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The Ethics of Ophthalmic Practice & Surgery: Keeping Sight of the Patients’ Best Interest

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Medicine as a Moral Practice

- Physicians are concerned primarily with advancing the interests of patients and doing for patients what they wish to have done for themselves.
- Unlike members of other kinds of practices (business, for example), the physician places the interests of others above her or his own interests.
- This feature of medicine is one of the defining characteristics of the health care professions.

Duane’s Clinical Ophthalmology, volume 5, chapter 68 by BD Weinstein, GW Weinstein, J. Burian

Ethics: Conflict of Interest

- Social science research has demonstrated that Conflict of Interest will inevitably bias behavior, often unconsciously, however honorable and well-intentioned specific individuals may be.

American Association of Medical Colleges (AAMC) 2007

Ethics: Conflict of Interest

- A competition between interests – everyone has conflicts among their various interests
  - Financial: personal gain or “ego”, academic advancement, pride and accomplishment – could the lure of these benefits potentially compete with the patient’s best interest?
- Ask yourself: Who is most likely to benefit and in what order? What are the hidden as well as apparent biases and conflicts of interest?

American Association of University Professors (AAUP) 2014

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Learning, Innovation, Research

- Innovation and life-long learning are fundamental to continuous improvement of surgical and non-surgical care for all diseases
- Physicians have an obligation to seek the best outcomes for their patients.
- When treatment options are inadequate, surgeons are likely to seek out alternative interventions.
- Ethical dilemmas are inherent in this process and must be recognized and managed.


Learning, Innovation, Research

- You cannot learn to play the piano by going to concerts.
- There always must be a “first time”.
- What should the surgeon say to the patient?
- How does surgical learning occur without jeopardy to the patient?
- Ethical dilemmas are inherent in this process and must be recognized and managed.

American Academy of Ophthalmology Code of Ethics - advisory opinion

- The ophthalmologist should disclose his/her level of experience as a surgeon and level of experience with a new technique.
- The operating surgeon should carefully evaluate patients postoperatively during the learning period.
- Dispassionate assessment and understanding how a complication arose will help avoid future complications.


The Best Interest of the Patient

- The Surgical Learning Experience and Surgical Innovation: “should be designed in the best interest of the patient, with both the patient and the physician taking heed of the potential risks as weighed against the desired outcomes”. (Levin and Spaeth 2009)

- Can you think of situations when this ideal ethical goal may be difficult to achieve?

Ethics of Surgical Informed Consent when the Procedure is New

- “Surgical practice has always been a science and an art form. It gradually has morphed more and more into science with less art, which is good, but the interactions with the patients remains 100% art.”

James W. Jones, MD, PhD, MHA
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- Patients often desire what is “new”, thinking that it must automatically be better
- Some authors have suggested that “new” and “innovative” are suggestive of a promise that may be unrealistic.
- They prefer terms like “unproven”, “experimental” and “non-validated”
- Patients must be involved in decision-making but the common bias for the “new”, even when it is not better, must be recognized.
Ethics of Surgical Informed Consent when the Procedure is New

• “Use a new procedure fast, while it still works.”
  — R. A. Saunders, MD

Ethics of Innovation: when is it called research?

• An off-label use of a product or device when the intent is “the practice of medicine”
• An innovative treatment introduced at a recent meeting that may be the “new standard of care”
• There is an intent to publish, in the future, a retrospective review of your experience with the procedure


An Ethical Grey Zone

• Clinical Innovation can be a “gray zone” in the ethics of modern clinical practice.

• Not every new procedure or modification of an existing procedure can be subjected to a randomized clinical trial.

• Even among IRBs*, there is confusion about what constitutes the spectrum of experimental, innovative, and commonly accepted care.

*IRB = Institutional Review Board for Protection of Human Subjects


An Ethical Grey Zone

• Classifying experimental care as innovative allows for the administering experimental procedures to patients without observing the ethical and scientific norms for experimenting on humans.


An Ethical Grey Zone

• Classifying innovative care as experimental might subject it to excessive ethical and scientific monitoring and could considerably delay patients’ benefiting from clinical advances.


An Ethical Grey Zone

• IRBs exist to protect the patient and the innovator. Consultation and oversight should be used whenever innovation is investigated or first implemented. This promotes careful planning and discussions of sample size, feasibility, and special informed consent.

**An Ethical Grey Zone**

**Opposing views #2**

- The complex processes characteristic of clinical innovation are often not reducible to a scientific protocol. They typically involve intuition, experience, and an evolving knowledge about the treatment and disease processes and the interaction between treatment and pathology.


