THE ETHICAL OPHTHALMOLOGIST

Informed Consent ● The Doctor-Patient Relationship ● Delegated Services

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(Material adapted from *The Ethical Ophthalmologist: A Primer,* a text by the Ethics Committee of the American Academy of Ophthalmology.)

Summary: This course covers ethical issues and concerns and their impact on every day decision-making in ophthalmology. The case study approach, with questions and discussion, provides an opportunity to recognize and analyze ethical dilemmas. These learning activities will also heighten awareness of ethical and moral principles in certain aspects of contemporary medical practice such as research and new technology, delegated services, commercial relationships, compensation, and advertising.

Audience: Ophthalmologists, eye care professionals, and ethicists.

Objectives: After completing The Ethical Ophthalmologist: Course II, you should be able to explain the ethical approach you would take in dealing with informed consent, doctor-patient relationship, and delegated services issues.

Accreditation: The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

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CME: CME credit is available to all users of this educational activity.

Financial Disclosure: The authors acknowledge no financial interest in the subject matter of this course.

Editor's Note: This text is for educational purposes. It is intended to promote discussion and understanding of the ethical issues facing ophthalmologists. This text does not interpret, modify, amend, or supplement the Code of Ethics of the American Academy of Ophthalmology or any of the Advisory Opinions.

All names used in the case studies in this text are fictitious, and have no intended relationship to any persons involved in any past or present ethics matter considered by the Academy's Ethics Committee. Any similarities in the names chosen in the case studies to those of actual ophthalmologists or other persons are entirely coincidental. Finally, although this project was undertaken with the full support and encouragement of the Academy's Board of Trustees, and was completed with the invaluable assistance of the Academy staff and resources, the text itself is the sole product of, and responsibility of, the individual authors and editors.

INTRODUCTION

Ethical principles and behavior are an integral part of the practice of medicine. For this reason, the ability to recognize and act on ethical issues is an essential qualification of the competent ophthalmologist.

Imagine, for example, that several patients have contacted you recently for a second opinion on the urgent need for cataract extraction. Each surgery was recommended by one particular ophthalmologist in your community. In each case, you find that new glasses improve the patient's vision to a level entirely satisfactory to the patient. What do you tell the patients? Do you have a larger responsibility to protect other patients from unnecessary surgery? What obligation do you owe the other ophthalmologist?

"Another example, a 3-year-old boy with developmental delay and cerebral palsy is brought to you for evaluation of esotropia and moderate hyperopia by concerned parents. The parents tell you that the child was recently examined by another eyecare professional who told them it was impossible to determine whether the child could see, and that the correction of strabismus with glasses and surgery was not advised because "it would really be just for cosmetic purposes and wouldn't last." What do you tell the parents?"

Neither of these two examples constitutes a life and death matter, and neither would be considered an ethical crisis. Yet, such situations raise a host of issues that test the ophthalmologist's knowledge, understanding, sensitivity, compassion, and moral judgment – in brief, his or her ethical awareness and behavior. Similar predicaments, some more mundane, some more dramatic, are part of the practice of medicine. Yet practical guidance in how to deal with these events has largely escaped attention in most of the books that fill our professional libraries. There is no *Duke Elder* or *Duane's* textbook to provide instruction. We may recognize the ethical competence of our physician role models and we can learn from them, but a specific presentation of ethical issues that permeate the practice of ophthalmology could prove a useful adjunct. Such a guide might serve to increase our moral awareness and competence in managing the obligations of our profession. These courses attempt to fill that need.

It should be clear; this is not a "cookbook" or "how-to" handbook for ethical conduct. It is only a guide. You will note that there are questions related to the various case studies presented. These are offered to illustrate the fact that, in many instances, no single response is the only correct course of action. Conflicting ethical concerns may be present; alternatives exist, and the physician must bear the choices based on the ethical principles that pertain to the conditions of the situation described. Hopefully, this activity can aid the teaching and learning process in which physicians become better healers: healers of their patients, their communities, and themselves.

