RECALLING ESSENTIALS OF BIOMEDICAL ETHICS AND PROFESSIONALISM

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ABSTRACT

All physicians are expected to be “ethical” practitioners and researchers who are familiar with key elements that underlie ethical practice, but many have not had formal courses or reviewed the literature on biomedical ethics for several years. As a consequence, practitioners and researchers may fail to consider ethical issues in their practice and are sometimes uncomfortable when asked to discuss ethical issues with students, colleagues and patients. This paper’s goal is to heighten physicians’ awareness of bioethical issues in clinical practice, research, and society by reviewing ethical concepts, theories and problem-solving approaches used to shape ethical decision making. When personal gain threatens to motivate or bias clinical or research actions, conflict of interest considerations must be faced and addressed. In the context of limited health care resources, new drugs and biomedical technologies raise concerns about the advisability, cost, and ethical implications of their use. In addition, large numbers of physicians teach medical students and residents often using their own patients. Some of these patients also become research subjects in clinical trials. Material drawn from the literature is presented which will allow readers to consider and discuss ethical issues with confidence.

INTRODUCTION

The term “ethics” refers to rules of conduct, norms of behavior, and theories of moral philosophy used for examining, guiding or understanding moral issues. [1] Every society has a generally recognized shared morality with standards of what is right or just in behavior that are rooted in law, religion or commonly accepted practice. Most people recognize the moral value of telling the truth, obeying the law, refraining from deception, harm or causing unnecessary pain, and, generally respect the rights, customs, and religious beliefs of others. Professional behavior
in medicine encompasses a comparable set of moral principles and holds physicians to high standards of practice by virtue of their training and licensure as well as their special relationship with patients and their families. In this sense, ethics and professionalism overlap. In exploring moral dilemmas, physicians need to recognize the influence of their own values and biases (religious, ethnic, social, etc.) and must also appreciate those of others who are involved in deliberations related to their patient care and research.

**THE PHYSICIAN-PATIENT RELATIONSHIP**

Medical ethics evolved from several early codes of ethics including the Hippocratic Oath [2] (400 BCE) which advocated acceptable practices appropriate to the time. While the principle of “above all, do no harm” does not appear in the original oath (but in other writings of Hippocrates) this and other modifications have served as the basis for new oaths with different content [3]. For example, the late Tufts University Professor, Louis Lasagna, suggested that a new oath should include avoidance of over-treatment and therapeutic nihilism and acknowledgment that medicine is an art as well as a science, with warmth, sympathy, and understanding serving a critical therapeutic role. He admonishes us not to be ashamed to say “I do not know” or fail to call in colleagues when the skills of another are needed, to respect the privacy and confidence of patients, and to treat all patients equally and remember that we do not treat a feverish chart or a cancerous growth but a sick human being.

The American Medical Association’s “Fundamental Elements of the Patient Physician Relationship” [4] recognizes the importance of patient rights and physician obligations. Some elements warrant emphasis: physicians should contribute to a mutually respectful alliance by
serving as their patients’ advocate; patients have the right to receive information (including their medical records) from physicians and to discuss the benefits, risks, and costs of treatment alternatives; patients should be apprised of potential conflicts of interest of their physicians, receive independent second opinions and feel free to accept or refuse any recommended treatment; patients are entitled to courtesy, respect, dignity, responsiveness, and timely attention to their needs; patients have a right to confidentiality (unless otherwise provided by law, e.g. reporting patients with specific communicable diseases). Physicians may not terminate treatment as long as further treatment is indicated without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care; physicians traditionally assume some responsibility for essential care of those who cannot afford it, and should advocate for patients when dealing with hospital administrators and insurance carriers.

