



Cataract Surgery: Risk Management Recommendations

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PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. If legal advice is desired or needed, an attorney should be consulted. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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Cataract surgery is the most frequently performed ophthalmic procedure in the United States, and thus the source of the majority of the medical malpractice claims reported to OMIC. Patient expectations about the outcome of cataract surgery have changed considerably. When intraocular lenses (IOLs) were introduced, patients were grateful to be able to wear regular eyeglasses instead of ones that looked like "Coke bottles." Now, exposed to advertising that promises to reduce or completely eliminate dependence upon glasses and contact lens, many patients undergoing cataract surgery have very high visual goals, especially if they invest their own money to upgrade to specialty IOLs. When the outcome does not match these heightened expectations, patients are more apt to complain not only to their ophthalmologist, but to acquaintances, insurance companies, regulatory agencies, malpractice attorneys, and, in increasing numbers, even to the Ethics Committee of the American Academy of Ophthalmology (AAO).¹

To reduce the ophthalmologist's exposure to cataract surgery claims, we offer various materials on our website, www.omic.com. The risk management recommendations in this document highlight the actions physicians can take to reduce the likelihood of claims and increase their

¹ The Academy Express of 4 April 2007 reported that "The [Ethics] Committee has received a number of complaints from disappointed and angry patients, suggesting the promised efficacy of new multifocal, accommodative and toric intraocular lenses may not match outcomes. Informed consent for these new IOLs should be given greater attention..

defensibility. The information sheet for patients gives a detailed explanation of the risks, benefits, and alternatives to cataract surgery; staff can give it to patients to review prior to the informed consent discussion with the surgeon. The sample consent form contains the minimum information OMIC recommends that the surgeon personally disclose to the patient.

Depending upon your particular patient population and practice, some recommendations may be difficult to implement while others may not apply to you at all. OMIC policyholders may call our Risk Management Hotline for confidential assistance in adapting the recommendations or the documents (1.800.562-6642, extension 651 or 662).

Balance risks and benefits in your advertising

Conferences for ophthalmologists are replete with sessions designed to help physicians attract patients and improve cash flow. One strategy is to advertise the availability of the newer, “deluxe” IOLs. What is often missing from these presentations is a warning that allegations related to physician advertising are surfacing with increasing regularity in medical malpractice claims. The first allegation, as complaints to the Ethics Committee attest, is lack of informed consent. Aggressive advertising may overstate the possible benefits of a procedure, and potentially mislead patients into consenting to an IOL or surgery without fully understanding or appreciating the consequences and alternatives. Unfortunately, stories of physician advertisements being introduced in court to destroy the validity of a consent form are all too often true. In addition to allegations of lack of informed consent, plaintiffs are also using state consumer protection laws to claim that the physician defrauded the patient. State law may allow the plaintiff to ask for punitive damages, which might double or triple the amount of money awarded to the patient by the jury. Physicians should be particularly concerned about these allegations, since most professional liability insurance policies do not pay for such damages.²

Manage patient expectations through careful assessment and counseling

It is hard to defend a cataract surgery lawsuit if the procedure was not indicated in the first place.³ The plaintiff attorney may allege that the patient’s cataract did not interfere with activities of daily living, the cataracts were not the cause of the visual difficulties, or that removal of the cataract would not improve visual acuity in the presence of other ophthalmic conditions such as diabetic retinopathy or age-related macular degeneration (AMD). If both eyes are impacted by cataracts, the plaintiff may allege that the wrong eye was operated on first. Finally, in the case of a (functionally) monocular patient, the plaintiff may claim that the risks of the surgery were simply too great. To prevent such allegations, consider the following aspects of the preoperative assessment. Document communications relative to these recommendations in the medical record, and include the names and relationships of any witnesses and/or interpreters.⁴

Determine the role of the cataract in the vision loss.

Preoperative visual acuity is a poor predictor of postoperative functional improvement, according to the revised AAO Preferred Practice Pattern, “Cataract in the Adult Eye” (page numbers of subsequent references to this document appear in parentheses).⁵ Visual function

² For more information, see “Advertising for Medical Services” and “Advertising Review Form” at www.omic.com.

³ If the cataracts are not visually significant or not present, OMIC considers the procedure to be refractive lens exchange (RLE). Coverage for all refractive surgery is excluded under the policy; coverage for RLE is available upon written approval and issuance of a policy endorsement. Contact the Underwriting Department at (800) 562-6642, extension 639 to verify coverage or request an application. Applications are also available at www.omic.com.

⁴ Recommendations on interpreters for deaf and limited-English-proficiency patients are available at www.omic.com.

