



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Quality of Care Issues Involving Manchester VA Medical Center and VA Boston Healthcare System

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Executive Summary

The purpose of the review was to determine the validity of allegations concerning quality of care issues involving a contract ophthalmologist at the Manchester VA Medical Center (medical center), and an ophthalmologist employed at VA Boston Healthcare System (system). Both facilities are under the jurisdiction of Veterans Integrated Service Network (VISN) 1.

The complainant (the patient) alleged that:

- There was a delay in treatment by the medical center's contract ophthalmologist. Specifically, the patient alleged that the surgeon should have performed vitrectomy surgery in November or December 2004.
- The system's ophthalmologist coerced the patient into having vitrectomy surgery for a second retinal detachment repair in the patient's left eye.
- The system's ophthalmology surgeon failed to inform the patient about the potential surgical complication of an epiretinal membrane.

We did not substantiate the first two allegations. Based on the opinion of a retinal specialist consultant and our review, we concluded that the treatment the patient received from the medical center's contract ophthalmologist and the system's ophthalmologist was appropriate.

We could not substantiate or refute the third allegation. However, we found that the processes and procedures that the system currently has in place ensure that patients are informed of the risks and benefits of retinal surgery. Further review of this case is not warranted, and we made no recommendations.



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

TO: Director, New England Healthcare System (10N1)

SUBJECT: Healthcare Inspection – Quality of Care Issues Involving Manchester VA Medical Center and VA Boston Healthcare System

Purpose

The Department of Veteran Affairs Office of Inspector General, Office of Healthcare Inspections (OHI), conducted an inspection to determine the validity of allegations concerning quality of care issues involving a contract ophthalmologist¹ at the Manchester VA Medical Center (medical center), and an ophthalmologist employed at VA Boston Healthcare System (system). Both facilities are under the jurisdiction of Veterans Integrated Service Network (VISN) 1.

Background

Located in Manchester, New Hampshire, the medical center provides primary care, urgent care, outpatient specialty care, and extended care. It is academically affiliated with Dartmouth Medical School. The medical center contracts with community providers to provide acute care services when patients are unable to travel to the nearest VA facility (for example, when a patient requires emergent care).

Located in Boston and Brockton, Massachusetts, the system consists of three divisions. Jamaica Plain provides primary care and ambulatory surgical services, West Roxbury provides acute inpatient medical and surgical services and primary care services, and Brockton provides long-term care and primary care services. The system is academically affiliated with Harvard Medical School and Boston University School of Medicine.

¹ Ophthalmologists are medical doctors who provide comprehensive eye care, including medical and surgical care.

The complainant (the patient) alleged that:

- There was a delay in treatment by the medical center's contract ophthalmologist. Specifically, the patient alleged that the surgeon should have performed vitrectomy² surgery in November or December 2004.
- The system's ophthalmologist coerced the patient into having vitrectomy surgery for a second retinal detachment repair in the patient's left eye.
- The system's ophthalmologist failed to inform the patient about the potential surgical complication of an epiretinal³ membrane.⁴

Scope and Methodology

We reviewed the patient's VA medical records, medical record information from the contract ophthalmologist that the medical center provided, and the contract ophthalmologist's credentialing and privileging file. We found that the medical center appropriately credentialed and privileged the physician to provide contract retinal eye surgery services.

We reviewed all documentation that the patient provided. This was a detailed chronology of symptoms and treatment provided by the medical center, the contract ophthalmologist, and the system. Additionally, a retinal specialist consultant from a VA facility outside of VISN 1 reviewed all the documentation. We interviewed the patient and medical center and system employees familiar with the case.

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

Inspection Results

Clinical Case Review

The patient is a 53-year old male with a medical history of Type 2 diabetes, depressive disorder, and generalized anxiety disorder. He presented to the medical center's Eye Clinic on October 12, 2004, with a chief complaint of a black spot over his left eye that he had noted on October 11. The examining optometrist found that the patient had multiple retinal tears with localized sub-retinal fluid and a vitreous hemorrhage in the left eye, and a retinal tear on the right side. A contract ophthalmologist at the medical center

² The surgical removal of the vitreous (a jelly like substance within the eye). The removed vitreous is replaced with gas or liquid.

³ Sometimes also written as "epi-retinal."