Physicians should avoid financial conflicts of interest situations, particularly relationships that could compromise one’s primary responsibility to the patient. Such relationships include, for example, holding an equity interest in a company that makes a drug being tested on one’s own patients and accepting gifts or favors from third parties that might influence a physician’s choice of patient management. Physicians have both fiduciary and ethical obligations to patients [5] that requires them to put the best interest of the patient first and respect the patient’s confidentiality, autonomy, and welfare. The patient has reciprocal duties of honesty in disclosing symptoms and of fidelity in cooperating with the treatment agreed upon. [5]

Critical ethical issues faced early on by medical students deserve discussion. Faculty should give ethical issues the same attention as they afford to patient medical work-up and treatment. Commonly seen issues include tradeoffs between good medical care and actions taken to ensure economic survival of academic medical centers (e.g. denying uncompensated services);
addressing cultural diversity and recognizing personal bias; Diagnostic Related Groups (DRG) upcoding; accepting gifts and favors from pharmaceutical companies and other for-profit suppliers; plagiarism, and falsification of research results; dishonesty in addressing personal errors in patient care; sexual indiscretions involving students, co-workers or patients; and, failure to abide by locally established codes of conduct including the reporting of observed unsafe, unethical or malpractice of colleagues [6].

**APPROACHES TO ANALYZING BIOETHICAL ISSUES**

There are two major approaches to analyzing medical ethics issues, Principalism and the Four Topics Approach.

**Principalism**

“Principalism” emphasizes the needs, feelings, motivations and experiences of persons receiving care and encompasses four principles: *autonomy, nonmaleficence, beneficence and justice*. When confronted with an ethical dilemma, the physician asks whether the action or inaction contemplated is supported by one or more of the four principles. If so, the action or inaction is more likely to be concordant with ethical standards and is given appropriate weight in making final decisions.

According to the principle of *autonomy* patients are encouraged to make their own decisions [1] and physicians are obliged to communicate effectively and listen carefully to discover whether patients truly understand their treatment options (including their desired and undesired effects). Respect for autonomy prevails except when a patient’s choice endangers the public health, threatens harm to others, goes against the physician’s belief (e.g. abortion) or requires a disproportionate share of a scarce resource. While autonomy generally results in
patients having significant say in what medical care should be given, caregivers must recognize that patients commonly rely on the advice of their physician. Thus, “informed consent” places great moral responsibility on physicians to inform as well as to assess comprehension of the issues by patients and only then act with the autonomy of the patient in mind.

*Beneficence* generally refers to acts of mercy, kindness, and charity [1] and implies that caregivers will act in the patients’ best interests. To some, beneficence connotes a moral obligation to act for the benefit of others. In medical care it applies both to the patient and (when feasible) to his or her family.

*Nonmaleficence* refers to the obligation of caregivers not to inflict harm or impose undue risk on patients. This is similar but distinct from beneficence since even in the absence of beneficence, there is still an obligation to do no harm. [7]

*Justice* is often regarded as synonymous with fairness and equity. In health care ethics, obligations of justice are sometimes subdivided into three categories: fair distribution of scarce resources, respect for people’s rights, and respect for law [7]. Legal justice requires fulfillment of contracts, and those contracts may or may not involve equal treatment (e.g. different benefit packages between public and private insurance.) There are two key categories of Justice: *Formal Aristotelean Justice* – “equal cases treated equally, and unequal cases being treated unequally” and *Distributive Justice*, which looks at how resources are being used. Justice is not absolute and when conditions of scarcity force a society to make tragic choices, (e.g. refusing limited organ donor tissue to an elderly person) principles of justice may be compromised. It may be that some patients benefit while others suffer or die.

*Empowerment* is a separate concept. A physician empowers patients to assume control of their own health care by providing information needed to make important choices.
Empowerment combines the two moral obligations of beneficence and respect for autonomy. [7] For example, a caring physician takes time to explain the consequences of lumpectomy as an alternative to mastectomy, and assists his/her patient in making a final decision.

Community Deliberation. In addition to counseling patients individually, doctors can also engage in community deliberations with broader implications, e.g. cloning, abortion, genetic testing, and stem cell therapy using the four principles as appropriate. This is a realm where Principalism is most valuable. It can be used to frame discussions better than it can be used to “solve” individual patient dilemmas.

The Four Topics Approach

The Four Topics Approach addresses specific patient care directly by proposing that every ethical dilemma faced in a specific patient should be analyzed by considering four issues related to that case: Medical Indications, Patient Preference, Quality of Life and Contextual Features [8]. Past experience with similar cases is an important indicator in deciding what actions to recommend. Also, because the previous “Four Principles” overlap they provide important guidance in deciding how much added weight is warranted in reaching an acceptable conclusion. Jansen’s “four box” approach is a methodology for approaching specific cases. The principle based approach is part of the theoretical underpinnings.

