W17: (Committee Activity) The Basis of Modern Health Care Ethics (Open Session)

Workshop Chair: Nina Davis, United States
07 October 2015 10:30 - 12:00

Start	End	Topic	Speakers
10:30	10:35	Welcome and introduction	Nina Davis
10:35	10:50	The evolution of modern health care ethics	Elise De
10:50	11:10	Human subjects research	Margot Damaser
11:10	11:20	Financial relationships and disclosure	Safwat Tosson
11:20	12:00	Discussion	All

Aims of course/workshop

Participants will gain an understanding of the precepts and principles underlying modern medical ethics. Discussion will then proceed to the application of ethics to the conduct and publication of research and to the reporting of financial and industry relationships. The second half of the course will consist of case presentations. Actual clinical scenarios will be used to demonstrate the application of ethical principles to clinical dilemmas.

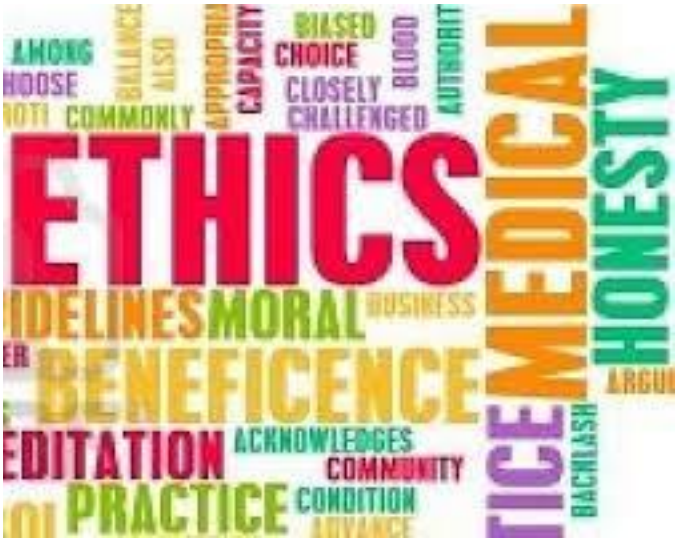
Learning Objectives

1. Trace the key historical events contributing to the development of current principles of health care ethics.

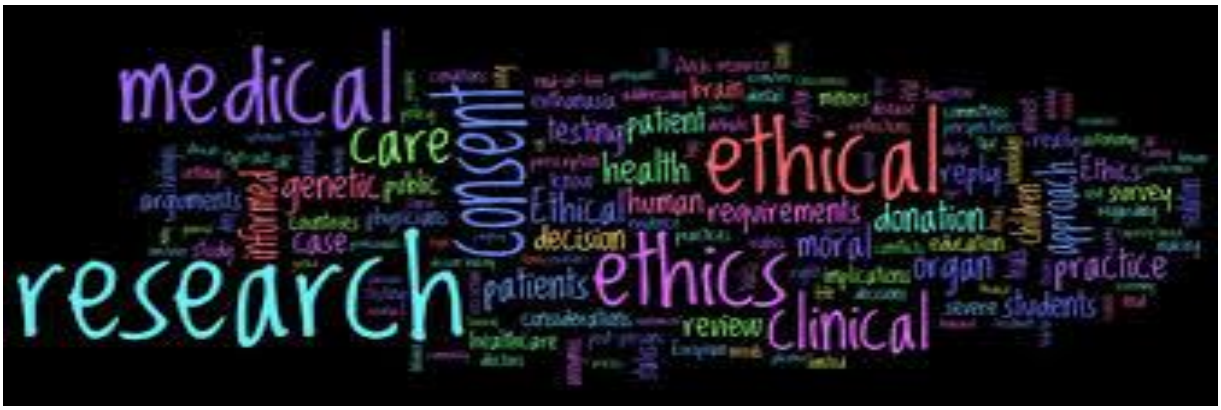
2. Recognize situations that constitute financial and research conflicts of interest

3. Define the ethical dilemmas presented by real-life cases in medical ethics

Workshop 17



The Basis of Modern Health Care Ethics



Introduction to Ethics - Nature of Ethics and Basis for Modern Bioethics

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Western medical ethics may be traced to the Hippocratic Oath, early Christian teachings, the first code of medical ethics (Formula Comitis Archiatrorum, published in the 5th century, during the reign of the Ostrogothic king Theodoric the Great, Muslim medicine (Ishaq ibn Ali al-Ruhawi wrote the Conduct of a Physician, the first book dedicated to medical ethics), Muhammad ibn Zakariya ar-Razi (known as Rhazes in the West), Jewish thinkers such as Maimonides, Roman Catholic scholastic thinkers such as Thomas Aquinas, and the case-oriented analysis (casuistry) of Catholic moral theology.

