ETHICS IN OTOLARYNGOLOGY/ FACIAL PLASTIC SURGERY

The Leslie Bernstein, MD, DDS Lecture

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Leslie Bernstein, MD, DDS

- Residencies—
  - Johannesburg Group of Hospitals
  - University of Iowa Hospitals
- Board certified—
  - ABOto
  - ABFPRS
  - Diplomate in Otolaryngology and Otology, the Royal College of Surgeons of England
Leslie Bernstein, MD, DDS

- "The best advice I can offer you is to sign up for two evening art courses in a nearby college: one for sketching and painting and the other for sculpture:

Leslie Bernstein, MD, DDS

- "You must accept the fact that plastic surgery is basically three-dimensional art (i.e., sculpture). Also, the best plastic surgeons are actually artists!"
In 1963 Dr. Bernstein founded the Rhinoplasty course that has been held constantly for the past 47 years, perhaps the longest-lasting international course in the world.

“I insisted that our teaching would be based on the Socratic Methods. Nobody ever goes to sleep during Socratic lectures....”

Dr. Bernstein has always advocated teaching plastic surgery techniques to medical students—“start them young and treat them well.”
Learning from Dr. Bernstein

- Careful assessment and detailed preoperative planning
- Extensive knowledge of anatomy and physiology
- Form and function are related—the “art” and the “science”
- Always do the best you can
- Learn from your work to improve your skills
- Hard work and dedication pay off

IT IS AN ETHICAL RESPONSIBILITY OF PHYSICIANS TO LEARN AS MUCH AS POSSIBLE AND CONTINUE TO LEARN FOR THE BENEFIT OF THEIR PATIENTS
The Ethical Otolaryngologist/Facial Plastic Surgeon

- In September, 1996, the journal Otolaryngology-Head and Neck Surgery published a special section from the AAO-HNS Ethics Committee entitled: “The Ethical Otolaryngologist”
- The section contained multiple chapters on ethical issues that were applicable to the specialty practice 14 years ago.

Have there been any substantive changes in the ethical challenges and issues facing otolaryngologists/facial plastic surgeons in 2010?
“The threshold principle in medical advertising is that communications to the public must be accurate. This principle does not hold otolaryngology or other professionals to an unrealistic standard, that they must never be wrong. The principle simply requires that communications to the public not be false, deceptive, or misleading.”

Ethical Advertising

- Consider the following questions regarding the case on advertising and marketing:
  - What are acceptable requirements for a surgeon to identify himself/herself as an "expert" in a new procedure?
  - What are the professional guidelines for surgeons to advertise and market their skills and knowledge ethically?

Case on Advertising and Marketing

- A community otolaryngologist attends a weekend course on a new surgical procedure to improve facial rhytids that can be performed in the office. Immediately after attending the course, the surgeon begins to advertise in local newspapers and trade journals that he is the first surgeon expert to perform this procedure in the city, and hires a new staff member whose sole responsibility is to recruit patients for the procedure. His ads also intimate that he has been part of the “innovative development” of this technique. The surgeon sets aside 50% of his office practice to devote to this new procedure.
Considerations in Ethical Marketing and Advertising

What are the professional guidelines for surgeons to advertise and market their skills and knowledge ethically?

- "It is not unethical for otolaryngologists to advertise their services. Advertisement must be truthful and not misleading...should not misrepresent his/her qualifications and/or training, and should not exaggerate the efficacy or uniqueness of treatments rendered."
- www.entnet.org/aboutus/ethics.cfm

AAFPRS Guidelines on advertising:

"Truthful advertising can inform patients about the skills, qualifications, services and other important information."

"However, advertising that is false, deceptive, or misleading can harm patients...physicians have an ethical obligation not to engage (in such) advertising...betrays the patients’ trust and confidence in the physician"

AMA Council on Ethical and Judicial Affairs

http://www.aafprs.org/physician/benefits/GuidelinesForTruthfulAdvertising.PDF
Considerations in Ethical Marketing and Advertising

- What are the acceptable requirements for a surgeon to identify himself/herself as an “expert” in a new procedure?
  “The authors conclude that any definition of an expert on the basis of workload is rather fragile, and the lack of routinely collected case mix data presents major challenges for clinical audit and governance in the future. “

How to Define an Expert?