⁵ American Academy of Ophthalmology Cataract and Anterior Segment Panel. Cataract in the Adult Eye. *Preferred Practice Patterns* 2006: 0.

status indices, however, have been found to reliably forecast both functional improvement and satisfaction with vision after cataract surgery.

- Ask about near and distant vision under varied lighting conditions for activities that the patient views as important.
- Document the functional impairment using the patient's own words.
- Consider using a vision-specific questionnaire designed to help ascertain the impact of the cataract on activities of daily living, such as the Activities of Daily Vision Scale (ADVS)⁶ or the Visual Function Index (VF-14).⁷

Evaluate the patient for ocular and medical comorbidities that can effect the outcome of cataract surgery.

Studies have shown that ocular comorbidities such as amblyopia, retinopathy, glaucoma, and uveitis put the patient at higher risk for complications which adversely impact the outcome. Certain eye characteristics—previous eye surgery or trauma, very large and small eyes, weak or absent zonules, etc.—increase the complexity of the procedure (24-25). Moreover, certain medical conditions and medications such as anticoagulants, antiplatelets and systemic sympathetic alpha-1a antagonists (e.g., Flomax) may create intra- and postoperative problems for both the surgeon and anesthesia provider. It is thus not surprising that the AAO National Eyecare Outcomes Network (NEON) database indicates that dissatisfied patients are more likely to have such comorbidities (20).

- Conduct an ophthalmic examination and review of systems to elicit risk factors for undergoing the planned procedure, anesthesia and/or sedation.
- Inform the patient of these and other findings that might impact the expected course and outcome of surgery/anesthesia, and how you plan to proceed if complications occur.
- Explain the pros and cons of combining cataract surgery with other ocular procedures, such as limbal relaxing incisions, glaucoma surgeries, penetrating keratoplasty, and vitreoretinal surgery.
- Ask about medications that could influence the choice of anesthesia and surgical technique, such as anticoagulants, antiplatelets, and systemic sympathetic alpha-1a antagonists such as Flomax. Note that reports suggest that any history of Flomax-like medications, even years in the past, can induce intraoperative floppy iris syndrome (IFIS).⁸
- Consider obtaining preoperative clearance from a primary care physician (PCP) for patients with severe systemic diseases, such as chronic obstructive pulmonary disease, recent myocardial infarction, unstable angina, poorly controlled diabetes, or poorly controlled blood pressure (13).
 - Inform the PCP of both the proposed surgical procedure and type of anesthesia, and ask the PCP to clarify the need for preoperative tests and medication adjustments. If you receive results of preoperative tests, clarify with the PCP who will be following up on them.
- Communicate any pertinent information to the anesthesia provider and surgical team by including it in the preoperative orders.
- Note discussions with the patient and other physicians in the medical record.

⁶ Mangione CM, Phillips RS, Seddon JM, et al. Development of the 'Activities of Daily Vision Scale.' A measure of visual functional status. *Med Care* 1992; 30: 1111-26.

⁷ Steinberg EP, Tielsch JM, Schein OD, et al. The VF-14. An index of functional impairment in patients with cataract. *Arch Ophthalmol* 1994; 112: 630-8.

⁸ For current recommendations on IFIS, see the AAO Focal Point article by Dr. David F. Chang, "Managing Intraoperative Floppy Iris Syndrome," available at www.aao.org.

Discuss the choice of anesthesia with the patient, the PCP as needed, and the anesthesia provider.

OMIC conducted an analysis of its anesthesia and sedation claims and found that ophthalmologists need to better educate their patients about this aspect of ophthalmic surgery.⁹ The majority of these claims relate to peri-and retrobulbar injections. These are particularly risky choices for patients with bleeding disorders or those on anticoagulant or antiplatelet medications (26). An English study reported similar findings.¹⁰ The ophthalmologist's liability risk for anesthesia depends in part upon who administers it. Eye surgeons are usually held vicariously liable for care rendered by their employees, such as nurses and technicians. As a general rule, they are not held liable for the negligent acts or omissions of anesthesiologists, or of Certified Registered Nurse Anesthetists (CRNAs), even if—for billing and regulatory purposes—ophthalmologists are deemed to be the “supervisor.” This general rule is true unless the ophthalmologist controls or directs the actions of the anesthesia provider.¹¹

- Consider alternatives to retrobulbar anesthesia, such as topical or sub-Tenon's.
- Obtain and document the patient's informed consent for both the surgical procedure and the anesthesia if you will be administering it.
- If you will not be administering the anesthesia, inform the patient of your recommendation for the type of anesthesia, and clarify that the ultimate decision will be made by the anesthesia provider.
- Document the decision-making process about your planned anesthesia, especially if your choice differs from that of patient, PCP, or anesthesia provider.