Medical Indications refers to the set of diagnostic tools and therapeutic interventions (e.g. medical history, physical exam, laboratory studies, etc.) that are needed to provide responsible care.[8]. If the doctor asks how a patient can benefit from each element of medical and nursing care, and how harm can be avoided, “medical indications” also invoke principles of autonomy, beneficence and nonmaleficence.
Patient Preferences suggests that physicians should consider treatment options based on the patient’s own values and personal assessment of anticipated benefits and burdens. Physicians should ask (the patient): What are the patient’s desires, goals, and needs? [8] By respecting the patient’s right to choose treatment options, physicians acknowledge the principle of autonomy.

Quality of Life of a patient is threatened by injury or illness.[8] By seeking the best treatments available and making the patient fully aware of the benefits and possible adverse consequences, the patient can choose those treatments that best meet future expectations. Thus, the physician shows respect for beneficence, nonmaleficence and autonomy.

Every medical case is situated in a broader cultural context involving persons, institutions, financial factors, and social arrangements which influence patient care [8]. Consideration must therefore be given to such Contextual Features as family issues, insurance benefits, religious or cultural factors, legal concerns and problems of allocation of limited resources. Physicians and patients should anticipate changes that are likely to occur over time in determining the course of treatment.

OTHER APPROACHES AND THEORIES

Other theoretical approaches taken largely from Beauchamp and Childress [1] provide a richer context for understanding the larger range of principles and ideas that form the palette of bioethicists.

Consequence-Based Utilitarianism, [9,10] holds that actions are right or wrong depending upon the balance of their good or bad outcomes, giving equal weight to the interests of each affected party. Human actions can be assessed in terms of their production of some valued end (e.g. happiness, freedom, health, pleasure, autonomy, achievement or success). The
utilitarian would implement those options that maximize the greatest good for the greatest number of individuals.

_Obligation-Based Theory_ or _Kantianism_ (a/k/a deontology) holds that some features of actions (and not solely their consequences) make them right or wrong [1]. To have moral worth, one must act for the sake of obligation, recognizing that certain actions are not permissible regardless of the consequences. For example, it is immoral to use experimental “therapies” on individuals without the expectation of therapeutic value even if desired results could have good consequences for millions of people. On the other hand, when informed human research subjects volunteer to test new drugs, Kant would not object as long as they are treated with respect and moral dignity. [1]

_Casuistry_ attempts to resolve ethical dilemmas by applying moral or religious precepts to particular situations and using past similar case-comparison to reach moral conclusions.

_Egalitarianism_ is the major contribution of John Rawls [11] who strived to remove inequalities among people by advocating for equal social, political and economic rights and principles. Although Rawls did not pursue implications of his theory for health policy, other ethicists have. [1] Norman Daniels, for example, argues in favor of a just health care system based on a Rawlsian principle of “fair equality of opportunity” and relies on the importance of health care needs. [12] Implications of the Rawls-inspired theory for national health policy is that each member of society, irrespective of wealth or position, would have equal access to an adequate, but not maximum level of health care. [1] The level would be contingent on available social resources and public processes of decision making. However, better services (e.g. boutique or V.I.P. medical care) would be available for purchase at personal expense.
Liberal Individualism is a rights-based theory that provides individuals or groups of individual’s vital protections of life, liberty, expression and prosperity. There is less emphasis on moral terms such as obligation, virtue and justification but more emphasis on rights or rules which protect against oppression, unequal treatment, intolerance and arbitrary invasion of privacy. [1]

Communitarianism or Community Based Theories hold that fundamental principles of ethics derives from communal values, the common good, social goals, traditional practices and cooperative values [1]. In sum, the common good takes priority over individual rights.

Old and new theories considered together illustrate the complexity of ethical problems and the unlikelihood of satisfying all involved parties. Indeed, definitions and emphasis on one or another interpretation vary among ethicists. While each theory provides an approach to resolving ethical issues, clinicians and patients together ultimately choose between them and make health care decisions appropriate for each situation at a particular point in time. With this background it is now reasonable to consider a practical generic approach to resolving ethical issues.

