



Ethical Issues in Clinical Practice in Endocrinology- Review Article

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Abstract

Advancements in different field of medicine have given rise to complex ethical dilemmas in clinical practice. The more the clinicians are sensitized to ethical problems and familiar with ethical decision-making, the more they can value professionalism in their practice. The current paper is designed to emphasize physicians to think ethically in the field of internal medicine and endocrinology. Being aware of the ethical issues and being sensitive to them are the first steps for ethical conduct. So, some important ethical issues will be described in brief, and an overview of professionalism and the principles of ethical decision making will be provided. Three ethical cases are included in order to make the discussion more practical.

Keywords: Medical ethics, Endocrinology, Professionalism, Ethical decision-making

Introduction

Professional integrity requires medical practitioners to practice according to the best medical and ethical standards in different field of medical care, research, and education. Professional authority would not justify doctors to overstep the ethical boundaries even if the medical decision is scientifically sound. Physicians should be informed about ethical principles and guidelines and put them into their practice all the time. Codes of ethics in various field of medicine protect professional integrity by providing guiding rules.

As a response to the necessity of ethical excellence in medical practice, physicians' charter and codes of ethics have been published by authentic organs such as World Medical Association (WMA) (1); American Board of Internal Medicine (ABIM), American College of Physicians-American Society

of Internal Medicine (ACP-ASIM), and European Federation of Internal Medicine (2). The Accreditation Council on Graduate Medical Education (ACGME) designated professionalism as one of six core competencies for resident physicians to demonstrate (3). In the special field like endocrinology, there have been special codes of ethics too. For instance, the Endocrine Society has provided ethical codes for medical conduct (4, 5).

According to the Code of Ethics of the Endocrine Society, codes of ethics have aspirational, educational, and regulatory features; so they play the roles of identifying the highest standards of professional behavior, indicating to members what collective expectations for their individual behaviors are, and indicating and supporting the appropriate rules of behavior and issuing sanctions, on

occasion, for violations (4). In other words, codes of ethics determine values, rights and responsibilities, not scientific and technical approaches. National ethical guidelines, taken into account socio-cultural and religious elements, are also effectively provided in some countries (6).

In this article, it is intended to review in brief ethical issues related to medicine in which endocrinologists are involved. This is an attempt to sensitize specialists and to reinforce their ethical knowledge and experience and strengthen the skill of decision making for ethical problems. We will try to make the discussion more practical by three cases.

Professionalism

Professionalism, as a complex multidimensional concept, may have defined in different words and meanings (7-9). The definitions often describe professionalism in terms of a list of physician qualities or behaviors such as responsibility, reliability, and accountability; honesty and integrity; respect and other interpersonal skills; and self-improvement (9).

There is a big difference between professionalism in medicine and in other science and professions, since the subject in medicine is human being's health. Respect to human body and soul, medical profession has a kind of holy essence in many cultural contexts. Medical professionals are required to direct all efforts for health and welfares of the people. So, medical society in all countries is expected not to be self-centered and do their best to satisfy patients' needs. The terms such as altruism, respect for others, honor, integrity, accountability, competence, and duty/advocacy are defined as elements of medical professionalism by some professional organizations (2, 3). Arnold and Stern (10) equated professionalism to *"the aspiration to and wise application of the principles of excellence, humanism, accountability, and altruism that rest upon a foundation of clinical competence, communication skills, and ethical and legal understanding."*

The Accreditation Council for Graduate Medical Education emphasizes that as the professionalism requirements, residents must demonstrate a commitment to carrying out professional responsibili-

ties, adherence to ethical principles, and sensitivity to a diverse patient population(3). It continues:

"Residents are expected to:

- *Demonstrate respect, compassion, and integrity; a responsiveness to the needs of patients and society that supersedes self-interest; accountability to patients, society, and the profession; and a commitment to excellence and on-going professional development,*
- *Demonstrate a commitment to ethical principles pertaining to provision or withholding of clinical care, confidentiality of patient information, informed consent, and business practices,*
- *Demonstrate sensitivity and responsiveness to patients' culture, age, gender, and disabilities"* (3).

