

**Practice Guidelines for Informed Consent  
American Academy of Ophthalmology (AAO)  
in cooperation with  
Ophthalmic Mutual Insurance Company (OMIC)**

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## **Introduction**

### **Objective**

The goal of these practice guidelines is to help guide ophthalmologists through a quality informed consent process. Communication and rapport are the foundations of this process, which emphasizes assessment and communication rather than documentation and legal liability. These guidelines serve as practical benchmarks for a process critical to quality of care and can be applied to various ophthalmic practice settings including private practice, hospital clinics, and academic programs.

### **Ethics**

When medical and surgical procedures are proposed, ethical principles and the law both require discussion between physician and patient of the significant associated risks. In some states, a community standard is used by which a physician must disclose any information about risks and other factors that the average prudent physician in the community would disclose. Most other states set a higher standard, requiring disclosure of all information possessed by the doctor that a reasonable patient would find significant in deciding whether to undergo a procedure. Although legal requirements are an important benchmark to build on, they should be regarded as a minimum standard that should be exceeded by the application of good professional ethics.

From the ethical perspective, any risks or potential complications that are sufficiently common or significant that they might reasonably influence the patient's judgment to accept the proposed treatment must be disclosed. Exclusions may include very rare or inconsequential risks. Similarly, if a risk is readily apparent to people of common sense, then discussion can reasonably be excluded unless the physician has reason to believe that such a disclosure is necessary for a particular patient. Essentially, the physician must explain the rationale for the treatment, significant benefits, risks, and reasonable alternatives to the treatment proposed in language that the patient can understand.

When a patient is too young to legally consent to treatment or lacks the capacity to comprehend and decide independently, the informed consent must be obtained from a surrogate who is legally entitled to provide consent on the patient's behalf. The same procedure for explaining the rationale, risks, benefits, and alternatives should be followed with a guardian or surrogate.<sup>1</sup>

### **Relevance to ophthalmic practice**

The need for practice guidelines on informed consent is reinforced by the Ophthalmic Mutual Insurance Company (OMIC) claims experience, which indicates that suits for professional negligence are regularly accompanied by allegations of lack of informed consent, and increasingly, of misleading advertising. Even when supportive of the ophthalmic care rendered, defense experts frequently criticize how consent was obtained and documented.<sup>2</sup> Research shows that both the patient's surprise over an unexpected adverse outcome and unfavorable provider-patient rapport are at the heart of a number of malpractice claims. This premise is supported in part by a 1994 study, which suggests that breakdown in patient-physician communications is associated with more than 70% of malpractice claims.<sup>3</sup>

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<sup>1</sup> American Academy of Ophthalmology. [Advisory Opinion of the Code of Ethics: Informed Consent](#). Revised June 2008.

<sup>2</sup> Menke AM. Cataract Surgery: Risk Management Recommendations. [www.omic.com/resources/risk\\_man/recommend.cfm#cataractsurgery](http://www.omic.com/resources/risk_man/recommend.cfm#cataractsurgery).

<sup>3</sup> Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice: Lessons learned from plaintiff depositions. *Arch Intern Med* 1994;154:1365-70.

Dysfunctional communication can be avoided by engaging the patient in a constructive informed consent dialogue designed to clarify misconceptions, minimize unrealistic patient expectations, and invite the patient to participate in their care. Rather than being a purely legal function, consent becomes an opportunity to establish a "therapeutic alliance" between the ophthalmologist and the patient, wherein each acknowledges the outcome uncertainties that exist to some extent with any medical or surgical intervention.<sup>4</sup>

If the outcome is different from what the patient anticipated or desired, the ophthalmologist can reinforce this therapeutic alliance by frankly explaining the results, reminding the patient of the uncertainties addressed during the informed consent discussion, and focusing on current care needs. Such dialogue contributes to making informed consent a powerful tool in dealing with unexpected clinical outcomes and thus to address the risk management issues of failed provider communications and rapport.<sup>5</sup>

Within this context, consent is not a single event or the signing of a form, but an ongoing process that begins preoperatively and continues through the operative and postoperative phases of treatment. For the process to be effective, it is important to enlist and educate the ophthalmologist's entire office staff.<sup>6</sup>

Understanding and practicing a quality informed-consent process has become increasingly important. The American Academy of Ophthalmology recommends use of [self-assessment questions](#) provided by OMIC for ophthalmologists to assess their understanding of informed consent.