Inform patients of options for near vision and astigmatism reduction

The many alternatives for near vision and astigmatism reduction after cataract or refractive lens exchange (RLE) surgery raise issues for patients and ophthalmologists alike. Indeed, reports to the Academy's Ethics Committee suggest that this aspect of cataract surgery warrants particular attention from eye surgeons.¹ Ophthalmologists have asked OMIC about the extent of the informed consent discussion related to intraocular lenses and whether the standard of care requires them to make new options available to patients. OMIC feels that it is advisable to inform patients of the types of options as part of the informed consent discussion. Only the individual ophthalmologist can decide, however, which specific IOLs to implant in his or her own patients. Just as surgeons should not feel obligated to offer all IOL options, patients should not feel pressured to choose more expensive lenses. Not all options are covered by CMS or private insurance. Moreover, surprises about out-of-pocket costs inevitably lead to patient complaints. Patients thus need to understand 1) the financial implications of their choice of IOL and method of astigmatism reduction, 2) if postoperative eyeglasses or contact lenses are covered, 3) what options are available if they are unable to tolerate the chosen IOL, and 4) if the fee includes postoperative refractive procedures. For example, Medicare will pay for one pair of eyeglasses or contact lens following cataract surgery with the insertion of an IOL. If a beneficiary's presbyopia-correcting IOL must be removed for some medical reason, Medicare will cover the insertion of a conventional IOL as a replacement for that lens.

⁹ OMIC's anesthesia claims experience is reported in *OMIC Digest* Spring 2006, vol. 16, no.2. Other website resources include 1) a video demonstrating sub-Tenon's technique, 2) “Ophthalmic Anesthesia Liability,” which compares the risks and benefits of each type of anesthesia, and provides more detailed recommendations about anesthesia providers, sedation risks, and management of anesthesia complications, and 3) an online course, for which OMIC policyholders can obtain a 5% risk management premium discount and CME credit.

¹⁰ Eke, T and Thompson, JR. Serious complications of local anaesthesia for cataract surgery: a 1 year survey in the United Kingdom. *British Journal of Ophthalmology* 2007; 91: 470-475.

¹¹ For more information on CRNAs, see *OMIC Digest*, Summer/Fall 2004, Volume 14, Number 3, available online at www.omic.com.

- Assess lifestyle and occupational needs, as well as the anticipated tolerance of potential visual phenomena, including halos, glare, loss of contrast sensitivity, and accessory images.¹²
- Discuss presbyopia and alternatives for near vision after cataract surgery.
- Discuss monovision. If a patient desires monovision, conduct a pre-operative trial with a contact lens or possibly spectacles to make sure the patient can tolerate monovision.
- Inform patients with astigmatism how it might impact their visual outcome. Explain the treatment options, which include glasses, contact lenses, refractive surgery (LASIK/PRK), toric IOL, and limbal relaxing incisions. Explain that postoperative residual astigmatism will need correction.
- Provide information a reasonable person would like to know, i.e., risks, benefits, and alternatives of the lens or procedure in question.
- Explain the rationale for your recommendation.
- Give patients who want an IOL or procedure that you do not offer information on how to obtain such care.
- Clarify that no guarantee can be made as to how well the patient will see after surgery, and that the results may differ from what was predicted or planned.
- Inform the patient that if the refractive result is considerably different than planned, eyeglasses, refractive surgery, or repositioning/replacement of the lens itself may be needed.
- Explain what will happen if the chosen lens cannot be placed due to problems arising during surgery.
- Encourage patients to check their plan about coverage, deductibles, and copayments for cataract surgery and postoperative IOL and eyeglass changes.
- Rules prohibit providing inducements to CMS beneficiaries that encourage them to use medical services, such as advertising that offers free rides to all patients who choose a premium IOL. Physicians may provide transportation assistance to individual patients if needed.

Obtain the patient's informed consent

While always an issue, lack of informed consent is rarely the main focus of malpractice lawsuits. Exceptions include when the surgeon performs a procedure that is different from the one planned (PRK instead of LASIK), or adds one without discussing it with the patient (LRI during cataract surgery). Consent allegations in lawsuits include failure to warn the patient of a particular complication for which the patient was at increased risk, coerced consent obtained the day of surgery, consent from a patient incapacitated by preoperative medication, or lack of consent for experimental treatment. Lack of documentation of the consent discussion inevitably leads to a credibility battle whose outcome depends upon subjective factors rather than medical facts. Informed consent begins as an **oral agreement** between the ophthalmologist and the patient **reached after a discussion**. The discussion includes the condition, recommended treatment or procedure, and the risks, complications, benefits, and alternatives. The discussion should include the consequences of refusing the recommended treatment or procedure. While only you as the surgeon can obtain the patient's informed consent, all members of your staff can assist you in educating patients. Helpful materials include AAO pamphlets and videos, and OMIC's "Cataract

¹² See the AAO document, "Informed Consent for Multifocal and Accommodative IOLs" at http://www.aao.org/member/ethics/upload/IOL_informed_consent.pdf

Surgery Patient Information Sheet” (at www.omic.com). Document all educational efforts, and include the names and relationships of family members and interpreters.