- **Surgical Endoscopy***
- Training in the da Vinci Surgical System:
  “Expert users were trained as advanced laparoscopic surgeons and had performed at least five human procedures using the da Vinci Surgical System”
- [http://www.unomaha.edu/biomech/pdf/Judkins%20Objective%20SE%202008.pdf](http://www.unomaha.edu/biomech/pdf/Judkins%20Objective%20SE%202008.pdf)
How to Define an Expert?

- **Expert Witness:**
  “Expert is an otologist, a specialist in the ear, medical and surgical care of the ear, facial nerve, skull base, balance system. He has expertise on the nervous system, specifically as it relates to the ear. He regularly performs intracranial surgery along with neurosurgeons for tumors of the skull base. He also performs intracranial surgery along with neurosurgeons for tumors of the skull base. He performs cochlear implants, BAHA implants and middle ear implantation.”


How to Define an Expert?

- **Merriam-Webster’s Medical Dictionary Online for “Surgical Expert:”**
- “The word you've entered isn't in the dictionary. Click on a spelling suggestion below or try again using the search bar above.”
- M-W’s main dictionary on “Expert:”
- **obsolete** : **experienced**
- 2 : having, involving, or displaying special skill or knowledge derived from training or experience
The Case of the Misleading Advertisement

- A panel of “peers” may be required to determine the validity of the surgeon’s claim (i.e., hospital’s department or credential’s committee).
- If surgeon does not have hospital privileges, then the grievance committee of the local medical society may be appropriate.
- Although difficult to censor, violators should be held to task.
- A call to the state medical board may be a last resort—they will investigate.
- Report an ethical violation to the AAFPRS or AAO-HNS.

PATIENT’S RIGHTS
Patient’s Rights

- “The physician is obligated to respect the autonomy of the patient, including the patient’s decision to reject treatment. Underlying all is the physician’s obligation to act for the patient’s welfare as medical—and human—skills, training, and experience enable him or her to judge what is in the patient’s best interests.”

Case on Patient’s Rights

- While reviewing this case, consider the following questions:
  - What are the limits, if any, to patient autonomy
  - Is it unethical to perform cosmetic surgery when the improvement will probably be minimal?
  - How does a surgeon identify the proverbial “slippery slope” with respect to patient autonomy vs. surgeon’s requirement for nonmaleficence and beneficence?
Case on Patient’s Rights

A 37 year-old female presents to the facial plastic surgeon’s office seeking facial rejuvenation. The patient is a successful model for casual and athletic clothing and exhibits a positive and gregarious personality during the consultation. She has not had previous plastic surgery. The patient feels that she is already reaching the age where modeling jobs favor younger women and she wishes to have full facial rejuvenation (forehead lift, blepharoplasties, facial rhytidectomy, and facial resurfacing).

Examination reveals good skin tone with only minimal brow ptosis, dermatochalasia, and facial rhytids. The surgeon determines that improvement of the patient’s face and neck would be minimal at best. However, the patient relates that she will be paying cash in advance for her procedures, pledges to be a low maintenance patient post-op (her father is an orthopedic surgeon) and to likely refer other models from her modeling agency to the facial plastic surgeon.
Case on Patient’s Rights

She further states that the decision to have this surgery is hers alone, and she will accept the probability of minimal improvement—and that outcome will be fine with her.

The facial plastic surgeon contemplates.....

Patient’s Rights

- **What are the limits, if any, to a patient’s autonomy?**
  “The principle of patient autonomy holds that an individual’s physical, emotional, and psychological integrity should be respected and upheld....also recognizes the human capacity to self-govern and choose a course of action among different alternative actions. Autonomous, competent patients assert some control over the decisions which direct their health care.”

