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ETHICS IN NEUROLOGY: THE ETHICAL ASPECTS IN CLINICAL TRIALS

Ethical consciousness begins with the philosophy of Socrates and Plato; Aristotle developed it into a science. Attainment of happiness was the main objective of Greek ethics. Thomas Aquinas incorporated Christian ethics with a god-given natural order. Kant's categorical imperative demands "Always act in such a way that the maxim of your action can be willed as a universal law of humanity". In the last century various European schools created different interpretations of ethical principles, the existentialistic ethics, the value ethics, bioethics, Marxist ethics, etc. Western bioethical principles do not include the ethical rules of Buddhism and of Confucianism, which stress the well being of the community, as well as the Islamic and Mosaic religious laws.

So called Western ethical rules have to follow the demands of modern technology strictly observing the basic principles of human rights. Ethical guidelines for all of mankind have to respect biological surroundings, traditions and cultures, as well as national and regional laws. A global ethics law has to wait for useful elaboration.

The bioethical principles influence the obligations of physicians as well as medical research involving human subjects. The basic principles of biomedical ethics have been developed in recent decades in order to regulate medical ethical behaviour. The World Medical Association laid down these principles in the Helsinki Declaration 1964. The clinical trials involving human beings have to follow the rules of "Good Clinical Practice", the IHC-GCP.

The guidelines for clinical trials in neurology have to be the basis of every project. A specific protocol has to be submitted to an Independent Ethics Committee (IEC), balancing the promising but unproven benefit of something new with its associated risks against established benefits and risks of something known, the risk of the individual who enters the study. Ethics Committee have to decide if all the rights of patients included in the Helsinki Declaration are observed in a practical way. It must be checked whether there is an adequate insurance. Every person in the study must have the possibility to leave the program. With these actions the Ethics Committee takes over the responsibility of the acting physician with the right of a consequent control including a revision.

A main ethical challenge in the neurological practice is continous education in neuroethics a well as in pregraduate as in postgraduate teaching. It is surprising that in recent time many neurologists have only a rough knowledge of clinical trials its connection with Helsinki Convention and its the rules of ICH-GCP

DANUBE CLINICAL NEUROLOGY TRAINING COURSE

Multiple Sclerosis, Headache and Parkinson's disease

27–28 May, 2004 Szeged, Hungary

Organized by:

International Danube Neurology Association of Central and East Europe and Department of Neurology, University of Szeged, Hungary

PROGRAM and ABSTRACTS

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