- Personally obtain the patient’s informed consent.
- Discuss known risk factors related to ocular or medical comorbidities, the surgery, or the anesthesia that increase the likelihood of complications, side effects, or poor outcome.
 - Consider circling or underlining the appropriate section of the consent and write in the reasons for the increased risk (e.g., rupture of the posterior capsule with dense cataracts).
 - Ask the patient to explain the risk in his or her own words to verify understanding.
- Obtain informed consent for planned comanaged care.¹³
- Conduct the discussion when the patient is awake and aware, free from the effects of any medication (e.g., Valium) that could interfere with the ability to participate in the decision-making process.
- Obtain consent before the day of the surgery whenever possible.¹⁴
- Use a procedure-specific consent form, such as the one provided on OMIC’s website, to document the content of the discussion, and offer the patient a copy.
- Obtain consent for each cataract procedure.¹⁵
 - Use either a new consent form or add a second date and signature line to the consent before it is signed for the first eye if bilateral surgery is planned.

Identify the patient, surgical site, and IOL prior to surgery

Perhaps no other type of medical error has received more attention than instances where the wrong procedure has been performed. OMIC has had a total of 42 of these “wrong” allegations, which are considered by plaintiff attorneys and juries to be completely preventable. The vast majority (26) involved claims of wrong power IOLs, followed by surgery on the wrong eye (10), block on the wrong eye (2), wrong procedure (2), and wrong patient (2). Fully 36% of these cases resulted in indemnity payments, which totaled \$573,515. Surprisingly, in many instances, the patient never filed a lawsuit. Patients who are promptly told the truth, offered an apology, and granted a waiver of the fees associated with the procedure tend to be more forgiving. Recommendations for preventing site errors include a pre-operative verification process, marking the operative site, and a “time out” immediately before starting the procedure. The “time out” involves the patient and the entire surgical team and frequently involves a checklist to verify the identity of the patient, correct site and side, procedure, patient position, and any implants, or special equipment. The verification process should be enforced prior to administration of anesthesia as well as before the operative procedure.

Disclose and document complications and unanticipated outcomes

After a detailed informed consent discussion, most patients can understand and accept a complication if they have a good rapport with their surgeon. Claims experience shows that maintaining an effective physician-patient relationship depends upon prompt, compassionate, factual communication. If patients are not informed of complications in a timely manner, and warned that they might also be at higher risk of experiencing other problems, they may lose faith in

¹³ A sample comanagement consent form and risk management recommendations are available at www.omic.com.

¹⁴ For a discussion of what to do when you are seeing the patient for the first time on the day of surgery and of “signature rules” please see “Obtaining and Verifying Informed Consent” at www.omic.com.

¹⁵ Bilateral simultaneous cataract surgery raises additional concerns. Please see “Cataract: Interval Between Surgeries” at www.omic.com.

their ophthalmologist and seek out second opinions and/or legal advice. The best course of action is to disclose complications to the patient.¹⁶

Provide discharge instructions and screen calls

Most cataract surgery takes place in ambulatory surgery centers. Patients may be discharged home before they fully understand their role in postoperative care or how to watch for serious problems.

- Give the patient written instructions about postoperative care, being careful to explain symptoms of possible complications that should be reported to you and your contact information.
- Inform the patient of the name and contact information of the surgeon who will be taking call for you if you will be unavailable.
- Have a prudent follow-up schedule after each surgery, and carefully document the history and physical examination.
- Screen after-hours callers for a history of prior ophthalmic surgery or procedures.¹⁷
- Instruct your staff to notify you at once if postoperative patients calls with problems, complaints, or questions.
- Conduct patient “hand-offs” and inform call partners of patients who have recently experienced significant complications.

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC’s confidential Risk Management Hotline by calling (800) 562-6642, extension 641.

¹⁶ OMIC policyholders are encouraged to call our Risk Management Hotline for confidential assistance at 1.800.562-6642, extension 641. Our approach to these events is outlined in “Responding to Unanticipated Outcomes,” available at www.omic.com.

¹⁷ See Telephone Screening of Ophthalmic Problems at www.omic.com for sample protocols and contact forms for physicians and staff.