questions and concerns. Some of the actions taken by the facility involved protected quality management reviews, the results of which could not be shared with the complainant. The other three contacts with the Patient Advocate office were issue specific and able to be resolved right away. One was to gain information on managing medication prescriptions from non-VA providers, another to communicate which VA staff was to no longer have contact with the patient and the final inquiry, made on behalf of the family, was to inquire about the patient's eligibility to use her Choice card.

Issue 2: Alleged Failure To Comply with the VACAA

Allegation: The facility did not comply with the Veterans Access, Choice, and Accountability Act of 2014 because: (a) the patient did not receive a Choice Card.

We did not substantiate that the facility failed to comply with the VACAA because the patient did not receive a Choice Card.

VACCA requires that Choice cards be sent out to all veterans who were enrolled in VA care as of August 1, 2014. In order to use the card for services, veterans must live 40 miles or more from the nearest VA medical center, including outpatient clinics, or be unable to be seen by the VA within 30 days.

Facility staff reported that Choice cards were mailed out from November 2014 through February 2015. The patient confirmed receipt of the Choice card along with a letter outlining the process to determine eligibility prior to using the card. Until recently, the patient's temporary residence was located within 40 miles of a VA medical center; however, the patient's return to her rural permanent residence makes it likely that she will be eligible to use the card based on distance. If determined to be eligible, the patient plans to use the card for primary care services.

(b) the facility refused to pay for the patient's lung transplant at a private hospital but instead is forcing the patient to travel to a VA facility out of state to receive the transplant.

We did not substantiate that the facility refused to pay for the patient's lung transplant at a private hospital, forcing the patient to travel to a VA facility out of state to receive the transplant. Instead, we determined that on hospital day 12 of her fall 2014 admission (day of transfer to the non-VA hospital), the facility authorized a lung transplant at the outside hospital, but the hospital would not accept the patient because the outside facility stated VHA reimbursement does not cover the cost of organ acquisition.

Under 38 CFR. 17.56, various pricing methodology control VHA's payment for non-VA inpatient and outpatient health care professional services, including applicable Medicare fee schedules and prospective payment amounts unless otherwise negotiated with a specific provider. Likewise, VHA's reimbursement for hospital-based services, including transplant procedures, is based on the fees established under Medicare Part A. While fees that would be paid to the outside hospital under the DRG code¹⁰ for lung transplantation would be comparable to Medicare, outside facilities recoup the cost of organ acquisition through a separate Medicare process.

Medicare Part A reimburses organ acquisition costs as pass through costs based on the ratio of Medicare transplants to total transplants. Medicare makes interim payments throughout the year based on reasonable cost estimates associated with organ acquisition. Then, at the end of the year, each hospital files a cost report.

The cost report describes the actual costs associated with the provision of medical services at the outside facility. Reported costs for organ acquisition include organ donor and recipient costs before hospital admission for the transplant and hospital inpatient costs associated with the donor. The outside facility informed us that the cost they would expect to recoup from Medicare through this process for a lung transplant would be approximately \$103,362 for two lungs.

VHA authorizes only a two percent surcharge on the inpatient lung transplant charges for the cost of organ procurement. In this case, the outside facility expected that amount to be \$6,380 based on DRG 007 lung transplant charges of \$319,000, meaning

¹⁰ Diagnosis Related Groups (DRGs) are groupings of hospitalized patients by diagnosis which are used to calculate appropriate Medicare reimbursement rates.

that VHA would pay an amount \$96,982 less than what the outside facility would expect to recoup through Medicare. As a result, the outside facility elected not to perform the procedure.

On learning of the transplant funding gap, staff at the facility explored funding options through VACAA and the National Surgery Office. Payment through VACAA was explored and, like non-VA care, was found to be based on fees established under Medicare. VACAA payments go through a third party administrator. In winter 2015, facility staff received confirmation from the National Surgery Office that Transplant Special Purpose Funding is limited to the support of approved VHA Transplant Programs and is not to be used for the financial reimbursement of solid organ transplantation when performed outside of an approved VHA Transplant Program.

