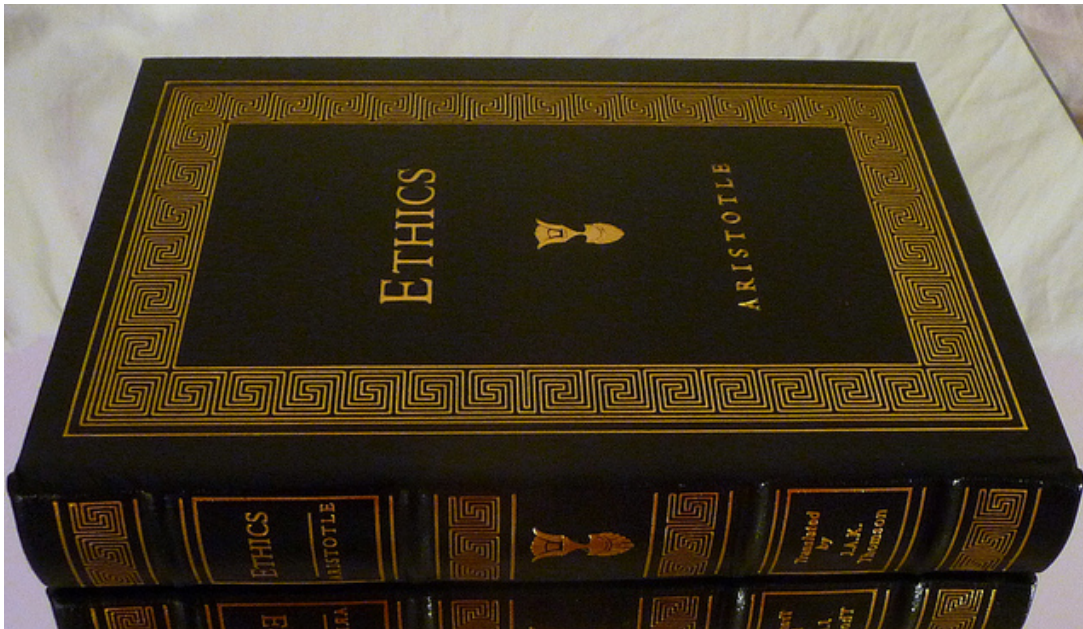


Research Ethics: Nuremberg Code, Belmont Report, and the Declaration of Helsinki

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The article has discussed the history and background of medical and research ethical reforms. The ethical reforms include the Nuremberg Code, the Declaration of Geneva, and the Hippocratic Oath. The reforms also include “The Belmont Report” resulting from the Tuskegee Syphilis Study. The declaration of Helsinki ties together the Nuremberg code and the declaration of Geneva. The article has also discussed the pillars of research ethics and the Research Ethics Board in detail.



History of Medical and Research Ethics

Back in the 19th century, there was no specific ethic devised for the use of human subjects in research. There was a total lack of consumer regulations, food and drug administration (FDA) and institutional review board (IRB). The history of ethics in medical sciences and research on human subjects started after 1906. IRB devised several codes of ethics and a manual in order to protect research methods.

From 1906 onwards, ethics have been designed, conducted and reviewed for safe clinical practices. The modern code of ethics started after the end of World War II in order to deal with war crimes trials in Nuremberg.

Nuremberg Code

Introduction

The Nuremberg Code was introduced in 1947 after doctors' trial in World War II. It has served as a foundation in clinical research. This code was introduced after criminal treatment of Nazi physicians and researchers with humans during research experiments was encountered. It was devised to deal with war crimes trials in Nuremberg after the end of World War II. The Nuremberg code comprised of ten basic points related to ethics in human research.

These points included:

- I. The consent of the human subject in absolute legal capacity is required.
- II. The aim of the research should be to create a positive impact on society.
- III. It should be based on any previously approved experiment in order to extend the ongoing research process.
- IV. The research procedure should not cause any physical or mental injuries or any harm to people.
- V. It should never be conducted where the risk of death of any participant or member of society is evident.
- VI. The risk associated with the research process should be correlated with the benefits associated with it for social wellbeing.
- VII. Proper arrangements and facilities should be arranged before conducting the research process in order to limit the risk of harm to subjects.
- VIII. The researchers and staff members involved in the research should be properly trained and scientifically qualified.
- IX. In case human subjects feel at risk of death or injury during an experiment, they can quit at any moment.
- X. If risks in a research process become so evident that it may cause harm to human subjects, the researchers should immediately stop the process.

Declaration of Geneva

It was formed at the physicians' second general assembly in Geneva in 1948 after World War II. It includes guidelines medical ethics of the profession.

Immediately post-World War II, the world's medical association adopted a physician oath known as the Hippocratic Oath in its first at Geneva in 1948. The conference embraced modern ethics by setting humanitarian goals. The adoption of the Hippocratic Oath was a move against medical crimes of Nazi German soldiers to harm the Jewish community.

Hippocratic Oath

The oath was set as a mandatory commitment by medical students and members related to the medical field to ensure safe humanitarian practices. This oath is widely known in Greek medical literature. Physicians swear upon many Gods that they will maintain the ethical medical standards.

The 11 tenets of this oath included:

- I. I commit to consecrate my life for humanity.
- II. I will be respectful towards my teachers and mentors.
- III. I will practice medicine profession with dignity and integrity.

