

ADVISORY OPINION OF THE CODE OF ETHICS

Subject: **Informed Consent**

Issues Raised: What are the professional responsibilities that govern discussion of risks, benefits, and alternatives when medical or surgical treatments are proposed?

Applicable Rules: Rule 1. Competence
Rule 2. Informed Consent
Rule 3. Clinical Trials and Investigative Procedures
Rule 4: Other Opinions
Rule 9. Medical and Surgical Procedures
Rule 10. Procedures and Materials
Rule 13. Communications to the Public

Background

When medical and surgical procedures are proposed, both ethical principles and the law require discussion of significant associated risk. Clearly, an ophthalmologist must understand and conform to the minimum required by applicable law. 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 or not to undergo a procedure. Although legal requirements are an important benchmark on which to build, they should be regarded as a minimum standard that is routinely exceeded by practice 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 minor, 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 or appropriate in view of the unique needs of 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 when a patient 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.

The following cases illustrate potential shortcomings in the informed consent process that may arise, despite the practitioners' self-assessments that they practice ethically. It is important for all ophthalmologists to examine their approach to informed consent in order to best uphold the rights of patients as plans for medical or surgical treatment are discussed.

First Inquiry

Facts - Mr. H. is a 50-year-old drill press operator. He had not been seeing well for the previous 4 months and went to Dr. D for help. Dr. D found normal acuity in both eyes but elevated pressures (30 mmHg in the right eye and 25 mmHg in the left). There was glaucomatous damage to both optic nerves (severe in the right and moderate on the left) and marked visual field loss. In the absence of other ocular abnormalities, Dr. D diagnosed primary open-angle glaucoma. He explained the nature of glaucoma in detail and why the intraocular pressure should be reduced if vision was to be preserved. He also described several forms of treatment, stating that eye drops are commonly used first and that surgery is employed later if medical treatment is not sufficient in controlling the disease. The discussion took 10 minutes.

When Mr. H asked, "What do you think I should do," Dr. D prescribed timolol 0.5% twice a day and instructed Mr. H to return in a week. He neglected to ask Mr. H whether he had a history of heart or respiratory problems. At the second visit, the pressures were significantly lower, although Mr. H complained that on four recent occasions he had experienced severe shortness of breath and was worried about his asthma returning, even though he has not experienced similar episodes for a long time. When Dr. D listened to his patient's chest, he instructed him to discontinue the timolol without other comment. It was now clear to Dr. D that the patient had a history of asthma. Dr. D had failed to mention asthma as a potential contraindication of the recommended drug therapy and to disclose the consequences of the omission. Mr. H now suspects that he had had an adverse reaction to the prescribed medicine, and he has asked if Dr. D acted ethically.

Resolution - Dr. D appears to have evaluated the ophthalmic problem properly and to have made the correct diagnosis (glaucoma); however, he failed to thoroughly assess the patient's medical history, which was a serious omission in his informed consent process. He described the nature of glaucoma and the basic options for treatment, and he prescribed an appropriate drug. However, although the consequences of nontreatment were mentioned, alternative drugs and their different benefits and risks were never discussed. Since timolol can exacerbate asthma and chronic obstructive lung disease, and cause potentially serious cardiac complications, this was a serious omission that deprived Mr. H of important information that may have affected his decision about the treatment recommendation. Although Dr. D also failed to mention alternative medicines and their risks and benefits, he was not obligated to enumerate every conceivable medicine or rare side effect. Nevertheless, it was an important omission to prescribe timolol without first asking questions that would identify contraindications and without discussing several common and easily identified side effects. Common alternatives, such as prostaglandin derivatives, were not mentioned. These omissions are deficiencies in the process of obtaining informed consent for treatment, as required by Rule 2 of the Code of Ethics.

Second Inquiry

Facts - Dr. A makes it his practice to discuss a proposed procedure with each patient before surgery. He asks cataract patients questions about functional needs and how the problem has affected their lifestyle. After an appropriate examination, he explains why cataract surgery is warranted. When observation may be appropriate, he explains nonsurgical management. If he recommends surgery, he discusses the rationale in common language as

well as poor outcomes, risks of anesthesia, and other significant complications. He indicates that there are some very uncommon complications but does not provide an exhaustive list. He gives each patient a chance to ask questions, but he does not provide printed information. For most elective cases, each patient is instructed to think the matter over and call the office to schedule surgery. When patients elect to have surgery, he performs his standard procedure: phacoemulsification through a superior incision with a silicone monofocal foldable lens implant. Dr. A has inquired whether his procedure is consistent with the Code of Ethics.