Thomas Percival, a physician and author, crafted the first modern code of medical ethics and coined the expressions "medical ethics" and "medical jurisprudence" in 1794 and 1803, respectively. In 1847, the American Medical Association adopted its first code of ethics,. This was based in large part upon Percival's work. In the 1960s and 1970s, building upon liberal theory and procedural justice, much of the discourse of medical ethics went through a dramatic shift and largely reconfigured itself into **bioethics.**

The World Medical Association (WMA)

As the only international organization that seeks to represent all physicians, regardless of nationality or specialty, the WMA has undertaken the role of establishing general standards in medical ethics that are applicable worldwide. The WMA began in 1947 in the setting of the unethical conduct exhibited by physicians in Nazi Germany and elsewhere. The WMA's first task was to update the Hippocratic Oath for 20th century use. The result was the Declaration of Geneva, adopted at the WMA's 2nd General Assembly in 1948. The second task was the development of an International Code of Medical Ethics, which was adopted at the 3rd General Assembly in 1949. The third task was developing ethical guidelines for research on human subjects, and in 1964 the guidelines were adopted as the Declaration of Helsinki. According to the WMA, three values: compassion, competence and autonomy, along with respect for fundamental human rights, serve as the foundation of medical ethics.

THE WORLD MEDICAL ASSOCIATION DECLARATION OF GENEVA is the updated Hippocratic Oath sworn by many graduating medical students worldwide. Whereas these oaths are often discussed with respect to physicians, the concepts are applicable to any provider trusted within the healing professions:

At the time of being admitted as a member of the medical profession:

I solemnly pledge myself to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude which is their due;

I will practise my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will respect the secrets which are confided in me, even after the patient has died;

I will maintain by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues will be my sisters and brothers;

I will 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;

I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;

I make these promises solemnly, freely and upon my honour.

The Current Framework for Medical Ethics can have Non-Rational and Rational Approaches.

Non-Rational:

• Obedience: e.g. children or those who work within authoritarian structures. Morality consists in following the rules.

• Imitation: following the example of the role model; e.g. medical personnel in training.

• Feeling or desire is a subjective approach to moral decision making and behaviour. What is right is what feels right or satisfies one's desire; what is wrong is what feels wrong or frustrates one's desire.

• Intuition is an immediate intellectual perception of the right way to act in a situation. It is subjective and

can vary greatly from one individual to another, and even within the same individual over time.

• Habit is a very efficient method of moral decision-making since there is no need to repeat a systematic decision-making process. However, there are bad habits (e.g., lying) as well as good ones (e.g., truth-telling).

Rational approaches: Ethics is primarily concerned with rational approaches.

• Deontology involves a search for well-founded rules (religious or otherwise) that can serve as the basis for making moral decisions. E.g. "Treat all people as equals." Once the rules are established, they have to be applied in specific situations, and here there is often room for disagreement about what the rules require (for example, whether the rule against killing another human being would prohibit abortion or capital punishment).

• Consequentialism bases ethical decision-making on an analysis of the likely consequences or outcomes of different choices and actions. One form, utilitarianism, uses 'utility' as its measure and defines this as 'the greatest good for the greatest number; e.g. QALYs (quality-adjusted life-years). Consequentialism is open to the charge that it accepts that 'the end justifies the means' - for example, that individual human rights can be sacrificed to attain a social goal.

• Principlism uses ethical principles as the basis for making moral decisions. Four principles in particular, **respect for autonomy, beneficence, non-maleficence and justice, have been identified as the most important for ethical decision-making in medical practice. The prioritization of respect for autonomy over the others is a reflection of Western liberal culture and is not necessarily universal.**

Moreover, these four principles often clash in particular situations and there is need for some criteria or process for resolving such conflicts. These principles form the foundation of Western medical ethics debates.