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INFORMED CONSENT

The process of informed consent involves the interplay of four elements: *disclosure* and *comprehension*, the informational components; and *competence* and *voluntary choice*, the consent components. Before considering these elements in detail, review three case studies that illustrate the significance of informed consent in the doctor/patient relationship.

Case #1

An 84-year-old retired schoolteacher, Mrs. Lee, comes to Dr. Rand with a complaint of decreased vision in both eyes. Examination revealed 20/80 best-corrected vision O.D. and 20/60 best corrected vision O.S. Biomicroscopy confirms the presence of 3+ nuclear sclerotic cataracts and an otherwise normal examination. Dr. Rand discusses the risks, benefits, alternatives, and procedures for cataract surgery and then asks if Mrs. Lee has any questions. She replies that she has none and will leave it to the doctor to decide whether or not the cataract is ripe and ready for surgery. Dr. Rand tells Mrs. Lee she will see better after the surgery, gives her literature regarding the procedure, and sends her to the booking secretary to schedule surgery.

Thought Questions

A. How should the ophthalmologist respond when the patient places the burden of choice on him?

B. Should the ophthalmologist utilize therapeutic privilege in this case?

Discussion

The ophthalmologist's obligation is to tell the patient that cataract surgery is an elective procedure. Therefore, Doctor Rand should explain the condition as fully as possible and answer any questions Mrs. Lee may have. In brief, his responsibility is to educate her to the point where she feels comfortable making the decision for herself. The ophthalmologist might explain the difference between informed consent in this situation and an emergency where the physician must exercise therapeutic privilege to act in the patient's best interests. He could also suggest that she take a little more time to decide, perhaps read the literature he has provided, and discuss the matter with her family; then she can return to review her decision with the doctor. He might also tell her that the more she understands before surgery, the less anxious she will be about the procedure. Finally, we should recognize that, although rare, there are patients who do not want to know details of the procedure and prefer to have the surgeon make the decision. If this appears to be the case after the physician's best efforts to educate the patient, the physician should attempt to engage a relative or friend in the process. An informed advocate who understands the issues of the proposed surgery might better assist in helping her reach a decision.

Case #2
A 74-year-old male recently immigrated from the former Soviet Union and speaks only Russian. He visits an ophthalmologist because vision in both eyes has been slowly decreasing, making it difficult for him to read. He conveys this information to the ophthalmologist through an interpreter, noting that reading is an important part of his life. An eye examination reveals the presence of cataracts in both eyes, with a best-corrected visual acuity of 20/80 in each eye. Biomicroscopy confirms nuclear sclerotic cataracts consistent with visual acuity. The remainder of his examination is unremarkable. The ophthalmologist concludes that the visual difficulties are due to the cataracts and that the patient would benefit from their removal. These conclusions are relayed to the patient through the interpreter, and surgery is recommended. The physician also states that clouding of vision, which occasionally occurs after surgery, can be easily treated with the laser. The patient is given informational brochures and an informed consent form printed in English, listing all known complications from cataract surgery, with clear definitions of each complication. The patient is told to bring the signed consent form when reporting for surgery and to ask any questions he may have of the ophthalmologist's assistant. The ophthalmologist then has the assistant review preoperative clearance procedures and outpatient surgery logistics with the patient. The patient has uneventful surgery. A retinal detachment is noted on the first postoperative day.

Thought Questions
A. Is there truly informed consent in this case, without persuasion or coercion?

B. Is the patient able to comprehend the nature of his condition and the planned treatment?

C .Is he competent to give consent, and is the consent voluntary?

Discussion
This is an unusual case that requires special care to ensure the patient's complete understanding of the nature of his medical eye condition and the procedure planned to restore his visual function. Obviously, an interpreter is essential. If available, a family member conversant in English might be asked to join the discussion so that questions arising after the patient leaves the office can be adequately addressed or referred back to the ophthalmologist. Such special circumstances clearly require a greater time commitment than usual; however, it is essential that all patients fully understand their condition and planned treatment if they are to give informed consent.