In summary, informed consent is a process that is critical to quality of care, is a thorough discussion between physician and patient that results in a clear understanding for both physician and patient of the rationale, risks, benefits, and alternatives to treatment, and is an opportunity for the physician to ensure that the patient has realistic expectations of the outcome. Ophthalmologists who implement the following risk management recommendations can promote patient safety and reduce the likelihood of a lawsuit for medical malpractice.<sup>7</sup>

### **Manage patient expectations through careful assessment and counseling**

Document communications about the indications for treatment in the medical record:

- Include cause of problem and document any functional impairment.
- Screen to ensure that the patient is a good candidate for the recommended treatment.
- When both eyes are affected and surgery is indicated, agree on which eye is to be operated first.
- Consider supplying the patient with additional literature or using visual aids such as diagrams or a DVD program during the informed consent discussion. Visual aids have been found to improve patient recall of facts and risks compared to verbal discussion alone.<sup>8</sup>
- Obtain patient agreement that the risks are acceptable.
- Manage expectations of vision outcomes.
- Include the names and relationships of any witnesses or interpreters.
- Document the problem in the patient's own words.

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<sup>4</sup> Gutheil TG, Burszajn H, Brodsky A. [Malpractice prevention through the sharing of uncertainty: informed consent and the therapeutic alliance](#). *N Engl J Med*. 1984;311:49-51.

<sup>5</sup> Holzer, JF. [Informed consent: A process, not just a legality](#). *Argus*. Mar 1991;B1-B2.

<sup>6</sup> Holzer, JF. [Practical approaches to informed consent in ophthalmic practice](#). *Ophthalmic Risk Management Digest*. 1992 Summer;2:2-5,8.

<sup>7</sup> Menke AM. Cataract Surgery: Risk Management Recommendations. [www.omic.com/resources/risk\\_man/recommend.cfm#cataractsurgery](http://www.omic.com/resources/risk_man/recommend.cfm#cataractsurgery).

<sup>8</sup> Moseley TH, Wiggins MN, O'Sullivan P. Effects of presentation method on the understanding of informed consent. *B J Ophthalmol* 2006;90:990-3.

### **Evaluate the patient for ocular and medical comorbidities that can affect the outcome**

- Conduct an ophthalmic examination and review of systems to elicit risk factors for the planned procedure, anesthesia, or sedation:
  - Identify ocular and medical comorbidities that may put the patient at higher risk of complications.
  - Identify the use of medications that may create intraoperative or postoperative problems.
- Inform the patient of these and other findings that might affect the expected course and outcomes of surgery and how you plan to proceed if complications occur.
- Note discussions with the patient and other physicians in the medical record.
- Discuss the choice of anesthesia with the patient and the anesthesia provider, as well as the primary care physician (PCP) as needed.
- Obtain and document the patient's informed consent for both the surgical procedure and the component of anesthesia that you will provide.
- 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.
- Consider obtaining preoperative clearance for patients with severe systemic diseases such as chronic obstructive pulmonary disease, poorly controlled blood pressure, and diabetes.
- 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. In most cases, preoperative clearance by the PCP is indicated.
- Communicate any pertinent information to the anesthesia provider and surgical team by including it in the preoperative orders.