⁴ Thin layer of scar tissue on the retina; also called a macular pucker. Epiretinal membranes have a variety of causes, including vitreous detachment, but the cause is often unknown.

confirmed the diagnosis. Because this was considered an emergent condition and the medical center did not perform eye surgery, the patient was seen in the private office of another contract ophthalmologist the same day, October 12. The contract ophthalmologist recommended cryotherapy to treat the retinal tears for both eyes and performed the procedure on the left eye October 12. He performed the procedure on the right eye October 22. In addition, the consultant noted the retinal tears were of the “horseshoe” variety; thus, they were associated with a significant risk for retinal detachment.

After this treatment, the patient reported that the vision in his left eye continued to improve. In November, he reported the presence of “floaters,” and he and the contract ophthalmologist discussed the possibility of vitrectomy surgery. The surgeon advised against performing the procedure at that time. By early December, the patient reported that the vision in his left eye had almost returned to normal. However, on or about December 9, he reported deterioration in vision of the left eye, and he began seeing an occasional black circle in the upper right quadrant of his field of vision.

On December 9, the contract ophthalmologist saw the patient and diagnosed worsening sub-retinal fluid associated with previously treated superior retinal tear. The ophthalmologist performed laser therapy to treat this condition. The medical record shows that the physician saw the patient again on December 28. The patient noted that his vision was “a little bit worse” in the left eye and he was seeing more floaters. On dilated fundus examination, it was noted that the retinal tears were healing and that there were no new tears or sub-retinal fluid accumulation. The physician recommended “conservative” treatment and that the patient be seen at the medical center’s Eye Clinic in 3 months.

The patient reported that he saw the contract ophthalmologist several times between December 2004 and February 2005, and that he told the physician that vision in his left eye “had gotten slightly worse.” The physician performed a dilated fundus examination on each visit and continued to monitor the patient. On or about February 11, the patient reported that he experienced a “veil” coming down across his field of vision in his left eye. A letter to the medical center’s Eye Clinic from the contract ophthalmologist shows that the patient saw the ophthalmologist on February 11. The ophthalmologist performed a dilated fundus examination that revealed an inferior retinal detachment⁵ in the left eye and performed vitrectomy surgery on February 15. A letter dated February 22, from the ophthalmologist to the medical center’s Eye Clinic, shows that the ophthalmologist reported that the retina was “completely reattached.”

During an appointment in early March, the ophthalmologist discovered that a cataract was developing in the patient’s left eye. Throughout March and most of April, the patient reported seeing the ophthalmologist regularly. During that time, the patient had

⁵ Separation of the retina and the underlying inner wall of the eye.

multiple complaints about the vision in his left eye. On April 21, the patient reported that the ophthalmologist discovered another retinal detachment. The patient was then referred to the VA Boston Healthcare System, Jamaica Plain division, for further treatment.

The patient was first seen at the system's Eye Clinic April 26 and scheduled for a cataract extraction with retinal detachment repair on May 5. The system's ophthalmologist performed the procedures as scheduled.

After the surgery at the system, the patient continued to have multiple concerns regarding his vision and the care he received from the medical center's contract ophthalmologist and from the system's ophthalmologist. According to a memorandum from the medical center's Chief of Staff (COS) dated August 2, 2006, clinical and quality management managers met with the patient on July 26, 2006. The patient's concerns with the care he received from the contract ophthalmologist were discussed. The memorandum shows that managers informed the patient of the options available to patients who feel their care resulted in an injury.⁶ The patient confirmed that he received this information. An interview with the system's Associate COS (ACOS) for Medical Quality Improvement (QI) revealed that the system's clinical managers had also informed the patient regarding his options.

Issue 1: Delay in Performing the Original Vitrectomy Surgery

We did not substantiate that the contract ophthalmologist delayed performing appropriate surgery. We asked a retinal specialist consultant from a VA outside of VISN 1 to review all available medical documentation from the medical center, the contract ophthalmologist, and the system. We specifically asked the consultant if vitrectomy surgery performed by the contract surgeon in February 2005 should have been performed in November or December 2004.

The consultant opined that there was no indication that vitrectomy surgery should have been performed in November or December. The consultant noted that there was no mention of "persistent vitreous traction, epi-retinal membrane formation, or peri-retinal proliferation to suggest that a vitrectomy was indicated." The consultant further noted that when the patient returned to the contract surgeon in February 2005, there was no question that an inferior retinal detachment had occurred; and the ophthalmologist performed vitrectomy surgery. It was also noted that an epiretinal membrane was suspected, and the performance of vitrectomy surgery was appropriate.