• Virtue ethics focuses less on decision-making and more on the character of decision-makers as reflected in their behaviour. Physicians who possess compassion, honesty, prudence and dedication are more likely to make good decisions and to implement them in a good way.

Focus on Principlism:

The "four principles" approach postulated by Tom Beauchamp and James Childress in their textbook *Principles of Biomedical Ethics*

- Respect for autonomy - the patient has the right to accept or decline treatment. (*Voluntas aegroti suprema lex*.)
- Beneficence - a practitioner should act in the best interest of the patient. (*Salus aegroti suprema lex*.)
- Non-maleficence - "first, do no harm" (*primum non nocere*).
- Justice - concerns the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality). (*Iustitia*.)

Other values that are sometimes discussed include:

• Respect for persons: The patient (and the person treating the patient) have the right to be treated with dignity.

• Truthfulness and honesty - the concept of informed consent has increased in importance since the historical events of the Doctors' Trial of the Nuremberg trials and Tuskegee syphilis experiment.

Autonomy

The principle of autonomy recognizes the rights of individuals to self-determination. This is rooted in society's respect for individuals' ability to make informed decisions about personal matters. Autonomy has become more important as social values have shifted to define medical quality in terms of outcomes that are important to the patient rather than medical professionals. The increasing importance of autonomy can be seen as a social reaction to a "paternalistic" tradition within healthcare. Respect for autonomy is the basis for informed consent and advance directives. Examples: Declining Immunization (conflict between individual autonomy and community benefit). End of life decisions (loss of competency versus advanced directives).

Informed consent - a person must be fully informed about and understand the potential benefits and risks of their choice of treatment. The process of obtaining consent, or the specific legal requirements, vary from place to place, for capacity to consent. Patients can elect to make their own medical decisions, or can delegate decision-making authority to another party. If the patient is incapacitated, laws around the world designate different processes for obtaining informed consent, typically by having a person appointed by the patient or their next of kin make decisions for them. The value of informed consent is closely related to the values of autonomy and truth telling. This involves explaining complex medical diagnoses, prognoses and treatment regimes in simple language, ensuring that patients understand the

treatment options, including the advantages and disadvantages of each, answering any questions they may have, and understanding whatever decision the patient has reached and, if possible, the reasons for it.

Beneficence

Taking actions that serve the best interests of patients. This principle can often be in conflict with others. For example we perform fistula surgery to help patients manage symptoms, but there are risks of the surgery.

Non-maleficence

The concept of non-maleficence is embodied by the phrase, "first, do no harm," (*primum non nocere*). Well-meaning practitioners are prone to using treatments that they believe will effect good, without first having evaluated them adequately to ensure they do no (or only acceptable levels of) harm. For example the introduction of vaginal mesh. It is essential that the patient understands the risks and benefits, and that the likely benefits outweigh the likely risks.

Justice

Justice is a complex ethical principle, with meanings that range from the fair treatment of individuals to the equitable allocation of healthcare dollars and resources. Justice is concerned with the equitable distribution of benefits and burdens to individuals in social institutions, and how the rights of various individuals are realized. Common definitions for Justice are often problematic for clinicians, as the explanations leave many questions unanswered. If Justice is a concept about treating people fairly, then it is prudent to wonder what it means to be “fair.” In discussing a different aspect of Justice, distributive Justice, the concern focuses on who gets what treatment in healthcare, and who decides what treatments are administered. Is the decision based on need? Age? Prognosis? These concepts leave clinicians with many unanswered questions as to what is fair and equitable in the treatment of individuals.

Double effect: Refers to two types of ethical consequences that may be produced by a single action.

<u>Beneficence and Non-Maleficence:</u>

An example would be performing a ureterosigmoidostomy on a patient with a devastated bladder and inoperable fistula in an under-resourced setting. Alternative surgeries may not be realistic in certain circumstances, so the patient is offered the benefit of the treatment of the incontinence but the risk of cancer in the long term.

<u>Autonomy and Beneficence:</u>

Autonomy can come into conflict with beneficence when patients disagree with recommendations that healthcare professionals believe are in the patient's best interest. When the patient's interests conflict with the patient's welfare, different societies settle the conflict in a wide range of manners. In general, Western medicine defers to the wishes of a mentally competent patient to make his own decisions, even in cases where the medical team believes that he is not acting in his own best interests. However, many other societies prioritize beneficence over autonomy.

