Ethical Decision Making: Framing the Discussion

"ETHICS:
THE ROLE OF INDUSTRY AND ACADEMIA"
Saturday, June 28, 7 – 12 PM
The Beckman Center, Irvine

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Objectives

- Discuss tools for ethical decision making
- Review ethical principles related to conflicts of interest
- Identify questions for further discussion.

Ethics/Morality

- Concerned with right conduct, belief system, or judgments
- Answers the questions:
 - What should/ought I (we) do in this situation?
 - Why should I (we) do X?
- Three features:
 - Prescriptive
 - Authoritative
 - Relational or interpersonal
- Personal morality may conflict with professional ethics



What ethics is not:

- Individual (moral) beliefs/opinion
- Mere common sense
- Law

The difference:

- Ethics requires identifying the questions that should be asked.
- Ethics requires argumentation/reasongiving
- Ethics is not subject to majority rule or other features of democracy

Types of Ethical Issues

- Conflict or uncertainty about relevant facts (e.g., impact of marketing on physician behavior, effects of industry employment)
- Competing interests (e.g., additional income <u>or</u> best products/meds for patients)
- Conflict or uncertainty about ethical norms, (e.g., fidelity to patients, loyalty under contract, what constitutes patient benefit, honesty)
 - meaning
 - extent of obligation
 - prioritization

Ethical Dilemma

- Situation involving a difficult or persistent moral problem in which two or more moral actions
 - Conflict
 - Can be supported
 - Are equally unsatisfactory
 - Are without conclusive evidence favoring one position
- Distinguished from a personal dilemma

Ethical analysis can help...



Ethical Analysis

- Gather relevant information from all perspectives (e.g., medical information, marketing data, patient values, clinician judgment, rights/laws, policies, professional duties, contextual factors)
- 2. Identify the problem(s), conflict(s) and value(s) at stake
- 3. Identify alternatives for resolution. Consider:
 - Goals to be achieved/expectations/obligations,
 - Analogous situations in the past/precedents/paradigm cases,
 - Ethical theories/values/norms
- 4. Develop guidelines: "What is the best we can do?"
- 5. Evaluate (future)
 - Are the guidelines working?
 - What have we learned?
 - What opportunities were missed?

Background Information Needed

- Identified problems/questionable behavior
- History
- Extent of the problem
 - Magnitude
 - Severity
- Persons involved
- Effects
 - Known
 - Unknown/hidden
- Similar situations
- Guidance from others (laws, policies, guidelines)

Ethical Theories as Tools

- Act (deontological)
 - What would I want done in all similar situations?
 - What is my duty?
- Consequences (consequential)
 - What is likely to happen with various courses of action?
- Intent (teleological)
 - What do you want to have happen, or intend?
- Agent (virtue)
 - What counts as a good nurse/health care professional?

Justifying Decisions

- 1. Necessity: Must we infringe on some values to achieve the intended goal?
- 2. Effectiveness: Will the chosen action be likely to work?
- 3. Proportionality: How important is the prioritized goal?
- 4. Least infringement: Is the action designed to minimize infringement on other values or goals?
- 5. Proper process: Has the decision been made using appropriate process?

Value

Definition

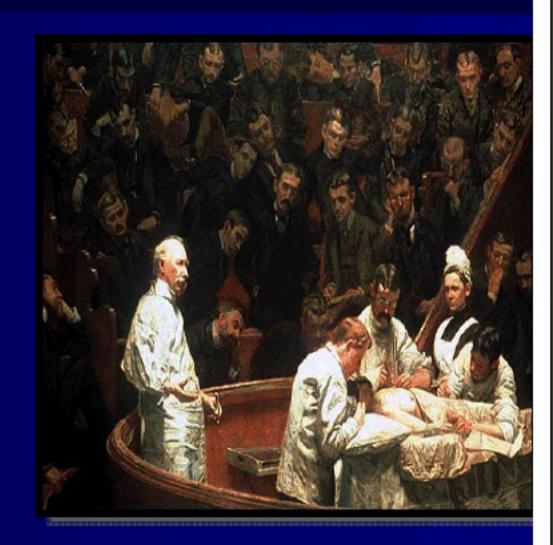
- the regard that something is held to deserve; importance or worth.
- principle or standard of behavior
- an ideal accepted by some individual or group

American Medical Association Code of Ethics (Values Summary)

- 1 competent medical care with compassion and respect for human dignity and rights
- professionalism, <u>honesty</u>, strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities
- respect the law, and responsibility to seek changes to benefit patient
- 4. respect the rights and safeguard patient confidences and privacy
- commitment to continuing medical <u>education</u>, seeking help, and patient education
- 6. <u>freedom</u> to choose whom to serve, except in emergencies
- 7. responsibility to improve the community and public health
- while caring for a patient, regard <u>responsibility to the patient</u> as paramount
- support <u>access</u> to medical care for all people.
 Adopted by the AMA's House of Delegates June 17, 2001.

