Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Evaluation of Cataract Surgeries And Outcomes in Veterans Health Administration Facilities

Report No. 11-02487-158

March 28, 2013

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections assessed Veterans Health Administration (VHA) medical facilities' compliance with national requirements for the provision of care to cataract surgery patients and evaluated cataract surgery patients' care outcomes.

This review assessed: (1) whether cataract surgery care complied with VHA policies related to informed consent, time-outs, operative report timeliness, and resident supervision; (2) whether cataract surgery patients had improved visual acuity after surgery; (3) selected comorbid conditions and postoperative complications within 30 days of surgery; and (4) whether quality management processes were in place to review care and improve outcomes.

We found the following compliance rates: 97.5 percent documentation of informed consents, 96.8 percent timeliness of operative reports, and 100 percent documentation of resident supervision in the operating room. Regarding the time-out process, we found a 99.5 percent compliance rate with the verification of the patient's correct identity and procedural site. VHA should continue to monitor and ensure consistent documentation of intraocular lens implant verification in the electronic health record for cataract surgeries.

We found that patients without diabetes, glaucoma, or macular degeneration had better visual acuity after cataract surgery than patients who had one or more of these three comorbidities. However, 82.6 percent of patients with the selected comorbidities did have improved visual acuities. The best outcomes were in those patients with diabetes only, macular degeneration only, and glaucoma only, in that order. When surgical complications occurred, patients received appropriate care and treatment.

We validated general compliance with requirements for identifying, reporting, disclosing, and trending cataract-related quality of care data. We found that 89.7 percent of the facilities reported that Ophthalmology Department M&M meetings were conducted at least quarterly. We noted the completion of the VHA Ophthalmic Surgery Outcomes Database (OSOD) pilot project. Ophthalmology leaders should analyze OSOD data and disseminate associated quality improvement processes to VA cataract surgery facilities.

We recommend that the Under Secretary for Health, in conjunction with Veterans Integrated Healthcare Network and facility senior managers:

- Monitor and ensure consistent verification and documentation of preoperative intraocular lens implant verification in the electronic health record for all cataract surgeries.
- Ensure the analysis of OSOD data and dissemination of associated quality improvement processes to VA cataract surgery facilities.

Introduction

Purpose

The purpose of this inspection was to assess Veterans Health Administration (VHA) compliance with national requirements for the provision of care to cataract surgery patients and to evaluate specific cataract surgery patients' care outcomes.

This review assessed: (1) whether cataract surgery care complied with VHA policies related to informed consent, time-outs, operative report timeliness, and resident supervision; (2) whether cataract surgery patients had improved visual acuity after surgery; (3) selected comorbid[1] conditions and postoperative complications within 30 days of surgery; and (4) whether quality management (QM) processes were in place to review care and improve outcomes.

Background

The most common type of cataract[2] is related to the aging process.[3] Other types of cataracts are secondary (cataract that forms after surgery for other eye problems such as glaucoma, or cataract that can develop in people with diabetes or after an extended use of steroids), traumatic (cataract that forms after an eye injury, sometimes years later), congenital, and radiation (cataract that forms after exposure to some types of radiation).[4]

The most common symptoms of cataracts are:

1. Cloudy or blurry vision.
2. Colors seem faded.
3. Glare or halo around lights.
4. Poor night vision.
5. Double vision or multiple images in one eye.
6. Frequent prescription changes in eyeglasses or contact lenses.

New eyeglasses, brighter lighting, anti-glare glasses, or magnifying glasses may help with early symptoms of cataracts. However, for

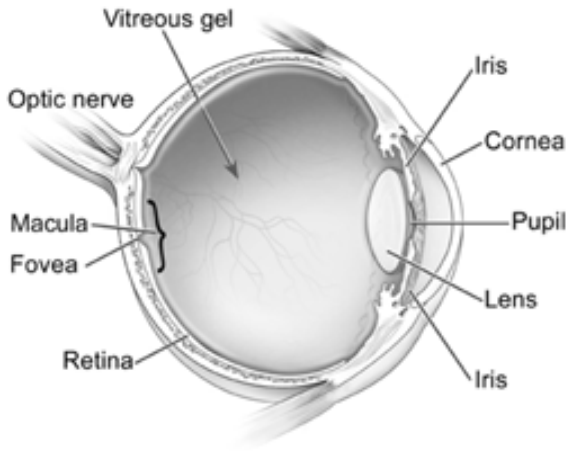

Illustration 1. Structure of the Eye.

[1] Comorbid refers to a disease, disorder, or a condition that occurs at the same time as another disorder.
[2] Clouding of the lens in the eye; see Illustration 1.
[3] Cataract is the clouding of the lens (part of the eye that helps focus light, or an image, on the retina).
[4] National Institute of Health (NIH), National Eye Institute (NEI), 2009. *Facts about cataracts.* Retrieved April 22, 2011, from http://www.nei.nih.gov/health/cataract/cataract_facts.asp.

advanced cataracts, surgery is the only effective treatment. Surgery may also be required if the cataract prevents examination and treatment of other eye problems such as macular degeneration (common cause of vision loss in older adults) or diabetic retinopathy (complication of diabetes and a leading cause of blindness).