### **Obtain the patient's informed consent**

- Discuss the patient's case with the patient and allow the patient to reach a decision:
  - Patient's condition
  - Rationale for recommending the treatment or procedure
  - Risks, complications, benefits, and alternatives, including the consequences of declining the recommended treatment or procedure.
- Warn patients at increased risk for a particular complication of that risk. Discuss known risk factors related to ocular or medical comorbidities, the surgery, or the anesthesia that may increase the likelihood of complications, side effects, or poor outcomes.
  - Consider circling or underlining the appropriate section of the consent and writing in the reasons for the increased risk (e.g., rupture of the posterior capsule with dense cataracts).
  - Ask the patients to explain the risk in their own words to verify their understanding.
- Discuss with the patient the potential need or intention to perform additional procedures (e.g., limbal relaxing incisions during cataract surgery).
- Personally obtain the patient's informed consent. Only you, the surgeon, should obtain the patient's informed consent, whereas all members of your staff can assist you in educating patients.

### **Verify informed consent**

- Ask the patient what procedure will be done and why *before* asking the patient to sign consent forms.
- If the patient does not appear to understand, discuss the procedure again with the patient to clear up any confusion or misunderstanding.

### **Document informed consent**

- Conduct the discussion when the patient is awake and aware, free from the effects of any medication that could interfere with the ability to participate in the decision-making process. Make sure that consent is given under circumstances devoid of coercion or any perceived pressure to consent.
  - Obtain consent before the day of the surgery whenever possible.<sup>9</sup>
  - Consent should be obtained prior to any preoperative medication.
  - Consent for experimental treatment should explicitly state the experimental nature of the treatment, must be approved by the appropriate Institutional Review Board, and usually carries additional consent responsibilities.
- Document all educational efforts, and include the names and relationships of family members and interpreters.
- Document repeated or additional consent discussions for clarification, in the patient's medical record, with a notation that the patient now appears to understand and has signed the consent form.
- Use a procedure-specific consent form, such as those provided on OMIC's website to document the content of the discussion.<sup>10</sup>
- For simultaneous bilateral procedures, use a separate consent form for the second eye.
- Obtain informed consent for planned comanaged care.<sup>11</sup>
- Patients should be given a copy of the signed forms.
- Make certain to perform the procedure for which consent was obtained (e.g., do not perform PRK instead of LASIK)

### **Identify the patient, surgical site, and any implants prior to surgery**

- Enforce a preoperative verification process prior to the administration of anesthesia, marking the operative site.<sup>12</sup>
- Perform a "time out" immediately before starting the procedure that involves the patient, the entire surgical team, and frequently, a checklist to verify the identity of the patient, correct site and side, procedure, patient position, and any implants and special equipment.

### **Ensure ethical off-label informed consent practices**

- Be well informed about the product.
- Base use on firm, scientific rationale and sound medical evidence.
- Maintain records of uses and effects.<sup>13</sup>
- Perform a risk analysis of treatment with off-label use to determine whether its use constitutes research and the extent to which institutional review and disclosure to the patient are required.<sup>14</sup>

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<sup>9</sup> For a discussion of signature rules and what to do when seeing a patient for the first time on the day of surgery, see Menke AM, "Obtaining and Verifying Informed Consent," at [www.omic.com](http://www.omic.com). For a more detailed discussion of same-day consent, see the Summer 2007 Hotline article of the *OMIC Digest* at [www.omic.com/new/digest/Digestsummer\\_fin2.pdf](http://www.omic.com/new/digest/Digestsummer_fin2.pdf).

<sup>10</sup> The most current procedure-specific informed consent forms are available at [www.omic.com](http://www.omic.com).

<sup>11</sup> A sample comanagement consent form and risk management recommendations are available at [www.omic.com](http://www.omic.com).

<sup>12</sup> For a discussion of time-out and time-out guidelines, see the [Recommendations of American Academy of Ophthalmology Wrong-Site Task Force](#). November 2008.

<sup>13</sup> Craven ER, Moran EC. [Medicolegal Implications of Using Off- Label Drugs and Devices](#). *Ophthalmic Risk Management Digest*. 1996 Winter;6:3-5.

<sup>14</sup> OMIC has devised a form to assist in this risk analysis, which addresses the drug or device's FDA status, manufacturing and distribution sources, conditions of use (research vs. "practice of medicine"), the extent of the role the drug or device plays in the treatment, the patient safety risks, and whether the use is considered therapeutic or cosmetic: [www.omic.com/resources/risk\\_man/forms.cfm](http://www.omic.com/resources/risk_man/forms.cfm).

