University of Jordan

Faculty of medicine

Batch 2013-2019

Medical Committee
The University of Jordan

Global health

Slide # : 4

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Health Care and Research Ethics

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Global Health Course

Summer Semester 2014/ 2015

Textbooks:

1. Global health 101, Richard Skolink, (2nd ed. 2012)

2. Understanding Global health, Markle W, Fisher M, and Smego R. (2nd ed. 2014)

What is Ethics

Ethics is a system of moral principles.

Ethics is that branch of philosophy dealing with values relating to human conduct, with respect to the rightness and wrongness of certain actions and to the goodness and badness of the motives and ends of such actions.

The Four Principles of Ethics

Painful ethical dilemmas arise in the pursuit of global health, whether planning healthcare provision, implementing public health measures, or conducting health research.

The four principles of ethics are:

1. Autonomy
2. Beneficence
3. Nonmaleficence
4. Justice

These principles provide a common moral language for use in any ethics related dialogue.

Autonomy

Autonomy **(from the Greek** *autos* **"self" and** *nomos*, **"rule") designates a norm of respecting the decision-making capacities of autonomous persons.**

- **The priority given to this principle has formed the basis for much debate. In the modern dialogue, self-rule has been extended to diverse meanings including self-determination, self-governance, liberty rights, privacy, individual choice, and freedom of the will.**

Nonmaleficence

Monmaleficence is a term used to designate a norm of avoiding causing of harm.

Throughout the centuries the concepts and practice of nonmaleficence and beneficence have played a central role in the medical ethics in all recorded cultures and civilizations. The maxim **"Above all, do no harm"** has thus been a foundational part of medical ethics teaching.

This concept did not originate within the Hippocratic traditions of medical ethics despite the Hippocratic Oath itself, which states, "I will use treatment to help the sick according to my ability and judgement, but I will never use it to injure or wrong them".

In the setting of global health, avoiding harm assumes **production of net benefit to one individual or to society.**

Beneficence

Beneficence: ***means (Do good)*** **– the flip side of nonmaleficence – describes a group of norms for providing benefit and for balancing benefit against risk and cost.**

Accordingly, act of mercy , kindness, and charity– colored by altruism, love, humanity, and a sense of obligation– drive global health work and its associated philanthropy.

Justice

Justice **is fairness, describes a group of norms for fairly distributing benefits, risks, and cost.**

Justice is commonly understood as law or lawfulness, in the context of global health, **the meaning of justice is closer to fairness and is considered a virtue.**

The concepts of legal justice, criminal justice, distributive justice, social justice, and the fair and equitable allocation of resources and benefits, further refine the notion of justice in the delivery of healthcare.

Many countries use distributive justice as "to each person an equal **share**", "to each person according to **need**", "to each person according to **contribution**", or "to each person according to **effort**".

The Role of Religion in Global Health Ethics: Christianity, Islam, and Judaism

Ethics are grounded in sociocultural, philosophical, or religious conventions deeply ingrained in the social fiber and culture of societies around the world. Healthcare choices and options are thus immensely influenced by religion. By their very nature, religions possess prescriptive moral ground rules for ethical judgement and fairness.

- ✓ As the cradle of 11 faiths, including the three major monotheistic faiths (Judaism, Christianity, and Islam) as well as Hinduism, Jainism, Confucianism and others, Asia has a rich recorded tradition of value, ethics, and humanism. Ideals such as love, harmony, tolerance, respect, and revenge, are expresses as a way of life.

The Role of Religion in Global Health Ethics: Christianity, Islam, and Judaism

Whereas Western societies, emphasized autonomy, justice, and rights, values that are practical and measurable.

In many societies, religion and culture influence belief about causation of ill-health such as “evil eye”, magic, spells, karma, possession by spirits, devil, departed ancestors, and sin as a cause of disease.

Research Ethics:

Research on Human Subjects

Research is essential to improve global health.

However, health research generates some ethical problems.

Eventually, all new healthcare interventions must be tested with human beings

But, most research studies are not designed to benefit the people who participate in them.

Instead, they are designed to create knowledge that can help patients in the future. Medical research therefore raises special ethical concern because research participants are put at risk for the sake of other people's health.

Research Ethics:
Research on Human Subjects

Key Human Research cases:

A number of historical cases of research on human subjects have raised ethical concerns and encouraged the development of **guidelines** for carrying out research ethically.

