

## Ethics in neurological clinical trials

Franz Gerstenbrand

### Introduction:

Moral is the search for an inner standard. Kant's categorical imperative lays down the behaviour of the individual towards himself and towards others in an inner commitment to the categories of good and bad. According to Kant, the individual should act in a way that his actions can be regarded as a general law. This law is the basis of the relation of the individual to a higher order.

Ethics is the part of philosophy dealing with morality. The main subject of ethics is, according to most philosophers, human deeds. Ethical consciousness began with the philosophy of Socrates and Plato. It was through Aristotle that ethics became a science in itself. The main objective of ethics of Greek philosophers was the attainment of happiness. Thomas Aquinas developed the system of Christian ethics by incorporating the Greek body of thought with its aim of happiness and its observation of a God-given natural order.

In the past century, the term "moral" as a moral attitude has been replaced by the term „ethics“ as the teachings of such through the various declarations of ethical principles and the founding of various schools of thought. The various schools of thought arose from interpretations of ethical principles in various regions, such as the existentialist ethics in France, the "value ethics" of German philosophers, the

American bioethics and the Marxist ethics of the Soviet way of thinking. In Eastern Europe, theological ethics have been influential.

Ethics constitutes altruism, a sense of honour, justness, respect for others, solidarity and the ability to forgive. Whereas formal ethics is based on metaphysical principles, catholic-theological ethics focuses on the belief in a personal God. Ethical standards are dependent upon the biological surroundings, tradition and culture.

The bioethical principles, as they are practiced in the various forms of medical conduct and physician's obligations as well as medical research involving human subjects, have developed from occidental culture with its roots in Greek philosophy and in the teachings of Christian philosophers such as Saint Augustine and Thomas Aquinas. They have been forced to adapt to the suddenly materialising demands of modern technology under strict observance of the basic principles of human rights.

Ethical rules of the Buddhist way of life with its basic renunciation of European progressiveness and the ethics of the Confucian way of living with its appreciation for the well-being of the community as opposed to the well-being of the individual, cannot readily be brought into line with the doctrine of Western bioethics. Currently, the principles of "occidental bioethics" demand the adaptation of the ethical principles of Buddhism and Confucianism without question. Modern scientific research is quite impossible without „Western ethical terminology“. For the benefit of mankind and their lives in general as well as to sustain and prolong the life of the individual, the acceptance of occidental bioethical principles is demanded of other cultures and spheres.

The basic principles of biomedical ethics have been developed in recent decades in order to regulate medical ethical behaviour. These principles were laid down in the Helsinki Declaration of 1964 by the World Medical Association and determine „medical conduct in the treatment of the sick person and research on human beings for the development of better medical procedures“. The basic principles of the Helsinki Declaration were set down in detail. Amendments were effected in the process of several revisions, the last one being in Edinburgh in October 2000. The use of new medications and the study of their effects on the ill is adapted in the rules of “good clinical practice – European Union” (EU-GCP) and has been regulated in an extensive paper since 1 July 1991. The practical application of ethical demands on research projects involving human subjects has been assigned to the responsibility of ethics committees.

#### Ethics Committee of the Medical Faculty of the University of Innsbruck:

As a consequence of increasing experience in the procedures of an ethics committee, definite regulations have emerged, which are applied in practice on a national as well as an international level. Whereas ethics committees were only established at individual universities in the early eighties, today every institution which performs studies involving new medications on human subjects or works with new diagnostic and therapeutic devices or novel operative treatment procedures is obliged to present its research program or project to the competent ethics committee by national and international laws. The following is to provide an overview of the work of the Ethics Committee of the Medical Faculty of the University of Innsbruck.

The committee was founded by faculty decision on 30 January 1980 and constituted on 18 June 1980 with the goal of evaluating medical experiments. The commission

first comprised a chairman and his representative, six professors, three representatives of the interns and three students. Initially, a Peer Committee was established, made up of two lawyers, one being the President of the Provincial High Court of Innsbruck and an attorney, the President of the Tyrolean Medical Council and the Head of the Institute of Moral Theology and Sociology. In 1994 the commission was expanded to include eight professors, four representatives of the non-professorial teaching staff and four students. The group of advisory members was increased to comprise seven members by including the director of the university hospital pharmacy, a patient representative and an insurance expert. In choosing the medical representatives from the body of professors and medical specialists from the faculty staff, aside from the main clinical fields, the head of the Institute of Biostatistics and of Forensic Medicine as well as representatives from the field of pharmacology were included. Representatives of non-medical and non-faculty fields were admitted to the advisory body.