Cataract surgery is one of the most common surgeries performed in the VA.[5] In 2011, VHA performed more than 49,000 cataract surgeries, which represented over 11 percent of all surgeries performed in VA facilities.[6]

The literature on cataract surgery outcomes shows improved vision and low complication rates. National studies have shown improved vision scores in 90 to 96 percent of patients after cataract surgery.[7,8,9] However, patients with pre-existing glaucoma, diabetes, or age-related macular degeneration were less likely to have improved vision.[10]

The two most common types of cataract surgery are (1) phacoemulsification, where the surgeon makes a small incision on the cornea and uses ultrasound waves to break up the lens (Illustration 2) and (2) extracapsular surgery, where a longer incision is made on the side of the cornea, and the cloudy core of lens is removed in one piece (Illustration 3). In both types of surgery, the surgeon removes the rest of the lens by suction and replaces it with an intraocular lens (IOL) implant. Risks 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.[11]

[5] Orcutt, James. *Safe Eye Care Presentation*, 2010.
[6] Orcutt, James. *Improving Quality and Safety of Cataract Surgery: Phase 1 of the National VA OSOD Project Presentation*. June 2011.
[7] Powe Nr, S. O. D. G. S. C. and et al. (1994). "Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation." Archives of Ophthalmology 112(2): 239-252.
[8] Steinberg, E. P., J. M. Tielsch, et al. (1994). "National study of cataract surgery outcomes. Variation in 4-month postoperative outcomes as reflected in multiple outcome measures." Ophthalmology 101(6): 1131-1140; discussion 1140-1131.
[9] NIH, NEI, 2009.
[10] Somaiya, M. D., J. D. Burns, et al. (2002)."Factors affecting visual outcomes after small-incisionphacoemulsification in diabetic patients." Journal of Cataract & Refractive Surgery **28**(8): 1364-1371
[11] NIH, NEI, 2009.

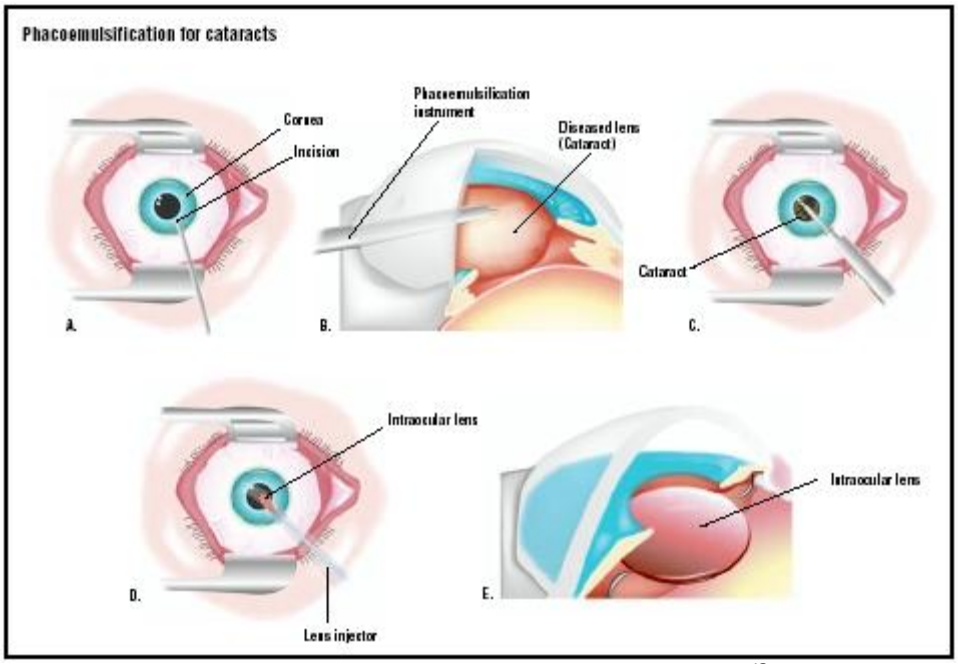

Illustration 2: Phacoemulsification for Cataracts.[12]

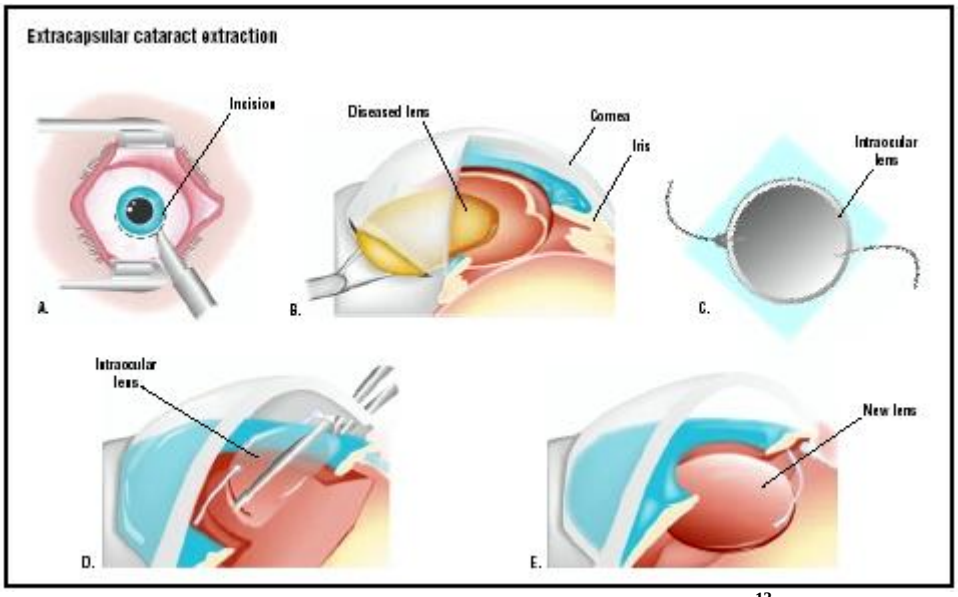

Illustration 3: Extracapsular Cataract Extraction.[13]