Issue 2: Coercion by System's Ophthalmologist

We did not substantiate that the system's ophthalmologist coerced the patient into having a vitrectomy secondary to another retinal detachment. On May 5, the patient was

⁶ The options are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, 28 U.S.C., Sections 1346(b) and 2671–2680.

scheduled for cataract extraction and retinal detachment repair of the left eye. The patient reported that he told the attending ophthalmologist that vision in his left eye was improving, and the main impediment to his vision was the cataract. The patient reported that he told the system's ophthalmologist that he only wanted to have the cataract extraction performed. He reported that the ophthalmologist told him that if the patient did not agree to both procedures the physician would cancel the surgery. The medical record does not reflect this. In a progress note dated May 5, 2005, the ophthalmologist wrote, "I spoke to him [the patient] extensively regarding the risks and benefits, and I recommended that we proceed with cataract extraction [and] with retinal detachment repair today." The surgeon also documented that the "Patient verbalized understanding and wishes to proceed." Additionally, a review of the case by the system's Chief of Ophthalmology found that in the surgeon's clinical judgment, both procedures were necessary for optimal outcome. The Chief of Ophthalmology agreed that both procedures were appropriate.

We specifically asked the consultant if the performance of vitrectomy surgery was appropriate. The consultant agreed that because the patient experienced a recurrent detachment the vitrectomy procedure was appropriate.

Issue 3: Failure to Inform about Surgical Complication

We could not substantiate or refute whether the system's ophthalmologist informed the patient specifically about the potential risk of an epiretinal membrane formation. According to the consultant's review, this condition was suspected back in February. As noted above, medical record documentation shows that on May 5, the day of the surgical procedures at the system, the ophthalmologist wrote in the progress note "I spoke to him extensively regarding the risks and benefits, and I recommended that we proceed with cataract extraction [and] with retinal detachment repair today." The progress note shows that the surgeon wrote, "Since this is a re-operation, I explained that there is a 10–15% risk of re-detachment after surgery. Patient verbalized understanding and wishes to proceed." There is also a paper consent form signed by the patient in the medical record. However, the patient reported that he would not have had the surgery if he had known that an epiretinal membrane was a potential complication.

Our interview with the system's ACOS for Medical QI told us that the system's Eye Clinic currently uses iMed Consent™, a computerized consent software package that electronically generates, signs, and stores consent forms for clinical treatments and procedures. This computerized consent form was not used at the time of the patient's surgery. Epiretinal membrane is included in the list of risks and complications in the iMed Consent™. However, the patient signed a traditional paper consent form; and we could not establish if this complication was specifically mentioned in discussion between the system's surgeon and the patient.

Conclusions

Based on the opinion of the consultant and our review, we concluded that the treatment the patient received from the medical center's contract ophthalmologist and the system's ophthalmologist was appropriate. We found that the processes and procedures that the system currently has in place ensure that patients are informed of the risks and benefits of retinal surgery. Further review of this case is not warranted, and we made no recommendations.

Comments

The VISN and facilities Directors agreed with the findings and conclusions. (See Appendixes A, B, and C, pages 7–9 for the full text of the Directors' comments.)

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 28, 2007

From: Director, New England Healthcare System (10N1)

Subject: **Healthcare Inspection - Quality of Care Issues Involving
Manchester VA Medical Center and VA Boston
Healthcare System**

To: Assistant Inspector General for Healthcare Inspections (54)

I have reviewed this report and agree with the findings and
conclusions.

(original signed by:)

JEANNETTE CHIRICO-POST, MD

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 17, 2007

From: Director, Manchester VA Medical Center (608/00)

Subject: **Healthcare Inspection - Quality of Care Issues Involving
Manchester VA Medical Center and VA Boston
Healthcare System**

To: Assistant Inspector General for Healthcare Inspections

I have reviewed this report and agree with the findings and
conclusions.

(original signed by:)

MARC F. LEVENSON, MD, MBA

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 28, 2007

From: Director, VA Boston Healthcare System (523/00)

Subject: **Healthcare Inspection - Quality of Care Issues Involving
Manchester VA Medical Center and VA Boston
Healthcare System**

To: Assistant Inspector General for Healthcare Inspections

I have reviewed this report and agree with the findings and conclusions.

(original signed by:)

MICHAEL M. LAWSON

OIG Contact and Staff Acknowledgments

OIG Contact	Katherine Owens, MSN, Director Boston Regional Office of Healthcare Inspections (781) 687-2317
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Acknowledgments	Jerome Herbers, M.D.
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