- IV. My patient's health will be my priority.
- V. I will take care of my patient's secrets even after his death.
- VI. I will honor all traditions and customs of the medical profession.
- VII. I will treat my peers with compassion.
- VIII. I will not let any impediment like disease, gender, race, sexual orientation etc. to intervene between my duties as a doctor or researcher.
- IX. I will show the utmost respect for human life.
- X. I will not use my medical knowledge to violate human rights even under threats.
- XI. I will make these promises upon my honor.

The Belmont Report

This report was issued after a famous Tuskegee Syphilis Study which was conducted from 1932-1972. This report was created to codify the protection of human subjects. It was issued on 30th September 1979 during a conference of the Howard Community College in the Belmont Conference Center. It was named after the location where it was conducted.

Core Principles

The core principles of this report included:

- Respect for persons
- Beneficence
- Justice
- Informed consent
- Assessment of risks and benefits associated with the research process
- Selection of subject

Criticism

The report was devised for a positive solution of problems associated with the research process for independent decisions. The report received criticism for its one-size-fits-all recommendations. The simple solution provided by this report for ethical issues in the research process don't cater problems associated with ethnic, gender and cultural differences. It does not provide any guidance to prioritize the core principles of the report.

The Declaration of Helsinki

The world medical association adopted a new set of ethical rules and regulations regarding human experimentation in 1964. It was upgraded in 2013 and termed as a cornerstone document related to human research ethics. This declaration ties together the Nuremberg code and the declaration of Geneva. It is not a binding document and is not enforced under international law. The major points of this declaration included respect decisions of capable people, autonomy, and respect for vulnerable people.

Beneficence emphasized good deeds by researchers, non-maleficence to avoid bad acts, justice to treat each ethical issue differently and the best interest to act in the best interest of the patients.

Criticism

There was severe criticism at the Declaration of Helsinki as it had no legal regime. It is

not enforceable by law and provides no guidance on how to rank pillars of ethics. It is an autonomous framework considered as a Western Ideal. It states informed consent as the best expression of autonomy.

Pillars of Ethical Research

The ethics of research and human experimentation is based on several pillars including:

- a. **Autonomy:** It states that all patients should be treated equally without any differentiation. They should be provided necessary treatment that they need to cure their diseases and problems.
- b. **Beneficence:** The doctors and researchers should aim at doing their best in the interest of people whether they are patients or society on the whole. The risk associated with the research process should be correlated with the benefits associated with it for their social wellbeing.
- c. **Non-Maleficence:** Any kind of bad acts and deeds should be avoided in any case in order to ensure the safe treatment to patients. In case human subjects feel at risk of death or injury during an experiment, they can quit at any moment. If risks in a research process become so evident that it may cause harm to human subjects, the researchers should immediately stop the process.
- d. **Justice:** The doctors and researchers should do justice for the conduct of research. Any impediment like disease, gender, race, sexual orientation etc. to intervene between duties as a doctor or researcher should be avoided.
- e. **Acting in the best interest of patients:** A physician and doctor should act in the best interest of a patient. The consent of a human subject in absolute legal capacity is required.
- f. **Fidelity:** A researcher should be morally an ethical person and should be bound to fidelity.
- g. **Trustfulness:** A physician should be truthful to its patients in order to help them to overcome their problems and issues.
- h. **Confidentiality:** A researcher should take care of their patient's secrets even after the patient's death.

Informed consent

The common factor in all principles or pillars of ethics of research is 'Informed consent' of a patient. It includes communicating all risks associated with the research process, along with benefits. It should avoid any coercion or intimidation to obtain consent. The permission of medical research is mandatory for safe practices. There are several challenges associated with taking informed consent of patients including consent received half-heartedly, a lack of proper understanding of a medical subject and researcher, and a lack of legal documents of informed consent leading to legal issues.

Elements of Valid Consent

The core elements of a valid consent include:

- Disclosure or risks associated with a research process to the subject.
- The subject should be educated and capable to deal with lingual, emotional and intellectual problems.
- Coercion should never be practiced to obtain consent.

Health Insurance Portability and Accountability Act (HIPAA)

This act was enacted in 1996 by the United States Congress for health insurance of workers and their families. It enacted the management of electronic health records of workers. The consent measures were also improved through the written authorization process. The authorization process under this Act is waived for records of patients who have already died.

Research Ethics Board

The Research Ethics Board was formed in order to protect the rights and welfare of workers. The Board ensures that the risks associated with a research process are minimized, only acceptable risks are tolerated and informed consent is accurate. It also keeps an eye on research in an ethical manner. The Board does not enforce ethical laws but forwards it to institutions.

Types of Epidemiological Research

Epidemiological research is conducted to study distribution and the pattern of their frequency of occurrence and recurrence.

Types Epidemiological is mainly of two types:

1. Experimental or interventional are further divided into:
 - Field studies: A sample is taken from a specific area like a large region or a country.
 - Group studies: A sample is taken from a particular group of population, social or ethnic group.
2. Observational are further divided into:
 - Cohort studies: Involves the study of two groups of healthy people. One group is exposed to a particular aggravating factor and the other is not and thus analysis is made.
 - Case-control studies: In these studies, diseased cases are compared with a control group which is not sick but is comparable to the sick.
 - Ecological studies: Studies the correlation of the collected data.
 - Cross-sectional studies: Includes the collection of whole data of a study at a particular point of time and the study of the disease comparing it with other variables.
 - Monitoring and surveillance: Regular recording of the information is further needed for description and registration.
 - Description and registration of data: Describe the incidence and prevalence of a disease in a particular population.

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