Complications related to cataract surgery are rare and depend on the type of procedure. Endophthalmitis occurs in 0.13 percent of cataract surgeries and is treated with intraocular and/or topical antibiotics. Other reported intraoperative and postoperative complications include posterior capsular tear and zonular dehiscence (3.1 percent),

[12] Encyclopedia of Surgery, 2012. *Phacoemulsification for cataracts*. Retrieved June 10, 2012, from http://www.surgeryencyclopedia.com/Pa-St/Phacoemulsification-for-Cataracts.html.
[13] Encyclopedia of Surgery, 2012. *Extracapsular cataract extraction*. Retrieved June 10, 2012, from http://www.surgeryencyclopedia.com/Ce-Fi/Extracapsular-Cataract-Extraction.html.

malposition (1.1 percent), vitreous prolapse or loss (0.8 percent), IOL retinal detachment (0.7 percent), iris prolapse (0.6 percent), and bleeding (0.3 percent).[14]

Patients who have cataract surgery are typically older adults who are more likely to have pre-existing medical conditions. While comorbid conditions do not adversely affect the outcome of cataract surgery, some medications such as anticoagulants or alpha-blockers are associated with increased complications and require cautious perioperative management.[15]

The VA National Center for Patient Safety reported 36 ophthalmology-related adverse events from 2007 through 2011. Of these, 21 involved the placements of the incorrect IOL implants during cataract surgery and 7 were surgeries performed on the wrong eye. [16]

In 2009, VA initiated the Ophthalmic Surgical Outcomes Database pilot project to evaluate potential risk factors associated with poor outcomes of cataract surgery and to assess quality of life/quality of vision outcomes of cataract surgery. Data on wrong eye and wrong implant were also collected during this planned 2-year pilot project at 5 VA facilities. According to VA leaders, this project was completed in November 2012. Data analysis is ongoing and dissemination of quality improvement methods to all VA surgery facilities has not yet taken place.

Scope and Methodology

The study population consisted of veterans who had cataract surgeries performed in a VA outpatient setting during fiscal year 2011 (FY11). We excluded cataract surgeries that were related to research. This resulted in a study population of 38,451 VA patients.

We reviewed VHA directives and handbooks and applicable standards from The Joint Commission (JC).[17] We reviewed progress notes; preoperative, intraoperative, and postoperative assessment notes; and operative reports. We also administered a facility self-assessment survey and reviewed cataract surgery QM/quality improvement documents to evaluate QM activities and processes. We communicated extensively with VHA program managers regarding expectations and requirements related to cataract surgery, management of complications, and resident supervision. It was not the intent of this report to compare cataract surgery between facilities.

We reviewed the electronic health records (EHRs) of sampled patients to determine facilities' compliance with the following VHA requirements.

[14] Powe Nr, S. O. D. G. S. C. and et al. (1994).
[15] Lumme, P. and L. T. Laatikainen (1994). "Risk factors for intraoperative and early postoperative complications in extracapsular cataract surgery." Eur J Ophthalmology 4(3): 151-158.
[16] VA National Center for Patient Safety SPOT database.
[17] JC, *Hospital Program: Edition – Leadership Standard LD.04.04.01*, January 1, 2011. Available at http://www.jointcommission.org/standards_information/up.aspx.

- **Informed consent.** VHA requires that patients be informed about health care options and that consent is obtained prior to treatment. A properly-completed consent form is valid for a period of 60 calendar days from the date signed.[18]
- **Time-out**. VHA requires that a "time-out" be performed immediately prior to the start of surgery.[19,20] The "time-out" process includes verifying the correct patient, procedure, and procedural site (right or left eye) prior to initiating the procedure. Verification must be documented in the patient's EHR. Documentation of the correct IOL implant must also be in the EHR.[21]
- **Operative report.** VHA requires that operative report be authenticated and released for viewing[22] within 30 days of surgery.[23]
- **Resident supervision**. VHA requires that all residents be directly supervised by an attending ophthalmologist who must be physically present in the operating room (OR).[24] Of the 29 facilities reviewed, all but 5 had an ophthalmology residency program. VHA ophthalmology leadership expectations are met if Level A, B, or C resident supervision is provided.

Level	Description
A	Attending physician performs the surgery.
B	Attending physician in the OR suite and scrubbed.[25]
C	Attending physician in the OR suite but not scrubbed.

We reviewed the care and EHR documentation preoperatively (30 days before surgery) as well as postoperatively (within 30 days of the surgery). Prior to our chart review, we selected three comorbid conditions of interest. These were diabetes, glaucoma, and macular degeneration. We assessed visual acuity outcomes by comparing postoperative Snellen visual acuity scores (VAS)[26] for patients with these three pre-existing conditions.