- Evaluate what information the patient needs to make an informed decision about its use:
  - If the physician reasonably believes that the approval status of the drug or device used in the patient's treatment will be a factor in the patient's decision to undergo the procedure, this information must be disclosed and documented.
  - If the treatment consists of simple and common procedures with risks that are generally understood to be remote, such as x-rays and blood tests, then consent rather than "informed" consent is all that is needed.
  - The extent of disclosure and documentation should be tailored to the level of risk
  - If the drug or device is unapproved, but not part of an official research protocol, disclose the drug or device's unapproved status to the patient as part of the informed consent process.
- Consider developing a specific consent form that outlines the risks, benefits, alternatives, and FDA status in cases in which treatment consists primarily of using the unapproved or off-label drug or device.
- Patients should be given a copy of the signed form.

### **Comanagement**

- Prior to surgery, disclose the comanagement plan to the patient and obtain his or her written, informed consent.
- Include in the medical record the reason for the transfer of care, the qualifications of the healthcare provider who will render the postoperative care, and any special risks that may result from this arrangement.<sup>15</sup>
  - For refractive surgery, the first postoperative visit should be conducted by an ophthalmologist.
- Ensure that the provider whom care is delegated to is both clinically competent and authorized by state law to provide postoperative care.<sup>16</sup>

### **Make no misleading statement about your training or experience**

Be truthful about your training and experience, particularly as it relates to board certification and experience performing a particular procedure. Lying to the patient during the consent process could pose serious legal consequences.<sup>17</sup>

### **Disclose and document complications and unanticipated outcomes**

- Maintain an effective physician-patient relationship by prompt, compassionate, factual communication.
- Inform patients of complications in a timely manner, and warn them that they might also be at higher risk of experiencing other problems.<sup>18</sup>

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<sup>15</sup> The American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery issued a joint position paper that provides guidelines for physicians considering comanagement: [Ophthalmic Postoperative Care: A Joint Position Paper of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery](#), February 2000. The societies stress that the delegation of postoperative care should be clinically appropriate and in the patient's best interest, neither driven by the providers' economic concerns nor a routine practice.

<sup>16</sup> Ophthalmic Mutual Insurance Company. [Confirmation of Postoperative Comanagement Selection by the Patient](#).

<sup>17</sup> See *Howard University v. University of Medicine and Dentistry of New Jersey*, 172 N.J. 537, 800 A. 2d 73 (N.J. 2002); *Johnson v. Kokemoor*, 545 N.W. 2d 495 (Wis. 1996).

<sup>18</sup> OMIC policyholders are encouraged to call the OMIC Risk Management Hotline for confidential assistance at (800) 562-6642, extension 641. Their approach to these events is outlined in Menke AM, "Responding to Unanticipated Outcomes," available at [www.omic.com](http://www.omic.com).

**Provide discharge instructions and screen calls**

- Give the patient written instructions about postoperative care, being careful to explain symptoms of possible complications that should be reported to you, and include your contact information.
- Inform the patient of the name and contact information of the physician who will be taking calls for you if you will be unavailable.
- Maintain 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.<sup>19</sup>
- Instruct your staff to notify you at once if postoperative patients call with problems, complaints, or questions.
- Conduct patient "hand-offs" and inform call partners of patients who have recently experienced significant complications.

**Conclusion**

The patient's right to obtain the information needed to make reasoned decisions about their own healthcare should always be honored. Because there are ethical, professional, and legal aspects to informed consent, and because informed consent often surfaces in the legal arena as an area of patient dissatisfaction, the informed consent process is an area worthy of assessment and improvement. Good physician-patient rapport and a process that facilitates clear communication and documentation are the foundations of quality informed consent.

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<sup>19</sup> For sample protocols and contact forms for physicians and staff, see "Telephone Screening of Ophthalmic Problems," available at [www.omic.com](http://www.omic.com).