The following slides will show some of the best known of these cases

Case 1: The Nazi Medical Experiments

The “Doctors’ Trial” at Nuremberg (1946-1947) led to the conviction of 16 of 23 Nazi German doctors who were charged with war crimes and crimes against humanity, seven of whom were later executed by hanging, and nine of whom were imprisoned.

In this first-of-its-kind international trial, The physicians were convicted with murder and torture in the conduct of medical experiments on prisoners of war and concentration camps inmates.

Experiments included deliberately injecting prisoners with infective agents like TB and malaria, and physiologic experiments such as high altitude, hypothermia, and seawater to benefit German pilots and soldiers. Josef Mengle, a camp doctor, studied 900children in his camp, where he conducted operations without anesthetic and infected children with infective agents.

Case 2: The Tuskegee Syphilis Study

In 1932, the US Public Health Services (PHS), in collaboration with the Tuskegee Institute, began a study of syphilis in Macon County, Alabama, and lasted for 40 years.

- **A total of 412 impoverished African American men with untreated syphilis were monitored and compared with 204 disease-free men to determine the natural history of syphilis.**

No informed consent was signed by any of the 412 study participants. They were told that they were treated for "bad blood" (a local term to describe syphilis, anemia and fatigue), and they received aspirin and iron to make think that they were being treated. The research continued despite the availability of penicillin and the known fact that penicillin cures syphilis.

- **In July 1972, a front-page article in the New York Times broke the story of the Tuskegee study, and its impact on the protection of human subjects of research was profound.**

- Did the researchers have a valid argument when they stated that "these poor African American males probably would not have been treated anyway?" and that the investigators were therefore "merely observing what would happen"?

Case 3: The "Short-Course" AZT Trials

In 1994, a study conducted by the AIDS Clinical Trial Group showed that zidovudine (AZT)reduced mother-to-child transmission of HIV by 65%. This complex "076 regimen" became a standard of care in developed countries. In most developing countries (where HIV/AIDS epidemic are worst), however, this is too complicated and too expensive to implement.

- Subsequently, the NIH sponsored 15 randomized placebo-controlled trials of a simpler "short-course" AZT regimen in developing countries, mostly in Sub-Saharan Africa.

✓ Opponents of the trials said that they would not be permitted to take place in developed countries where 076 is the standard of care an this is an ethical double standard.

✓ Proponents of these trials argued that the results will benefit the communities from which participants were drawn. The 076 will not be available to women in these countries and they are not being deprived of treatment, and not exploiting these poor people for the gain of people in developed countries. And finally, using a placebo-controlled design is scientifically necessary.

Research Ethics guidelines

Research Ethics Guidelines

1. The Nuremberg Code

At the close of the Nuremburg Trial in 1947, the three presiding U.S. judges issued the Nuremberg Code (see Table 4-1) [1]. It was the first document to specify the ethical principals that should guide physicians engaged in human subjects research.

- ✓ It states that "voluntary consent of the human subject absolutely necessary.
- ✓ The Nuremberg Code was foundational for later research ethics guidelines and national regulations.

1. The Nuremberg Code

TABLE 4-1 The Standards of the Nuremberg Code

- Those who participate in the study must freely give their consent to do so. They must be given information on the "nature, duration, and purpose of the experiment." They should know how it will be conducted. They must not be forced or coerced in any way to participate in the experiment.
- The experiment must produce valuable benefits that can not be gotten in other ways.
- The experiment should be based on animal studies and a knowledge of the natural history of the disease or condition being studied.
- The conduct of the research should avoid all unnecessary physical and mental suffering and injury.
- The degree of risk of the research should never exceed that related to the nature of the problem to be addressed.
- The research should be conducted in appropriate facilities that can protect research subjects from harm.
- The research must be conducted by a qualified team of researchers.
- The research subject should be able to end participation at any time.
- The study will be promptly stopped if adverse effects are seen.

2. The Declaration of Helsinki

In 1964, the World Medical Association (WMA) developed a set of ethical principles to guide physicians conducting biomedical research with human subjects.

- ✓ Though the declaration targets physicians, its principles are supposed to apply equally to nonphysicians.
- ✓ It is the most influential and most cited set of international research ethics guidelines.
- ✓ The Declaration of Helsinki was revised in 1975, 1983, 1989, 1996, 2000, and 2008.

Some key principles from the Declaration of Helsinki are summarized in Table 4-2 [1].

2. The Declaration of Helsinki

TABLE 4-2 The Declaration of Helsinki: Key Principles

Scientific Validity

- Medical research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature.