In a common project, American Board of Internal Medicine (ABIM), American College of Physicians-American Society of Internal Medicine (ACP-ASIM), and European Federation of Internal Medicine prepared "Professionalism Charter" published in 2002 (2), which defined three fundamental principles and a set of professional responsibilities (Table 1).

In a literature review of professionalism definitions, Wilkinson et al (8) defined 5 clusters of professionalism which were formed: adherence to ethical practice principles, effective interactions with patients and with people who are important to those patients, effective interactions with people working within the health system, reliability, and commitment to autonomous maintenance / improvement of competence in oneself, others, and systems.

The concept of professionalism has close links to physicians' duties and patients' rights. Therefore, in addition to the professional ethical guidelines, the physicians should be familiar with patient's rights charters and regulations in each country. No doubt, the healthcare system and socio-cultural tradition in which we want to define and apply professional conduct would be very impressive on the issue. Policy-makers should provide contextual appropriate charters in various societies.

Ethical issues in endocrinology

There are general and specific ethical challenges with which an endocrinologist may be confronted.

Issues related to physician-patient communication, informed consent, truth-telling, privacy and confidentiality, end-of-life decisions, conflicts of interests, reproduction ethics, transplantation, stem cell therapy and research ethics are some ethical issues which physicians should learn how to deal with them in their practice. Some major topics will be discussed to determine the ethical dimensions of medical care.

Informed Consent

Informed consent is based on the ethical principle of respect for autonomy, which highlights patient's self-sufficiency. Accordingly, the patients should be able to express their preferences in clinical practice. Jonsen et al. (11) nicely describes in-

formed consent as an ethical basis for the patient-physician relationship which characterized by mutual participation, good communication, mutual respect, and shared decision making. A comprehensive description of the main elements of informed consent is suggested by Beauchamp and Childress (12) (Table 2).

Although the requirements of informed consent may be relative to the social and institutional context, the primary goal is to enable patients to make autonomous decisions. Topics of "truthful disclosure", "the role of family in making decisions", "decisional capacity", and "surrogate decision makers" are some subjects related to the notion of informed consent. Religious and cultural diversity may have influential effects on the topics.

Table1: Fundamental principles and the professional responsibilities defined by the Professionalism Charter

Fundamental principles	- Principle of primacy of patient welfare - Principle of patient autonomy - Principle of social justice
Professional responsibilities	- Commitment to professional competence - Commitment to honesty with patients - Commitment to patient confidentiality - Commitment to maintaining appropriate relations with patients - Commitment to improving quality of care - Commitment to improving access to care - Commitment to a just distribution of finite resources - Commitment to scientific knowledge - Commitment to maintaining trust by managing conflicts of interest - Commitment to professional responsibilities

Table 2: Seven elements of informed consent (Beauchamp and Childress, 1994)

I- Threshold Elements	1. Competence (to understand and decide) 2. Voluntariness (in deciding)
II-Informational Elements	3. Disclosure (of material information) 4. Recommendation (of a plan) 5. Understanding (of 3 and 4)
III- Consent Elements	6. Decision (in favor of a plan) 7. Authorization (of the chosen plan)

For a consent to be valid, three elements are required; at first, the patient must have knowledge; secondly, the patient must be competent; and thirdly, the consent must be voluntary (13). In the field of endocrinology, patients may need more

specific information about the disorders (which may be unfamiliar to general population), diagnostic process, therapeutic options, benefits and burdens, and the course of treatments and follow-ups. In most cases, physicians can clinically judge

whether the patient has capacity to understand information.

