

ADVISORY OPINION OF THE CODE OF ETHICS

Subject: Determining the Need for Medical or Surgical Intervention

Issues Raised: Under what circumstances is the performance of procedures and

surgery considered necessary?

Applicable Rules: Rule 2. Informed Consent

Rule 6. Pretreatment Assessment Rule 9. Medical and Surgical Procedures Rule 10. Procedures and Materials

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Background

Performing unnecessary surgery is a major betrayal of the surgeon's paramount obligation to place the patient's best interests first in all therapeutic decisions and violates the Code of Ethics. Surgeons have a responsibility to evaluate all of the procedures they perform and to consider whether those procedures are appropriate for a particular patient. Withholding necessary surgery may also be unethical. If a procedure is likely to benefit the patient, is medically justified, and is desired by the patient, denying this service may be considered unethical.

Performing unnecessary surgery violates Rules 6 and 10 of the Code of Ethics. It may also violate Rules 2 and 9, which require that the surgeon fully advise the patient about the proposed surgical procedure, the reasons for proposing it and any substantial risks, benefits, and alternatives. Rules 2 and 9 also require that after the patient is informed and demonstrates understanding of this critical information, he or she voluntarily consents to the surgery. In most cases of unnecessary surgery, there is a failure to convey adequate information concerning the risks, benefits, and alternatives, or the ophthalmologist may have misrepresented the procedure in order to obtain patient consent.

Performing unnecessary procedures or surgery may be a basis for malpractice liability or tort actions for fraud and battery even if there is a satisfactory surgical outcome. Claiming reimbursement for unnecessary surgery could also constitute fraud under Medicare/Medicaid or private insurance policies. Performing a higher volume of particular procedures or operations than would be expected given practice specialization and disease prevalence may also suggest the existence of unethical practice and become a subject of scrutiny.

Surgery is unjustifiable when the risks and costs exceed the likely therapeutic benefits to the patient. Typically, no one factor alone can determine whether a particular surgery is needed; instead, individual patient needs must be taken into account. A cataract operation on a 65-year-old man who reports that his vision meets his needs might be unnecessary, whereas a similar cataract in a 55-year-old school bus driver might require surgery.

The surgeon's decision to recommend surgery, made in close consultation with the patient and subject to the patient's consent, although typically straightforward, may occasionally be complex. Well-qualified and reasonable surgeons can differ as to the need for surgery in certain situations. For ethical purposes, the term "unnecessary surgery" should be applied only when (1) in an individual case there is a decision to perform a procedure or surgery that

is not justifiable in light of the patient's needs and is substantially inconsistent with accepted professional standards for determining the need for surgery, and/or (2) there is a pattern or practice of performing procedures or operations in what would generally be considered marginally justifiable cases. The following examples illustrate these concepts.

First Inquiry

Facts - Dr. T is a well-known cataract surgeon who is participating in a clinical trial of a new presbyopia-correcting intraocular lens. He sees a 60-year-old taxi driver who has a relatively insignificant nuclear cataract. The patient reports that he experiences some glare under certain conditions, such as night driving, but that he has recently requalified for a drivers' license and can drive comfortably. He states that he is currently satisfied with his corrected visual acuity, but he is ultimately convinced by Dr. T to proceed with cataract surgery and implantation of the investigational presbyopia-correcting intraocular lens.

Resolution - Dr. T may have acted unethically. The patient did not feel that his vision was limiting his occupational or social functioning. A decision to defer surgery would have borne no significant risks in this case. Surgery for a non-visually limiting cataract in a 60-year-old man would not ordinarily be justified unless the patient thought his occupational or social functioning was significantly impaired and the surgeon determined that the cataract was the cause of the impairment. Thus, medical justification for the surgery was lacking in this case. If Dr. T's recommendation for surgery was influenced by financial incentives for enrolling the patient into the clinical trial, then he is clearly placing his own interests above those of the patient and is acting unethically. Even if this is not Dr. T's conscious motive, he should be aware of the patient's vulnerability and how easily the patient can be coerced into agreeing to proceed with surgery despite his misgivings. In such a case, the patient's consent is not voluntary and informed but rather the result of implicit or explicit coercion.

Second Inquiry

Facts - Dr. S is an experienced ophthalmologist who has cared for a 60-year-old patient with advanced chronic open-angle glaucoma. The patient has documented visual field loss and progressive cupping of the optic disc in spite of treatment with maximum medical therapy. Dr. S strongly recommends filtration surgery, which she advises has some risks but may reduce the risk of further visual loss. The patient at first hesitates, saying that she has not noticed pain or visual loss and does not think that she needs an operation. After Dr. S explains her findings, the risk of vision loss associated with persistently elevated intraocular pressure, and the relevant alternative treatments (e.g., laser trabeculoplasty surgery), the patient consents to filtration surgery.