- **AMA Code of Medical Ethics, 10.02.**
Physician’s Rights

“It may be ethically permissible for physicians to decline a patient when:
(b) The treatment request is known to be scientifically invalid, has no medical indication, and offers no possible benefit to the patient.”

- AMA Code of Medical Ethics. 10.05.

Patient’s Rights Vs. Physician’s Rights

- In cases where the patient is requesting treatment which, in the physician’s considered opinion, is likely to have no demonstrable benefit or is likely to harm the patient, it is a responsibility of the physician to decline providing that treatment and to adequately explain the physician’s concerns to the patient.
- In this case, the issue is a bit “grey”
- The surgeon’s sense of honesty, ethics, and doing what is right for the patient must prevail
Patient’s Rights VS. Physician’s Rights

- In this case, resolution in an ethically acceptable manner will depend upon the surgeon’s “motives” for accepting or declining the request for surgery:
  - Can the surgery benefit the patient’s sense of well-being and/or overall happiness (beneficence)?
  - Is the surgery likely to be disappointing to the patient and therefore diminish her sense of well-being and happiness (nonmaleficence)?
  - Is the surgeon mostly interested in the financial rewards and the potential referrals to his practice (unprofessional at the least, probably unethical)?
  - Is it a valid argument that since the surgeon realizes the patient will seek out and convince another surgeon to operate on her—isn’t it better that it be an “excellent” surgeon, such as this one? No!

Potential courses of action:
- Obtain a psychological evaluation
- Discuss the patient’s requests on a number of office visits to better understand the patient’s psyche, social and emotional aspects
- Perform an initial procedure of low risk (and probably low yield) such as a mild facial resurfacing to determine the patient’s response and then discuss further surgery with the patient as appropriate
- Obtain a second opinion from a colleague or partner
- Decline any procedures but ask the patient to return in one year to re-evaluate
Traditional codes of ethics forbade alliances that would result in financial gain from other than professional services. In days past, morally responsible physicians would shun relationships that had even the ‘appearance’ of a commercial enterprise.”

OTO-HNS. 1996; 115: 220-223
Ethics of Commercial Relationships

“Commercial relationships of all varieties now abound, involving physicians and affecting their patients. New associations have perhaps changed the patient-physician relationship.

The ethical questions we must ask ourselves are these:

- As physicians, are we satisfied with the present commercial climate of health care delivery?
- Are we willing to look to our own welfare, and to assume that proficient performance of our technical duties alone will serve the best interests of our patients?”

Case on Commercial Relationships

Consider the following questions when reviewing the case:

- What are the confidential obligations of a journal reviewer?
- How close must a physician scientist/commercial relationship be before it is considered unhealthy to the profession?
- What should be the appropriate penalties for disregarding confidentiality obligations?
Case on Commercial Relationships

- A respected senior reviewer for a top international medical journal is asked to review a manuscript involved the efficacy of a commercial device. The reviewer happens to have a very close financial relationship with the company that manufactures the device, and in fact, has performed his own studies with the devices, sponsored by the company.

Case on Commercial Relationships

- As the reviewer studies the manuscript, he learns that the findings of this excellent study will be potentially detrimental to the perception of the device’s efficacy and safety and could have an impact on the device’s sales and utilization.

- Because of his concern, he faxes a copy of the manuscript to his colleague at the company. Subsequent events lead to the discovery by the journal of the breach of confidentiality.
Case on Commercial Relationships

- What are the confidentiality obligations of a journal reviewer?
- Conflicts of interest regarding reviewers concern not only financial issues, but also rivalry, academic scientific and technologic competition, and philosophical values and beliefs. Reviewers, when asked to review a manuscript, should be instructed specifically with respect to conflicts of interest. Precisely because they are experts in the field under consideration (i.e., they are peers), reviewers are apt to have conflicts of interest, financial or otherwise. Thus the existence of a conflict is not really the issue, but rather whether the conflict is sufficient to limit the reviewer's ability to evaluate the manuscript fairly and objectively. Journals should instruct their reviewers to disqualify themselves if they feel they cannot render fair and objective assessments. If reviewers have any questions in this regard, they should be urged to consult with the editor.