Privacy and Confidentiality

The preservation of patient's privacy and confidentiality has long been recognized as a basic (legal and ethical) duty of professionals in health care setting. Without assurance of confidentiality, patients may refuse to share all necessary information which is needed for an accurate diagnosis. Confidentiality is not an absolute principle that cannot be overridden under any circumstances, and there are exceptions in which physicians are permitted to disclose their patients' secrets. However, moral principles of respect for autonomy, beneficence, non-maleficence and justice should be always considered to make decisions in complex cases.

Specialists in endocrinology may face patients who think they are entitled to keep some information secret. No doubt, they should respect patients' desires until another stronger moral principle is overriding. The physicians' obligations to third parties (like patient's spouse) and the duty to protect society may be intervene with the patient's autonomy. Reproductive medicine and management of infertility and sexual disorders often involve complex ethical issues including the privacy and confidentiality of patient. The spouse and other family members may need to be involved in decision making. Social and religious contexts should be always considered and respected as far as possible.

Conflicts of Interests

The terms of "conflict of interest" (COI) has defined as: "*a situation in which an individual (or group) is subject to influences that have a significant potential to lead him (or them) to act contrary to his (or their) professional or ethical responsibility...*" (14). For instance; the health care professionals may be motivated to use a newly marketed drug by incentive programs of pharmaceutical companies, while there is a known effective drug for the disease.

In medicine, there may be conflicts of interests for physicians in two distinct fields of clinical setting and research setting (15). Actually, physicians can-

not escape conflicts on interest. Relationships of physicians with pharmaceutical industry, gifts and unusual compensations, third-party payers, kick-backs and fee-splitting, physician investment and ownership of medical services are some realms which may cause conflict of interest.

Moreover, specific circumstances of an individual may cause duality of interest in which two or more interests of person are in conflict. For instance, a university faculty may be involved in a number of activities outside the university which influence her/his roles as a professor or a clinical practitioner in the university. Stock ownership of paraclinical services and monetary relationship with other organizations are two common examples which should be disclosed and managed to not influence fulfilling main responsibilities. Many medical centers and organizations have policies on conflicts of interest and duality of interest. As a case in point, American Diabetes Association (ADA) in its policy statements emphasizes on disclosure of conflicts of interests and declares that "*Closely related dualities of interest are not inherently wrong or bad, but the Association must be made aware of such interests in order to be able to evaluate fully their impact on the mission and activities of the Association*" (16). The Endocrine Society Ethics Advisory Committee has suggested a sequence of events, which may often prove helpful in cases of conflicts (5). This strategy is as follows:

- 1. Individuals in identified areas of activity are required to declare dualities of interest, whether financial or non-financial.*
- 2. These are considered by the relevant community—e.g. a committee or council or group of individuals directly affected.*
- 3. An assessment is made concerning whether the dualities constitute a potential or actual conflict.*
- 4. If it appears that a COI is present or likely, practical strategies are devised to separate the pursuit of the conflicting interests. In some cases, this may entail withdrawal from or curtailing of a particular activity; in others, it may be sufficient to find an independent person to conduct one of the functions or to appoint a committee or group of individuals to discharge the particular function involved.*

5. *The decisions and practical outcomes are communicated to the constituency affected to ensure continuing transparency."*

As a conclusion, transparency and disclosure of conflict of interest are ethical obligations of health care professionals. The conduct in cases of conflict must always be based on sound moral justification. Welfare of patients, not financial gain or academic promotion, must be the top priority in all situations.

Research Ethics

Research is an essential part of medical practice, particularly in specialized fields and in sub-specialty. Endocrinologists should also rely on research when the standard effective treatments for disorders are not known. So, they should be aware of the fundamental ethical principles and concerns which govern biomedical research. Several ethical issues should be taken into account in carrying out a research. The first and main point is that the researchers are obliged to distinguish research from clinical practice and treatments. The participants should be fully informed about the research and its process. In other words, the researchers ought to be honest in sharing information when they recruit participants for clinical trial.

