AMERICAN ACADEMY™
OF OPHTHALMOLOGY

ADVISORY OPINION OF THE CODE OF ETHICS

Subject: Ethical Issues in Global Ophthalmology

Issues Raised: What are the ethical issues involved in volunteering and working as well as training young ophthalmologists to provide ophthalmic care abroad? The issues range from medical education to surgical skills transfer to cultural competence and beyond.

Applicable Rules:
Rule 1. Competence
Rule 2. Informed Consent
Rule 3. Research and Innovation in Clinical Practice
Rule 6. Pretreatment Assessment
Rule 7. Delegation of Services
Rule 8. Postoperative Care
Rule 10. Procedures and Materials
Rule 11. Commercial Relationships
Rule 15. Conflict of Interest
Rule 17. Confidentiality

Background

There is continual interest among ophthalmologists-in-training and practicing ophthalmologists to participate in global health activities and international ophthalmic care. In U.S. ophthalmology residency training programs, the Accreditation Council for Graduate Medical Education (ACGME) now recognizes an international elective rotation for ophthalmology trainees.[1] At the post-residency level, many global health training programs are available in ophthalmology, such as externships, fellowships, internships, observerships, and preceptorships.[2]

With this growing interest in coordinating global health, and ophthalmic care initiatives specifically, the ethical challenges presented to physicians and trainees who choose to work and teach internationally take on increasing importance. A focus on ethical guidelines is imperative because experiences may vary significantly due to the lack of a standardized global ophthalmology training.

Because of the broad nature of the topic of global ophthalmic care, this Advisory Opinion is focused more on principles than details, including principles related to training, clinical care, and research, and on ophthalmologists-in-training rather than on experienced practitioners who work with established organizations such as Orbis International, Rotary International, SEE International, and Doctors Without Borders.

Within this scope are topics such as appropriate supervision; competence; informed consent; preoperative assessment; delegation of care; postoperative care; patient vulnerability; patient privacy; and conflicts of interest, including research and industry sponsorship.

[1] See the ACGME's Program Requirements for Graduate Medical Education in Ophthalmology, https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/240_Ophthalmology_2020.pdf?ver=2019-02-19-121341-650.

[2] See the American Academy of Ophthalmology Global Directory of Training Opportunities, https://www.aao.org/training-opportunities.

General Principles

Preferred practice patterns may vary and standards of care may be different when working in different areas of the world, but one fundamental issue remains paramount in the performance of global clinical care and research: consideration must always be given to act in the best interest of the individual patient and the local community. It is essential to maintain high standards of quality care and professionalism while practicing outside the country in which one resides.

When providing global ophthalmic care, significant ethical issues may arise that are unique and/or more challenging than in domestic settings. Ophthalmic care providers in any stage of training or practice should recognize and consider these issues *before* initiating travel and take necessary steps for appropriate preparation. Noted below are several ethical issues that global practitioners or trainees should take into consideration. This list should not be considered all-inclusive and, depending on the area in which one intends to travel/practice, other ethical issues may dominate.

General Discussion of Ethical Issues

The ophthalmologist who practices globally for self-education or to facilitate an educational activity should be aware of the following ethical issues that may arise:

A. The Learning Curve – The learning curve is an integral part of acquiring new skills, and all ophthalmologists work through this process at various stages in their careers. There are many methods of addressing the learning curve such as formal study, mentoring, and the study of literature; however, practicing globally without a formal academic framework simply to learn new skills on a vulnerable population is unethical. Global ophthalmic care should not be used exclusively as a means to hone surgical or medical skills.

1. Training – When developing the curriculum for a global ophthalmology elective, the residency or fellowship program must be clear about the motivation and expectations that the trainee and host have for the program. Ideally, the host program should coordinate the development of the training experience with the residency or fellowship program in order to facilitate a mutually beneficial relationship within an agreed upon ethical framework for all parties, with patient care remaining the utmost priority. Global health training that ophthalmology residency and fellowship programs participate in should:

- Provide an experience where both the ophthalmologist-in-training and the host benefit.
- Ensure proper supervision of trainees at all times.
- Develop a practice protocol to avoid potential exploitation of patients and the host institution.

2. Competence – Competence involves technical ability, cognitive knowledge, and ethical concerns for the patient. An ophthalmologist should perform only those procedures in which he or she is competent by virtue of specific training or experience or is assisted by one who is. Trainees and practitioners who practice globally may be presented with types of ophthalmic disease and degrees of ocular trauma for which they have insufficient knowledge or experience. An ethical global ophthalmic care provider must honestly assess his or her competence before treating patients in these settings.

