ADVISORY OPINION OF THE CODE OF ETHICS

Subject: Ethical Issues in Global Ophthalmology

Issues Rose: 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 growing interest among ophthalmologists-in-training and practicing ophthalmologists to participate in global health activities and international ophthalmic care. In ophthalmology residency training programs, the Accreditation Council for Graduate Medical Education (ACGME) now recognizes an international elective rotation for ophthalmology trainees.\(^1\) On the fellowship level, a number of global health training programs have been developed in ophthalmology; however, none of them are currently defined or accredited by the American Board of Ophthalmology or the ACGME.\(^2\)

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\(^1\) See the ACGME’s Program Requirements for Graduate Medical Education in Ophthalmology, [http://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/240_ophthalmology_2016.pdf](http://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/240_ophthalmology_2016.pdf)

\(^2\) See the “The ABCs of Fellowship Applications”, [http://www.aao.org/yo/newsletter/200903/article05.cfm](http://www.aao.org/yo/newsletter/200903/article05.cfm)
With this growing interest in global health and global ophthalmic care, the ethical challenges presented to physicians and trainees who choose to work and teach internationally take on increasing importance. In addition, experiences may vary significantly because there is currently no standard global ophthalmology training curriculum and very little consistent information on which to base such a curriculum.

Due to the broad nature of this 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 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.

**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 taken to act in the best interest of the individual patient and the local community. It is essential to maintain ophthalmology’s 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 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 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 to educate him or herself or facilitates an educational activity designed to contribute to generalizable knowledge and skill of all ophthalmologists 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 exclusively be used 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. Global health training that benefits the trainee at the cost of the host institution is unethical and must be avoided. Ophthalmology residency and fellowship programs participating in global health activities 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 they are qualified and withdraw from performing procedures in which they do 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 (printed 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, as medications or equipment for surgical procedures may not be available or familiar to the ophthalmologist, or a lack of trained healthcare providers to provide adequate pre- and post-operative care. However, properly trained non-physicians (i.e., Assistant Medical Officers) routinely can and do provide pre- and post-operative care for ophthalmic surgery that does not jeopardize the surgical outcomes. 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 post-operative 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 assure the legality of providing clinical care to patients in the country to be visited and assure that the liability coverage will extend to this international setting and circumstances. 

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 him or herself with the surgical facility and equipment prior to performing surgery, and 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 than that with which he or she is familiar – any of these elements may complicate the surgical plan or increase surgical risk.

3. Preoperative Assessment - A global ophthalmic care provider 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.

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4. Informed Consent - A global ophthalmic care provider should obtain an 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 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. If necessary, having a dedicated interpreter, either a member of the surgical team or a qualified interpreter,

E. Obtaining consent from the patient or a surrogate, and

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. 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 therefore be reassured that their care will not be compromised in any way should they decline to be photographed.

Be aware 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 is fortunate to be selected to be operated on or have medical eye care provided by the visiting ophthalmologist.

5. Traveling Internationally to Perform 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 for purely educational purposes and is not 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 him 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 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 than 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 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; and

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.

G. Include the postoperative care plan as part of the informed consent process and assure 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.4

6. Postoperative Plans - A global ophthalmic care provider should include the postoperative care plan as part of the informed consent process and assure 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 socio-economic 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 taken 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

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research in the same manner as if the practitioner were in his or her native country; this may include the need for 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.

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 his or her 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 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. How much information to disclose to the patient should be based on what the practitioner believes the patient would be likely to regard as significant in

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deciding whether or not to participate in the research and undergo the treatment. 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. Conflict of Interests - 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 where their 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 than 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 assure that participation in the program is not 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
These recommendations are offered to assure that ophthalmologists and ophthalmologists-in-training are cognizant of the numerable ethical challenges involved in global health care and international ophthalmic care. Ophthalmologists should adhere to appropriate standards of ethics and professionalism by acting in the best interests of the patients and thus maintaining the public’s trust in our profession.

Additionally, 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**

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.

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

3. **Research and Innovation.** Research and innovation shall 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. Basic science and clinical research are 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 research and innovative procedures must recognize their special nature and ramifications. 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.

6. **Pretreatment Assessment.** Treatment shall be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs. The ophthalmologist must evaluate the patient and assure that the evaluation accurately documents the ophthalmic findings and the indications for treatment. Recommendation of unnecessary treatment or withholding of necessary treatment is unethical.

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.

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.

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.

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.

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.

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

References

The Code of Ethics of the American Academy of Ophthalmology
http://www.aao.org/about/ethics.


Ethical issues in Patient Safety Research: Interpreting existing guidance [http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf](http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf)


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