  - http://www.councilscienceeditors.org/services/draft_approved.cfm#Paragraphsix

Case on Commercial Relationships

- Most journals approach this issue with fairly general and open-ended advice. However, *JAMA* requires reviewers to complete a specific section of the review form disclosing any potential conflicts of interest. This assures that the reviewer consider the issue and make a direct statement that he or she has or does not have any such conflicts.
- A problem may occur when the topic is quite narrow and there are few capable reviewers.
Case on Commercial Relationships

- "When reviewers receive invitations to review manuscripts with which they have a clear conflict of interest, it is their responsibility to turn down the invitation or divulge the conflict of interest. Conflicts of interest can be of several sorts, the most common being a relationship between the reviewers with either the company that sponsored the research or with a company that competes with the sponsor of the research to be reviewed. It is fairest for reviewers with such conflicts of interest to decline the reviews."
- [http://www.councilscienceeditors.org/services/draft_approved.cfm#Paragraphsix](http://www.councilscienceeditors.org/services/draft_approved.cfm#Paragraphsix)

Case on Commercial Relationships

- *How close must a physician scientist's commercial relationship be before it is considered unhealthy to the profession?*
- "A physician’s clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises or other actual or potential conflicts of interest."
- AAFPRS Code of Ethics
Case on Commercial Relationships

- “...it is now more than ever essential that we maintain the integrity of *The Laryngoscope*. This can be accomplished if we are completely transparent in disclosing real or potential conflicts of interest to our readers...I have asked every reviewer to call to my attention any potential conflicts before agreeing to review a manuscript.”


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Case on Commercial Relationships

- Obligations of a Reviewer:
  - “We have asked that all reviewers disclose to the editors any real or potential conflicts that they may have when reviewing an individual manuscript. In a small specialty such as ours, this is sometimes difficult....Not so subtle conflicts include financial relationships with companies making products that compete with the materials described in the scientific report.”

Case on Commercial Relationships

- What should be the appropriate penalties for disregarding confidentiality obligations?
- Apology to the article’s author(s)
- Dismissal from the editorial review panel
- Public sanction
- Letter to the dean of the reviewer’s medical school
- Letter of admonition to the company
- Review of reviewer assignment policies
Ethics of Informed Consent

“The purpose of the (informed consent) is to ensure that the subject understands fully the purpose of the study, the procedures to be performed and their attendant risks.

The process of informed consent involves the interplay of four elements:
- Disclosure
- Comprehension
- Competence
- Voluntary choice”

OTO-HNS. 1996; 115: 179-185

Ethics of Informed Consent

“It is the relationship between the patient and physician in the clinical setting that sets the stage for informed consent.

Ultimately, it is not the signed form that is the essence of informed consent—it is the character and quality of the conversations that the physician has with the patient.”

OTO-HNS. 1996; 115: 179-185
Case on Informed Consent

- Consider these questions when reviewing this case:
  - Can consent under the conditions of a medical mission in a developing country be considered “informed?”
  - Is “implied consent” under such conditions to be considered valid and appropriate?
  - What are the ethical issues in using patient photographs obtained without written or specific consent?
  - Does HIPAA apply to medical missions and humanitarian relief efforts?

Case of Informed Consent

- An otolaryngologist (or facial plastic surgeon) on a medical school faculty volunteers as a member of a humanitarian mission team to a developing third world country for the purpose of performing surgery on patients who otherwise would not have the access to a surgeon. The medical infrastructure of the country is very poor and English is not spoken by over 95% of the populace.
Case of Informed Consent

- The surgeon performs facial trauma repair, exploration of neck wounds and masses, I & D of abscesses, and elective ENT procedures as possible. In the course of the preparation for surgery, a general consent form for the indicated procedures was signed or marked (many patients were illiterate in their own language as well) through the use of a non-medical interpreter.