In this case study, the ophthalmologist may have abrogated his responsibility to the patient by providing information on cataracts and cataract extraction written only in English. Moreover, requiring the patient to return with the signed consent form at the time of surgery, without knowing whether anyone had been available to assist the patient in translating or understanding the form, was negligent. Further, requesting the patient to defer other questions until he reported for surgery ignored the probable emotionally charged state of the patient before surgery especially a patient who does not speak the language of his caregivers.

Having a relative or friend present at surgery to help communicate with the patient was a worthwhile possibility not considered by the ophthalmologist.

From the information presented, it appears that the patient was not truly informed, did not fully comprehend the issues surrounding his care, and was not able to make a voluntary choice regarding surgery. To the extent that this inference is accurate, we may conclude that the ophthalmologist failed his patient with respect to the informed consent process, not only morally and clinically, but possibly from a legal standpoint, as well.

Case #3
A 68-year-old taxi driver consults his HMO ophthalmologist because of difficulty seeing well enough to drive. The cause of the problem is determined to be cataracts; otherwise, the taxi driver is in excellent health. The ophthalmologist advises cataract extraction and briefly discusses the risks and benefits of surgery. All the patient's questions are answered fully, and surgery is scheduled on an outpatient basis. When the patient reports for surgery some weeks later, he finds that the surgery will be performed by the HMO ophthalmologist scheduled for that week.

Thought Question
Has the HMO doctor violated any of the elements of informed consent?

Discussion
Although the ophthalmologist answered "all of the patient's questions fully," a truly informed consent was not obtained in this case. It is reasonable for the patient to want to know who will be performing surgery, and the ophthalmologist should have volunteered the information without expecting the patient to ask. Arrangements between patients and insurance companies, HMOs, etc. are sometimes written such that the patient may elect to give up the right to choose the physician. When the patient has so elected, a signed covenant between the patient and physician takes on increased complexity.

Analysis of Principles
Competence
In a context of informed consent, competence refers only to the patient's capacity to reason and to make an autonomous decision based on discussions with the physician. It does not refer to the patient's ability to perform some other task, nor does it allude to the treating physician's professional qualifications. In the clinical setting, responsibility for determining whether the patient is able to give informed consent falls to the physician. The physician must ascertain whether the patient can understand the information presented, and must evaluate the patient's ability to reason, to weigh risks and benefits, and to decide issues related to his or her health care. These assessments are not always easy or possible. Occasionally, the task goes beyond the skills of the treating physicians and requires consultation with other health professionals, such as a primary care physician or a psychiatrist.

Disclosure
The term "informed consent" came into use in the 1950s, when the duty to disclose became a legal requirement. Subsequent series of legal cases spelled out the elements of disclosure: risks, benefits, procedure, alternatives. In most cases, discussion with the patient should include:
1. What is to be done.
2. Anticipated benefits, their probabilities, and expected consequences for the patient.
3. The significant and/or frequent risks involved and their probabilities.
4. All reasonable alternatives, whether performed by the surgeon or not.

Finally, in deciding what information to give a patient, the physician must assume that he or she is talking to a "reasonable" person, and then ask the patient if more information would be helpful. Once again, good communication skills on the part of the physician are essential for a meaningful dialog to occur, one in which the patient can communicate freely his or her fears, concerns, and questions.

Comprehension
Comprehension is an extension of competence: While competence is required *before* disclosure, comprehension is assessed *after* disclosure. Ideally, comprehension should be an ongoing process to be assessed throughout the disclosure process so that explanations can be adjusted to fit the informational needs of the patient. Assessments of a patient's comprehension and comparisons with a "reasonable patient" standard are obviously subjective judgments on the part of a physician. However, if the dialog between the patient and physician involves a conscientious effort to evaluate the patient's comprehension, as well as to inform the patient, the physician has fulfilled his or her ethical responsibility in regard to this aspect of informed consent.