Some historical tragedies in medical research, such as the Nuremberg Trials and Tuskegee Study, resulted in adopting codes of ethics. The Nuremberg Code (1947) (17) and the Declaration of Helsinki (1964) (18) were the first ethical guidelines of medical research. The latter, as the most accredited codes of ethics, has gone through several revisions by now. International Ethical Guidelines for Biomedical Research Involving Human Subjects (19) and Good Clinical practice (GCP) (20) are two other guidelines adopted by the Council for International Organizations of Medical Sciences (CIOMS) and International Conference on Harmonization (ICH), respectively. National ethical guidelines have also been compiled and promulgated in many countries. As a case in point, general and six specific ethical codes for biomedical research were introduced by ministry of health in Iran (6, 21). Specific codes are consisted of the ethical guidelines for clinical trial, research on mi-

nors, genetic research, gamete and embryo research, transplantation research, and research on animals (6, 21).

Scientific validity of the research, assessment of risks and benefits, informed consent, and approval by ethics review committee are important elements which may ensure the ethical integrity of the research. The benefits that might be gained from a research cannot justify harms to human beings. Responsible conduct of research (RCR) is a notion that includes subject protection, research integrity, environmental and safety issues, and fiscal accountability (22). Currently, there are "RCR courses" in research centers in some countries. Research subjects, including human beings or animals, should be protected and their rights must be preserved. Research integrity requires researchers to observe ethical principles in recruitment of participants, data collection, management, storage, sharing, and ownership of data, authorship and publication of the results. Safety concerns also necessitate observing the physical and psychological safety and well-being of subjects. Fiscal accountability, as Macrina stated (22), involves two principle areas of the responsible use of research funds, and financial conflicts of interests. Not being accountable may compromise ethical integrity of the research.

Novel treatments such as stem cell therapy and tissue transplantation also raised some ethical issues (23). Although there have been many successful experiences of such treatments, some scientists believe that it may take many years until all questions and doubts about the efficacy and safety are answered. So, ethical approval of treatment plans and ongoing ethical oversight are necessary. Stem cell research and its various scientific, ethical and religious issues have been widely discussed in recent decade (24, 25).

Ethical Cases

We strove to point out some main ethical issues emerging thinking and sensitizing of internists and endocrinologists to ethical cases in their practice. Contemplating on the following 3 cases can sheds more light on the issue.

Case 1: The fellowship of endocrinology asks the first-year resident if he wants to perform a Fine Needle Aspiration (FNA) of thyroid in an out-patient clinic. The patient has a solid lesion in the right lobe of his thyroid gland. The resident theoretically knows well about FNA but he has not observed or done such a procedure yet. He is concerned that whether he is experienced enough to do the procedure. What should he do? Do you verify the fellowship's request?¹

Case 2: M.B. is a 5 years old child with Down syndrome. The parents come to you to consult about GH therapy for their child. What ethical concerns do you think about? What would be your decision?

Case 3: A company of medical appliances and devices suggests you payments to refer diabetic patients to them for Glucometer, proper shoes and other devices. You will receive a fixed amount of money for each patient. They provide patients with necessary information and services. The company is scientifically approved and renowned for its innovative activities.

There are situations when ethical decision making is neither clear nor easy. Therefore, we briefly explain ethical principles and frameworks for decision making, and then we will review some ethical issues surrounded the cases.

Ethical Decision Making

Solving ethical problems is an art which needs knowledge and clinical experience. At the first step, the physicians should be sensitized to ethical problems in their practice. They should be familiar with different ethical theories. Virtue-based ethics, duty-based theory (deontology), utilitarianism, and

the principle-based theory (principlism) are the most well-known approaches to ethical decision-making.