A GENERIC APPROACH TO DIAGNOSIS, ANALYSIS AND RESOLUTION OF ETHICAL DILEMMAS

I. Diagnosis:

1. What are the ethical issues being considered?

2. Who are the primary and secondary parties involved?

For example, in decisions pertaining to end of life practices for people in a comatose or vegetative state, the primary parties include: the afflicted party, the immediate family, attending physicians and the hospital ethics committee.
Secondary parties who may be impacted by the decision because of its broader implications? (E.g., special interest groups, professional societies).

3. What rights, responsibilities, ethical norms, and legal considerations enter into the case (e.g., a right to privacy, informed consent, protection from harm and equal protection under the law)?

4. Are there rights in conflict? Which of these rights take primacy?

For example: The patient’s right to privacy may be in conflict with the physician’s right or obligation to inform the public health community about an infectious disease.

5. Are there priority norms or rules?

For example, “informed consent” in a clinical trial is a priority rule as is respecting the autonomy of persons who serve as research subjects.

6. How will the decision conform to or conflict with deeply rooted religious, cultural, or secular norms in a society?

II. Analysis

1. How will a decision in the case impact the well being (psychological or physical), risks, benefits, and liabilities of the impacted parties?

For example, who will benefit or be harmed from the development of human embryonic stem cells.

2. Which party or parties in the decision have primary consideration for a determination of risks, benefits and liabilities?

For example, on the question of the use of a stored viable fertilized human egg, the genetic donors of the egg and sperm and the owners of the egg bank are primary parties on the dispute over whether the egg shall be destroyed.

3. Once the rights and legal considerations are clarified, what is the weight of benefits and liabilities to each of the major impacted parties for each decision path.

III. Resolution.

1. Decision makers must decide if the ethical problem should be resolved by a determination of fundamental rights (deontological approach); by a determination of maximizing the good (utilitarian approach), by an appeal to some set of virtues (virtue ethics) or by some other theory acceptable to the primary parties which is within local laws and religious beliefs of affected parties. This is of course the rub, since one party may appeal to autonomy “rights” and the other to the utilitarian concerns of society.
SOCIETY VERSUS THE INDIVIDUAL

Whether based on religious grounds or personal opposition to allopathic medicine, people sometimes refuse effective medical treatments for themselves and sometimes for their children. [2] If patients’ actions endanger the community (e.g., those with tuberculosis refusing proven treatments), doctors must act in accord with local public health authority and seek legal consultation while addressing such ethical issues.

ECONOMIC ISSUES

Because scarcity of resources such as expensive drug therapies, dialysis, and other life sustaining technology including organ transplantation exists, physicians should be prepared to face questions about how such resources should be allocated. While some managed care systems have devised schemes to lower costs, creating the potential for conflict between cost control and patient care, physicians should be particularly wary of incentives to keep costs down by lowering the standard of care [2].

END OF LIFE CARE AND EUTHANASIA

When terminally-ill patients or those with painful, hopeless disabilities express wishes regarding their own medical treatment, decisions about the nature and extent of their care must be made. Palliative care and pain management commonly require the use of narcotics and sedatives in potentially lethal doses. [2] Doctors assist patients and their families in making rational, legal and morally sound decisions about withdrawing life-sustaining supports as well as responding to valid requests for aid-in dying. When patients, families and health care teams
agree on withdrawing care or making a patient CMO there is usually no need for an ethics consult. Do Not Resuscitate, Do Not Intubate and Do Not Feed orders require special attention. A clear definition of death including “brain death” must be agreed upon because many ethical issues apply to the evaluation and determination of brain death. Another set of ethical issues apply to the use of brain dead patients for organ transplantation, research, and teaching. [5]

**RESEARCH ETHICS**

The Nuremberg Code of research ethics for human subjects established during the war crime trials at the close of World War II responded to gross abuses in human experimentation (which included painful, harmful and lethal “procedures” without consent of subjects) performed in Nazi Germany. In 1966 Beecher reported on a variety of abuses of human subjects in medical research at major university medical centers in the United States [14] including the use of subjects without their consent and participation in medical research of subjects who had not been offered the option of standard treatment. Also worthy of special concern is the Tuskegee Study, sponsored by the United States Public Health Service to assess the clinical course of untreated syphilis. The study was terminated in 1972 after 40 years, at the direction of the Congress of the United States, when it was found that effective treatment had become available but was withheld from black men enrolled in the study in order to retain their ongoing participation. In response to these abuses, the President appointed a Commission to identify basic ethical principles and establish guidelines for use in human research. (The Belmont Report). [15]

While not a research issue but clearly a related ethical concern for physicians in the armed forces is their involvement in any aspect of prisoner torture. Assuredly, increasing
attention will be paid to this serious problem by physicians, human rights groups, and other concerned parties.

