Medical Ethics in Contemporary Clinical Practice

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This review article describes and analyzes ethical issues in medical practice, particularly those issues encountered by physicians in their relationships with their patients. These relationships often involve ethical conflicts between 2 or more interests, which physicians need to recognize and resolve. The article deals with 4 topics in clinical practice in which ethical conflicts occur: physicians' duty of confidentiality in a digital environment, their responsibilities for dealing with abuses of the human rights of patients, their role in clinical research, and their relationships with commercial enterprises. The ethical policies of the World Medical Association provide the basis for determining appropriate physician conduct on these matters. The article concludes with reflections on the need for international standards of medical ethics. [*J Chin Med Assoc* 2005;68(11):495–499]

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Introduction

At all times and in all cultures, ethics has been at the heart of medicine. Medical ethics guides physicians in their relationships with patients, colleagues and society in general. It provides standards of behavior and decision-making that enable physicians to know what is expected of them by their colleagues, their patients and society in general. It also sheds light on major social issues that affect the practice of medicine, such as abortion, organ transplantation, euthanasia and medical research.

There are considerable variations in medical ethics from one country to another, inasmuch as ethics is grounded in philosophy, religion and political ideology. Pioneers of Chinese medical ethics, such as Sun Ssu-Miao (581–682) and Lu Chih (754–805), drew their inspiration from Confucian, Buddhist and Taoist teachings.[1] Beginning with Song Guo-Bin (1893–1956), Chinese ethicists have integrated Confucian with Western medical ethics.[2] Although differences of emphasis and interpretation remain, the fundamentals of medical ethics are basically the same across cultures, as is evident in the widespread acceptance of the ethical policies of the World Medical Association (WMA).

Contemporary medical ethics deals with a large number of topics in medical practice, medical research and public policy. The focus of this article will be selected ethical issues in clinical practice, that is, those that arise from and affect physicians' relationships with patients. The topics to be treated include physicians' duty of confidentiality in a digital environment, their responsibilities for dealing with abuses of the human rights of patients, their role in clinical research, and their relationships with commercial enterprises. These topics have a common theme – the conflict between 2 or more opposing values or interests. The article will conclude with reflections on the need for international standards of medical ethics.

Confidentiality

During the past decade, the traditional medical ethical principle of confidentiality, that is, the physician's duty to protect the patient's personal health information, has come into increasing conflict with a perceived need for health information databases serving administrative, planning and research purposes. Computerization has greatly facilitated the establishment and linking of such

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databases and, thereby, has made breaches of confidentiality much easier. In response, many governments have adopted laws to regulate health databases. These laws have generated much controversy: privacy advocates complain that they are more about facilitating access to personal health information than protecting privacy, whereas administrators, researchers and some medical associations criticize the bureaucratic requirements that the laws impose on routine medical and research practices.

Genetic databases and biobanks have been of particular concern because of the sensitive nature of personal genetic information as well as its commercial value. At its 2002 General Assembly in Washington, DC, the WMA adopted a major policy statement on health databases.[3] The initial impetus for this policy was a request from the Icelandic Medical Association to support its opposition to certain aspects of proposed legislation on the creation of a comprehensive genetic database in that country, particularly the provisions on consent.

Numerous national medical associations have been very active in lobbying their governments for legislation and regulations that protect patient information while facilitating its exchange for patient care and legitimate administrative and research purposes. To help their members interpret and implement the requirements of database legislation in their jurisdictions, several associations have prepared guidance documents and related tools.[4–6]

Physicians have strong reasons for preserving confidentiality. In order to receive medical care, patients have to reveal personal information to physicians and others who may be total strangers to them—information that they would not want anyone else to know. They must have good reason to trust their physicians not to divulge this information. The basis of this trust is the ethical and legal standards of confidentiality that physicians and other health care professionals are expected to uphold. Without an understanding that their disclosures will be kept secret, patients may withhold personal information. This can hinder physicians in their efforts to provide effective interventions or to attain important public health goals.

Physicians also see the need for limited disclosure of their patients' health information – to other health care providers to assist in the care of the patients, to insurance companies and other agencies for reimbursement of payment for health services, and to database managers for public health, health system administration and research purposes. As a general rule, physicians should give priority to the patient's interests over those of others. Disclosure of personal health information should protect patient confidentiality as much as possible. Where confidentiality cannot be maintained, patients should be informed about how their personal health information will be used and whether the information will be identifiable or anonymized.

Human Rights Abuses

Physicians are often among the first to be aware of violations of human rights since they are called upon to deal with the medical sequelae of torture and inhuman treatment. However, they often find themselves constrained from dealing with these violations because of pressure from the governments, military or police who authorize or commit abuses. The ethical challenge is how to protect the patient in the face of such pressure.

Physician participation in torture has long been regarded as a serious violation of medical ethics. The 1975 WMA *Declaration of Tokyo: Guidelines for Medical Doctors Concerning Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in Relation to Detention and Imprisonment*,[7] forbids any such participation on the grounds that there must be "no use made of any medical knowledge contrary to the laws of humanity".