Virtue ethics is an Aristotelian approach which places value on moral character and habit. According to this approach, people can be trained to act in a virtuous manner in order to reach to the best decision and create happiness (26). Being virtuous, as this theory determines, makes people able to make ethically sound decisions. Duty-based approach, which is founded by Immanuel Kant, determines particular duties upon which the moral correctness of an action should be assessed. For instance, one duty is that your actions ought to be universalizable. Moreover, Kantian theory emphasizes on the actor's intention as an element which makes an act praiseworthy (26). Utilitarianism is a main approach of the theory of consequentialism according to which an act is morally correct provided its outcome is beneficial. The utilitarianists emphasizes on "*the greatest good for the greatest number of people*" and the least harm.

Principle-based theory directs decision-making by using the four main principles of respect to autonomy, beneficence, non-maleficence, and justice. Principlism was firstly outlined by Beauchamp and Childress (27). This approach diminishes traditional paternalism of physicians and gives great emphasis to individualism. Informed consent is one of the most important implications of the principle of respect to autonomy. Beneficence and non-maleficence require health care professionals to do their best in order to maximize benefits and minimize harms. Justice is the fourth prima facie moral principle which has a relatively elusive meaning. Gillon subdivides obligations of justice into three categories: "*fair distribution of scarce resources (distributive justice), respect for people's rights (rights based justice) and respect for morally acceptable laws (legal justice)*"(28).

The ethical theories and approaches can determine standards of ethical practice. Currently, there are frameworks for ethical decision making of which the approach offered by Jonsen et al. (11) is applicable in many societies. Jonsen model is a "four-box method" which includes medical indication, patient preferences, quality of life, and con-

¹. We got the idea from the case of "Commitment to Honesty with Patients" in the book of "Professionalism in Medicine: A Case-Based Guide for Medical Students" by Spandorfer J, Pohl C, Nasca T, Rattner SL (eds). Cambridge University Press; 2010. Available from: <http://professionalism.jefferson.edu/video1/>

textual features. Medical facts about the case, the treatment goals, plan and clinical care are discussed under the topic of "medical indication". The box of "patient preferences" has derived from the principle of respect to autonomy and covers various issues of competency, informed consent, surrogate decision making, and so on. Probable physical, mental, and social deficits after treatment, forgoing treatment, and palliative care are some issues related to the "quality of life". Contextual features consist of socio-cultural, religious, economic, and legal features in which the case occurs.

The ethical theories and frameworks just help clinicians manage the cases in an ethically sound manner. There may not be clear-cut distinction between right and wrong decision in all clinical cases, and the physicians may need to consult with experienced ethicists, lawyers or other specialists.

Cases Discussion

There may be many concerns in each case, that we tend to highlight some, but no means all, aspects and issues.

In case 1, there is a conflict between the patient's right to receive the best medical services and the right and duty of medical students to learn procedures. There should be significant benefit to justify carrying out the procedure by an inexperienced person. The principles of respect to autonomy and non-maleficence require students to obtain patients' consent and to master necessary requisites for doing the procedure in a safe way. Personal and social benefits cannot justify the act if the harm is considerable or when the patient does not agree against a low risk.

There is a question that whether the patient's consent to overall plan of FNA is enough or the resident should keep the patient informed that he is doing the procedure for the first time. The other issue is the responsibility of the fellowship and how s/he should be certain about the resident's qualifications. No doubt, the medical students' inexperience may cause some harm for patients but they need to gain practical experience by doing procedure on some patients in order to become competent physicians in future. So, the pos-

sible solution is honest communication and disclosure to patient. The skill of communication with patients and their family and how to share information with them are parts of professionalism which should be also learned in medical practice. Socio-cultural and religious backgrounds have important influences on physician-patient communication process. So, physicians should be aware of their patients' beliefs and the possibilities and constrains of the context in order to make the best decision.