Case of Informed Consent

- The discussion prior to consent signing/marking was minimal and most information in the consent was considered “implied” if the patient nodded his/her head.
- Upon return to the US, the faculty member gave multiple local, regional, and national presentations on his experiences, showing patient photographs through the course of their care.
Case of Informed Consent

- *Can consent under the conditions of a medical mission in a developing country be considered “informed?”*
- An extensive review of the literature found no definitive guidelines for this. Additionally, there are very few references to the use of photographs obtained during humanitarian relief efforts or medical missions.
- The issue of informed consent in international research in developing countries is better documented and enforced by global organizations such as WHO.
- Personal discussions with Matthew Wynia, MD, director of AMA Institute of Medical Ethics.
- WHO and HAP: Medical Ethics Round Table Report—October 2002.
Case of Informed Consent

- The Humanitarian Aid Accountability Covenant, based on the Declaration of Helsinki, states:
  - “In cases of urgency...it may not be possible to secure the informed consent of beneficiaries, but the ‘human imperative’ may still justify intervention.”
  - All possible efforts should be made to obtain an informed consent, through a medical translator, for both the medical/surgical care and the issue of confidentiality should be raised.


Case of Informed Consent

- Is “implied consent” under humanitarian or medical missions to be considered valid and appropriate?
  - “Consent is either implied or expressed. Expressed consent is further divided into oral or written.
    - Implied consent (aka tacit consent). The patient presents herself to the physician requesting assistance and consent is implied
Case on Informed Consent

- **Expressed consent**—in writing or by word of mouth. Better than implied consent.
  - Oral consent: A patient is asked if they mind being photographed and they verbally agree to this. Some further documentation of this consent must be maintained (i.e., declarations of photographer and witnesses).
  - Written consent: usually an addendum to a procedural consent form or a special photography consent form. Should also indicate what the photos may be used for.
- Ethics in Healthcare. [www.cladonia.co.uk/consent.html](http://www.cladonia.co.uk/consent.html)

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Case on Informed Consent

- What are the ethical issues in using patient photographs obtained without written consent?
- Hundreds of thousands of photographs are used in presentations of some sort each year of a medical nature obtained during missions.
- If submitted to a journal, then strict guidelines must be followed, including well documented consents, non-identification of subject, and declarations by authors.
Professional standards require physicians to preserve human dignity regardless of the physical circumstances of patient care.

While HIPAA is a US regulation, the spirit of patient confidentiality applies now in the global community of medical care.

Physicians who performed medical missions and humanitarian relief efforts should be cognizant of cultural and issues that might bear on informed consent and subsequent use of patient images.

Hadlock, Sabini, Quatela, and Cheney have reported on an excellent model for a medical mission:

- Annual trips to the same location
- Strong relationships with local surgeons
- Dedication to long-term care
- Teaching mission
- Maintaining detailed electronic medical records
- Meticulous photography
- Strong native speaker as part of the team

*Arch Fae Plast Surg.* 2008; 10: 350-352
Responsible Use of Patient Photographs from Medical and Humanitarian Missions

- Make good faith effort to inform the patient/family using a native interpreter and obtain/maintain some documentation of consent, even if tacit or oral.
- Indicate to patient/family that the photographs may be used to train future or current surgeons and to highlight the needs of their country.
- Be sensitive to the patients and their families in the same way as other patients—humanistic.
- Be cautious, judicious, professional, and compassionate in the use of any photographs of patients from such missions.
- Always be a good steward of America and American medicine in whatever country you serve in.

SUMMARY
The Ethical Otolaryngologist/Facial Plastic Surgeon

- Over the past 14 years, there have been few substantive changes in the ethical challenges for us.
- Commercial interests, technological advancements, and conflicts of interest are the main ethical challenges.
- International missions pose both a challenge and an opportunity to be an outstanding surgeon who cares for those in need and provides a unique service. However, one must also recognize the obligations and responsibilities to those who have little to offer in return—save for their gratitude—which is why we became physicians!
- Facial transplantation is a recent topic of considerable discussion, but most of the ethical concerns have been worked out.