Autonomy and beneficence/non-maleficence may also overlap. For example, a breach of patients' autonomy may cause decreased confidence for medical services in the population and subsequently less willingness to seek help, which in turn may cause inability to perform beneficence. For example screening for HIV.

The principles of autonomy and beneficence/non-maleficence may also be expanded to include effects on family or the overall population. For example treating and containing Ebola.

Other Important Concepts:

Confidentiality - Confidentiality is commonly applied to conversations between providers and patients and is most closely related to autonomy as well as respect for human dignity. Legal protections prevent physicians from revealing their discussions with patients, even under oath in court (the patient-physician privilege). Confidentiality is mandated in the U.S. by HIPAA (Health Insurance Portability and Accountability Act). However, numerous exceptions exist: for example, many states require physicians to report gunshot wounds to the police and impaired drivers to the Department of Motor Vehicles. Confidentiality is also challenged in cases involving homicidal or suicidal ideation, the diagnosis of a sexually transmitted disease in a patient who refuses to reveal the diagnosis to a partner, and in the termination of a pregnancy in an underage patient, without the knowledge of the patient's parents. Confidentiality is also impacted in some countries where the government requires physicians to report certain injuries or diagnoses.

Culture and Ethics

Culture differences can create difficult medical ethics problems. Some cultures have spiritual or magical theories about the origins of disease, for example, and reconciling these beliefs with the tenets of Western medicine can be difficult. Euthanasia, access to care, life-extending technologies are approached differently by different countries sometimes due to morality and sometimes due to situational influences (e.g. resources, political stability).

Truth-telling

Some cultures do not place a great emphasis on informing the patient of the diagnosis, especially when cancer is the diagnosis. American culture rarely used truth-telling in medical cases, up until the 1970s. In American medicine, the principle of informed consent now takes precedence over other ethical values, and patients are usually at least asked whether they would like to know the diagnosis.

Conflicts of interest

Physicians should not allow a conflict of interest to influence medical judgment. In some cases, conflicts are hard to avoid, and doctors have a responsibility to avoid entering such situations. However, research has shown that conflicts of interests are very common among both academic physicians and physicians in practice.

REFERENCES

Tom Beauchamp: *Principles of Biomedical Ethics, 6th ed.* Oxford University Press, Oxford 2009.

Medical Ethics. in Wikipedia, The Free Encyclopedia. Retrieved June 9, 2015, from https://en.wikipedia.org/w/index.php?title=Medical_ethics&oldid=666586961 (includes paraphrasing and direct quotation).

Percival, Thomas (1849). *Medical Ethics*. John Henry Parker. pp. 49–57.

World Medical Association *Medical Ethics Manual 2005* (Includes paraphrasing and direct quotation).

Feinsod FM, Wagner C. The ethical principle of justice: The purveyor of equality. *Annals of Long-Term Care*. 16(1): January, 2008.

Research Ethics

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Take Home Points:

- Research integrity is of the greatest value
- Ethical approaches must be taken with regard to:
  - human & animal subjects
  - design of the experiment
  - collection, analysis, and reporting of data
  - authorship on presentations and manuscripts
  - inventorship if intellectual property is involved
- Both clinical and preclinical research ethics include conducting research studies with high integrity and validity to increase translational potential

Overview of Research Ethics

Medical research, both clinical and preclinical, requires no licensing process. Thus, researchers have only their own integrity to support their capability to conduct ethical research. The peer-review process required for publication of most manuscripts is considered the current method of ensuring validity of the research. However, peer-review is established to ensure that the research can be repeated, not that it was performed ethically in the first place. Therefore, once the integrity of a researcher is questioned, it is difficult or impossible to regain the trust of the scientific community as there are few to no methods in place to validate that future research is performed ethically. Thus, maintenance of one's own integrity is of paramount importance to anyone participating at any level in research.

Several guideline documents are helpful in this regard to inform researchers of the ethics expectations from the scientific community. For this purpose and to maintain a high standard of medical research, the World Medical Association developed the Declaration of Helsinki just over 50 years ago as a set of ethical principles for the

medical community in relation to experimental research in humans. This seminal work was intended for the protection of human subjects and has become the cornerstone document of human research ethics. This workshop will provide an overview of the Declaration of Helsinki along with historical and current perpsectives (1). Topics of importance include use of the instutational review board or human subjects ethical committee, proper informed consent of research subjects, and vulnerable subject population worthy of special consideration (2). A case study will be discussed in which ethical violations led to withdrawal of a paper (3;4).