3. Exceeding Expertise – A global ophthalmic care provider must be prepared to provide care at a level at which he or she is qualified and withdraw from performing procedures in which he or she does not have adequate experience. Just as with all procedures, practitioners should not undertake complex surgery without adequate mentorship, training, and experience.

B. Clinical Care - Rules 6, 7, 8, and 10 of the Code of Ethics (included in full below) are all relevant to clinical care in the international arena, which can present unique challenges to even the most experienced ophthalmologist. These may include limited resources, since medications or equipment for surgical procedures may not be available or familiar to the ophthalmologist, or a lack of trained health care providers to provide adequate preoperative and postoperative care. However, properly trained nonphysicians (i.e., assistant medical officers) routinely can and do provide preoperative and postoperative care for ophthalmic surgery in international settings. As discussed in Rule 6, pretreatment assessment should be performed by the primary surgeon, regardless of whether a local surgeon has previously determined a need for surgery. Additionally, the delegation of services, such as the provision of postoperative care, must be determined and disclosed prior to surgery. As noted in Rule 8, it is not unethical for an ophthalmologist other than the operating surgeon to provide the postoperative care, as long as he or she is qualified to do so and the patient agrees to such an arrangement prior to surgery.

1. Liability and other nation-specific practice issues – A global ophthalmic care provider should consult with institutional authorities and/or his or her liability carrier to ensure the legality of providing clinical care to patients in the country to be visited and ensure that the liability coverage will extend to this international setting and circumstances.[2]

Additionally, the provider should determine what, if any, permissions are required to provide medical and surgical care in the destination country and obtain such permissions prior to initiating travel.

2. Familiarity with location, equipment, staff – If performing surgery, the international ophthalmic care provider should carefully familiarize himself or herself with the surgical facility and equipment prior to performing surgery, preferably prior to leaving home. In international settings the surgical suite, staff, instrumentation, sterilization, lighting, voltage, and even the size of the surgical gloves available will likely be different from that with which he or she is familiar. Any of these elements may complicate the surgical plan or increase surgical risk.

3. Preoperative Assessment – The surgeon should evaluate the patient prior to surgery to confirm accuracy in the documentation of findings and recommended treatment plan prepared by other health care providers.

4. Informed Consent – A global ophthalmic care provider should obtain informed consent from the patient. In an international setting where language and customs are frequently different from those in the surgeon's native country, obtaining a fully informed consent may prove difficult. Particular attention must be paid to:

A. An assessment of the patient's competence to decide.

B. The disclosure of relevant information in a manner appropriate to the customs and culture of the country.

C. A realistic assessment of the patient's comprehension of the discussion.

D. Having a dedicated interpreter, if necessary, either a member of the surgical team or a qualified interpreter.

E. Obtaining consent from the patient or a surrogate.

F. Obtaining consent for photographs/videos to be taken and distributed including over the internet. Often, global ophthalmic care providers fail to get patient releases for any images they capture in which the patient is identifiable.

[2] American Academy of Ophthalmology. Advisory Opinion of the Code of Ethics, Live Surgery. San Francisco, CA. American Academy of Ophthalmology; 2015. Available at: https://www.aao.org/ethics-detail/advisory-opinion-live-surgery .

It is important to obtain such a release and to explain to the patient that the patient's image along within medical formation may appear on the internet. Not only is such a release a best practice, but it is possible that in certain political situations, receiving assistance from Western medical providers could put the patient at risk if discovered. Patients should be reassured that their care will not be compromised in any way should they decline to be photographed.

Be aware that an element of disinformation at best and coercion at worst may be present in this setting, where the patient may believe or have been led to believe that he or she is fortunate to be selected to be operated on or have medical eye care provided by the visiting ophthalmologist.

5. Live Surgery - The ophthalmologist who travels internationally to perform live surgery as an educational activity with the intention of transferring the demonstrated surgical technique to the local surgeons should:

A. Carefully assess his or her motivations to ensure that participation in the live surgical event is primarily for educational purposes and is not unduly influenced by a commercial or industry relationship, the potential for increased professional reputation/recognition or surgical acumen, or the potential for publication following the trip.

B. Determine what credentialing is required prior to traveling to the country where the surgery will be performed. All required documentation should be provided and approval obtained prior to the performance of surgery in the country.

