EVOLUTION DES CONCEPTS
(HISTORICAL OVERVIEW)

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MEDICAL ETHICS

• The moral conduct and principles that govern members of the medical profession
• As old as medicine or the art of healing
• Hippocrates of Cos (460-357 BC): “Father of Medicine”, introduced the scientific approach to healing by seeking physical rather than magical/religious-supernatural causes for disease
• The Hippocratic Oath: an ancient ethical guide for the medical profession
• Generally incorporated into the graduation ceremonies of medical students
• Contains many quaint/archaic elements
MAIMONIDES (1135-1204)

- Moshe (Moses) ben Maimon alias Maimonides was a medieval Spanish-Jewish Rabbi, Physician and Philosopher, who lived the second half of life in Cairo and wrote in Arabic immediately translated into Hebrew.
- Apart from *A Guide for the Perplexed* he wrote the “Physician’s Prayer”, perhaps the purest expression of medical ethics ever written.
- The “Prayer of Maimonides” encapsulates the quintessence of the Hippocratic Oath and in practice makes it redundant.
THE GENEVA CONVENTION
(1864-1949)

• A series of international treaties concluded in Geneva relative to ameliorating the effects of war on soldiers and civilians
• First adopted by 12 nations in Geneva on 12th August 1949
• History closely connected with the Red Cross founded by Henri Dunant
• Jean-Henri Dunant initiated international negotiations establishing in 1864 the Convention for care of the sick and wounded and for the neutrality of medical personnel
• A red cross on a white background – the Swiss flag in reverse – was chosen as emblem
• In 1901, Dunant was awarded the first Nobel Peace Prize
NUREMBERG TRIALS/CODE (1947)

- Post WW2 tribunal found Nazi doctors guilty of unethical experimentation on human beings
- Resulted in the Nuremberg Code
- Main thrust: voluntary informed consent of subject absolutely essential in medical research
- Marked the birth and separation of research ethics from the main body of medical ethics
- Gave rise to the Universal Declaration of Human Rights (1948)
CHECKLIST OF USA ABUSES AND MALPRACTICES

- Tuskegee syphilis experiments on poor black Americans (1932-1972)
- Radiation exposure Experiments on cancer patients, pregnant women, mentally retarded children at various sites including the Universities of Cincinnati, Columbia, Vanderbilt, the Oregon State Prison etc.
- Thalidomide experiments on pregnant women, resulting in serious birth defects
- Cancer cells experiments (1963) on elderly Jewish patients
- Willowbrook Hepatitis experiments on retarded children
- Detroit Psychosurgery Experiments on sexual psychopaths
USA REGULATORY AND GUIDANCE FRAMEWORKS

• Food and Drug Administration (FDA)
• Centers of Disease Control and Prevention (CDC)
• National Research Act (1974)
• National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974)
• (Henry Beecher 1966) - The Belmont Report (1979)
• President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1980)
• National Bioethics Advisory Commission (1994)
• Office for Human Research Protections- OHRP- (Department of Health and Human Services)
• Over 50 Regulatory and Guidance Documents
The Geneva Declaration (1948)

• Adopted by the General Assembly of the World Medical Association (WMA) in September 1948

• The content of the Declaration is general, ethical and ideological rather than specifically prescriptive

• Precursor to the Declaration of Helsinki many years later
THE WMA AND THE DECLARATION(S) OF HELSINKI

• The WMA was founded on 18 September 1948
• It is an independent confederation of medical associations of different countries around the globe
• The first General Assembly of the WMA was in Paris with representation from 27 countries
• Membership today stands at about 70
OUTLINE HISTORY OF THE DECLARATION OF HELSINKI

• The Declaration of Helsinki is a set of ethical principles, not a legal document or detailed regulations and rules
• It has undergone several revisions as follows:
  • 1964 – first version in Helsinki
  • 1975 – Kyoto, major revisions
  • 1983 – Venice, minor revisions
  • 1989 – Hong Kong, minor revisions
  • 1996 – Somerset West, major revisions
  • 2000 – Edinburgh, major revisions and continuing controversies
HELSINKI 2000 (Edinburgh)

