Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-02412-69

Healthcare Inspection

Ophthalmology Service Concerns
VA Illiana Health Care System
Danville, Illinois

January 8, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by an anonymous complainant about the Ophthalmology Service at the VA Illiana Health Care System (facility), Danville, IL.

We did not substantiate that surgery was performed on the wrong eye of a patient. We found that the ophthalmologist reversed the order of cataract removal surgeries on a patient because of a misread of pre-operative test results.

We did not substantiate that the ophthalmologist ordered an antibiotic 2 days after surgery when the patient should have had the antibiotics started a day before surgery.

We did not substantiate that the patient's death 4 months later was due to two eye infections or that the facility Mortality and Morbidity Committee reviewed the case but "covered up" any issues related to the patient.

We did not substantiate that a staff optometrist believed that the ophthalmologist used unsterile instruments, causing a fungal infection in the patient.

We did not substantiate that the ophthalmologist did not perform retinal exams or treat glaucoma due to an inability to read optical coherence tomography tests.

We substantiated that the ophthalmologist saw a patient in her private practice and referred the patient back to the VA; however, it was appropriate for the ophthalmologist to send the patient back to the VA.

We did not substantiate that the ophthalmologist self-referred VA patients to her private practice or that patients were inappropriately referred by the ophthalmologist to a retinal specialist.

We substantiated that patients are not referred back to the facility's Optometry Service after the ophthalmologist performs surgery on them; instead, non-VA care is arranged through the facility. However, this is done so the facility optometrists can see new patients sooner.

We substantiated that the ophthalmologist was taking VA patient records to her private practice but with facility knowledge, approval, and appropriate controls in place.

We substantiated that there were three (two outside and one internal) investigations and that the Ophthalmology and Optometry Services had serious interpersonal problems amongst the staff and providers. We found that recommendations from the internal and external reviews to improve working relationships had not been implemented.

We recommended that all recommendations for interpersonal training for the staff and providers in the Ophthalmology and Optometry Services be implemented.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 10–12, for the full text of the Directors' comments. We will follow up on the planned actions until they are completed.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant about the Ophthalmology Service at the VA Illiana Health Care System (facility), Danville, IL.

Background

The facility is a 398-bed acute, long-term, and ambulatory care facility that provides a broad range of health care services to veterans residing in Central Illinois and West Central Indiana. The population of veterans in the service area is approximately 150,500. Affiliations include the University of Illinois College of Medicine at Urbana-Champaign and Indiana University School of Optometry in Bloomington, IN.

Reusable Medical Equipment

Reusable medical equipment (RME) refers to devices that are designed for use on multiple patients and made of materials that can withstand repeated cleaning and sterilization.[1] These devices must be properly reprocessed (cleaned, disinfected and/or sterilized) between patients to ensure safe use. If these devices are not adequately reprocessed, they may be contaminated and compromise patient safety.

Cataract Surgery

Cataract surgery is one of the most common surgeries performed in VA. Patients who have cataract surgery are typically older adults who are more likely to have other pre-existing medical conditions. While other medical conditions do not typically adversely affect the outcome of cataract surgery, patients with pre-existing glaucoma, diabetes, or age-related macular degeneration are less likely to have improved vision. However, if these patients have advanced cataracts, surgery is the only effective treatment. Risks of cataract surgery include bleeding, a slight increase in risk of retinal detachment, and endophthalmitis (a rare but serious infection of the eye that can lead to loss of vision)—the most serious complication after eye surgery. Endophthalmitis occurs in 0.13 percent of cataract surgeries and is treated with eye drops and/or topical antibiotics. Compliance with the sometimes complicated pre- and postoperative eye medication regimen is key in preventing eye infections and other problems.[2]

Allegations

The OIG received an anonymous complaint concerning the Ophthalmology Service and a specific ophthalmologist at the facility. The allegations are summarized as follows:

[1] VHA Directive 2009-004, *Use and Reprocessing of Reusable Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009. RME is any medical equipment designed by the manufacturer to be reused for multiple patients. All RME must be accompanied by reprocessing instructions provided by the manufacturer.
[2] VAOIG Report No. 11-02487-158, *Healthcare Inspection, Evaluation of Cataract Surgeries and Outcomes in Veterans Health Administration Facilities*, March 28, 2013.

- The ophthalmologist performed surgery on the wrong eye of a patient.