Case 2, however, brings some other issues to our attention. Growth hormone therapy in children with Down syndrome is controversial (29). The treatment plan has been under investigation for increasing height and muscle strength, and improvement of cognitive function. There is no definitive indication for treatment but the option may be assessed case by case (30). No doubt, we are not ethically permitted to deny a benefit on the basis of mental retardation. For ethical decision making, several factors including the benefits of intervention, potential risks, the pain and suffering caused by treatment plan, psychologic burden, standards of care, distributive justice, the cost-effectiveness and burden on the society, and ethical guidelines should be taken into account.

Decision making in such cases ought to be evidence-based and professionally convincing. If the treatment is not consistent with professional integrity and scientific facts, physicians should not confine themselves to social judgments and insistence of the patients or family. First of all, the goals of treatment should be determined. Physician should be certain about the efficacy of the therapy. Medical practitioners should sometimes protect their patients from unreasonable requests of the parents or other family members, particularly when the patients are not legally competent. In case of Down syndrome, the children are less capable to make decision by their own on complex issues like GH therapy than many other children. The necessity of a multidisciplinary team for decision-making is sometimes self-evident; including specialists in endocrinology, genetics, gynecology, psychology, ethics, law, and sociology.

Financial relationship in health care system and sharing the profits are the issues which case 3 tends to represent. Multidisciplinary approach in some endocrine disorders makes referring patients to other specialists and services necessary. In the realm of physicians and interprofessional relations, financial issues need special attention to preserve ethical excellence. In the last edition of the American Medical Association (AMA) Code of Ethics (31), one subtitle has been assigned on "*Opinions on Fees and Charges*" in which the issues such as fee-splitting and financial incentives to patients for referrals are discussed. The opinion 6.02 of the Code declares: "*Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical.*", and continues: "*A physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source.*" Violation of the doctors' honesty with patients and colleagues is emphasized as the main reason.

Nowadays, gifts are also used as a common way for advertising by pharmaceuticals and other companies. Some opponents claim that such gifts may result in conflicts between patients' interests and physician and health care professionals' interests. Physicians may claim that they are in no way influenced in their prescribing habits by the drug companies' gifts, however, the evidence shows that in the long run the physicians prescribe the newer and more expensive drugs without enough scientific support. The Code of Ethics of the Endocrine Society insists that physicians should be cautious in accepting gifts since these gifts are surely intended to influence opinion (4). The ethical integrity requires doctors to do the prescriptions only based on the quality and efficacy of the drug or product prescribed.

The AMA Code of Ethics, under the section of "*Opinions on Practice Matters, 8.61*", describes the gifts that doctors may accept and not accept. As a general rule: "*Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value*". Accordingly, textbooks, modest meals, drugs samples for personal or family use, and individual gifts of minimal value (e.g.,

pens and notepads) are permitted (31). The upper limit on the amount of choice that is acceptable may be various in different countries with diverse economic conditions; however, AMA determines a limit of eight choices provided that each of the choices must have a value of no more than \$100. The codes emphasize that some types of gifts including cash gifts, gifts of substantial value, and compensation for time spent at conferences without active role are not permissible (31).

Conclusion

Professionalism requires all physicians to act with medical excellence and ethical integrity in their clinical practice, research and education. Simply stated, ethics defines the standards of conduct in the profession, so it has a close relationship with professionalism. Being sensitized to ethical issues helps prepare physicians to better navigate through the many ethical challenges they face in their daily practice. Then the physicians should be skillful to make ethical decision and find effective ways to manage ethical problems by using principles and standard frameworks.

In the field of endocrinology, general and specific codes of ethics address the related ethical concerns. Different codes of ethics emphasize that "patient" should be the first consideration in any medical decision. Informed consent, protection of patients' privacy and confidentiality, avoiding or disclosure of conflicts of interests, and observing research ethics are some main issues which we highlighted in this chapter. Challenges related to financial conflicts of interests need special attention in many societies. Appropriate guidelines can address the problems in an effective way. However, the way in which professionalism is applied and trained may be adapted according to the cultural, religious, and even socio-economic environment of each country.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission,

redundancy, etc.) have been completely observed by the authors.

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