The patient completed the work up for a lung transplant at the VATC in Madison, WI, soon after the new year, 2015. While in Wisconsin the patient learned that a caregiver would be required from the time of placement on the lung transplant list through the initial outpatient care following transplantation. VATC staff reported that multiple people could assume the role of caregiver throughout this time as long as there was no gap in time as one caregiver switched over to another. At the time of the transplant evaluation, the patient's son was identified as the person most likely to serve in this capacity. The patient reported being told that the total amount of time away from home could be up to 9 months.

The patient was presented to the Madison, WI, VATC Lung Transplant Review Board, and the decision was made that the patient was eligible for lung transplant listing. The patient was notified of this decision and declined to be listed. Reasons given for the declination included the lack of an onsite caregiver to accompany her to the VATC, a desire to remain closer to family, and the understanding that the VA would pay for the transplant at the outside hospital closer to home.

At the time of this inspection, factors contributing to the delay in lung transplantation for this patient included the lack of a full-time attendant to accompany her to a VATC and the lack of a funding mechanism to cover the payment gap using the approved VA fee schedule at an outside hospital.

In spring 2015, the OIG contacted senior staff within VHA to discuss the case of this veteran. VHA confirmed knowledge of the situation and indicated efforts were underway to put a lung transplant surgery contract in place with the local outside hospital. About 3 weeks later, the OIG received confirmation that the contract had been executed.

Conclusions

We did not substantiate the allegation that the patient received poor care during a summer 2014 admission to the facility. Further, we could not substantiate whether or not family members were explicitly told the patient had pneumonia, but did determine

that the patient and family members understood that the patient had received antibiotics for “an infection.”

We did not substantiate the allegation that the patient received inadequate treatment for her worsening respiratory condition between summer and fall 2014. Rather, clinicians determined that the patient’s lung transplant evaluation should be prioritized in light of the rapid progression of her ILD and aggressively pursued testing needed to determine whether or not the patient could receive a lung transplant. We further noted that the radiologist’s report from the late summer 2014 CT scan did not conclude that the patient had radiographic findings suggestive of pneumonia.

We substantiated that while an inpatient in fall 2014, physicians did not properly address the patient’s multiple episodes of oxygen desaturation because providers did not investigate potentially reversible causes of the patient’s deteriorating respiratory status.

We did not substantiate that the facility failed to appropriately train floor nurses on the oxygen equipment in the patient’s room but noted that some floor nurses had limited experience caring for this type of patient and were often not comfortable caring for this patient’s respiratory needs.

We substantiated that the patient sustained an acute kidney injury during the course of her fall 2014 hospitalization but did not conclude this resulted from poor quality of care, or that this disqualified her from receiving a lung transplant.

We did not substantiate the allegation that the facility failed to appropriately address concerns regarding the patient’s care when brought to the attention of the patient advocate and the Chief of Staff.

We did not substantiate that the facility failed to comply with the VACAA because the patient did not receive her Choice Card or that the facility refused to pay for the patient’s lung transplant at an outside hospital, forcing her to travel to a VA facility out of state to receive the transplant. Instead, we determined that in fall 2014, the facility authorized a lung transplant at the outside hospital, but the hospital would not accept the patient because the outside facility stated VHA reimbursement does not cover the cost of organ acquisition.

Recommendations

1. We recommended that the Interim Under Secretary for Health review how the Veterans Health Administration compensates non-VA facilities for lung transplantation to ensure that reimbursement is appropriate for the services performed.
2. We recommended that the System Director conduct a focused professional practice evaluation of the care provided by attending physicians at the facility during the patient’s fall 2014 hospitalization.

Interim Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: APR 28 2015

From: Interim Under Secretary for Health (10)

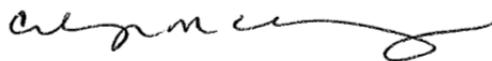
Subj: Office of Inspector General (OIG) Draft Report: Healthcare Inspection Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation, Iowa City VA Health Care System, Iowa City, Iowa (VAIQ 7594010)

To: Assistant Inspector General for Healthcare Inspections

1. Thank you for the opportunity to review the OIG draft report on the Healthcare Inspection of Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation at the Iowa City Health Care System in Iowa City, Iowa.

2. I concur with the findings and recommendations in the draft report and provide comments in response to recommendation 1. Comments in response to recommendation 2 will be provided to OIG by the facility Director.