- The patient called the ophthalmologist 2 days after surgery and an antibiotic was ordered at that time, but the patient should have had the antibiotics started a day before surgery. The patient developed two eye infections and subsequently died. The patient's case was reviewed by the facility's Mortality and Morbidity Committee, but a facility employee thinks the death and other issues concerning this patient will be "covered up."

- A provider believed that the ophthalmologist used unsterile instruments causing a fungal infection in the patient.

- The ophthalmologist does not perform routine retinal exams or treat glaucoma due to an inability to read optical coherence tomography (OCT).[3]

- Patient referral issues:

  - A patient chose to seek surgical care outside the VA and coincidentally went to see the ophthalmologist in her private practice. The ophthalmologist referred the patient back to the VA. The same ophthalmologist then referred the patient to another ophthalmologist outside the VA to avoid having to do a surgical procedure on the patient.

  - The ophthalmologist self-referred VA patients to her private practice.

  - Patients are referred by the ophthalmologist to a retinal specialist who shares an office with her outside the VA.

  - Patients are not referred back to the facility's Optometry Service after the ophthalmologist performs surgery on them, but are referred to external facilities/providers at a cost to the VA (Non-VA Medical Care formerly known as fee basis care).[4]

- The ophthalmologist violated VA privacy policy[5] by taking patient records[6] to her private practice office.

[3] Optical coherence tomography (OCT) is a non-invasive imaging test that uses light waves to take cross-section pictures of the retina, the light-sensitive tissue lining the back of the eye.
[4] VHA Directive 1601, *Non-VA Medical Care Program*, January 23, 2013. VHA Policy states that admission of any Veteran to a private or public hospital at VA expense will only be authorized when VA health care facilities are not feasibly available, in accordance with title 38 Code of Federal Regulations (CFR) §17.53.
[5] VHA Handbook 1605.1, *Privacy And Release Of Information*, May 17, 2006. This Handbook establishes VHA policy regarding the provisions of the Standards of Privacy of Individually-Identifiable Health Information, Title 45 Code of Federal Regulations (CFR) Parts 160 and 164.
[6] VHA Handbook 1907.01, *Health Information Management And Health Records*, July 22, 2014. This handbook provides basic health information procedures for managing the patient's health record.

- Because the ophthalmologist only works 2 days a week, veterans have to wait for surgery and appointments are continuously postponed and rescheduled.

- Two ophthalmologists have left because of the actions of another ophthalmologist, and one is ready to leave. There have been two outside investigations, and nothing is being resolved. Nobody in the department is getting along.

Scope and Methodology

We reviewed VHA and local policies, physician credentialing and privileging files, peer review results, and electronic health records (EHRs) of selected patients. We reviewed an administrative investigation report and other relevant documentation.

We interviewed the facility Director, Quality Management staff, and a staff optometrist.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Case Review

The patient was an elderly male in his late eighties with a past medical history significant for hypertension, diabetes mellitus, and lung disease. In August of 2013, he was diagnosed at the facility with bilateral cataracts. The provider and patient agreed to proceed with cataract surgery on both eyes.

The patient and his family were educated on using an antibiotic beginning the day prior to surgery on the first eye. The first surgery (right eye) was uneventful, and the patient was sent home the same day with several prescriptions for eye drops. Follow-up calls to the family indicated the patient was doing well and using the eye drops as prescribed.

The second surgery (left eye) was performed approximately 1 week later. Again, the surgery was uneventful. Upon discharge, patient was given instructions for the use of eye drops and a follow-up appointment with the eye clinic. A provider called the patient's family the day after surgery and documented in the patient's EHR that he reported to be "doing fine" with "…blurry but improved vision." His wife confirmed that he was using the eye drops as prescribed.

At the follow-up appointment, 10 days later, the patient reported "eye pain." The patient stated his right eye had been bothering him for "about 1 week." At that appointment, he also reported that he "had not received the eye drops yet for the left eye." The exam documented a decrease in visual acuity in the right eye, as well as drainage. The patient was sent to a corneal specialist in the community that same day for an urgent evaluation. After the evaluation, he underwent an emergent vitrectomy.[7] He was prescribed several eye drops as well as an oral anti-fungal medication. Four days later, he was evaluated at the facility eye clinic and his visual acuity had declined further. The family admitted that the patient had not been compliant with the administration of the eye drops. It was also not clear if he had started taking the oral anti-fungal medication. The patient was transferred to a private hospital where he was an inpatient for 13 days. He had a subsequent follow-up evaluation at a non-VA facility, 5 days later for corneal ulcers in the right eye.