The Ethics Commission of the Medical Faculty of the University of Innsbruck currently comprises 17 members from the medical field. From the non-medical field, the commission has eight members including a patient representative, a representative of the nursing staff, the technical staff, and of the hospital pharmacy, as well as two lawyers, the representative of the Tyrolean Medical Council and a representative of the Institute of Moral Theology.

The work of the Ethics Commission of the Medical Faculty of Innsbruck is regulated according to statutes, which were amended with the experiences of the Commission in its work and laid down in a final version in 1994.

The work of the Commission increased drastically between 1980 and 1999. In 1985, five sessions were held. The number of sessions doubled in the year 1999. From 16 submissions to the Commission in 1985 and 72 in 1995, the number of projects processed in 1999 rose to 176. The duration of each session increased from 1 ¼ hours in 1985 to 5 hours.

In the 20 years of the activities of Ethics Committee Innsbruck, more than one thousand applications from all areas of medicine have been processed and 175 sessions have been held. Each application undergoes a pre-workup at the Ethics Institute of Innsbruck and is then discussed with the competent director and his co-workers. The fundament of the project (pharmacological, instrumental, etc.) is discussed. The relevant international literature is requested as a reference, and the planned statistical analysis are reviewed. Special attention is paid to the patient information forms and consent forms. The insurance contracts to be concluded for the patients subject to the study are scrutinised as to their usability. The director of the project presents his program at the following session, explains details and answers questions posed by the Commission. In the absence of the applicant, the Commission then discusses the project presented and poses additional questions.

The project is evaluated and a positive or a negative opinion is given after extensive discussion. Should doubt be raised in connection with the entire project or parts thereof, a revision of the project can be requested.

A special institute is working for the Ethics Commission headed by Prof. Dr. Holger Baumgartner, and three co-workers. The Ethics Commission of Innsbruck is

responsible for all hospitals of the Province of Tyrol, meaning that projects of the various regional hospitals are processed centrally.

Summary:

The biomedical principles govern every form of medical intervention in patients and volunteers. These principles are laid down in the Helsinki Declaration and its revision, the most recent being from Edinburgh in October 2000, and in the EU-GCP (Good Clinical Practice – European Union). All research work involving human subjects is regulated by law and follows internationally recognised bioethical principles. Every research project concerning the application of new medications, new devices, new treatment methods and new methods of diagnosis are to be submitted to the Ethics Committee for evaluation.

The judgement of the competent Ethics Committee is based on the analysis of the project submitted. The decision of the Ethics Committee is not binding by law.

However, regulatory authorities require approval of ethical committees, and today editors of renown scientific journals refuse publication of the results of a project if the evaluation of the competent Ethics Committee is not submitted. The export of "risk" from Western countries represents an additional ethical problem.

Ethics constitutes „unlimited responsibility for everything living“. This statement by Albert Schweitzer should serve as an admonition.

1. Augustinus, Bekenntnisse und Gottesstaat, Alfred Kröner , Stuttgart, 1951.

2. Baumgartner H., Gerstenbrand F. Neuroethics – A New Approach in Neurological Services. In: Progress in Neurology, Vol II; Ed.: Bergen D.C., Chopra J.S., Silberberg D., Barac B., Lechner H. , Livingstone, Wien, 281-284, 1999.

3. Baumgartner H., Allocation of Resources in Neurology: East and West – a Challenge to European Solidarity, EFNS-Newsletter, 3 ,1, (2000).

4. Council of Europe, Committee of Ministers. " Explanatory report to the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine"; Strasbourg, January 1997.

5. Council of Europe, Directorate of Legal Affairs. "Convention for the protection of human rights an dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine", Strasbourg, November 1996.

6. De Wachter, M. A. M.:The European Convention on Bioethics, Hastings Centre Report 27, 1 , 13-23, 1997.

7. European Agency for the Evaluation of Medicinal products, Human Medicines Evaluation Unit "Note for guidance on Good Clinical Practice (CPMP/ICH/135/95)", ICH Harmonised Tripartite Guideline; January 1997.

8. Good Clinical Practice for trials on medicinal products in the European Community 11.07.1990 (III/3976/88-EN, final);GCP.

9. Kant I.: Zur Kritik der reinen Vernunft, Philipp Reclam jun., Leipzig, 1966.

10. Wrede R.:Worte des Konfuzius, Aus dem Buch der Gespräche, Paul Hugendübel, München, 1942.



**MYNISTRY OF HEALTH CARE OF THE REPUBLIC OF BELARUS  
VITEBSK STATE MEDICAL UNIVERSITY  
BELARUSSIAN SCIENTIFIC SOCIETY OF NEUROLOGISTS**

**CLINICAL NEUROLOGY**  
*International EFNS Teaching Course*

**Vitebsk**

**June 6 - 7, 2002**