3. Please direct questions or concerns regarding the content of this memorandum to Karen Rasmussen, MD, Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.


Carolyn M. Clancy, MD

VISN Acting Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 15, 2015

From: Acting Director, Veterans Integrated Service Network (10N23)

Subj: **Draft Report**—Healthcare Inspection – Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation, Iowa City VA HCS, Iowa City, IA

To: Director, Seattle Office of Healthcare Inspections (54SE)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the document and concur with the recommendations. Relevant action plans have been established as detailed in the attached Director's Comments to OIG's Report.

2. If you have any questions or would like to discuss this response, please contact Natalie Good, Chief Quality Management, at 319-339-7173.

Steven C. Julius MD, Acting Chief Medical Officer,
SCJ
STEVEN C. JULIUS, M.D.

System Director Comments

Department of
Veterans Affairs

Memorandum

Date: April 13, 2015

From: Director, Iowa City VA Health Care System (636/00)

Subj: **Draft Report**—Healthcare Inspection – Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation, Iowa City VA HCS, Iowa City, IA

To: Acting Director, VA Midwest Health Care Network (10N23)

1. Thank you for the opportunity to review the draft report of the **Draft Report**—Healthcare Inspection – Alleged Poor Quality of Care and Refusal to Pay for Lung Transplantation, Iowa City VA HCS, Iowa City, IA.

2. I have reviewed the document and concur with the recommendations. Relevant action plans have been established as detailed in the attached Director's Comments to OIG's Report.

3. We appreciate the professionalism demonstrated by the OIG Team and the consultative attitude demonstrated during the review process.

4. If you have any questions, please contact Natalie Good, Chief Quality Management, at 319 339-7173.


JUDITH L. JOHNSON-MEKOTA, FACHE
Director

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 Interim Under Secretary for Health review how the Veterans Health Administration compensates non-VA facilities for lung transplantation to ensure that reimbursement is appropriate for the services performed.

Concur

Target date for completion: December 2015

VHA response: Currently, VA has two programs that may be used when a Veteran requires a transplant. The first program is administered by VA's National Surgery Office (NSO) using special purpose funding. As identified by the report, NSO utilizes a number of criteria for the approval of transplant services. This program is separate and distinct from VA's other authority that may be used to provide transplant services. In accordance with regulatory authority found at 38 Code of Federal Regulation (CFR) 17.38, VA may use the Non-VA Care (NVC) program to authorize and reimburse non-VA transplant services. This option is generally used when the transplant program administered by NSO cannot be utilized either because of urgency or the Veteran's ability to meet NSO criteria. When the NVC program is used, reimbursement for the services must be in accordance with 38 CFR 17.55 and 17.56. These regulations set VA reimbursement rates, absent a contract, at Medicare rates. As identified by the report, these rates are not adequate in the circumstances of reimbursement for non-VA transplant services.

VHA's Chief Business Office (CBO) will work with NSO to review VA's authorization for funding and reimbursing transplant services received from non-VA facilities. Additional guidance may be developed based on the outcome of the review.

To complete this action plan, VHA will provide the following documentation:

- 1.) Recommendations from the review conducted by CBO and NSO.
Action plans for addressing CBO/NSO developed recommendations, if any.

Recommendation 2. We recommended that the System Director conduct a focused professional practice evaluation of the care provided by attending physicians at the facility during the patient's fall 2014 hospitalization.

Concur

Target date for completion: July 1, 2015

Facility response: For the physicians who are current members of the medical staff involved in this case, the Medicine Service Line will perform a Service Line focused professional practice evaluation (FPPE) of the care provided to this patient during fall 2014. This FPPE will be added to the existing FPPE process.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Susan Tostenrude, MS, Team Leader Andrea Buck, MD

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Midwest Health Care Network (10N23)
Director, Iowa City VA Health Care System (636/00)

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: Richard J. Durbin, Joni Ernst, Charles E. Grassley, Mark Kirk, Roy Blunt, Claire McCaskill
U.S. House of Representatives: Rod Blum, Cheri Bustos, Sam Graves, Steve King, David Loebsack, David Young

This report is available on our web site at www.va.gov/oig.