The EHR reflected that the family called the facility in mid-November 2013 to report that the patient had been treated at a local hospital for pressure ulcers. They requested an urgent post-hospitalization follow-up with primary care. The patient was seen the same day and referrals for home care were made. Two days later, after an appointment with a non-VA ophthalmologist, he was admitted again to the private hospital for endophthalmitis and corneal ulcerations. He underwent subsequent evisceration[8] and surgical closure of the right eye.

[7] The surgical operation of removing the vitreous humor from the eyeball.
[8] The removal of the eye's contents, leaving the scleral shell and extraocular muscles intact.

In the 2 months that followed, the patient was admitted several times to outside facilities for other comorbidities. He was diagnosed with a mediastinal mass[9] that was impairing his ability to swallow. A percutaneous endoscopic gastrostomy tube[10] was placed to assist with feeding. In mid-December 2013, the patient presented to the facility Urgent Care Clinic with shortness of breath. He was admitted to the facility with the diagnosis of pneumonia. As his health continued to deteriorate, he was transferred to the palliative care unit and died in January 2014.

Issue 1: Misread of Pre-Operative Test Results

We did not substantiate that surgery was performed on the wrong eye of a patient. We found that the ophthalmologist reversed the order of cataract removal surgeries on a patient because of a misread of pre-operative test results.

VHA requires that patients and/or families be informed if, as part of routine clinical care, a harmful or potentially harmful adverse event has occurred during the course of care.[11] Specific documentation in the EHR is not required for all clinical disclosures.

The patient agreed to undergo bilateral cataract surgery. The first surgery was to be performed on the left eye. Four days prior to the scheduled surgery, the ophthalmologist contacted the patient and explained that after a detailed review of the visual field testing, she felt it was best to proceed with surgery on the right eye first. The patient agreed and was instructed to use the same pre-operative eye drops on the right eye instead of the left eye. The surgery on the right eye was performed in September 2013, without complications.

Three days after the surgery, the ophthalmologist documented in the EHR that, in error, she interpreted visual field testing results of the right eye, as results for the left eye. The patient and his family were informed of the error. A few weeks later, surgery was performed on the left eye.

The physician's error did impact the order of the planned procedures, but the patient did not suffer harm as a result. An internal review of the patient's surgical care was completed, and no further recommendations were made. In addition, the patient and family were appropriately notified.

Issue 2: Poor Quality of Care

We did not substantiate that the patient called the ophthalmologist 2 days after surgery and an antibiotic was ordered at that time, when the patient should have had the antibiotics started a day before surgery. We did not substantiate that the patient's death 4 months later was due to two eye infections.

[9] Mediastinal mass or tumors are growths that form in the middle of the chest area, which separates the lungs from the rest of the chest.
[10] A feeding tube inserted through the abdominal wall into the stomach.
[11] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

Review of the EHR revealed that antibiotics were ordered appropriately pre-and post-operatively. According to the patient's autopsy report, the patient had multiple comorbidities, including pneumonia, lung disease, severe heart disease, a mediastinal mass, and an eye infection, all of which contributed to his decline and death.

We did not substantiate that the facility Mortality and Morbidity Committee reviewed the case, or "covered up" any issues related to the patient. The case was reviewed appropriately by the facility.

Issue 3: Unsterile Instruments

We did not substantiate that a staff optometrist believed that the ophthalmologist used unsterile instruments, causing a fungal infection in the patient.

VHA requires that reusable equipment/instruments that touch mucous membranes of the eye must be cleaned, disinfected, and thoroughly rinsed according to the manufacturers' recommendations.[12,13]

We interviewed the provider to whom the remark was attributed, and he denied saying that he thought the patient got an infection because a provider used poor technique or unsterile instruments. We reviewed facility RME policies, committee minutes, and sterilization logs. We found that the facility had appropriate RME processes in place. We did not find evidence supporting the allegation that eye clinic providers were using unsterile RME for ophthalmic procedures in the facility eye clinic.

Issue 4: Physician Credentials and Privileges

We did not substantiate that the ophthalmologist did not perform retinal exams or treat glaucoma due to an inability to read OCTs.

