
ARTICLE REVIEW

Medical Ethics: What You Should Know?

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ABSTRACT

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Introduction Medical ethics is a system of moral principles that apply values and judgments to the practice of medicine. As a scholarly discipline, medical ethics encompasses its practical application in clinical settings as well as work on its history, philosophy, theology, and sociology. The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. A physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. This paper presents some information regarding medical ethics, including the values and principles of ethical conduct. Later the requirements of consent form is presented to guide the researchers before conducting a study.

Keywords Medical Ethics - ethical conduct – consent.

INTRODUCTION

The practice of medicine has changed in ways that highlight the relevance of ethical issues. Medical science can intervene in ways (such as genetics, stem cells) that were not previously possible; patients are better informed; litigation is more common; physicians have to be aware of the cost implications of their treatment for society; they have to juggle obligations to the hospital, the health region and the government.¹ The medical profession since time immemorial has conducted itself with a high level of ethical behaviour that has earned the trust that patients have in doctors today².

In recent times, national, regional and world associations of doctors as well as other health care professionals have revised existing codes of ethics and formulated new ones to keep up with advances in medical knowledge, medical practice and research as well as changes in society.

Definition of Ethics

Ethics are the inner guiding moral principles, values, and beliefs that people use to analyze or interpret a situation and then decide what is the right or appropriate way to behave (Jones & George 2008).³ Ethics are also defined as an understanding of the nature of conflicts arising from moral imperatives and how best we may deal with them.⁴ Specifically they deal with conflicts in potential outcome (consequences of actions) or with duties and obligations. Ethics do not decide what is morally right or wrong; rather they consider how we should act best in the light of our duties and obligations as moral agents. Clinicians have specific duties of care to their patients and to society. It is generally held that clinicians should always act in the best interest of their patients; but sometimes there is a conflict between obligations to a patient and those perceived to be owed to the community or to other patients. It may not always be the case that what the clinician believes is in the best interest of the patient is what the patient wishes or will consent to. Central to modern medical ethics is a respect for patient autonomy and the fundamental principle of informed consent.⁴

Definition of Medical Ethics

Medical ethics are defined as rules of conduct recognized in respect to particular class of human actions or particular group, culture.⁵ Also medical ethics defined as the principles of proper professional conduct concerning the rights and duties of the physician, relations with patients and fellow practitioners, as well as actions of the physician in patient care and interpersonal relations with patient families.⁶ This trust goes beyond written words and leads the public at large to expect of the doctor to have not only a high

standard of medical ability and skill but also impeccable behaviour.

Ethics are the branch of philosophy which deal with moral aspects of human behavior. Some differentiate between ethics and morals. Ethics deal with the theories and principles of values and the basic perceptions and justifications of values, whereas morals include the customs and normative behavior of people or societies. Nevertheless, these terms are often used interchangeably, their meanings now overlap and they are becoming virtually synonymous. Medical ethics in the narrow historical sense refers to a group of guidelines, such as the Oath of Hippocrates, generally written by physicians, about the physician's ideal relationship to his peers and to his patients.⁷ Medical Ethics are practical subjects as well as a branch of moral philosophy. They are also an essential branch of medicine.⁴

The idea of specific medical ethics was first summarised in about the 4th century BC by Hippocrates in the Hippocratic Oath – which doctors still take today. In simple terms, the Hippocratic Oath says that doctors should always work to protect their patients from harm. Since the 1970s, the growing influence of ethics in contemporary medicine can be seen in the increasing use of Institutional Review Boards to evaluate experiments on human subjects, the establishment of hospital ethics committees, the expansion of the role of clinician ethicists, and the integration of ethics into many medical school curricula.⁸ This covers a lot of areas, but in modern medicine ethics are often broken down into four main principles.

- Autonomy means respect for the patient. Where possible, doctors should take the wishes of the patient into consideration when deciding on treatments, and should never withhold information from them or share confidential information with others.
- Beneficence means acting in the patient's best interests. For example, doctors should never perform an operation where the risk of killing a patient is higher than the chance of curing them.
- Non-maleficence means never doing anything that intentionally harms a patient, such as deliberately giving them an overdose.
- Justice means that all patients should be treated equally, so it is wrong to refuse to treat someone because they are of a certain race, for example. Justice also means that doctors should think about how what they do affects society as a whole.