Voluntariness
Once the information provided has been understood, the patient must be permitted to make an autonomous decision free of external constraints for informed consent to be valid. The subtleties of persuasion in the typical medical encounter related to informed consent are difficult to detect and control. However, the moral physician, who acts in the best interests of the patient need have no concerns with this issue because there will be no attempt to influence the patient's decision.

THE DOCTOR-PATIENT RELATIONSHIP
Seeking medical advice can be a frightening experience for many individuals. Patients may fear their symptoms, relatively minor by clinical standards, are signs of sight- or life-threatening disease. Floaters become the first signs of total blindness; mild ophthalmic pain indicates "cancer." While the results of an examination may ease the patient's concerns, fear may linger that the physician has not told the patient "the whole story," in part because the patient often does not fully comprehend the physician's explanation of the symptoms.

Good communication skills engender trust. Trust allows for a meaningful physician-patient relationship. This is what is at the heart of good medicine. It is what the patient wants. It is what drives the most appropriate decision about treatments. However, ethical issues can arise in situations in which good communication and trust are not easily achieved.

Case #4
A pediatrician refers a 2-week-old female child to the ophthalmologist for the management of bilateral dense cataracts. The infant is accompanied by both parents. The ophthalmologist notes that the father is wearing aphakic spectacles and exhibits sensory nystagmus. The father explains that this is their first child. He is not surprised by the presence of cataracts, as he too had cataracts at birth. He first received medical attention at the age of 3 years in his native Russia. He does not recall whether these early operations improved his vision, but he has been regarded as legally blind for as long as he can remember. He also recalls spending many unpleasant hours in hospitals and doctors' offices, none of which helped him see better. He believes that his vision did improve significantly after, on his own initiative, he underwent vision training with a form of eye exercises. On testing the father, the ophthalmologist finds his best corrected visual acuity to be in the 20/200 range.

Examination of the infant confirms the presence of dense bilateral cataracts. No evidence of ocular or systemic pathology is found. Bscan-ultrasonography reveals no posterior pathology. The ophthalmologist concludes that the appropriate treatment in this case is the prompt surgical removal of lenses with optical correction of the aphakia. The physician further explains to the parents that the surgery is only the first step in the proposed treatment; many visits and patching will be required to prevent amblyopia. If all goes well, the child's vision may be close to normal.

The father responds. He is totally opposed to any intervention because surgery "did him no good" and in his mind, only the use of self-initiated eye exercises helped his vision. He adds that in his experience, there are far worse things than limited vision, and that he has had a full and productive life. If his daughter chooses to undergo surgery at a later date, that will be her decision.

Thought Questions
A. Who is the patient?

B. What actions are in the best interest of the patient?

C. How might the attitudes and prejudices of the family affect the outcome for the patient?

Discussion
The physician is obligated to respect the autonomy of the patient, including the patient's decision to reject treatment. However, in this case, a question quickly arises: Who is the patient, the infant or the whole family? In a strict sense, the child alone is the patient, but since she is obviously unable to act on her own behalf, the parents as surrogates decide for the child whether or not to accept treatment.

If the ophthalmologist concludes that rejection of surgery is not in the best interests of the patient, several options may be pursued. One alternative is to continue efforts to convince the parents that with timely surgery and optical correction the child's vision may reasonably be expected to reach 20/40 or better, the father's unfortunate experience not withstanding; the care he received was, by today's standards, sub-optimal. The ophthalmologist must acknowledge, however, that risks are present in any surgical intervention and that the outcome cannot be predicted with absolute certainty.

Another, more extreme option is taking legal action. The ophthalmologist, as advocate for the patient, could try to obtain a court order for surgery. If the court concurs with the physician's recommendation, the court would appropriate the responsibilities of surrogacy from the parents. This alternative is not without consequences; however, given the important role the parents play in the child's visual rehabilitation after surgery.

Analysis of Principles
The issue of patient rights within ophthalmology relates directly to the same principles of ethical practice that apply to all physicians: patient autonomy, physician beneficence/ nonmaleficence, and justice, including its corollary, truth-telling.