Resolution - In many respects, Dr. A's procedure is an excellent model of an informed consent process, apparently meeting both ethical and legal requirements. First, he fulfills the requirements that a physician explain in understandable language the nature of the disorder, its prognosis without treatment, the rationale and risks of treatment, and nonsurgical alternatives. Dr. A also includes a discussion of living needs, allowing a more meaningful assessment of indications for surgery or continued observation. Second, the patient must understand the information: Dr. A asks questions to assess whether the patient understands important elements of the discussion. Third, the patient must voluntarily give consent. Dr. A understands that at the emotionally charged moment of considering surgery, a patient's abilities for rational decision making may be compromised. It is therefore particularly helpful that Dr. A gives a patient time to consider a proposed treatment outside the environment of the doctor's office. The fact that Dr. A does not give the patient written information is unimportant; it is the quality of open communication and understanding that matters. Likewise, while it may be helpful and advisable to have the patient sign a written consent for risk-management reasons, it is not critical from a purely ethical viewpoint if the patient has given a careful and informed consent.

One crucial element that Dr. A does not mention is alternatives to the "standard" surgical procedure that he offers: Does Dr. A always perform only one specific technique and use only one type of lens? Other surgeons in his community may consider presbyopia-correcting lenses. They also might alter their technique to avoid lenses that may be less desirable or contraindicated in some clinical situations, depending on the patient's needs and associated conditions. If such alternatives are potentially indicated, he should advise the patient of this fact so that the patient can consider all reasonable options. Although an ophthalmologist often helps the patient by recommending a particular course of action, the patient should not be denied the opportunity to consider the advantages and disadvantages of important alternatives, even if access to them might require referral to another ophthalmologist.

Third Inquiry

Facts - Mrs. R, a retired school teacher, had a cataract operation performed by Dr. B, a Fellow of the Academy. Her preoperative acuity was OD 20/25 and OS 20/30. Vitreous loss occurred during the procedure, although no vitrectomy was done. Iridocyclitis and vitritis ensued, followed by a retinal detachment. Two reattachment procedures were then unsuccessful because of proliferative vitreoretinopathy. Mrs. R is angry about the outcome of her surgery, and she filed a legal claim that she was not informed of the risk of these complications and would have declined the original procedure had she been aware. It was subsequently discovered that Dr. B never discussed the potential risks and benefits of surgery with Mrs. R and that his nurse had asked her to sign a long consent document containing technical language about surgical risks including vitreous loss, iridocyclitis, and retinal detachment on the day of the procedure. Mrs. R asked no questions and signed the form. She has asked the Academy whether Dr. B acted unethically.

Resolution - Dr. B acted unethically for several reasons. First, for a retired patient with

modest visual impairment such as Mrs. R, it is particularly important to ensure that the patient understands the nature of cataract and alternatives to the proposed surgery, including observation, unless there is some compelling need for surgery. (This presupposes that the surgeon has made a judgment regarding medical need: see Rule 10 of the Code of Ethics "Procedures and Materials.") In this case, it appears that a discussion about the need for surgery never occurred. Second, merely presenting a technically worded consent document and asking for a signature on the day of surgery would rarely satisfy the ethical obligation to obtain informed consent. Many studies have shown that in the emotionally charged environment of a health care facility, together with the complex wording of such forms, patients do not adequately assimilate the information. Because of the lack of understanding, this is not *informed* consent. It is Dr. B's obligation to convey understandable information about the risks, benefits, and alternatives to surgery and to confirm that the patient understands what they mean. This kind of personal communication also improves doctor/patient relations, which in itself can be helpful in avoiding legal claims. Finally, Dr. B's conduct also fails to satisfy the "voluntary" criterion of informed consent and could be considered coercive. If a patient is scheduled for elective surgery and is advised of the risks of surgery for the first time on the day of the procedure, the process fails as a true decision point on whether or not to proceed, Patients might feel obliged to cooperate with an initiative already in progress rather than make an independent decision to have surgery.