The relationship between researchers and research participants is the ground on which human

research is conducted. The values set out: respect for human beings, research merit and integrity, justice, and beneficence, help to shape that relationship as one of trust, mutual responsibility and ethical equality.

Among these values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. Such respect includes recognising the value of human autonomy, the capacity to determine one's own life and make one's own decisions. But respect goes further than this. It also involves providing for the protection of those with diminished or no autonomy, as well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so.

Ethical principles are normally easy to understand, but can get complicated around issues like euthanasia, abortion and stem cell research, when there is a conflict between different principles. For example, a patient might have an incurable disease and asks their doctor to stop the treatment which is keeping them alive – which causes a conflict between autonomy and non-maleficence. Ethical questions often cause passionate debate, but a doctor must always know and obey the laws of the country they work in, no matter what their personal beliefs are.

Human Research

All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures.

Human research is research conducted with or about people, or their data or tissue.⁹ It has contributed enormously to human good. Many human researches carry little risk but they can involve significant risks and there are possibility for things to go wrong. Sometimes they are realised because of technical errors or ethical insensitivity, neglect or disregard. This range of possibilities can give rise to important and sometimes difficult ethical questions about research participation. Since earliest times, human societies have pondered the nature of ethics and its requirements and have sought illumination on ethical questions in the writings of philosophers, novelists, poets and sages, in the teaching of religions, and in everyday individual thinking.

Reflection on the ethical dimensions of medical research, in particular, has a long history, reaching back to classical Greece and beyond. There has been increased attention to ethical reflection about human research since the World War II. The judgement of the Nuremberg military tribunal included ten principles about permissible

medical experiments, since referred to as the Nuremberg Code. Discussion of these principles led to the World Medical Assembly in 1964 to adopt what came to be known as the Helsinki Declaration, revised several times since then.⁹ Written ethical guidelines have also been generated in many areas of research practice as an expression of professional responsibility. Participants involved in the research should be accorded the respect and protection that is due to them and the research must be of benefit to the participant and/or the community.

Values and Principles of Ethical Conduct

The values on ethical conduct of research rest on four guiding principles: respect for persons, beneficence, justice and research merit and integrity.

Respect for Persons

The principle of respect for persons involves recognizing that each human being has value in himself or herself. Researchers must equally respect the dignity of those involved in research. The moral requirement is based on the acknowledgement of the participant's autonomy and protecting those with diminished autonomy. It is the duty of the researcher to obtain informed consent from study participants and to maintain confidentiality on their behalf. Due scope must be given throughout the research process to the capacity of human beings to make their own decision (voluntariness). Where the participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary. Researchers should respect the privacy, confidentiality and cultural sensitivities of participants and where relevant, of their communities. Any specific agreement made with the participants or the community should be fulfilled.

Beneficence

The principle of beneficence weighs between the potential benefit and harm of participation. The likely benefit of the research must justify any risks of harm or discomfort to participants and/or the wider community. Researchers have an obligation to maximize possible benefits and minimize possible harm. Researchers are responsible for:

- (a) designing the research to minimize the risks of harm or discomfort to participants
- (b) clarifying to participants the potential benefits and risk, and
- (c) the welfare of the participants in the research context

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Where there is no likely benefit to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.

Justice

The principle of justice involves regard for human sameness that each person share with others, that equals should be treated equally. It means a fair distribution of the burdens and benefits of research and encompasses fair treatment in recruitment of participants and in the review of research. Researchers must ensure that the vulnerable are not exploited and that eligible candidates who may benefit from participation are not excluded without good cause.

The principle of justice raises 3 questions:

- (a) Who ought to receive the benefits of the research?
- (b) Who ought to bear its burden?
- (c) Is it just to use public funds for this research?