Professionalism Professional Values and Principles

- The non-technical values and practices that typify the caring and competent physician, including the placement of patient interest above self interest.
 - Primacy of patient welfare
 - Patient autonomy
 - Social justice
 ABIM Physician Charter 2002 (Ann Int Med/Lancet)



Example: AAOS -- Principles of Medical Ethics and Professionalism in Orthopaedic Surgery

- 1. Physician-Patient Relationship
- Integrity
- Legalities and Honor
- 4. Conflicts of Interest
- Confidentiality
- Medical Knowledge
- Cooperation
- 8. Remuneration
- Publicity
- 10. Social Responsibility

Adopted October 1991 Revised May 2002

A Primary Problem Addressing Conflicts of Interest



Guidance from the AMA: E-8.032 Conflicts of Interest: Health Facility Ownership by a Physician

In general, physicians **should not refer** patients to a health care facility which is outside their office practice and at which they do not directly provide care or services **when they have an investment interest** in that facility. ... Where there is a true demonstrated need in the community for the facility, the following requirements should also be met: (I) physicians should **disclose** their investment **interest** to their patients when making a referral, provide a list **of** effective alternative facilities if they are available, inform their patients that they have free choice to obtain the medical services elsewhere, and assure their patients that they will not be treated differently services elsewhere, and assure their patients that they will not be treated differently if they do not choose the physician-owned facility; (2) individuals not in a position to refer patients to the facility should be given a bona fide opportunity to invest in the facility on the same terms that are offered to referring physicians; (3) the opportunity to invest and the terms of investment should not be related to the past or expected volume **of** referrals or other business generated by the physician investor or owner; (4) there should be no requirement that a physician investor make referrals to the entity or otherwise generate business as a condition for remaining an investor; (5) the return on the physician's investment should be tied to the physician's equity in the facility rather than to the volume **of** referrals; (6) the entity should not loan funds or guarantee a loan for physicians in a position to refer to the entity; (7) investment contracts should not include "noncompetition clauses" that prevent physicians from investing in other facilities; (8) the physician's ownership interest should be disclosed to third party payers upon request; (9) an internal utilization review program should be established to ensure that investing physicians do not exploit their patients in any way, as by inappropriate or unnecessary utilization; (10) when a physician's commercial interest conflicts to the detriment of the patient, the physician should make alternative arrangements for the care of the patient.

AMA E-8.061 Gifts to Physicians from Industry

Guidelines for avoiding acceptance of inappropriate gifts:

(1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should **not be of substantial value**... (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads). (3) legitimate "conference" or "meeting" [is] any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made. (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible.... any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. ... Token consulting or advisory arrangements cannot be used to justify the compensation of physicians...(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution....(7) **No gifts** should be accepted if there are strings attached. Code of Ethics and Professionalism for Orthopaedic Surgeons: Relevant Sections © October, 1988, Revised December 2004,

I. The Physician-Patient Relationship

- **A.** The orthopaedic profession exists for the primary purpose of caring for the patient. The **physician-patient relationship is the central focus** of all ethical concerns.
- **B.** The physician-patient relationship has a contractual basis and is based on **confidentiality**, **trust**, **and honesty**.

III. Conflicts of Interest

The practice of medicine inherently presents potential conflicts of interest.

A. Patient best interests – primary action guide B/C/D. <u>Disclosure</u>

- of interest--financial or ownership interest in a durable medical goods provider, imaging center, surgery center or other health care facility
- of payment or gifts
- "unethical to receive compensation [except reimbursement of admin costs] of any kind from industry for using a particular device or medication"
- of interests in research
- **E. <u>Accommodation</u>** -- Right to dispense medication, devices, etc.; provide facilities; and render services for convenience or accommodation to the patient without taking financial advantage of the patient.

Questions

- What impact do industry relationships have on clinician behavior?
- What is the risk of bias?
- Is conflict of interest the most important problem?
- What constitutes a conflict of interest?
- Should conflicts of interest be disclosed?
 - If so, how?
- Is disclosure of conflicts of interest enough
 - To protect the patient?
 - To protect the physician?
 - To maintain professional integrity?
- What other guidelines are needed?
- Who is responsible
 - for identifying/addressing problems?
 - enforcing guidelines



"Now wasn't that nice? We talked, we agreed on some things, we disagreed on some things, and noone threatened to sue anybody."