We separately reviewed the EHRs of 27 patients who had postoperative complications associated with their cataract surgeries in 2011. These patients required treatment for endophthalmitis and/or had subsequent surgery on the same eye within 30 days of the surgery. Prior to this set of chart reviews, we selected additional comorbid conditions of interest. These were diabetes, hypertension, congestive heart failure, use of

[18] VHA Handbook 1004.01.
[19] VHA Directive 2010-023, Ensuring Correct Surgery and Invasive Procedures, May 17, 2010.
[20] JC, *Hospital Program: E-dition - Universal Protocol: Performing a Time-Out*, January 1, 2011. Available at http://www.jointcommission.org/standards_information/up.aspx.
[21] VHA Directive 2010-023.
[22] Attending physicians authenticate operative reports completed by a resident by adding an electronic signature. Operative reports are released for viewing once electronically signed by an attending physician.
[23] VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006.
[24] VHA Handbook 1121.01.
[25] Appropriately dressed in sterile gown and gloves and prepared to perform or participate in surgery.
[26] Visual acuity describes the "sharpness" of one's vision, the ability of the eye to perceive details. The Snellen eye chart is used to measure visual acuity.

anticoagulants, and history of smoking. We also examined the occurrence of selected comorbid conditions in these cases.

Sampling

We used a two-stage sample design to select patients for EHR review. We first randomly sampled 29 facilities out of the 113 facilities where cataract surgery is performed. From each of these 29 facilities, we then randomly selected 30 patients. This resulted in a sample of 870 patients for EHR review. If the patient had more than one cataract surgery during FY11, we included only the first cataract surgery in our review.

Additionally, we separately reviewed all 27 cases in the sampled 29 facilities with postoperative complications within 30 days of the initial surgery.

Statistical Data Analysis

We took into account the sample design in all our statistical analyses to estimate results for the entire VA patient population. We also calculated 95 percent confidence intervals (CI) of the study population.[27] The 95 percent CI were calculated based on a logit[28] transformation to ensure that the calculated confidence limits contained only the proper range of 0–100 percent. Statistical analyses were conducted using SAS System 9.3 software.[29]

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

Results

Compliance with VHA Requirements

Informed Consent

We found that either the iMedConsent™ or a VA consent form was consistently used to document informed consent, and we found documentation of the correct eye on the consent forms. All records contained documentation of the date and time of consent. Patient and practitioner signatures were present in all EHRs reviewed.

Based on our statistical sample of patients, we estimated 97.5 percent (95% CI: 91.05–99.35) compliance rate with the administration and documentation of informed consent

[27] A CI gives a range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95% CI indicates that among all possible samples we could have selected of the same size and design, 95% of the time the population parameter would have been included in the computed intervals.
[28] Function used in mathematics, especially in statistics.
[29] SAS Institute Inc., Cary, NC.

within 60 days of surgery (Table 1), and 2.5 percent were completed more than 60 days prior to surgery.

Table 1. Informed Consent Timeliness.

Informed Consent	Number of Sampled Patients	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Within 1 day	233	19.4	12.20	29.35
1–60 days	620	78.1	67.81	85.86
>60 days	16	2.5	0.65	8.95
Total	869*			

*One case was cancelled on the day of the surgery and before a consent form was completed.

Time-Outs

We observed general compliance with documentation requirements related to patient and procedural site verification during the "time-out" process. We estimated that 99.5 percent (95 % CI: 97.49–99.92) of cataract surgery documentation included verification of each patient's identity. We also estimated that 99.5 percent (95% CI: 97.67–99.89) verified the procedural site prior to initiating the procedure.

On July 1, 2011, VHA released a revised surgery template to all facilities. This updated electronic template included a mandatory field for documenting preoperative implant verification. We analyzed our data using the cutoff date of July 2, 2011, to compare the VA compliance rate of preoperative implant verification for surgeries that occurred from October 1, 2010, through July 1, 2011, with the VA compliance rate for surgeries that occurred from July 2, 2011, through September 30, 2011, after the revised template was implemented.

We estimated that 78.2 percent (95% CI: 71.34–88.73) of cataract surgeries performed from July 2, 2011, through September 30, 2011, had documentation of IOL implant verification (Table 2), which is statistically significantly higher (at the significant level of 5%) than the estimated 67.6 percent (95% CI: 64.00–70.97) compliance rate from October 1, 2010, through July 1, 2011.

Table 2. IOL Implant Documentation of Verification Before and After Implementation of Revised Template.

Date of Documentation	Number of Patients with Documentation of IOL Verification	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Before implementation of revised template[a]	695	67.6	64.00	70.97
After implementation of revised template[b]	174	78.2	71.34	88.73
Total	869*			

*One case was cancelled on the day of the surgery. [a](October 1, 2010, through July 1, 2011) [b](July 2, 2011, through September 30, 2011)

After the implementation of the revised surgery template, 19 (of the 29) facilities accomplished 100 percent documentation of IOL implant verification. However, 10 facilities continued to need improvement. We noted that the revised surgery template was helpful in triggering the documentation of required preoperative implant verification, but this template was not consistently used by all facilities during our review period.

Timeliness of Operative Reports

We found that operative reports were generally completed timely. We estimated that 96.6 percent (95% CI: 94.52–97.86) of operative reports were authenticated and released within the required 30 days (Table 3). The majority, 71.9 percent (95% CI: 64.23–78.53), of the operative reports were released within a week of the surgery.

Table 3. Operative Report Timeliness.