C. Consult with his or her liability carrier to determine whether liability coverage will be provided.

D. Carefully familiarize himself or herself with the surgical site in advance of the event. In international settings the surgical suite, staff, instrumentation, sterilization, lighting, voltage, and even the size of the surgical gloves available will likely be different than that with which he or she is comfortable. These elements may complicate the surgical plan.

E. Evaluate the patient, or (less optimally) review another health care provider's evaluation, to confirm accuracy in the documentation of findings and recommended treatment plan.

F. Obtain a fully informed consent from the patient. In an international setting where language and customs may be different from those in the ophthalmologist's own country, obtaining a fully informed consent may prove difficult. Particular attention must be paid to:

1) An assessment of the patient's competence to decide.

2) The disclosure of relevant information in a manner appropriate to the customs and culture of the country.

3) A realistic assessment of the patient's comprehension of the discussion.

4) Obtaining consent from the patient or a surrogate. It should be emphasized that an element of coercion may be present in this setting, where the patient may believe or have been led to believe that he or she will be the recipient of this care only by virtue of agreeing to the live surgery.

5) Making the patient aware of the possibility of the surgery being recorded and consenting to this.

G. Include the postoperative care plan as part of the informed consent process and ensure it is understood and agreed to by the patient. The operating surgeon is responsible for the postoperative care of the patient. Portions of the postoperative care may be delegated to other appropriately trained individuals that the operating surgeon knows to be competent to perform the delegated tasks.[3]

6. Postoperative Plans - A global ophthalmic care provider should include the postoperative care plan as part of the informed consent process and ensure that it is understood and agreed to by the patient prior to surgery. The operating surgeon is typically responsible for the postoperative care of the patient, although the postoperative care may be delegated to other appropriately trained individuals that the operating surgeon knows to be competent to perform the delegated tasks.

7. Patient Vulnerability – A global ophthalmic care provider may be unfamiliar with the degree of vulnerability of patients seeking medical eye care in the international clinical setting. The vulnerability may result from their particular disease, social or socioeconomic status, or a number of other concerns. Care should be taken to ensure that the patient understands, desires, and agrees to the medical eye care procedures being contemplated.

8. Privacy - Special consideration should be given to respect the confidential physician-patient relationship and the safeguarding of confidential health information consistent with the law and patient welfare. All those involved in the international clinical care setting should be reminded to maintain confidentially and to protect patient privacy.

C. Research – Research conducted in international settings on potentially vulnerable patient populations is controversial. Many researchers consider it "easier" to perform clinical trials and research in other countries due to less stringent regulations. The ethical international researcher should conduct research in the same manner as if he or she were in his or her native country; this may include the need for Institutional Review Board (IRB) approval at home and approval from an IRB or equivalent entity in the country in which the research will take place. All research should be approved by appropriate review mechanisms to protect patients from being subjected to or potentially affected by inappropriate, ill-considered, or fraudulent basic science or patient-oriented research. In emerging areas of ophthalmic surgery and treatment where recognized guidelines do not exist, the ophthalmologist should exercise careful judgment and take appropriate precautions to safeguard patient welfare.

Health care professionals may not have the primary intention of performing research while participating in an international medical program. However, they may find that their sponsoring organization conducts clinical research in conjunction with clinical services. They should be aware that they may be directly or indirectly contributing to clinical research (e.g., collecting data about new techniques, devices, or therapeutics) when providing health care abroad.[4]

1. Patient Protection - Short-term research, to develop new information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenesis, may not be appropriate in the international setting given the temporary nature of the visit. With any research study, the ophthalmic care provider should consider the sustainability of the benefit to the patient after the provider's departure. Depending on local health care options, sustainability may not be possible. Protecting the patient and the patient's long-term well-being is an important consideration in determining

[3] American Academy of Ophthalmology. Advisory Opinion of the Code of Ethics, Live Surgery.
[4] American College of Obstetricians and Gynecologists. Ethical Considerations for Performing Gynecologic Surgery in Low-Resource Settings Abroad. Committee Opinion No. 759. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;116:793–9.

whether to participate in these studies.

As with all research, the patient protections afforded by the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report must be respected.

2. Informed Consent - When consent for research is required, Rule 3 of the Code of Ethics states that "Appropriate informed consent for these procedures must recognize their special nature and ramifications." Informed consent for participation in research activities has at least several basic elements:

- The global ophthalmic care provider must inform the patient about the proposed treatment, its likely effects on the patient, and the purposes of the research. In addition, regulations of the host country may govern informed consent for research activities.
- The patient's consent must be based on comprehension; that is, the patient must understand the basic information and engage in a rational decision-making process concerning participation in the research.
- The patient must clearly indicate voluntary consent to the treatment proposed.