In 1997, the WMA Assembly adopted the *Declaration of Hamburg Concerning Support for Medical Doctors Refusing to Participate in, or to Condone, the Use of Torture or Other Forms of Cruel, Inhuman or Degrading Treatment*,[8] which called on the medical profession to actively oppose torture and to support physicians who speak out against such violations of human rights.

The 2003 WMA Assembly in Helsinki adopted a *Resolution on the Responsibility of Physicians in the Denunciation of Acts of Torture or Cruel or Inhuman or Degrading Treatment of which they are Aware*[9] that provides specific guidance to physicians who are in this situation. In particular, physicians should guard their professional independence to determine the best interests of the patient and should observe, as far as possible, the normal ethical requirements of informed consent and confidentiality. Any breach of these requirements must be justified and must be disclosed to the patient. Physicians should report to the appropriate authorities any unjustified interference in the care of their patients, especially if fundamental human rights are being denied. The Resolution encourages national medical associations to promote laws and programs for the abolition of torture.

When physicians have responsibilities and are accountable both to their patients and to a third party and when these responsibilities and accountabilities are incompatible, they find themselves in a situation of "dual loyalty". Third parties that demand physician loyalty include governments, employers (e.g. hospitals and managed health care organizations), insurers, military officials, police, prison officials and family members.

An important resource for physicians and other health care professionals involved in dual loyalty situations is the report of the International Dual Loyalty Working Group, a collaborative initiative of Physicians for Human Rights and the School of Public Health and Primary Health Care, University of Cape Town, South Africa.[10] It contains chapters on the dimension of the problem, proposed general guidelines for health professional practice, proposed guidelines for practice in difficult settings, and institutional mechanisms to protect human rights in health practice.

Physicians working in prisons face many dual loyalty conflicts. To help identify and deal with these issues, the Norwegian Medical Association, in collaboration with the WMA, is offering a web-based course on human rights and ethics directed specifically towards prison doctors.[11]

In addition to combating gross violations of human rights such as torture, physicians are expected to uphold the other basic human rights of their patients and colleagues. The ones that are especially important for medical ethics include the right to life, to freedom from discrimination, to freedom of opinion and expression, to equal access to public services in one's country, and to medical care. Oaths and codes of medical ethics, such as the WMA's *Declaration of Geneva*, require that physicians not "permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient."

The Physician's Role in Medical Research

All physicians make use of the results of medical research in their clinical practice. To maintain their competence, physicians must keep up with the current research in their area of practice through continuing medical education (CME)/continuing professional development (CPD) programs, medical journals, and interaction with knowledgeable colleagues. Even if they do not engage in research themselves, physicians must know how to interpret the results of research and apply them to their patients. Thus, a basic familiarity with research methods is essential for competent medical practice.

The most common method of research for practising physicians is the clinical trial. The rapid increase in recent years in the number of ongoing trials has required finding and enrolling ever-larger numbers of patients to meet the statistical requirements of the trials. Those in charge of the trials, whether independent physicians or pharmaceutical companies, now rely on many other physicians, often in different countries, to enrol patients as research subjects.

Although such participation in research is valuable experience for physicians, there are potential problems that must be recognized and avoided. In the first place, the physician's role in the physician-patient relationship is different from the researcher's role in the researcher-research subject relationship, even if the physician and the researcher are the same person. The physician's primary responsibility is the health and well-being of the patient, whereas the researcher's primary responsibility is the generation of knowledge, which may or may not contribute to the research subject's health and well-being. Thus, there is a potential for conflict between the 2 roles. When this occurs, the physician role must take precedence over the researcher role.

Another potential problem in combining these 2 roles is conflict of interest. Medical research is a well-funded enterprise, and physicians are sometimes offered considerable rewards for participating. These can include cash payments for enrolling research subjects, equipment such as computers to transmit the research data, invitations to conferences to discuss the research findings, and co-authorship of publications on the results of the research. The physician's interest in obtaining these benefits can sometimes conflict with the duty to provide the patient with the best available treatment. It can also conflict with the right of the patient to receive all the necessary information to make a fully informed decision as to whether or not to participate in a research study.

These potential problems can be overcome. The ethical values of the physician apply to the medical researcher as well. So there is no inherent conflict between the 2 roles. As long as physicians understand and follow the basic rules of research ethics, they should have no difficulty participating in research as an integral component of their clinical practice.