Timeliness of Operative Reports	Number of Patients	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Within 1 day	337	32.7	21.97	45.67
2–7 days	290	39.2	30.46	48.70
8–14 days	139	16.5	13.03	20.56
15–30 days	71	8.2	5.46	12.07
>31 days	29	3.4	2.14	5.48
Total	866*			

*One case was cancelled on the day of the surgery, one was aborted intraoperatively, one had no attending signature, and one report was missing (not in the EHR).

Resident Supervision

We observed general compliance with the documentation requirements related to resident supervision in the OR. Facilities also appropriately documented the level of supervision in the preoperative and postoperative (perioperative) phases of surgery.

Supervision in the OR

Of the 24 (out of 29) facilities with ophthalmology residents, we found high compliance with the resident supervision documentation requirements in the OR. We estimated that 19.9 percent (95% CI: 11.92–31.44) of the surgeries were performed by the attending physician, that 79.7 percent (95% CI: 68.31–87.72) of the surgeries had the attending physician present in the OR and scrubbed, and that 0.4 percent (95% CI: 0.11–1.22) of the surgeries had the attending physician present but not scrubbed (Table 4).

Table 4. Resident Supervision Levels in the OR.

Resident Supervision in the OR	Number of Patients	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Level A	142	19.9	11.92	31.44
Level B	574	79.7	68.31	87.72
Level C	2	0.4	0.11	1.22
Total	718			

Perioperative Care

We found that resident physicians provided the majority of the perioperative care. We estimated that 67.5 percent (95% CI: 54.81–78.03) of the cataract surgery patients received perioperative care from resident physicians supervised by attending optometrists and/or ophthalmologists. Another 12.2 percent (95% CI: 6.55–21.51) of the patients received perioperative care from ophthalmologists only, and 7.9 percent (95% CI: 3.81–15.76) of the patients received preoperative care from an ophthalmologist and supervised postoperative care from resident physicians. The remainder of the patients received preoperative and postoperative care from various members of the eye care team.

Visual Acuity Improvement after Cataract Surgery

We looked at three comorbid conditions reported to impact visual acuity outcomes—diabetes, glaucoma, and macular degeneration. We estimated that 51.5 percent (95% CI: 47.47–55.55) of cataract surgery patients had none of the three conditions, 31.6 (95% CI: 27.49–36.00) percent had diabetes only, 5.2 percent (95% CI: 3.59–7.53) had macular degeneration only, and 5.3 percent (95% CI: 3.98–6.95) glaucoma only.

We found that 87.2 percent (95% CI: 83.15–90.44) of the patients who had none of the selected comorbidities (diabetes, macular degeneration, and/or glaucoma) had improved Snellen VAS after surgery (Table 5). We also found that 82.6 percent (95 percent CI: 76.00–87.74) of patients with at least one of the selected pre-existing comorbidities had improved visual acuities. Of patients with these comorbidities, more patients with diabetes had improved visual acuity than did patients with macular degeneration or glaucoma (in that order). Of those previously diagnosed with diabetes only, we found that 84.7 percent (95% CI: 77.54–89.94) had improved Snellen VAS after surgery. Of those patients with macular degeneration only, 79.9 percent (95% CI: 66.03–89.00) had improved postoperative Snellen VAS. Lastly, of the patients with glaucoma only, 75.8 percent (95% CI: 60.64–86.48) had improved postoperative Snellen VAS.

Table 5. Preoperative Condition and Snellen VAS Improvement.

Preoperative Condition	Number of Patients	VA Estimates Improvement in VAS				VA Estimates No Improvement in VAS				VA Estimates Worse VAS			
		No.	%	95 Percent Confidence Interval Limits		No.	%	95 Percent Confidence Interval Limits		No.	%	95 Percent Confidence Interval Limits	
				Lower	Upper			Lower	Upper			Lower	Upper
None	451	395	87.2	83.15	90.44	25	6.2	4.46	8.67	31	6.5	4.58	9.22
Diabetes Only	263	227	84.7	77.54	89.94	13	5.4	3.25	8.78	23	9.9	5.65	16.69
Macular Degeneration Only	47	37	79.9	66.03	89.00	7	13.3	6.26	26.13	3	6.8	2.06	20.41
Glaucoma Only	49	37	75.8	60.64	86.48	7	13.3	5.63	28.21	5	10.9	4.28	24.98
More than one Diagnoses	56	47	80.1	66.23	89.24	7	16.0	7.33	31.53	2	3.8	1.09	12.71
Total	**866***	**743**				**59**				**64**			

*Once case was cancelled on the day of the surgery, one was aborted intraoperatively, and two EHRs had no VAS documentation.

Cataract Surgery Complications

We found that ophthalmologists provided adequate care and treatment in response to surgical complications. We identified 27 patients from the 29 facilities who had postoperative complications requiring either treatment for endophthalmitis or a return to the OR (RTOR) within 30 days of the initial surgery. The types of complications requiring a RTOR included, but were not limited to: (1) posterior capsular tear (the rupture of the posterior capsule of the natural lens of the eye), (2) vitreous prolapse (leaking of vitreous gel into the anterior chamber of the eye), (3) retained lens material in the eye, (4) iris prolapse, and (5) zonular dehiscence (severed fibers that suspend the lens and hold it in position). Of the 27 complication cases, we found 25 patients who RTOR

and 5 patients who were treated for endophthalmitis. Three of these five patients with endophthalmitis were amongst those who returned to the OR for further surgical interventions.