It must be stressed that failure to obtain adequate informed consent is a serious ethical violation, even if there is no harm or poor outcome. Surgical success, no matter how good the result, is never a justification for failing to obtain informed consent. The law supports this concept in a majority of states, in which legal claims can be based on inadequate informed consent even in the absence of injury. Dr. B has also clearly violated Rule 2 of the Code of Ethics requiring informed consent. In addition, Dr. B's management of the surgical complication raises concerns: the physician should be competent to manage complications or refer patients to others as required by the condition. In this respect, Dr. B may have violated Rules 1 and 4 of the Code of Ethics through lack of competence to manage the vitreous loss and failure to make a timely referral for subspecialty management.

Fourth Inquiry

Facts - Mr. P is a 44-year-old truck driver who has successfully worn contact lenses to correct his 3 diopters of myopia. He removed his contact lenses to read at night. After seeing advertising by various ophthalmologists who offer refractive surgery, he wished to learn more about available procedures. In one newspaper advertisement Dr. W, a Fellow of the Academy, was identified as a "leading expert" in refractive surgery. It was stated in the advertisement that he had successfully treated "thousands of patients" and that these patients "no longer needed glasses or contact lenses." When Mr. P called for an appointment, he was sent appointment cards for two surgical sessions, one for each eye, and a brochure on refractive surgery. The brochure enumerated advantages of refractive surgery and noted that "while a few patients occasionally experience complications, most are entirely pleased with the results."

When Mr. P arrived at the surgery center for his first appointment, a technician evaluated his current refractive error and a receptionist gave him a three-page surgical "consent form." It listed a few possible complications of refractive surgery, such as variable acuity and glare, but it did not refer to others. Mr. P read and signed the form. He first met Dr. W in the operating room. Dr. W asked him if he was ready and if he had any questions. Mr. P asked if it would hurt, to which Dr. W replied "no" and then began the procedure. Mr. P had a disappointing postoperative result due to high residual astigmatism, and he has inquired if Dr. W acted unethically.

Resolution - Dr. W. clearly violated numerous ethical principles, the rules of the Code of Ethics, and possibly the law. First, the advertising violates Rule 13, which specifically requires that communications to the public disclose any significant risks of surgical procedures. Although reports in the scientific literature support the assertion that most refractive surgery patients are pleased with initial results, there are also reports of late complications, unpredictability, and visual loss. By referring to "successful" surgery in "thousands of patients" without reference to risk, an "unjustified expectation of success" may result and therefore be considered deceptive. A general reference to "occasional complications" is probably insufficient. If the procedures offered are relatively new, it may be necessary to inform patients about the extent of clinical history and the possibility of unforeseen long-term risks. A detailed description of the risks and possible outcomes of refractive surgery is particularly important, because these procedures are generally elective. For this particular patient, indications for surgery were questionable despite the presence of myopia, because the patient was well adjusted to his current correction and was functioning well.

Dr. W compounded the ethical shortcomings of his advertising by not engaging in any discussion with the patient prior to entering the operating room. Even at that point, he had not considered whether surgery was appropriate. Up to the moment that surgery began, Dr. W made no effort to ascertain the degree to which Mr. P understood the procedure. Dr. W acted unethically in many aspects of this particularly egregious case. Asking for questions occurred far too late in the process for the patient to engage in a meaningful discussion of risks, benefits, and alternatives. For elective surgery, the informed consent discussion should ordinarily occur at least several days prior to surgery.

Applicable Rules

"Rule 1. Competence. An ophthalmologist is a physician who is educated and trained to provide medical and surgical care of the eyes and related structures. An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is. An ophthalmologist must not misrepresent credentials, training, experience, ability or results.

"Rule 2. Informed Consent. The performance of medical or surgical procedures shall be preceded by appropriate informed consent."

"Rule 3. Clinical Trials and Investigative Procedures. Use of clinical trials and investigative procedures shall be approved by adequate peer review mechanisms. Clinical trials and investigative procedures are those conducted to develop adequate information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenesis in circumstances in which insufficient information exists. Appropriate informed consent for these procedures must recognize their special nature and ramifications."

Rule 4: Other Opinions. The patient's request for additional opinions shall be respected. Consultation(s) shall be obtained if required by the condition.

"Rule 9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service."

"Rule 10. Procedures and Materials. Ophthalmologists should order only those laboratory procedures, optical devices or pharmacological agents that are in the best interest of the

patient. Ordering unnecessary procedures or materials or withholding necessary procedures or materials is unethical.

"Rule 13. Communications to the Public. Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics and other means. They must not omit material information without which the communication would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way, and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments about the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent."

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