Because advances in the practice of medicine come largely from knowledge obtained through scientific research, physicians must make their own judgements about the validity of research results reported in scientific journals, the internet, the lay press or other media. They must be aware of widely publicized abuses and accusations related to the integrity of specific research endeavors that may have led the public and their own patients to question the ethical underpinning of the scientific study. While there have been some highly visible instances of outright fraud [16] it seems more likely that “questionable” research practices stem from laziness, expediency, disregard for accepted practices, and the expectation of personal financial or professional gain. Common errors include: failure to acknowledge and comply with recommendations of Institutional Review Boards (IRB’s) and Hospital Ethics Committees; fabricating or falsifying research data; plagiarism; and irresponsible authorship including ghost writing and honorary authorship.

Perhaps the most serious and dangerous research-related concern of physicians, lawyers, educators, bioethicists, legislators, laymen and academic medical centers is the potential for financial interests influencing new product development and reported outcomes of research studies [17]. The conflict of interest danger affects researchers themselves, their institutions and the for-profit pharmaceutical and medical devices companies that may be involved. In this regard collaborative efforts and sources of financial support must be disclosed in all publications, continuing medical education programs, federal advisory committees, advertisements, clinical guidelines, press reports and even in discussions with patients.
Finally, as the pace and the scope of international collaborative biomedical research continue to increase, long-standing ethical issues, especially those related to clinical trials, have reemerged. [18] The potential for exploitation of poorer nations by wealthier ones must be avoided. Now that greater numbers of privately-funded clinical trials are being carried out in Third World nations, physicians should advocate establishment of a uniform international ethical standard that addresses the different health care standards between the developed and the developing countries (e.g. testing new drugs on sick patients who have no access to alternative proven therapies available in more affluent countries and are not likely to have such access in the future).

HEALTH POLICY AND SELECTED PROMINENT BIOETHICAL ISSUES

As biomedical issues enter the mainstream of public dialogue, physicians are more frequently called upon to play an active role in deliberations by diverse groups, including patient groups and medical organizations with vested interests. While few ethical dilemmas have simple answers the issues must be dealt with and resolved. Moreover, the responses are frequently influenced by legal, religious, ethnic, socio-economic and other factors that may change over time thereby compounding or simplifying answers. Because there are no certain answers, a few contemporary issues adapted from the literature [2,5,13] are posed as questions deserving of thought:

- What rights do humans have to control their bodies and embryos created from their sex cells?
- Does life begin at conception, at implantation, when the heart beats or at some other point in time?
• Is the manipulation of human cells through genetic engineering contrary to ethical or cultural norms or religious values?

• Is genetic information the exclusive property of patients or also the concern of insurers, employers, and society?

• Should functional MRI results be used to assess criminal tendencies?

• When is it ethically acceptable to use cells, tissues and organs from aborted fetuses or human embryos frozen at infertility clinics or donated for transplantation or experimentation in biomedical research?

• How can we balance the risks of human somatic gene therapy with the potential benefits to treating certain inherited or non-inherited diseases?

**UNETHICAL ACTIONS BY ETHICALLY INFORMED HEALTH PRACTITIONERS AND RESEARCHERS: THE ULTIMATE DILEMMA**

While it is apparent that most physicians (and other health professionals) act ethically and professionally, some, from time to time, do not. Unethical actions by physicians familiar with key ethical principles deemed acceptable or worthy of thoughtful consideration before actions are taken, constitute the ultimate dilemma. Why apparently well parented, highly educated and presumably caring individuals act unethically even when they know their actions are wrong, or for personal gain at the expense of others, deserve the attention and input of biomedical practitioners, researchers and perhaps most importantly educators at all levels. However brief, this paper has presented enough familiar or possibly new information about principles, theory and practices of biomedical ethics to guide physicians (and other health practitioners) in their personal pursuit of ethical practice.
REFERENCES