Autonomy
The principle of autonomy signifies the right of a patient to make personal choices regarding medical care that the patient believes are in his or her best interests. Implicit in this concept is the patient's right to be informed on the nature of his or her disease and on appropriate avenues of treatment, together with the authority to accept or reject recommended therapy and to seek other opinions. These rights place a burden on the ophthalmologist beyond the responsibilities associated with his or her medical expertise, specifically the obligation to understand, respect, and act in accord with the patient's needs and expectations. Consequently, identical eye findings may require different therapeutic interventions, depending on the particular patient's desires, needs and expectations.

Beneficence and Nonmaleficence
These principles are a charge to the physician to act first and foremost for the well-being of the patient, and, above all, to do no harm. This is a heavy responsibility. The physician can give no unequivocal guarantee that a given procedure will improve a patient's condition or quality of life, nor can the physician be certain that surgery or any other intervention will not result in damaging complications. What the physician can do is marshal all of his or her professional training and experience to weigh the probable benefits of an appropriate course of action against the attendant risks and potential harm of no therapeutic intervention.

The principles of beneficence and nonmaleficence cannot be qualified, however, by the present tendencies of some to view the practice of ophthalmology more as a business than a profession. The temptation to order an extra test or to perform surgery at an earlier date than "may be necessary" may be rationalized as doing no harm to the patient, especially if insurance will pay for the procedure. Equally disconcerting is for a physician to fail to offer a procedure to a capitated patient because the physician's income will not benefit. In these

instances the interests of the patient obviously have been superseded by those of the physician.

Justice/Truth-Telling
The need for a careful and sometimes prolonged discussion of diagnoses and proposed courses of treatment must be stressed. The difficulty, of course, is that multiple truths often exist in any given situation. The physician can only base his or her "truth" on the accuracy of observations made and the depth of knowledge and experience gained in the course of training and clinical experience. Without doubt, the definition of "truth" may change over time subtly, as the physician grows in clinical proficiency. Whatever the physician's level of clinical sophistication, the patient is owed the best conception of truth that the physician possesses, even if an answer must be "I don't know" or "nobody knows." At times these too are truths.

Truths may be told in many ways, and the manner of telling the truth to a patient is perhaps as important as the truth itself, especially when bad news or a poor outcome must be divulged. Telling the truth about the best management for an ocular melanoma must acknowledge the differing opinions on dealing with this entity. Explaining unanticipated vitreous loss and the need to alter intraocular lens strategy may be a real test of how to tell the truth.

DELEGATED SERVICES
A generation ago, direct patient care was almost exclusively the province of the medical and nursing professions. More recently, our society has acknowledged the role of non-physician practitioners in health care, such that it is now rare that a physician performs all of the tasks that may be required. It is now widely expected that physicians delegate certain aspects of care to non-physician practitioners and technicians in the interest of efficiency. Although efficiency is increasingly essential for the economic viability of a health care delivery, inappropriate delegation of duties has the capacity to affect the traditional ethical underpinnings of health care. The risk of erosion of quality through diminished competence or training, loss of professional confidentiality, and other concerns central to the best interest of the patient raise important ethical concerns.

Case #5
Dr. Ross is an ophthalmologist and a fellow of the Academy. He has developed a large practice over the years. In order to see more patients, he has worked hard to organize his office efficiently, and has developed what he calls "staged competence." By this, he means that a patient entering the practice will meet a series of people with increasing levels of competence until the patient's problem is resolved. He employs technicians, optometrists, and fellows to manage the flow of patients. He is always available to answer any questions, but he routinely sees patients only after history and visual acuities have been taken, refraction performed, pupils evaluated, and the eyes dilated. After Dr. Ross sees the patient, an assistant writes out any prescriptions or instructions and escorts the patient out of the examining room. Dr. Ross is particularly proud of two aspects of his practice. He has a collection of hi-tech screening equipment including OCT, corneal topography and an IOL master as well as instruments for electronically evaluating various other eye functions. He feels that these modalities enhance the effectiveness of his practice and make it less likely that
any mistakes will be made.