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**An Ethical Grey Zone**

**Examples in ophthalmology**

- Kelman – the invention of phacoemulsification
- Machemer – the invention of vitrectomy
- Osher – “Courage at the Cutting Edge” Chapter 6 in The Real ABCs – Achievement, Balance, Contentment. 2009

> “When it comes to bringing my patients the best possible technology, I have always been willing to take some political and regulatory gambles…. While I never felt at ease “smuggling” in these products, I was certain that placing patient benefits above personal vulnerability was justified.”

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**A Cautionary Tale of Innovation in Refractive Surgery.** George O. Waring III. Arch Ophthal 117, Aug 1999

- How did hyperopic ALK, hot-needle thermal keratoplasty and hexagonal keratotomy become transiently popular?
  - Those ignorant of history are doomed to repeat it.
  - Propagation based on informal experience, newspaper communication and authoritative endorsement.
  - Initial reports were not detailed, not consecutive and without a high percentage of follow-up.

**Recommendations:**

- Insist on a staged evaluation of new techniques with a limited number of eyes treated and reported in the peer-reviewed literature in the early stages of development, with later expansion, follow-up, and reporting of larger numbers.

- Disclose the weaknesses, drawbacks, and complications of a procedure, in spite of attempts to conceal them by industry sponsors or surgeon progenitors, while extolling its virtues and advantages, so that more impressionable colleagues will have a balanced understanding. Evaluate it – don’t sell it.
An Ethical Grey Zone
Examples in ophthalmology

  
  **Recommendations:**
  
  - Avoid premature dissemination of evolving and unproven procedures so that student surgeons do not operate on large numbers of patients using partially developed or inadequate techniques.

An Ethical Grey Zone
Examples in ophthalmology

  
  **Recommendations:**
  
  - Invest the money, time, and energy to do simple prospective trials: train office staff, ensure 90% or more patient follow-up, contract with skilled individuals who can help compile and analyze the results, write and publish an article that reports all cases and complications.

An Ethical Grey Zone
Examples in ophthalmology

  
  **Recommendations:**
  
  - Publish communications in peer-reviewed journals – not just ophthalmic newspapers. All peer-reviewed journals publish letters to the editor, brief reports, and preliminary results – in addition to detailed original articles.

An Ethical Grey Zone
Examples in ophthalmology

  
  **Recommendations:**
  
  - Publish negative results and reasons why a technique should be or has been abandoned. This helps reduce repetition of the same problems in the future. Indeed, those who fail to heed prior mistakes are doomed to repeat them – to the detriment of our patients and our professional reputations.

Ethics of teaching surgery
things have evolved

- 1921: “In reciprocity for receiving free medical care, the poor have an ethical obligation to submit themselves as teaching material.”
  
  - S. Bard 1921 (from Two Discourses Dealing with Medical Education in early New York)

- 2013: “Bard’s argument is not persuasive in an era that has rightly emphasized patients’ rights. However, all patients have some obligation to “pay it forward.”
  

A Conflict of Three Commitments

- **First**, the ethical obligation to respect the patient’s wishes with regard to trainee involvement.

- **Second**, the ethical obligation to future patients to see that they receive excellent surgical care by educating residents and fellows.

- **Third**, the surgeon has the professional responsibility to provide excellent care.

Surgical Teaching: quotes from Duane’s text

• "It is often possible for an ophthalmologist to fulfill both responsibilities: to promote patient welfare and to respect the patient's right of self-determination."

• "If the ophthalmologist takes the time to educate the patient and has sufficient interpersonal skills, patients may come to realize that surgery performed by residents under the skilled supervision of attending physicians may well be in their best interests."

• "The ophthalmologist is justified in making a benevolent deception (???) only if he is prepared to give primacy to restoring vision..."

International Council of Ophthalmology
Professional Standards for Surgical Teachers

• Maintain responsibility for the patient's welfare and provide teaching supervision that minimizes risks to the patient.

• Acknowledge the responsibility to teach and train future ophthalmologists.

• Give feedback on progress and performance, including assisting in remediation programs where necessary.

• Encourage self-assessment and reflection through clinical/surgical audit.

• Be honest, factual, objective, and constructive when providing feedback.

Ethics and Ophthalmic Surgery

• Ethical dilemmas and conflicts of interest are ever-present and must be recognized and managed in a way that promotes the best interest of the patient.

Thank you!