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Biomedical ethics: practical impact at the hospital level

Lazare Benaroyo MD, PhD
University of Lausanne

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| le savoir vivant |

Biomedical ethics : practical impact at the hospital level

Overview

- *The Rise of Bioethics :* Research ethics and the four principles – the applied ethics model
- *The Specificity of Clinical Ethics:* Reflecting on the applied ethics model - practical wisdom and deliberative approach

Nuremberg Trial (1947)

History of Bioethics (Biomedical Ethics)

- Nuremberg Code (1947)
- Declaration of Helsinki (1964)
- Belmont Report (1979)
- Principles of Biomedical Ethics (1979)
- Universal Declaration on Bioethics and Human Rights – UNESCO (2005)

Directives for Human Experimentation

NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

The New England
Journal of Medicine

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SPECIAL ARTICLE

ETHICS AND CLINICAL RESEARCH*

HENRY K. BEECHER, M.D.†

BOSTON

HUMAN experimentation since World War II has created some difficult problems with the increasing employment of patients as experimental subjects when it must be apparent that they would not have been available if they had been truly aware of the uses that would be made of them. Evidence is at hand that many of the patients in the examples to follow never had the risk satisfactorily

Experimentation in man takes place in several areas: in self-experimentation; in patient volunteers and normal subjects; in therapy; and in the different areas of *experimentation on a patient not for his benefit but for that, at least in theory, of patients in general.* The present study is limited to this last category.

WORLD MEDICAL ASSOCIATION
DECLARATION OF HELSINKI

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; and the 41st World Medical Assembly, Hong Kong, September 1989.

O. Introduction

I. Basic Principles

II. Medical Research Combined with Clinical Care (Clinical Research)

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Assembly binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care, which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures, and the understanding of the aetiology and pathogenesis of disease.

In current medical practice, most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research, which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research, a fundamental distinction must be recognized between medical research, in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

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

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

Protection of Human Subjects

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

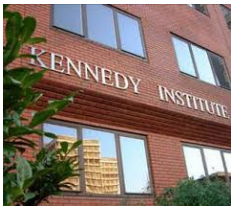
AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four day period of discussions that were held in February 1976 at the Smithsonian Institute's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of ethical problems that surround the conduct

Institutionalisation of Bioethics



IRB
INSTITUTIONAL REVIEW BOARD SERVICES

1971

Principles of Biomedical Ethics (1979)

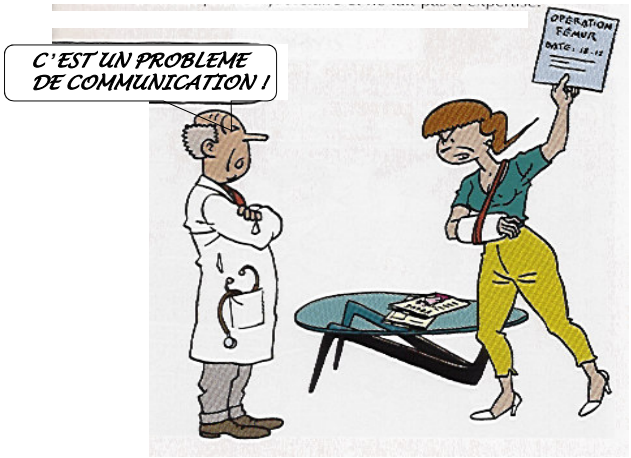
- **Autonomy**
- **Beneficience**
- **Non-maleficience**
- **Justice**

Universal Declaration on Bioethics and Human Rights (2005)

- Respect of human dignity and human rights
- Respect for autonomy of persons
- Respect for human vulnerablity and personal integrity
- Equality, justice and equity, Respect for cultural diversity and pluralism
- Solidarity and cooperation
- Social responsibility and health
- Sharing of benefits
- Protecting future generations
- Protecting the environment, the biosphere and diversity

Applied Ethics Model and Medical Progess

Risk of misunderstanding at the bedside: Reflecting on the Applied Ethics Model



Brochure Forum Santé, droits des patients

The Specificity of Clinical Ethics

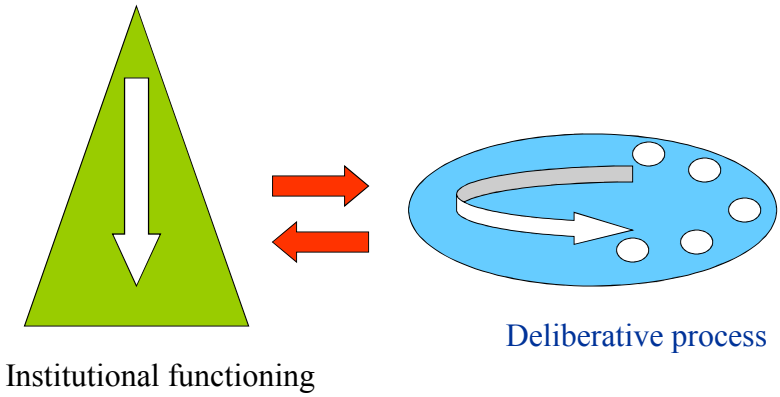
- Respect for Dignity in Context
  - Integrity
  - Autonomy
  - Vulnerability
- Confidence and Trust in Context
  - Welcoming (Phenomenology of Illness)
  - Interpretation (Hermeneutics)
  - Care plan (Dialogue and Decision Sharing)

« Medical Prudence »
« Pratical Wisdom »

Ability to identify the appropriate action in a specific context, adapted to the singularity of the situation

Ethical Deliberation and Practical Wisdom

Ethical Deliberation Process



Practical Wisdom and Ethical Skills

- **Communication skills**
- **« Turn taking »**
- **« Restating »**
- **Keep active listening**
- **Paying attention to the other**
- **Humility**
- **…**

Thank you for your attention

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