A second source of Dr. Ross's pride is a personal innovation: He has moved one of his senior ophthalmic assistants to the reception and telephone area to manage incoming calls, questions, and new patients so that they are seen in a most efficient and logical manner. In this way, emergency patients can be evaluated immediately while other patients can be fit into the schedule as time and conditions allow. Dr. Ross feels this practice makes optimal use of his time while giving patients maximum attention to their particular problems and concerns. He has not yet applied this system to surgical scheduling but he is seriously considering the move.

Thought Questions
A. Is there an ethical limit to the tasks that an ophthalmologist may delegate to others?

B. If supervised technicians can provide adequate patient care more efficiently than ophthalmologists, is society best served by moving in this direction?

C. Do the credentials of the provider make any difference to a patient, provided that the care is competently rendered?

D. Does competence include ethical behavior as well as technical expertise?

Discussion
Rule #7 of the Academy's Code of Ethics states that those aspects of eye care within the "unique competence of the ophthalmologist" must not be delegated. But how do we identify those aspects that require unique competence? There is no question that Dr. Ross is ultimately responsible for the quality of the care provided by his practice. Nor is there doubt that he is uniquely qualified within that facility to determine what is "competent" in ophthalmic practice since he is the only ophthalmologist present. We may wonder whether it is within the acceptable practice of ophthalmology to spend one's time teaching, supervising, and checking on the quality of services, without actually providing any of the services personally? This managerial approach to medicine may be viewed as an attempt to increase the ophthalmologist's output purely for monetary gain, or it may be seen as the most efficient use of an ophthalmologist's training and talent. The ultimate test will be whether the welfare of the individual patient is being served by the particular practice arrangement in question.

In the business of medicine, delegation of authority is not only efficient, but often mandatory, though one must keep in mind that professions differ from businesses in several respects. Professions are groups of individuals who provide services to the public under state regulations intended to ensure that the public will not be exploited when they are most vulnerable. Businesses are private enterprises that exist primarily to make a profit for the owners. Professionals may make money, and businesses may put the customer first, but these are not the controlling goals. When conditions are adverse, a business must make money, and a professional must put the interest of the client above his or own by definition.

Delegation of authority, already inherent in our profession, will be utilized to a progressively greater extent in the future. It serves to both prevent overloading the physician and increase the efficiency of the practice in order to meet the cost requirements of the public, third party payers, and the government. However, these changes must be motivated by a primary concern for patient care. As physicians and professionals, we hold a collective privilege because we are perceived to have a collective dedication to the welfare of our patients over our own self-interests. When looking to the future of medicine, *intent* will be as important as event or content.

RELATED RESOURCES
For additional information related to subject matter addressed in this course, we suggest investigating the following:

- American Academy of Ophthalmology, Code of Ethics
- American Medical Association, Principles of Medical Ethics
- World Medical Association, The International Code of Medical Ethics and the Declaration of Geneva
- The Hippocratic Oath
- Advertising Directives

TEST

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Directions: To receive CME credit, please print and complete both pages of the test and course evaluation forms below, and submit them to the Clinical Education Division of the Academy by fax (415.561.8533) or mail (P.O. Box 7424, San Francisco, CA 94123).

Test Question: In Case #5, as far as we can tell, Dr. Ross has not violated any ethical principle because he has not delegated any services that are within the "unique competence of the ophthalmologist".

Please write a response indicating whether you agree or disagree with the above statement, and include your reasons.

Evaluation: Please indicate your agreement with the following statements about this course.

1. This online ethics course met its stated objectives.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

2. The topic area was comprehensively covered.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

3. The information presented in this course will be useful in my practice.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

4. The option of downloading and printing the course material is important.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

5. CME credit was an important reason for taking this online course.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

6. I would recommend this online course to others.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

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