

BIOETHICS



INTRODUCTION

1. What is Bioethics?
2. Prominent BioEthical Codes
3. History of Bioethics
4. The Belmont Report
5. Rules for discussing Bioethical issues

What is bioethics

- ∞ *Ethics* is a set of well-founded standards of *right and wrong* that prescribe what humans ought to do, usually in terms of rights, obligations, benefits to society, fairness, or specific virtues.
- ∞ *Ethics* is the study and development of one's ethical standards.

- ∞ Not bioethics:
 - pre-Civil War slavery laws and the old apartheid laws of present-day South Africa
 - a morally corrupt society of Nazi Germany.

- ∞ Bioethics denoted the reflective activity of applying an ethical theory or ethical principles to the domains of the biological sciences, medicine, and health care.

Ethical values

1. That are held in common by virtually all human beings.
2. That have had to be worked out by all human societies.

Sissela Bok, *Common Values* Columbia, MO: University of Missouri Press, (1995)

THREE CRITERIA OF A VALID AND WORTH ETHICAL CONCLUSION

1. if the arguments that lead to the particular conclusion are convincingly supported by reason;
2. if the arguments are conducted within a well established ethical framework;
3. if a reasonable degree of consensus exists about the validity of the conclusions, arising from a process of genuine debate.

Reiss, 1999

∞ moral philosophy has widened its scope in two important ways.

- First, intergenerational issues (Cooper and Palmer, 1995).
 - i.e our actions may affect not only those a long way away from us in space (e.g. acid rain produced in one country falling in another) but also those a long way away from us in time (e.g. increasing atmospheric carbon dioxide levels may alter the climate for generations to come).
- Second, interspecific issues (Rachels, 1991).
 - considering biotechnology and ecological questions.
 - for example, the use of new practices (such as the use of growth promoters or embryo transfer) to increase the productivity of farm animals.

Central Issues in Bioethics

- ∞ At its inception, the central issues in bioethics were research with human subjects, genetics, organ transplantation, death and dying, and reproduction.
- ∞ bioethics reflects a wide range of theoretical approaches in normative ethics, including utilitarianism, deontology, natural law, contractarianism, virtue ethics, communitarianism, pragmatism, and feminist ethics

Prominent ethical codes

- ∞ Oath of Hippocrates (4th c BC)
- ∞ Nuremberg Code (1947): human experimentation
- ∞ Declaration of Geneva (1948)
 - Issued as a development on the Oath of Hippocrates
- ∞ Declaration of Helsinki (1964) (WMA): issue of human experimentation
 - First serious attempt of medical community to regulate itself
- ∞ Belmont report (1979)
- ∞ CIOMS Guidelines (1993)
 - Council for International Organizations of Medical Sciences
 - 'International Ethical Guidelines for Biomedical Research Involving Human Subjects'
- ∞ Universal Declaration on Bioethics and Human Rights (2005)
 - UNESCO - United Nations Educational, Scientific, and Cultural Organisation

History of bioethics



Nazi Medical War Crimes (1935-45)



Nuremburg Code (1947)

- Gruesome experiments conducted by Nazi doctors in German concentration camps during WW II
- 23 doctors found guilty of research misconduct during the Nuremburg Trial
- Nuremburg Code followed as a result (10 principles)



Nuremburg Code (1947) *(continue)*

10 principles:

1. Voluntary IC is essential
2. Experiment to be for the good of society
3. Based on animal studies
4. Avoid physical & mental suffering and injury
5. Patients to be protected against injury, disability and death
6. Weigh risks against benefits
7. No expectation of death or disability
8. Human experimentation to be conducted only by scientifically qualified individuals
9. Patients can terminate involvement
10. Investigators can terminate the experiment if injury, disability or death is likely to occur

Historical abuse

Some research still conducted without IC despite strict requirement for it in the Nuremburg Code



1. Tuskegee Syphilis Experiments (1932-72)
2. Cold War Human Radiation Experiments (1944-1974)
3. Thalidomide Experience (1962)
4. Jewish Chronic Disease Hospital Study (1963)
5. Willow brook Hepatitis Study (1963-66)
6. San Antonio Contraceptive Study 1970's)

Tuskegee Syphilis Experiment 1932-1972

The New York Times
Syphilis Victims in U.S. Study
Went Untreated for 40 Years

By JEAN HELLER
 The Associated Press

WASHINGTON, July 28—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective drug was eventually discovered.

The study was conducted to determine from autopsy what the disease does to the human body.

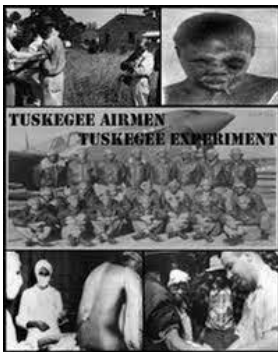
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering what ever other medical service they can give to the survivors while the study of the disease' effects continues.

Dr. Martin C. Taylor, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, is overseeing the study. He said that he was making an immediate investigation.