- Virtually a completely new Declaration
- All the paragraphs (articles) of the old Declaration underwent changes
- 3 paragraphs had only one word changed
- 9 paragraphs underwent minor rewarding
- 12 paragraphs underwent substantial changes
- 8 completely new paragraphs were added
- Numbering simplified
THE ‘NEW’ HELSINKI

• Major changes and new additions include:
  • Research on identifiable human tissue or data (Article 1)
  • Transparency of finances (Articles 13 and 22)
  • Transparency of information (16, 27)
  • Use of placebo (29)
  • Post-study access to best treatment (30)
HELSINKI 5, 29 & 30

- Intractable controversy has continued because of the difficulty in accepting the full implications of the above articles of Helsinki
- Other regulatory documents have tried to handle the controversial issues in various ways
- The CIOMS guidelines purport to interpret Helsinki and to indicate how its principles can be effectively applied in developing countries
INTERNATIONAL ETHICAL GUIDELINES

- Nuremberg Code (1947)
- Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000)
- ICH Guideline on Good Clinical Practice
- Ethical Considerations in HIV Preventive Vaccine Research (UNAIDS 2000)
ETHICAL IMPERATIVES OF RESEARCH, ANYWHERE, ANY TIME

• “...considerations related to the well-being of the human subject should take precedence over the interests of science and society (Helsinki 5)
• No harm (primum non nocere)
• No exploitation
• No deceit (Informed Consent)
• No cheating (justice and fairness)
CHARACTERISTICS OF INDUSTRIALIZED WORLD MEDICAL RESEARCH

Market-oriented
Profit-driven
Susceptibility to morally blind economic forces
High degree of ad hoc rationalizations and ethical ‘justifications’
Examples:
Definition of death and personhood debate directly related to need for non-therapeutic abortion and harvest of human spare parts from the ‘dead’
Placebo-control studies debate (Helsinki/CIOMS) directly related to need for HIV/AIDS vaccine research
TRIPLE VULNERABILITY OF DEVELOPING WORLD POPULATIONS

- Vulnerability: “Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. ...they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (Paragraph 1, Commentary on CIOMS 13)
- Vulnerability: Liability to be harmed, exploited, deceived or unfairly treated
- As members of economically disadvantaged groups (Helsinki #8, CIOMS 10 & 13)
- As members of medically disadvantaged groups – high burden of disease (Helsinki #8, CIOMS 13)
- As minors (Helsinki #8, CIOMS 9 & 14)
- In Africa vulnerability equally applies to governments, institutions, scientists, researchers
NEED FOR CLEAR DISTINCTIONS AND EXPLANATIONS

• Treatment or research? Or treatment combined with research?

• Scientific knowledge or art of treatment and healing?

• Business/commerce or altruistic philanthropy?
THE INDISPENSABLE NECESSARY PRECONDITIONS OF MEDICAL RESEARCH

• Good science/scientific design

• Adequate resources/funding

• Well-informed, free and willing subjects
Distributive Justice?

- What about a well-informed contract between:
  - Sponsor
  - Investigator
  - Subject
  - ???
• MORAL INTEGRITY AND NOBLE INTENT DECLARATION

• We, the investigators, sponsors and funders of this study/research, hereby solemnly declare, on our honour, that our intentions in carrying out this research are noble and primarily motivated by the desire to acquire knowledge that could help in alleviating suffering and improving the lot of human beings, without any distinction or discrimination; that we have no overt or covert intention or any hidden agenda to harm, deceive, exploit or unfairly to treat, now or in the future, any human being or group of human beings. We solemnly pledge that, in carrying out this research, we will maintain the utmost respect for all participants and experimental subjects and objects, including any plants and animals. We will do everything within our powers to prevent knowledge gained through this research from being abused or used in ways contrary to the above solemnly declared aims and intentions.