Fairness

- Populations that are underrepresented in medical research should be provided appropriate access to participation.
- Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that it stands to benefit from the results of the research.
- Study participants are entitled to be informed of the study's outcome and to share benefits that result from it, such as access to interventions identified as beneficial in the study.

Risks and Benefits

- The well-being of the individual research subject must take precedence over all other interests.
- The importance of the objective of a study must outweigh the risks to the research subjects.
- Physical, mental, and social risks must be minimized.

Placebos

- A new intervention must be tested against the best current proven intervention, except when:
  - No current proven intervention exists; or
  - Where for methodological reasons the use of placebo is necessary and subjects who receive placebo will not be subject to any risk of serious or irreversible harm.

Consent

- Potential subjects must give voluntary, informed consent.
- For a potential research subject who is incompetent, the physician must seek informed consent from a legally authorized representative.
- Where possible, the physician must seek the assent and respect the dissent of an incompetent potential research subject.

Oversight and Accountability

- The research protocol must be submitted to an independent research ethics committee before the study begins.
- Every clinical trial must be registered in a publicly accessible database before recruitment begins.
- Authors have a duty to make publicly available the results of their research, including negative and inconclusive results.

3. The Belmont Report

On July 12, 1974, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created.

The Commission's mandate was to identify basic ethical principles for the conduct of Biomedical and behavioral research with human subjects, and to develop guidelines for researchers so that all human research would conform to the principles identified.

The commission prepared what has come to be the known as the Belmont Report.

The ethical principles and their applications are outlined in Table 4-3 [1].

3. The Belmont Report

TABLE 4-3 The Belmont Report

Basic Ethical Principle	Application of the Principle
Respect for Persons: • Treat individuals as autonomous persons. • Protect individuals with diminished autonomy.	Informed Consent: • Individuals should be allowed to make an informed, voluntary decision about what happens to them. • Individuals whose capacity is limited should be given the opportunity to choose to the extent that they are able.
Beneficence: • Maximize possible benefits. • Minimize possible harms.	Assessment of Risks and Benefits: • A data-based risk/benefit assessment should be made. • Risks to subjects should be outweighed by the sum of the benefits to subjects and the benefit to society. The interests of the subjects should be given priority. • Risks should be reduced to those necessary to achieve the research objective.
Justice: • The benefits and burdens of research must be distributed fairly.	Selection of Subjects: • There must be fair procedures and outcomes in the selection of those participating in the research.

Source: U.S. National Institutes of Health, Office of Human Subjects Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Available at: http://ohsr.od.nih.gov/guidelines/belmont.html. Accessed September 9, 2010.

Therapeutic and Reproductive Cloning and Stem Cell Research: Ethical Challenges

After mapping and sequencing of human genome have enabled human beings to think about self cloning, current debate focuses on reproductive cloning, stem cell research applications, and the moral consequences of these activities (Dolly the sheep in 1997).

This ability for self generation (Regenerative cloning (reproductive cloning) has led all major religions globally to ban cloning of an entire human being. The fundamental debate centers on the concept of life itself (When does the embryo becomes a "human being"?

Limited stem cell research is currently occurring after successful cloning of sheep. However, **therapeutic cloning** is gaining favor because it relates to curing disease as well as improving health and quality of life for all humanity (treatment for diabetes, Parkinson's Alzheimer's).

Here science and commercial interests will be driving forces, hoping that societal moral forces can prevent abusive practices.

Evaluating the Ethics of Human Subjects Research

The Nuremberg Code, the Declaration of Helsinki, and the Belmont Report all provide ethical principles that should be used to **evaluate** research protocols.

Most countries today require an independent ethical review by a research ethics committee (REC) for all clinical research on human subjects. It is also called an institutional review board (IRB). The REC provides oversight and safeguard against the exploitation of human subjects in research.

How should one carry out this evaluation?

A simple framework, derived from the general principles in the Belmont Report can help us systematically evaluate ethics of proposed clinical research studies.

Evaluating the Ethics of Human Subjects Research

According to this framework, a clinical research protocol must satisfy at least six conditions:

1. **Social value** (generates beneficial knowledge to help people)
2. **Scientific validity** (good methodology to answer the question)
3. **Fair subject selection** (equitable distribution of benefit and risk)
4. **Acceptable risk/benefit ratio** (risk vs. individual and social benefit)
5. **Informed consent** (to understand the study and voluntarily participate)
6. **Respect for enrolled subjects** (right to withdraw and confidentiality)