Informed consent may not be required in all research activities; however, the determination of whether informed consent is required or a waiver may be obtained should rest with the IRB or equivalent entity. As noted above, it is important to maintain the standards for the provision of care and professionalism while practicing ophthalmology outside the country in which one practices.

3. Conflicts of Interest - A conflict of interest exists when professional judgment concerning the well-being of the patient has a reasonable chance of being influenced by other interests of the provider. An international ophthalmic care provider should be aware of situations in which his or her involvement may be benefiting someone or something other than the individual local patients.

Conflicts of interest can seriously undermine trust in the medical profession. Conflicts may be perceived and considered by local populations differently from those in the practitioner's home country. Conflicts may include one's health-care organization, local practitioners who may benefit from the provision of care in an unknown way, the medical organization sponsoring travel, and industry investment into technology transfer.

A global ophthalmic care provider should carefully assess his or her motivations to ensure that participation in the program is not unduly influenced by a commercial or industry relationship, the potential for increased professional reputation/recognition or surgical acumen, and the potential for publication following the international visit. Potential conflicts of interest should be identified and managed before initiating international travel for the purpose of providing ophthalmic care. If the conflicts are not manageable or are not disclosed to the satisfaction of those involved, then the intended international ophthalmic care provider should withdraw from the proposed research.

Summary

The above recommendations are offered to ensure that ophthalmologists and ophthalmologists-in-training are cognizant of the unique and numerous ethical challenges involved in global health care and international ophthalmic care. To facilitate compliance with ethical guidelines, ophthalmologists should work with host country personnel to address the issues noted above in advance of planned joint ventures, whether in the realm of training, clinical care, or research. Ophthalmologists should adhere to appropriate standards of ethics and professionalism by always acting in the best interests of the patients.

In addition, ophthalmologists should keep in mind the potential for devaluing the public's perception of ophthalmology and medical care in the global arena by putting their own interests ahead of the patients in their host country. Practicing ethically sound ophthalmology, in all respects, should be the goal of ophthalmologists practicing domestically and abroad.

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. When obtaining informed consent, pertinent medical facts and recommendations consistent with good medical practice must be presented in understandable terms to the patient or to the person responsible for the patient. Such information should include alternative modes of treatment, the objectives, risks, and possible complications of such a treatment, and the consequences of no treatment. The operating ophthalmologist must personally confirm with the patient or patient surrogate their (his or her) comprehension of this information."

"Rule 3. Research and Innovation. Research is conducted to provide information on which to base diagnostic, prognostic, or therapeutic decisions and/or to improve understanding of pathogenesis in circumstances in which insufficient information exists. Research and innovation must be approved by appropriate review mechanisms (Institutional Review Board [IRB]) and must comply with all requirements of the approved study protocol to protect patients from being subjected to or potentially affected by inappropriate or fraudulent research. In emerging areas of ophthalmic treatment where recognized guidelines do not exist, the ophthalmologist should exercise careful judgment and take appropriate precautions to safeguard patient welfare. Appropriate informed consent for research and innovative procedures must recognize their special nature and ramifications. The ophthalmologist must demonstrate an understanding of the purpose and goals of the research and recognize and disclose financial and nonfinancial conflicts of interest. Commensurate with the level of his/her involvement, the investigator must accept personal accountability for patient safety and compliance with all legal and IRB-imposed requirements."

"Rule 6. Pretreatment Assessment. Treatment (including but not limited to surgery) shall 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 7. Delegation of Services. Delegation is the use of auxiliary health care personnel to provide eye care services for which the ophthalmologist is responsible. An ophthalmologist must not delegate to an auxiliary those aspects of eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must be qualified and adequately supervised. An ophthalmologist may make different arrangements for the delegation of eye care in special circumstances, so long as the patient's welfare and rights are the primary considerations."

"Rule 8. Postoperative Care. The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist. The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in special circumstances, such as emergencies or when no ophthalmologist is available, so long as the patient's welfare and rights are the primary considerations. Fees should reflect postoperative eye care arrangements with advance disclosure to the patient."

"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 11. Commercial Relationships. An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises."

"Rule 15. Conflict of Interest. A conflict of interest exists when professional judgment concerning the well-being of the patient has a reasonable chance of being influenced by other interests of the provider. Disclosure of a conflict of interest is required in communications to patients, the public, and colleagues."

"Rule 17. Confidentiality. An ophthalmologist shall respect the confidential physician-patient relationship and safeguard confidential information consistent with the law."

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