Comorbidities in Patients with Postoperative Complications

We looked at five additional comorbid conditions for patients with postoperative complications. These were hypertension, use of anticoagulant, history of smoking, diabetes, and congestive heart failure. We found that 81.5 percent (95% CI: 60.92–92.55) of patients with postoperative complications had hypertension (high blood pressure) and 55.6 percent (95% CI: 35.71–73.78) had a history of taking aspirin or anticoagulants (medications used to prevent blood clots) before surgery (Table 6).

Table 6. Comorbid Condition in the 27 Patients with Postoperative Complications.

Comorbid Condition	Number of Patients	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Hypertension	22	81.5	60.92	92.55
Use of Anticoagulants	15	55.6	35.71	73.78
History of Smoking	13	48.1	29.30	67.54
Diabetes	9	33.3	17.53	54.04
Congestive Heart Failure	6	22.2	9.78	42.97

Cataract Surgery Complications

For patients who had additional procedures or returned to the OR within 30 days, we noted the following number of cases for each type of surgical complication (Table 7)—posterior capsular tear, vitreous prolapse, retained lens material in the eye, iris prolapse, and zonular dehiscence.

Table 7. Cataract Surgery Complications in Patients Who Had Additional Procedures or Returned to the Operating Room Within 30 days.

Surgical Complications	Number	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Posterior Capsular Tear	11	40.7	23.23	60.96
Vitreous Prolapse	5	18.5	7.45	39.08
Retained Lens Material in Eye	6	22.2	9.78	42.97
Iris Prolapse	2	7.4	1.69	27.16
Zonular Dehiscence	4	14.8	5.30	35.10
Total	27			

Unplanned Intraoperative Procedures During the Initial Surgery

For the 27 patients who had postoperative complications, we found 19 where the ophthalmologists performed unplanned procedures in the OR to address unexpected operative events which occurred during the initial cataract surgery. The three most frequently performed unplanned procedures were automated vitrectomy (to remove vitreous gel, retained lens material, or dislocated lens implants), use of trypan blue stain (to improve visualization during surgery), and placement of capsular tension ring (to stabilize the eye) (Table 8).

Table 8. Additional Unplanned Procedures Performed Concurrently during Cataract Surgery.

Unplanned Procedures	Number	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Automated Vitrectomy	11	40.7	23.23	60.96
Use of Trypan Blue Stain	7	25.9	12.24	46.76
Placement of Capsular Tension Ring	3	11.1	3.35	31.07
Kenalog Injection[30]	2	7.4	1.69	27.16
Posterior Synechiae[31]	1	3.7	0.45	24.54
More than one unplanned procedure	6	22.2	9.78	42.97

Return to the Operating Room Within 30 Days

We found that 24 patients returned to the OR for further intervention (Table 9). Of these, 12.5 percent (95% CI: 3.73–34.49) returned to the OR within 24 hours, and 33.3 percent (95% CI: 16.68–55.52) during the 1st postoperative week. The remaining 54.2 percent (95% CI: 33.21–73.75) returned to the OR during the 2nd through 4th postoperative week (Table 10).

[30] Intravitreal or sub-tenon's injection of kenalog, a steroid.
[31] Adhesion of the iris to the lens.

Table 9. Procedures Performed in Patients Who Returned to the Operating Room Within 30 Days.

RTOR – Procedures	Number	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
IOL Repositioning	12	44.4	26.22	64.29
Vitrectomy	12	44.4	26.22	64.29
Removal of Retained Fragments/Debris	4	14.8	5.30	35.10
Intravitreal Antibiotics Administration	3	11.1	3.35	31.07
Lensectomy	2	7.4	1.69	27.16
Iridotomy	1	3.7	0.45	24.54
Synechiolysis[32]	1	3.7	0.45	24.54

Table 10. Time to Return to the Operating Room.

Time from original Surgery to RTOR	Number of Patients	VA Estimates		
			95 Percent Confidence Interval Limits	
		Percent	Lower	Upper
Within 24 hours	3	12.5	3.73	34.49
2–7 days	8	33.3	16.68	55.52
8–30 days	13	54.2	33.21	73.75
Total	24			

Endophthalmitis

We observed 5 patients from the 29 facilities who had been diagnosed with and treated for endophthalmitis after cataract surgery during FY11. We noted the presence of specific comorbid conditions in these patients (Table 11).

[32] Repair of an adhesion of the iris to the lens.

Table 11. Preoperative Risk Factors of Patients Diagnosed with Endophthalmitis.

	Diabetes	Hypertension	Congestive Heart Failure	Current Use of Aspirin or Other Anticoagulants	Social History of Smoking
Patient 1	Yes	Yes	Yes	Yes	Yes
Patient 2	Yes	Yes	Yes	Yes	No
Patient 3	No	Yes	Yes	Yes	Yes
Patient 4	No	Yes	Yes	Yes	Yes
Patient 5	No	Yes	Yes	Yes	No

We noted the following specific situations for these five patients (Table 12).

- Patient 1, who had previous eye trauma and zonular dehiscence, required an iridotomy (the opening of a new pathway in the colored part of the eye to reduce the pressure in the eye) 3 days after cataract surgery. The patient was diagnosed with endophthalmitis 2 weeks later.
- Patients 2 and 3 had unplanned intraoperative procedures.
- Patients 4 and 5 were diagnosed with endophthalmitis during routine follow-up appointments with an ophthalmologist. These patients did not have any unusual events during surgery.