VHA Handbook 1100.19 requires that all health care professionals must be fully credentialed and privileged prior to their initial appointment or reappointment.[14] Credentialing refers to the systematic process of screening and evaluating provider qualifications (for example, licensure, education, training, experience, and health status). Privileging is the process by which a provider is permitted by law and the facility to provide specified services within the scope of their license. Privileges must be specific to the facility and provider and be within available resources.

We reviewed the ophthalmologist's credentialing and privileging files maintained by the facility. We found that the file was complete, and the approved privileges were appropriate for the ophthalmologist's education and training. The ophthalmologist's privileges did not include retinal exams, treatment of glaucoma, or interpreting OCTs.

[12] VHA Directive 2009.004.
[13] Department of Veterans Affairs Memorandum to All VA Optometrists and VA Ophthalmologists, June 29. 2009.
[14] VHA Handbook 1100.19, *Credentialing and Privileging,* published October 14, 2002.

Issue 5: Patient Referral Issues

We substantiated that a patient saw the ophthalmologist in her private practice and was referred back to the VA; however, because the patient was inadvertently referred to the ophthalmologist through the facility's Non-VA Medical Care[15] service, it was appropriate for the ophthalmologist to send the patient back to the VA.

We did not substantiate that the ophthalmologist self-referred VA patients to her private practice or that patients were inappropriately referred by the ophthalmologist to a retinal specialist who shares an office with her outside the VA.

Federal law prohibits the practice of a physician referring a patient to a medical facility in which the physician has a financial interest, be it ownership, investment, or a structured compensation arrangement.[16]

We learned that the facility, in response to rumors, conducted an investigation and could not find evidence of self-referrals by the ophthalmologist.

The only instance that we found of referral to a retinal specialist outside the VA was for a VA patient who required urgent treatment that could not be accomplished through VA resources.

We substantiated that patients are not referred back to the facility's Optometry Service after the ophthalmologist performs surgery on them; instead, they have Non-VA Medical Care arranged through the facility. However, according to the facility's Chief of Surgery, this was found to be a cost-effective approach for post-operative care that allowed facility optometrists to see new patients sooner.

Issue 6: Removal of VA Patient Records

We substantiated that this provider was taking VA patient records to her private practice but with facility knowledge and approval.

VHA Handbook 1907.01 states that only the Chief of Health Information Management, or designee, can approve the physical removal of original health records from the treating facility.[17]

The facility did not have the software needed to calculate the dimensions of lenses needed for patients, so the ophthalmologist was taking records from the facility to her private practice to do the calculations. We learned that the facility's privacy officer and other staff helped devise a method that allowed the necessary records to be taken to

[15] Non-VA Medical Care services, formerly referred to as Fee Basis, is medical care provided to eligible Veterans outside of VA when VA facilities are not available.
[16] http://starklaw.org/, Accessed on the WWW on August 19, 2014; [Federal Law 42 U.S.C.S. '1395nn.]
[17] VHA Handbook 1907.01, *Health Information Management and Health Records*, July 22, 2014 and September 19, 2012

the ophthalmologist's private practice while maintaining security of personally identifiable information and patient privacy.

Issue 7: Staffing and Scheduling Issues

We did not substantiate that because the ophthalmologist only works 2 days a week, veterans have to wait for eye surgery, and appointments are continuously postponed and rescheduled.

We reviewed workload reports for the ophthalmologist for FY 2013 and FY 2014 through May 2014. A decrease in the number of patients seen during the second quarter, FY 2013, was noted. We were told that this was because other providers were not referring patients to the ophthalmologist's clinic and that had been rectified. We reviewed clinic schedule reports for FY 2013 and FY 2014 through May 2014. We did not identify any patterns of appointment cancellations or delayed surgical procedures for the ophthalmologist.

Issue 8: Poor Interdepartmental Relationships

We could not substantiate that two ophthalmologists left because of the actions of an ophthalmologist, or that one is ready to leave. We learned that two optometrists left, but facility leadership was not aware of any providers (optometrists or ophthalmologists) leaving expressly because of an individual.

We substantiated that two outside investigations had been conducted and that serious interpersonal problems existed amongst the staff and providers within the Ophthalmology and Optometry Services.

