Ethics in human medical research

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Introduction

The use of human experimentation to evaluate the efficacy of a new medicine or therapeutic procedure by its outcomes is an ancient idea in Western civilisation. It was discussed anecdotally in the writings of ancient Greek, Roman, and Arab physicians. Building on this, Hippocrates was the first physician to define the ethical principles of research in humans, which are still valid today:

- Autonomy – to respect the autonomy of the participant or of their representative
- Beneficence – to act always in the best interest of the participant
- Non-maleficence – to do as little harm as possible to the participant
- Justice – to act fairly to all

History of ethics in medical research

In the 18th century, Edward Jenner was the pioneer of vaccination against infectious diseases – however, his research did not respect the principal rights of humans in research, because these had not yet been defined. Louis Pasteur understood the need for comprehensive information generated by research in animals before exposing a human being to an experiment. Urgent patient need drove his first administration to humans in 1885.

In the 20th century, medical research experienced a quantum leap, with rapidly developing methodology, precision measurements, and quick development of new scientific disciplines. However, unethical experiments with human beings were still performed in many countries, such as the Tuskegee Syphilis Study, conducted between 1932 and 1972 by the U.S. Public Health Service, or studies in concentration camps during World War II.

Post-WWII definition of principles of ethical research in humans

Beginning with the Nuremberg trials in 1947, the principles of ethical research in human beings were defined based on the voluntary informed consent of research participants. The United Nations (UN) and World Health Organization (WHO) followed with a focus on priority of the wellbeing of the individual over the interests of the patients at large. In 1961, public opinion around the world was shocked by the 'thalidomide scandal' during which 2,000 children died and 10,000 were seriously disabled. Governmental authorities were required to take action and make regulatory arrangements to oversee the testing of new medicines. In 1964, the World Medical Association (WMA) developed and continues to review and adapt the *Declaration of Helsinki* as a guide for physicians performing research in human beings.

During the last sixty years, there has been a rapid emergence of different codes, regulations, and acts to govern ethical research in humans. As Medical experimentation moved into the public domain, decisions previously left to the conscience of individual physicians came under collective surveillance. A new balance of authority and an increase in autonomy began to be observed between researcher and research subject.

The progress of science and technology has led to continued development of ethical principles and guidelines as a variety of different new research topics continues to expand, for example assisted reproduction, stem-cell research, prenatal diagnostics, and euthanasia.

The assessment of trial applications by research ethics committees and National Competent Authorities helps to ensure the well-being, safety, and protection of persons who participate in clinical trials. It is in the best interest of all stakeholders (including patient representatives) to cooperate to improve the ethical conduct of clinical trials.

References

World Medical Association (2013). *WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects*. Online. Retrieved 28 July, 2015, from: http://www.wma.net/en/30publications/10policies/b3/