Four of these five endophthalmitis patients had an RTOR for follow-up surgeries and intravitreal injections (treatment to deliver medication into the eye between the lens and the retina) of antibiotics while the fifth patient received antibiotic eye drops in the outpatient setting. In all five cases, the endophthalmitis resolved, and there were no further instances of morbidity.

Table 12. Endophthalmitis Cases—Operative Events and Treatment.

	Operative Events	Treatment		
		RTOR	Intravitreal Injections of Antibiotics	Antibiotic Eye Drops
Patient 1	Cornea Guttae[33]	Yes	Yes	No
Patient 2	Retained Lens Material	Yes	Yes	No
Patient 3	Uveitis	Yes	Yes	No
Patient 4	None	No	Yes	No
Patient 5	None	No	No	Yes

[33] An accumulation of focal outgrowths on the inner surface of the cornea.

Quality Management

Morbidity and Mortality Reviews

Morbidity and mortality (M&M) reviews, or surgical case discussions among clinicians about the care provided to patients who experienced complications or died, are mechanisms for assessing and improving patient care.[34] All sampled facilities (100 percent) reported that their Ophthalmology Departments conducted regular M&M conferences (Table 13).

In the self-assessment surveys, facilities reported the frequencies of Ophthalmology Department M&M reviews. We found that 89.7 percent (95% CI: 70.86–96.86) of the facilities reported that Ophthalmology Department M&M meetings were conducted at least quarterly.

Table 13. Reported Frequencies of M&M Reviews or Surgical Case Discussions.

Reported Frequency of Ophthalmology M&M Conferences	Number of Facilities	VA Estimates		
		Percent	95 percent Confidence Interval Limits	
			Lower	Upper
Weekly	3	10.3	3.14	29.14
Bi-weekly	1	3.4	0.43	22.96
Monthly	12	41.4	23.34	60.77
Quarterly	10	34.5	18.90	54.30
Bi-annually	2	6.9	1.58	25.45
Annually	1	3.4	0.43	22.96
Total	29			

VHA requires that surgical complications be reported and analyzed for trends.[35] The use of incident reporting systems is one of the various processes used to track ophthalmology complications. As reported in the self-assessments, 37.9 percent (95% CI: 21.58–57.57) used the incident reporting system to track cataract surgery adverse events.

[34] VHA Directive 2008-077, *QM and Patient Safety Activities that can Generate Confidential Documents*, November 7, 2008.
[35] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

VHA recognizes the ethical responsibility to disclose adverse events related to clinical care to patients.[36] Facilities reported that 24.1 percent (95% CI: 11.41–44.02) had a disclosable cataract surgery adverse event for which disclosure was performed.

VHA requires that data collected for key QM components be trended and reported through the facilities' QM system of committees.[37] Through the self-assessments, 41.4 percent (95% CI: 24.34–60.77) reported that aggregated cataract surgery data was trended and reviewed at a standing leadership committee. VHA also requires that improvement opportunities need to be identified, evaluated, and prioritized. Thirty-one percent (95% CI: 16.31–50.96) reported that cataract surgery quality improvement initiatives were implemented. These improvement projects included the time-out process, site marking, and resident physician training.

Conclusions

Based on our review, we found 97.5 percent compliance with the administration and documentation of informed consents, 96.8 percent timeliness of operative reports, and 100 percent documentation of the resident supervision level in the OR Regarding the time-out process, we found 99.5 percent compliance with the verification of each patient's correct identity and the procedural site. However, VHA should continue to monitor and ensure consistent documentation of IOL implant verification in the EHRs for cataract surgeries.

We found that more patients without the selected comorbid conditions (diabetes, glaucoma, and macular degeneration) had improved visual acuity after cataract surgery than those with at least one comorbidity. However, we also found that 82.6 percent of patients with at least one of these comorbidities still had improved visual acuities. More patients with diabetes had improved vision scores than those with macular degeneration or glaucoma.

We observed that patients have improved vision with cataract surgeries despite the presence of multiple comorbidities. When surgical complications occurred, patients received appropriate care and treatment.

The facility self-assessments indicated general compliance with requirements for identifying, reporting, disclosing, and trending of cataract-related quality data. However, the frequency of M&M reviews was not consistent. We noted the completion of the OSOD pilot project. Ophthalmology leaders should analyze OSOD data and disseminate associated quality improvement processes to VA cataract surgery facilities.

[36] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 12, 2012 (corrected copy).
[37] VHA Directive 2009-043.

Recommendations

Recommendation 1: We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, monitor and ensure consistent verification and documentation of preoperative intraocular lens implant verification in the electronic health record for all cataract surgeries.

Recommendation 2: We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure the analysis of OSOD data and dissemination of associated quality improvement processes to VA cataract surgery facilities.

Comments

The Under Secretary for Health agreed with the findings and recommendations and provided a summary of actions accomplished. See Appendix B (pages 20–22) for the full text of his comments. We have reviewed the actions and consider the status of these recommendations completed.

