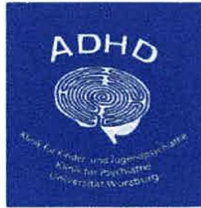


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**Special Symposium
of the
International Society for Amelioration of Quality of Life
in severest neurological conditions**



**in connection with the
39th International Danube Symposium
for Neurological Sciences and Continuing Education**
in conjunction with the
1st International Congress on ADHS
from childhood to adult disease



**THE RIGHT TO AND THE ETHICAL OBLIGATION FOR CARE
IN SEVEREST AND HOPELESS CONDITIONS**

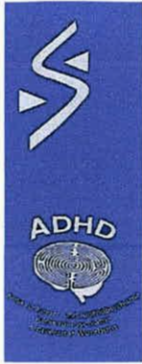
F. Gerstenbrand, B. Hess, C. Hess

Ethical principles are the main obligations of every physician. In the individual responsibility for his patient the treating physician has to follow the medical guidelines of the Declarations of Helsinki and Paris as well as the Hippocratic principles. The physician's ethical obligation is to follow all the directives allowing him to present himself as well trained and fully educated in modern medicine, providing the ability and his willingness to integrate individual clinical expertise and the best external evidence following "true evidence based medicine". The physician has to be free from economic considerations. The ethical obligations have to direct the physician's acting under his personal moral responsibility with the acceptance of medico-legal instances under domestic law. Every physician has to follow a consequent way in diagnosis and treatment. He has to know that each of his decisions is carried out on his personal responsibility. Best available medical care is a granted right for the patient. As a demand to the treating physician, the patient himself, or in case of a state being unable to consent, the patient's relatives or the solicitor have to be informed in all details. Medical care for patients in severest and hopeless conditions requests special acceptance for somatic or mental suffering.

Patients in severest conditions like apallic patients, patients with dementia after a progressive neurodegenerative disease and after a severe local or diffused brain damage, all of them with loss of consciousness or patients with a severely diminished brain functional level, including patients with the so-called minimally conscious state, need special medical care with a supporting treatment program. Patients in a Locked-in syndrome as well as patients with a progressive disease of the motoric system, including amyotrophic lateral sclerosis, all in a helpless state, but with contact to surroundings, need consequent special care.

The instructions for the treating physicians are given by the Hippocratic principles, with the obligation to heal and not to harm, to treat the patient but not to over-treat him and to free him from pain. The regulation for patients with severest neurological conditions is the continuation of the basic medication and a fully equipped nursing care, following a long-term activating program. Neurological patients with a hopeless prognosis have to be treated in a special nursing care unit. As the third neurological system, the new movement for "Amelioration of Quality of Life" worked out directions for special institutions.

The main point in care of neurological patients with a hopeless diagnosis is the non-negotiable demand for absence of a discussion about end-of-life-decisions as well as plans for diminishing vital support or finishing of necessary medication. Economic considerations are not acceptable. These patients with hopeless prognosis have to be treated with dignity and with the use of all modern possibilities. An "End of life decision" using interruption of nutrition and liquid is ethically unacceptable. An act of withdrawal of nutrition and liquid would be accused in Central European countries as active euthanasia. The renunciation of maximal therapy with all possibilities of modern medicine can be accepted in accordance with the Hippocratic principles.



**39th International Danube Symposium
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**1st International Congress on ADHS
from childhood to adult disease**

2 - 5 June 2007 Würzburg Germany



FINAL PROGRAM

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2007



39th International Danube Symposium
for Neurological Sciences and Continuing Education
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from childhood to adult disease



The right to and the ethical obligation for care in severest neurological conditions

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**Special Symposium of the International Society
for Amelioration of Quality of Life in Chronic
Neurological Conditions**

Würzburg, Germany, June 2 - 5, 2007

Definition of severe neurological conditions

- Progressive brain damages
 - Creutzfeldt-Jakob Disease
 - Neuro-degenerative diseases (Huntington Disease, Parkinson Disease, ALS, etc.)
 - Dementia - end state, different origin
 - End state of Multiple sclerosis
- Defect states after severe acute brain damages
 - Apallic syndrome (hypoxic, traumatic, etc.)
 - Locked-In syndrome
 - Minimally Conscious State (different origin)
- Defect states after brain damage without sufficient neuro-rehabilitation program
 - Severe traumatic brain lesions
 - Infectious brain lesions (viral, bacterial, parasitic)
 - Cerebro-vascular diseases