In research that is just:

- (a) the selection, exclusion and inclusion of research participants is fair and accurately described in the research reports
- (b) the process of recruiting participants is fair
- (c) there is no unfair burden of participation in research on particular groups
- (d) there is fair distribution of benefits of participation in research
- (e) there is no exploitation of participants in the conduct of the research; and
- (f) there is fair access to the benefits of research

Research outcomes may be made accessible to research participants.

Research Merit and Integrity

The involvement of human participants in the research cannot be ethically justifiable unless the proposed research has merit and the researchers have integrity. Research that has merit is

- (a) justifiable by its potential benefit (contribution to knowledge, understanding, skill or expertise of researchers and improvement in social welfare and/or individual wellbeing)
- (b) designed using methods appropriate for achieving the aims of the proposal
- (c) based on current and previous literature . This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation

- (d) designed to ensure that respect for participants is not compromised by the aims of the research, by the way it is conducted, or by the results
- (e) conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research
- (f) conducted using facilities and resources appropriate for the research

Application of these values and principles

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making.

The themes must always be considered in human research: the risks and benefits of research, and participants' consent. The potential risk of harm to participants has led to widespread agreement that sound ethical standards must be observed in clinical research regardless of the perceived benefits.¹⁰ Research will be ethically acceptable only if its potential benefits justify those risks.

What is Risk?

A risk is a potential for harm, discomfort or inconvenience. It involves the likelihood that a harm (or discomfort or inconvenience) will occur; and the severity of the harm, including its consequences.

Harm

Any research may lead to harms, discomforts and/or inconveniences for participations and/or others. The list of harm is not exhaustive but may include:

- (a) physical harms: including injury, illness and pain
- (b) psychological harms: including feelings of worthlessness, distress, guilt, anger or fear (for example, to disclosure of sensitive or embarrassing information, or learning about the genetic possibility of developing an untreatable disease)
- (c) devaluation of personal worth: including being humiliated, manipulated or treated disrespectfully or unjustly
- (d) social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatization; and findings of previous unknown paternity status

- (e) economic harms including the imposition of direct or indirect costs on participants
- (f) legal harms: including discovery and prosecution of criminal conduct.

Discomfort

Discomfort is less serious than harm and can involve body and/or mind. Examples:

- (a) minor side-effects of medication
- (b) discomforts related to venepuncture
- (c) anxiety induced by an interview.

Where a person's reactions exceed discomfort and become distress, they should be viewed as harm.

Inconvenience

Less serious than discomfort is inconvenience. Examples of inconvenience may include:

- (a) having to travel to participate in the research
- (b) filling in a form
- (c) participating in a survey, or
- (d) giving up time to participate in research.

Research may also pose risks to non-participants and these may include risk of distress for a participant's family members identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harm that may arise from research misconduct or fraud, and harm to members of research teams from other forms of misconduct (for example, harassment or bullying). These forms of misconduct may also lead to potential harm to participants.

Low and Negligible Risk Research

'Low risk research' describes research in which the only foreseeable risk is one of discomfort and 'negligible risk research' is one when any foreseeable risk is no more than inconvenience. Research in which the risk for participants is more serious than discomfort is not low risk.

Gauging and Minimising Risk

Gauging risk involves taking into account:

- (a) the kind of harm, discomfort or inconvenience that may occur
- (b) the likelihood of these occurring
- (c) the severity of any harm that may occur

In designing a research project, researchers have an obligation to minimise the risks to participants. Minimising risk involves an assessment of the research aims, their importance, and the methods by which they can be achieved.

Managing Risk

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- (a) researchers include, in their research design, mechanisms to deal adequately with any harm that occur; and
- (b) a monitoring process is in place and carried out

The greater the risk to participants in any research for which ethical approval is given, the greater the need for certainty that the risks are well managed, and the participants clearly understand the risks they are assuming.

Benefit

Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions. Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to people who are well. Such willingness should be taken into account in deciding whether the potential benefits of the research justify the risks involved.