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

Appendix A

VHA Facilities Reviewed

Facility Name	Location	VISN
Providence VA Medical Center	Providence, RI	1
VA New Jersey Health Care System – East Orange Campus	East Orange, NJ	3
James J. Peters VA Medical Center	Bronx, NY	3
VA New York Harbor Healthcare System – Manhattan Campus	New York, NY	3
Northport VA Medical Center	Northport, NY	3
Lebanon VA Medical Center	Lebanon, PA	4
VA Pittsburg Healthcare System – University Drive Campus	Pittsburgh, PA	4
Hampton VA Medical Center	Hampton, VA	6
Atlanta VA Medical Center	Decatur, GA	7
Bay Pines VA Healthcare System	Bay Pines, FL	8
Lake City VA Medical Center, North Florida/ South Georgia Veterans Health System	Lake City, FL	8
Chalmers P. Wylie Ambulatory Care Center	Columbus, OH	10
Louis Stokes VA Medical Center	Cleveland, OH	10
VA Northern Indiana Health Care System – Fort Wayne Campus	Fort Wayne, IN	11
Clement J. Zablocki VA Medical Center	Milwaukee, WI	12
Jesse Brown VA Medical Center	Chicago, IL	12
Harry S. Truman Memorial	Columbia, MO	15
Kansas City VA Medical Center	Kansas City, MO	15
St. Louis VA Medical Center – John Cochran Division	Saint Louis, MO	15
VA Eastern Kansas Health Care System	Leavenworth, KS	15
Alexandria VA Health Care System	Alexandria, LA	16
New Mexico VA Health Care System	Albuquerque, NM	18
Southern Arizona VA Health Care System	Tucson, AZ	18
West Texas VA Health Care System	Big Spring, TX	18
Grand Junction VA Medical Center	Grand Junction, CO	19
VA Eastern Colorado Health Care System	Denver, CO	19
VA Montana Health Care System	Fort Harrison, MT	19
Minneapolis VA Health Care System	Minneapolis, MN	23
Sioux Falls VA Health Care System	Sioux Falls, SD	23

Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: February 22, 2013

From: Under Secretary for Health (10)

Subject: **OIG Draft Report, Healthcare Inspection – Evaluation of Cataract Surgeries and Outcomes in VHA Facilities**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft report. Veterans Health Administration (VHA) concurs with the report's recommendations. We have provided VHA's action plan in the attachment to this memorandum.

2. Please contact Dr. Karen Rasmussen, Acting Director, Management Review Service (10AR) at (202) 461-6643 or karen.rasmussen@va.gov for questions or concerns about the content of this memorandum.

(original signed by:)
Robert A. Petzel, MD

Attachment

Under Secretary for Health Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1: We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, monitor and ensure consistent verification and documentation of preoperative intraocular lens implant verification in the electronic health record for all cataract surgeries.

VHA Comments

Concur

Independent of this OIG report, the VHA has established a process to monitor and ensure consistent verification and documentation of preoperative implant verification in the electronic record for all surgeries, including intraoperative lens implant verification for cataract surgeries. In August 2011, the VistA Surgery Package was upgraded to establish forced capture of the intra-operative timeout process including verification of pre-operative images and correct medical device implantation. In May 2012, the VHA added the VAMC Timeout Checklist Responses Report to the VA National Surgery Office (NSO) Quarterly Report to provide for monitoring and promote correction of any reported timeout deficiencies by facility.

During the 4th quarter of fiscal year 2012 (FY12 Q4), VHA performed 99,507 surgical procedures of which 12,208 (12 percent) were cataract procedures and during FY13 Q1, VHA performed 94,564 surgical procedures of which 12,195 (13 percent) were cataract procedures. The NSO Quarterly Report recorded 91 percent and 95 percent compliance with pre-operative image verification for cataract procedures in FY12 Q4 and FY13 Q1, respectively. Furthermore, 100 percent compliance for correct implant verification for all cataract procedures was recorded during these two reporting periods.

In addition, VHA completed an internal review of wrong implant and wrong site intraocular lens surgery events FY 2010-2012, identifying

systems issues and lessons learned. Based on these case reviews, VHA published a Patient Safety Alert (AL 13-03), "Incorrect Eye Surgery Adverse Events in VHA Facilities" on January 15, 2013, to emphasize the importance of VHA Directive 2010-023 and established VHA policy requirements to verify pre-operative images including lens calculations and verification of correct lens selection.

Status: Completed.

Recommendation 2: We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure the analysis of OSOD data and dissemination of associated quality improvement processes to VA cataract surgery facilities.

VHA Comments

Concur

VHA established the Ophthalmic Surgery Outcomes Database (OSOD) pilot project to determine the optimal method for monitoring and reporting of cataract procedure outcomes. In summary, 3,809 patients underwent 4,925 procedures with 94.5 percent of patients achieving an improvement in visual acuity. Of the 5.5 percent of patients that experienced equal or worse visual acuity, only 1.0 percent had visual acuity worse than 20/40. No wrong side or wrong implant events were identified. Seven cases of endophthalmitis (0.1 percent) were report, which compares favorably with existing literature. Overall, preoperative physical status did not impact outcomes.

The OSOD pilot project results identified that major morbidity events associated with VHA performed cataract procedures are rare. VHA has established a Quality Management System under VHA Directive 2009-043 to systematically evaluate major morbidity associated with cataract procedures and disseminate quality improvement methods consistent with the findings of this project.

Status: Completed

Appendix C

OIG Staff and Contact Information

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Mary Toy, RN, Project Leader Daisy Arugay, MT Elizabeth Bullock Limin X. Clegg, PhD Matthew Frazier, MPH Monika Gottlieb, MD Douglas Henao, RD Jackelinne Melendez, MPA Simonette Reyes, RN Kathleen Shimoda, RN Julie Watrous, RN Jarvis Yu, MS

Appendix D

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