Resolution – Although Dr. S vigorously advocates surgery over the patient's initial objection, she acted ethically. She has examined the patient, detected progressive disease, and accurately outlined for the patient the therapeutic options, benefits, and risks. That the patient did not previously perceive the need for surgery and initially was not sure she wanted it does not make the surgery unnecessary given the serious medical justification (progressive visual loss).

Third Inquiry

Facts - Dr. C is a competent cataract surgeon who was sued 2 years ago for malpractice in a case involving persistent postoperative corneal edema and cystoid macular edema. Although he successfully defended his case, he resolved to perform specular microscopy of the corneal endothelium, corneal pachymetry optical coherence tomography (OCT) imaging of the

macula, and fluorescein angiography before surgery in every case, in an effort to better defend himself in the event of future lawsuits.

Resolution - Dr. C appears to have adopted an unethical practice pattern. It is ethical for an ophthalmologist to utilize all appropriate diagnostic procedures in a particularly difficult case where these procedures may be necessary to identify pre-existing pathology and to counsel patients regarding surgical risks. However, the range of diagnostic procedures that are appropriate to a particular case varies, and the choice of which ones to use must be made on an individual basis. This is an example of "defensive medicine" for legal purposes. This practice is unethical, because some diagnostic procedures (e.g., fluorescein angiography) bear a degree of risk to the patient. Since the patient must bear these risks (and perhaps some of the costs), the ophthalmologist should not use these procedures unless he or she concludes that the benefits to the patient outweigh the risks. Otherwise, the ophthalmologist has placed his or her own interests above those of the patient, and this is unethical.

Fourth Inquiry

Facts - Dr. R is an experienced corneal transplant surgeon who maintained an excellent reputation for many years. In recent years, his practice has been somewhat less active. Dr. R decided 2 years ago that he did not believe in newer lamellar procedures (e.g., Descemet's stripping endothelial keratoplasty [DSEK]) to treat corneal edema. He candidly tells all of his Fuchs endothelial corneal dystrophy patients that he thinks these newer procedures are not reliable and that they will be better served if he performs a conventional penetrating keratoplasty.

Resolution - Dr. R presents the converse of unnecessarily aggressive surgery: possibly inappropriate conservatism. There is nothing wrong with this surgeon limiting his practice to those types of procedures that he has experience in performing. Additionally, it is ethical for the ophthalmologist to inform patients why he does or does not perform particular procedures. However, if Dr. R does not offer all appropriate surgical options, especially those that have been shown to have advantages over procedures with which he is familiar, he must inform the patient. Dr. R should ensure that the patient is fully informed about the alternative surgical procedures, including those that he does not perform but that could be provided by other accessible physicians. Therefore, if Dr. R informs all patients with Fuchs endothelial corneal dystrophy that penetrating keratoplasty is a better surgical procedure than endothelial keratoplasty, he is not rendering justifiable medical advice. Moreover, if he performs conventional penetrating keratoplasty on all of his patients, including those whom most corneal surgeons would consider good candidates for endothelial keratoplasty, he may be acting unethically.

Applicable Rules

"Rule 2. Informed Consent. Informed consent is the process of shared decision-making between the ophthalmologist and the patient and must precede the performance of medical or surgical procedure. During the informed consent process, pertinent medical and surgical facts, and recommendations consistent with standard of care in medical/surgical practice must be presented in understandable terms to the patient or patient surrogate. Such information should include the indications, benefits, objectives, risks and possible complications of the procedure, alternatives to the procedure, and the potential consequences of no treatment. The operating ophthalmologist must personally confirm comprehension of this information with the patient or patient surrogate."

"Rule 6. Pretreatment Assessment. Treatment (including but not limited to surgery) should be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs. The ophthalmologist must evaluate and determine the need for treatment for each patient. If the pretreatment evaluation is performed by another health care provider, the ophthalmologist must ensure that the evaluation accurately documents the ophthalmic findings and the indications for treatment. Recommendation of unnecessary treatment or withholding of necessary treatment is unethical."

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

"Rule 10. Procedures and Materials. Ophthalmologists should order and/or utilize only those laboratory and surgical procedures, optical devices or pharmacological agents that are in the best interest of the patient. It is unethical to prescribe or provide unnecessary services and procedures or seek compensation for those services. It is equally unethical to withhold necessary services or procedures."

Other References

American Academy of Ophthalmology Advisory Opinion of the Code of Ethics, "Informed Consent" and "Appropriate Examination and Treatment Procedures". Available at: https://www.aao.org/clinical-education/redmond-ethics-center.

American Medical Association, Code of Medical Ethics Opinions 2.1.1 ("Informed Consent") and 8.054 ("Financial Incentives and the Practice of Medicine"). Available at: https://www.ama-assn.org/

American College of Surgeons, Statements on Principles, Code of Professional Conduct. SEC. J, "Unnecessary Operations."

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