The foundational document of research ethics is the WMA's *Declaration of Helsinki*,[12] first adopted in 1964 and amended several times since, most recently in 2000. The *Declaration* is a concise summary of

research ethics. Other, much more detailed, documents have been produced in recent years on research ethics in general (e.g. Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 1993, revised in 2002)[13] and on specific topics in research ethics (e.g. Nuffield Council on Bioethics [UK], *The Ethics of Research Related to Healthcare in Developing Countries*, 2002, 2005).[14]

Despite the different scope, length and authorship of these documents, they agree to a very large extent on the basic requirements of research ethics, namely:

- every proposal for medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed;
- a medical research project involving human subjects must be justifiable on scientific grounds;
- a medical research project must contribute to the well-being of society in general;
- the risks to the research subjects must not be unreasonable or disproportionate to the expected benefits of the research;
- research on human subjects cannot proceed without their informed consent;
- research subjects have a right to privacy with regard to their personal health information;
- research results must be reported accurately;
- anyone who has knowledge of unethical research has an obligation to disclose this information to the appropriate authorities.

These principles have been incorporated in the laws and/or regulations of many countries and international organizations, including those that deal with the approval of drugs and medical devices.

Not all aspects of research ethics enjoy general agreement. As medical science continues to advance in areas such as genetics, the neurosciences, and organ and tissue regeneration, questions arise regarding the ethical acceptability of new techniques, procedures and treatments for which there are no ready-made answers. Moreover, some older issues are still subjects of continuing ethical controversy, for example, under what conditions should a placebo arm be included in a clinical trial and what continuing care should be provided to participants in medical research. At a global level, the 10/90 gap in medical research (only 10% of global research funding is spent on health problems that affect 90% of the world's population) is clearly an unresolved ethical issue. When researchers do address problems in resource-poor areas of the world, they often encounter problems due to conflicts between their ethical outlook and that of the communities where they are working. All these issues will require much further analysis and discussion before general agreement is achieved.

Physicians and Commercial Enterprises

The relationship between physicians and commercial enterprises, particularly pharmaceutical and medical device companies, has been a subject of intense scrutiny by medical associations, medical journals and the popular press for well over a decade. As for-profit companies have become ever more prominent in the funding of medical research and CME/CPD, the potential for conflict of interest in the relationships of physicians with these companies has increased.

Commercial enterprises such as pharmaceutical and medical device companies depend on sales of their products to survive and thrive. The more they sell and the higher the price, the more successful they are. At the same time, patients need these products to prevent or treat illness. Those who pay for the products, whether patients, insurers or governments, want to pay as little as possible for them, particularly when there are problems of affordability. Physicians are caught in the middle between these 2 interests. They want a wide range of effective products for their patients, which means favoring the producers of the products, but they also want their patients to have access to the products, which may require curbs on the profits of the companies.

In order to win the favor of physicians, pharmaceutical companies, medical device manufacturers and other commercial organizations frequently offer them gifts and other benefits that range from free samples to travel and accommodation at educational events to excessive remuneration for research activities. A common underlying motive for such company largesse is to convince the physician to prescribe or use the company's products, which may not be the best ones for the physician's patients. Physicians are then faced with a conflict between their own interests and those of the company, on the one hand, and the interests of the patients, and perhaps of third-party funders, on the other. To prevent these conflicts from arising, and to help physicians deal with them when they do occur, many national medical associations and other medical organizations have developed policies and educational resources on this topic.[15–17] The WMA recently adopted its own set of guidelines, which deal with the funding of medical conferences, gifts to physicians, participation in industry-sponsored research, and other relationships of physicians with commercial entities.[18]

The basic general principle underlying all these guidelines is that the physician must give priority to the patient in any conflicts of interest. This requires maintaining professional and clinical independence from commercial interests and ensuring that relationships with companies do not lead to any action that is not in the best interests of the patient. In particular, physicians should not rely solely on pharmaceutical company representatives or industry-sponsored promotional events for their knowledge of medicinal products, and they should not ask their patients to take part in industry-sponsored research studies unless the study fulfils all the ethical requirements of the *Declaration of Helsinki*.

Conclusion

In an increasingly globalized world, the need for international standards of medical ethics has never been greater. Clinical trials often involve researchers and patients in many different countries, and the same ethical requirements must apply in all cases if the trials are to receive approval. Outside the research context, there remain differences in how general ethical rules are applied, for example, with regard to informed consent. In some countries, patients must be told all they need and want to know about their medical condition and the options for treatment so that they can make informed decisions, whereas in other countries, it is felt that terminally ill patients should not be informed of their prognosis. However, as both physicians and patients migrate in large numbers from country to country, either temporarily or permanently, there is an increasing need to recognize the fundamental similarities of the principles of medical ethics everywhere and to reconcile the different applications of these principles.

The many ethical statements and resolutions of the WMA are proof that it is possible to reach international consensus on the most difficult ethical issues in medical practice. Such consensus does not always come easily; it is often the result of considerable discussion and consultation. Moreover, the policies require periodic review, since both medical science and ethics do evolve, sometimes at a very rapid pace. The WMA recently instituted a systematic review process to ensure that its policies remain up-to-date.[19] Through these activities and its close relationships with national medical associations throughout the world, the WMA is committed to ensuring that ethics will continue to be at the very heart of medicine wherever it is practised.

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