In addition to human subjects research, ethical considerations are important in animal research as well. These issues will be addressed in the workshop, including study design, ethics board approval, and reporting of research. It is important to recognize that the design of preclinical research studies can affect which therapies move on to clinical trials. The frequent failure of investigational therapies during clinical trials and clinical translation is potentially harmful to trial participants and the general patient population. Moreover the costs of these failures are passed on as higher prices. Guidelines have been created to improve the design and execution of preclinical animal studies with the goal of improving the success rate of clincal translation of novel therapies (5).

Ethics in publication is an important and timely matter, as too many studies go unreported (6). With pressure to publish, authors can too often publish many small papers, reaching for the „least publishable unit,“ also nicknamed „salami science“ for the thinly sliced nature of these publications. This can make it difficult for the field to draw meaningful conclusions from the research. In addition, the pressure to publish in high impact journals can lead to fraud. Significantly, it is the very high impact journals, such as *Science, Nature*, and *Lance*t, that often report investigations of fraud and resultant withdrawal of published work.

Authorship deserves ethical consideration as well and includes determining when to publish, how much to publish and where to publish. These last considerations become particularly important and vulnerable to ethical violations when intellectual property is involved. These topics will be discussed and case studies provided for the education of the workshop attendees.

Reference s

(1) Shrestha BM. The Declaration of Helsinki in Relation to Medical Research: Historical and Current Perspectives. *Journal of Nepal Health Research Council* 10[22], 254-257, 2012.

(2) Nijhawan LP, Jonodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N, et al. Informed consent: Issues and challenges. *Journal of Advanced Pharmaceutical Technology & Research* 4[3], 134-140, 2013.

(3) Abbott A. Doctors accused of doing illegal stem-cell trials. *Nature* 2008 May 1;453(7191):6-7.

(4) Abbott A. Report finds grave flaws in urology trial. *Nature* 2008 Aug 21;454(7207):922.

(5) Henderson VC, Kimmelman J, Fergusson D, Grimshaw JM, Hackam DG. Threats to validity in the design and conduct of preclinical efficacy studies: a systematic review of guidelines for in vivo animal experiments. *PLOS Medicine* 10[7], e1001489, 2013.

(6) Federico CA, Carlisle B, Kimmelman J, Fergusson DA. Late, never or non-existent: the inaccessibility of preclinical evidence for new drugs. 171, 4247-4254, 2014.

Financial Relationships and Disclosure

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This presentation will provide an overview of what constitutes a conflict of interest in medicine, the role of organizational codes of conduct and the importance of disclosure.

Definition:

Conflict of interest (**COI**)– a conflict of interest refers to any situation in which an individual is in a position to exploit a professional or official capacity in some way for their personal or corporate benefit. Further, such financial or personal considerations imply compromise or bias of professional judgment and objectivity.

- financial gain
- self-referral
- career advancement/self-aggrandizement
- enrichment of familial interests
- nepotism

For medical professionals, COI may result in a violation of their **obligation** to act in the best interests of their patients, a violation of duty and trust.

Management of COI:

Disclosure – The professional reveals all relationships with industry or other financial entities, thereby establishing transparency and allowing scrutiny of such relationships. Enhances trust. Allows detection of bias during a presentation.

Prohibition – Acceptance of luxury gifts, high-priced entertainment or meeting sponsorship are considered unethical by numerous medical organizations and institutions. Avoidance ensures maintenance of professional integrity.

Limits – creating financial limits for gifts, restricting access to data from funded research or accepting fees commensurate with services rendered are another means of avoiding COI.

Reaffirmation – self-monitoring of practice and dedication to doing what is best for patients on a daily basis

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General Online References

General Bioethics: www.bioethics.net

General information on bioethics: www.nlm.nih.gov/bsd/bioethics.html

Research: www.niehs.nih.gov/research/resources/bioethics/index.cfm

AUA ethics course for urologists:
https://www.auanet.org/education/modules/**ethics**

Website for CMAJ/JAMC: www.cmaj.ca

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Notes