Risks to research participants are ethically acceptable only if they are justified by potential benefits of the research. Steps to arriving at judgment on the ethical acceptability of risks should include:

- (a) identification of the risks, if any
- (b) assessment of the likelihood and severity of risks (researcher and reviewers of research should base their assessments on the available evidence, whether qualitative or quantitative. They should consider whether to seek advice from others who have the experience with the same methodology, population and research domain)
- (c) identification of who (participants and/or others) the risks may affect
- (d) establishment of the means to minimize risks

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- (e) identification of the potential benefits (whether potential benefit justify the risk involved). Research reviewers should take into account any willingness by participants to assume greater risks because of the potential benefits to them, their families, or groups to which they belong.
- (f) identification of whom the benefits are likely to accrue.

General Requirements for Consent

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.

Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research. It should be noted that a person's consent to participate in research may not be sufficient to justify his or her participation. General guidelines for a subject information sheet and consent form are listed below.

- The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it (purpose, methods, demands, risks and potential benefits of the research)
- This information must be presented in a way that is easily understood by the participant.
- The process of communicating information to participants and seeking their consent must aim towards a mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.
- Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:
 - (a) the nature, complexity and level of risk of the research; and
 - (b) the participant's personal and cultural circumstances.
- The subject information sheet must contain:
 - (a) Title of research;
 - (b) Introduction (purpose, the sources of funding for the research);
 - (c) Subject's involvement;
 - Method and procedure (the amount and quantity of tissue, fluids, or body parts to be taken and from where; if the tissues, fluids or body parts to be taken for research are part of standard medical procedure or specifically harvested for the research)
 - (d) Benefits of research;
 - (e) Potential risks;
 - Provision of services to participants adversely affected by the research
 - (f) Privacy and confidentiality, as well as any alternatives to participation;
 - (g) A clear statement regarding voluntary participation;
 - (h) The participant's right to withdraw, along with any implications of withdrawal, and on withdrawal, participants will not be deprived of the standard medical care;
 - (i) Any payments and compensation to participants;
 - (j) The likelihood and form of dissemination of the research results, including publications;
 - (k) Contact details of the researchers;
 - (l) Contact details of Research Ethics Committee;
 - (m) other relevant information.

Coercion and Pressure

No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes.

Reimbursing Participants

Participants may be reimbursed for the costs of taking part in research, such as travelling cost. However, payment that is disproportionate, or any

other inducement that is likely to encourage participants to take risks, is ethically unacceptable.

Where others need to be involved in participation decisions

Where a potential participant lacks the capacity to consent (*children and young people, people highly dependent on medical care who may be unable to give consent, people with a cognitive impairment, an intellectual disability, or a mental illness*), a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information, and decide whether subject will participate. Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

Consent to future use of data and tissue in research

Consent may be:

- (a) 'specific': limited to the specific project under consideration;
- (b) 'extended': given for the use of data or tissue in future research projects that are:
 - i. an extension of, or closely related to, the original project; or
 - ii. in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
- (c) 'unspecified': given for the use of data or tissue in any future research.

Extended or unspecified consent is also required if data is to be entered into a data bank or the tissues collected to be kept in a tissue bank. When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded. Data or tissue additional to those covered by the original extended or unspecified consent will sometimes be needed for research. Consent for access to such additional data or tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

Declining to consent and withdrawing consent

Persons who elect not to participate in a research project need not give any reason for their decision. Researchers should ensure those who decline to participate will suffer no disadvantage as a result of their decision. Participants are entitled to withdraw

from the research at any stage. Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.

CONCLUSION

Ethics are the standards of behaviour that guide managers and doctors in their work. It provides a balance and looks into the interest of patients, family members, caregivers and community. Ethical review and approval should be obtained in all cases of research on human subjects. The primary justification for research is the expected benefit in improved treatments or prevention of disease. There are many core values running through the ethical beliefs of the various communities. Some of these values are extracted here for the guidance in medical ethics.²

1. The physician must maintain the utmost respect for human life and the human person.
2. The physician must stay abreast and practice in accordance with current medical knowledge, continually improve his skills and seek help whenever needed.
3. The physician should not recommend nor administer any harmful material and should render help regardless of the financial ability, ethnic origin or religious belief of the patient.
4. The physician should protect the patient's confidentiality and adopt an appropriate manner of communication. He should examine a patient of the opposite sex in the presence of a third person whenever feasible.
5. The physician should not criticize another physician in the presence of patients or health personnel.

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