The experiment, called the "Tuskegee Study," began in 1932 with about 600 black men

Syphilis experiment conducted by the United States Public Health Service



- o 400 Black ♂ with syphilis
- o 200 Black ♂ without syphilis (controls)



were recruited for the research
 - without informed consent
 - "misinformed" in many cases

They were used for the experiment
 as
 untreated syphilis patients



Note:

Penicillin was found to be an effective cure in the 1940's and was widely available by 1951

Cold War Human Radiation Experiments (1944-1974)

U.S. radiation research: TRACER STUDIES

Several hundred cancer patients in the US were exposed to total-body irradiation (TBI)

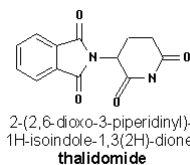
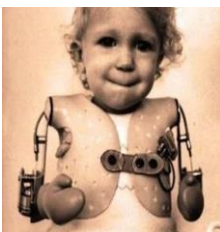
1. To study the effects of various doses of radiation
→ not for therapeutic aims
2. To study radioactive which could be as a biomarker for a biological dosimeter.

- several studies involved levels of radiation that would be unacceptable today.
- Sometimes these exposures took place without the knowledge or consent of the subjects.



Thalidomide Experience (1962)

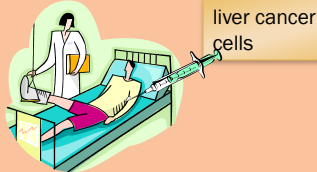
- ∞ Tranquilizer, pain-killer, etc. eased effects of morning-sickness in pregnant women.
- ∞ Responsible for over 12,000 babies in 46 countries born with phocomelia
- ∞ Not known that drugs could cross placental barriers and affect fetus
- ∞ U.S. escaped major effects as one doctor (Kelsey) refused FDA approval



Thalidomide still being used to treat leprosy and plasma cell myeloma



Jewish chronic disease



22 senile patients who were hospitalized with various chronic debilitating diseases.

The aim of study:

To determine whether healthy people rejected cancer at a faster rate than those who were already debilitated

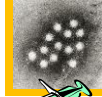
- ⌘ Patients nor their families were told so as “not to frighten them” unnecessarily
- ⌘ Researchers “defended” their views by with the assertion that they had good cause to predict the cancer cells would be rejected.

Willowbrook hepatitis

Mentally retarded children housed at the Willowbrook State School in Staten Island, New York



Hepatitis virus



The study began in 1956 and lasted for 14 years

A letter explaining the research was sent to parents whose children were on a waiting list for admission to Willowbrook.

Willowbrook State School
Office of the Director
Staten Island, New York
November 15, 1958

Dear :

We are studying the possibility of preventing epidemics of hepatitis on a new principle.

Virus is introduced and gamma globulin given later to some, so that either no attack or only a mild attack of hepatitis is expected to follow. This may give the children immunity against this disease for life. We should like to give your child this new form of prevention with the hope that it will afford protection.

Permission form is enclosed for your consideration. If you wish to have your child given the benefit of this new preventative, will you so signify by signing the form.

Sincerely,
H. H. Berman, MD
Director

The aim of the study:

- to track the development of the viral infection.
- to determine the effectiveness of gamma globulin injections as protection against hepatitis.

Declaration of Helsinki



Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects

Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and as revised 8 times by the World Medical Assembly in Tokyo, Japan in 1975, in Venice, Italy in 1983, and in Hong Kong in 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Last version is 2008. 2008 version currently under revision [2014]

“Concern for the interests of the subject must always prevail over the interests of science and society.”

National Research Act

- ∞ 1973 Kennedy Hearings “Quality of Health Care - Human Experimentation”
- ∞ 1974 National Research Act
 - Established the “National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research”
 - Required IRBs at institutions receiving HEW support for human subjects research

Congressional Legislation

National Research Act (1974)

National Commission for the Protection of
Human Subjects of Biomedical and Behavioral
Research

The Institutional Review Board (IRB)

The Belmont Report

The Belmont Report (1979)



The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research



The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

The Belmont Report

Basic Ethical Principles:

- ☞ Respect for Persons
 - Individual autonomy
 - Protection of individuals with reduced autonomy
- ☞ Beneficence
 - Maximize benefits and minimize harms
- ☞ Justice
 - Equitable distribution of research costs and benefits

T. Beauchamp and J. Childress, Principles of Biomedical Ethics, 5th edition, New York/Oxford: Oxford University Press, 2001.)

Belmont Report

- ∞ Autonomy. Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent; Be truthful, no deception
- ∞ Beneficence: The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects
- ∞ Justice : ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly (the fair distribution of costs and benefits to *potential* research participants) and equally.

CIOMS Guidelines (1982)

- Council for International Organizations of Medical Sciences Guidelines
- Intend to apply department of Health in developing countries
- Specific attention to large-scale vaccine **trials** and medications
- Includes section on compensation for injuries related to research
- Shortcomings: Lacks separate section devoted to risk-benefit ratios





Universal Declaration on Bioethics and Human

Rights

Universal framework of

Principles and Procedures for applying the principles

Article 6: Consent

Article 9: Privacy and Confidentiality

Article 11: Non-discrimination and Non-Stigmatization

Article 13: Solidarity and cooperation

Article 19: Ethics Committees

Article 21: Transnational Practices

Animal Research

- MRC Guideline Book 3: Use of animals in research and training (2004) prescribes:
 - Ethical principles involves
 - Ethical code of behaviour for researchers, educators and animal care staff
 - Human obligation/duties
 - A legal mandate for animal studies
 - Ethical review process for animal research

Animal Research (continue)



- **Replacement:** of sentient animals with non-sentient research models or systems
- **Reduction:** of numbers of animals in experiments by design strategies that facilitates the use of the smallest number that will allow valid information to be obtained
- **Refinement:** of animal sourcing to minimise or remove physical or psychological distress