Because of ongoing complaints and conflicts among the staff and providers, facility leadership had two different reviews done. The Chief of Ophthalmology from another VA medical center evaluated the service, followed by a second review by a Lead Optometrist from a different VA medical center. Both determined that the staff "didn't get along." In addition, the facility completed an internal investigation to evaluate allegations of inappropriate professional activities, hostile work environment, inappropriate conduct causing adverse effects on patient care, and other issues centering around the Optometry/Ophthalmology work environment.

The reviews identified problematic interpersonal relationships in the services that could potentially have a negative effect on quality of patient care. Interpersonal training was recommended but, at the time of our review, had not been initiated.

Conclusions

We did not substantiate that the ophthalmologist performed surgery on the wrong eye of a patient. The patient was scheduled for bilateral cataract surgery. The surgeon planned to operate on the left eye first. However, because the test results for the left

eye were misinterpreted for the right eye, the ophthalmologist operated on the right eye first.

We did not substantiate that a patient called the ophthalmologist 2 days after surgery and an antibiotic was ordered at that time, when the patient should have had the antibiotics started a day before surgery.

We did not substantiate that the facility Mortality and Morbidity Committee reviewed the case, but "covered up" any issues related to the patient's death.

We did not substantiate that a staff optometrist believed that the ophthalmologist used unsterile instruments, causing a fungal infection in a patient.

We did not substantiate that the ophthalmologist did not perform retinal exams or treat glaucoma due to an inability to read OCTs. The ophthalmologist was primarily credentialed and privileged to perform cataract surgeries.

We substantiated that a patient saw the ophthalmologist in her private practice and was referred back to the VA; however, it was appropriate for the ophthalmologist to send the patient back to the VA.

We did not substantiate that the ophthalmologist self-referred VA patients to her private practice or that patients were inappropriately referred by the ophthalmologist to a retinal specialist outside the VA.

We substantiated that patients are not referred back to the facility's Optometry Service after the ophthalmologist does surgery on them; instead, they have Non-VA Medical Care arranged through the facility. This was done as a cost-effective approach for post-operative care that "freed up" the facility optometrists to see new patients sooner.

We substantiated that the provider was taking VA patient records to her private practice but with facility knowledge and approval. The provider had access to equipment and software for lens calculations in her private office that was not available at the VA. The records that were removed from the facility were free of personally identifiable information, and patient privacy was protected.

We substantiated that there were three (two outside and one internal) investigations and that the Ophthalmology and Optometry Services had serious interpersonal problems amongst the staff and providers. However, we found that recommendations from the internal and external reviews to improve working relationships had not been implemented.

Recommendation

1. We recommended that the Facility Director implement all recommendations for interpersonal training for the staff and providers in the Ophthalmology and Optometry Services.

Appendix A

VISN Director Comments

Department of
Veterans Affairs

Memorandum

Date: December 2, 2014

From: Director, Veterans In Partnership (10N11)

Subject: **Draft Report**— Healthcare Inspection- Ophthalmology Service Concerns, VA Illiana Health Care System, Danville, IL

To: Director, Region Office of Healthcare Inspections (54SP)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Attached is the VA Illiana Health Care System's response to the draft report.

2. If you have any questions, please contact Carol Jones, Quality Management Officer, at 734-222-4302.

Paul Bockelman, FACHE
Network Director VISN 11

Appendix B

Facility Director Comments

Department of
Veterans Affairs

Memorandum

Date: November 24, 2014

From: Facility Director, VA Illiana Health Care System (550/00)

Subject: **Draft Report**— Ophthalmology Service Concerns, VA Illiana Health Care System, Danville, IL

To: Director, Veterans In Partnership (10N11)

1. Listed is the individual response to the recommendation from the inspection.

2. Please contact Alissa Broderick, Chief, Quality Management, at 217-554-5082 if you have any questions on the information provided.

Japhet C. Rivera
Director, VA Illiana Health Care System (550/00)

Comments to OIG's Report

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

OIG Recommendation

Recommendation 1. We recommended that the Facility Director implement all recommendations for interpersonal training for the staff and providers in the Ophthalmology and Optometry Services.

Concur:

Target date for completion: September 30, 2015

Facility response:

Interpersonal training will be scheduled for all staff and providers in the Ophthalmology and Optometry section of Surgical Service. The National Center for Organizational Development (NCOD) will be conducting a work assessment with staff and providers in Ophthalmology and Optometry by February 13, 2015, and depending on those results, the appropriate interpersonal training will be conducted.

Appendix C

OIG Contact and Staff Acknowledgments

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

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