Apallic syndrome, pat. G.B., 36^a traumatic brain injury, 1975



No modern treatment

Irreversible tertiary lesions, complications

Exitus after 14 months

Apallic syndrome, pat. E.S., 19^a traumatic brain injury, 1992



Modern treatment program in special center for apallic syndrome patients

No tertiary lesions, minimal complications

Remission after 5 months to minimal defect state

Terri Schiavo (USA)

Apallic syndrome/vegetative state, remission state II-III, contact with the surrounding



- Emotional reaction
- Optic fixation to her mother
- Turn towards
- Contact reaction
- Well-balanced body state
- Vegetative system regulated
- No artificial respiration
- Nutrition by PEG

End of life decision by court, withdrawal of liquid and nutrition.

Project: TV production. Book of „widower“ as basis of script

Apallic syndrome – sindrome apallico (traumatic), Salvatore C., 38^a (Italy)



- Traumatic brain injury, August 2003
- Late onset of remission
- Defect state with neurological and orthopedic deficits.

During remission noises of the surrounding could be heard. Pains and physical contact were registered, patient felt deep desperation.

Patient L.I.S , 45^a, female



Post traumatic etiology
Defect state

Apallic syndrome, end state, Alzheimer's Disease



Patient A.S., 67a
Course over 28
months
Exitus heart
infarction

Definition of ethics

- **Ethics:** Part of philosophy dealing with morality
- **Moral** is search for an inner standard
- **Kant's categorical imperative:**
The individual shall always act in a way that this action can be regarded as general law

Ethics

- Altruism
- Sense of Honour
- Fairness
- Respect for others
- Solidarity
- Ability to forgive

Occidental Ethics

Western ethical thinking, "Christian Ethics"

- Founders:
 - Socrates, Plato, Aristoteles
Greek philosophy: moral virtue
values are natural rather than conventional ethics as science
 - Saint Augustinus, Thomas Aquinas
Incorporation of Greek ethics
Attainment of happiness
God given natural order
 - Immanuel Kant
Categorical imperative: the individual shall act in a way, that his action can be regarded as general law
 - Modern ethics
Different schools:
Value ethics, existentialistic ethics, American bioethics, Marxian ethics, theological ethics

Bioethical principles

Medical conduct, physicians obligations
(Belmont Criteria, 1979)

- Autonomy of the patient
- Beneficence
- Non-maleficency
- Justice
- Trust

Hippocratic oath

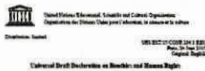
Obligation to heal
 Not do anything to harm the patient
 No continuation of therapy in untreatable disease
 No therapy in advanced physical and mental destruction
 No continuation of life prolongation for hours or days
 No prolongation of suffering during dying
 Not to tell anyone the details of patients
 No admitting of lethal poison, even as advice

Will to respect the teacher like own parents, sharing one's life support with teacher and his successors, treated as own brothers
 Medical teaching to own sons and the sons of the teacher or to pupils bound on physicians rules and oath

World Medical Association, Helsinki Declaration, 1964 Medical Research Involving Human Subjects Ethical Principles

- Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects
- In medical research on human subject, considerations related to the well-being of the human subject should take precedence over the interest of science and society
- International Code of Medical Ethics : A physician shall act only in patient interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient
- Ethical Principles to provide guidance for physicians and other participants in medical research involving human subjects including identifiable material or identifiable data

UNESCO-Declaration on Bioethics and Human Rights Paris, 24.6.2005



UNESCO
 • SHS: Social and Human Sciences
 • BIOETHICS

UNESCO Bioethics Declaration on Human Rights Paris, September 2005 Aims – Article 2

- Universal framework of principles and procedures to guide States in bioethics
- to guide the actions from individuals as well as communities, public and private
- to promote respect for human dignity and protect human rights
- to recognize the importance of freedom in scientific research
- to foster multidisciplinary and pluralistic dialogue
- to promote equitable access to medical, scientific and technological development
- to safeguard and promote the interest of the present and future generations
- to underline the importance of biodiversity

UNESCO Bioethics Declaration on Human Rights Paris, September 2005

Scope:
 Ethical issues related to medicine, life sciences and associated technologies as applied to human beings

Focused to person's identity:

- biological
- psychological
- social
- cultural and
- spiritual dimensions

UNESCO Bioethics Declaration on Human Rights Paris, September 2005

- Art. 3: Human dignity and human rights
 – Fundamental freedoms: fully respect
- Art. 4: Benefit and harm
 – Applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients including research participants
- Art. 5: Autonomy and individual responsibility
 – Persons to make decisions while taking responsibility for those decisions and respecting the autonomy of others
- Art. 6: Consent

Informed consent generally

... is necessary for each human being (patient and healthy volunteer) involved in:

- any preventive, diagnostic and/or therapeutic medical intervention
- scientific research (basic research, clinical studies) according to
 - ICH-GCP (Good Clinical Practice)
 - GMP (Good manufacturing practice)
 - Clinical trial for new diagnostic and therapeutic methods

Informed consent

... is based on:

- Domestic and international law in accordance with human rights law
- Declaration of Helsinki, 1964 (with amendments)
- Declaration on Bioethics and Human Rights, Paris, 2005

Declaration of Paris, 2005 Article 6a - Consent

Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.

The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

Declaration of Paris, 2005

Article 7

Persons **without** the capacity to consent I

In accordance with domestic law, special protection shall be given to persons who do not have the capacity to consent:

- a) authorization for **research and medical practice** should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent.

Declaration of Paris, 2005

Article 7

Persons **without** the capacity to consent II

- b) **Research** should only be carried out for the patient's direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent.

Declaration of Paris 2005

Article 7

Persons **without** the capacity to consent III

- b) **Research** which does not have potential to direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Informed consent

patient incapable included in a clinical trial according to Declaration of Paris, 2005

- If the subject is incapable of giving personal consent (e.g. unconsciousness), the inclusion of such patients may be acceptable if
 - The Independent Ethics Committee (IEC) is in principle in agreement
 - Participation will promote the welfare and interest of the subject
 - If possible, written consent of a legally valid representative
- Consent in a non-therapeutic study the legal representative always has to be informed
- Any information becoming available during the trial which might be of relevance for the subject must be made known to the legal representative

Patient-Doctor Relationship

- Expectation of personal attention
- Trust
- Individualized treatment
- Best available and best care
- Best benefit to risk/ratio

Rights and responsibilities Physician and patient

- The treating physician has the individual responsibility for his patient. Highest level of his education and training is essential and necessary.
- The treating physician is guided by ethical principles, medical guidelines, declaration, domestic and international law and human rights law.
- The personal responsibility of the physician to his patient can't be replaced.
- Patient's right is to accept or to refuse the recommendation of a treatment program.
- Patient's right is to interrupt a running treatment program
- The physician's obligation is to inform the patient about the danger for his health to refuse or to interrupt a treatment program.

Quality of medical care

Three factors will determine the quality of medical care:

- individual clinical expertise
- Individual clinical experience
- scientific evidence

Best available medical care & quality of scientific evidence - 1

Providing the best possible medical care of an individual patient depends on the doctor's

- ability and willingness of the responsible physician to
 - integrate individual clinical expertise
 - and the best external evidence
 - (true evidence-based medicine)

Best available medical care & quality of scientific evidence – 2

Sound scientific evidence is the basis for modern medicine

- prevention
- diagnosis
- treatment
- rehabilitation
- but also for regulatory approval

Best available medical care & quality of scientific evidence – 3

- The practice of contemporary medicine depends crucially on the quality of scientific evidence
- Experience based medicine has to be taken in consideration even without EBM background

Best available medical care & quality of scientific evidence – 4

Scientific evidence

- is never static
- is subject to constant change and adjustment (new facts)
- can be flawed in many different ways
- can never be perfect

Evidenced Based Medicine Ethical based position

- a cultural and methodological approach to clinical practice helping to make decisions based on clinical expertise and an intimate knowledge of the individual patient's situations, beliefs, and priorities
- considered to be the scientifically grounded art of medicine
- it deemphasizes intuition and unsystematic clinical experience as grounds for medical decision-making

Factors influencing European medicine

- Progress in basic research
- Progress in research of biology and genetics
- Progress in clinical medicine
- Increasing influence of ethical rules in clinical research
- Forced use of ICH-GCP in clinical trials
- Scarcity of resources
- Demographic developments
- Political changes in Europe
- Process of globalisation

- Trend to a predominance of Evidence Based Medicine
- Trend to the use of Cochrane library
- Loss of Experienced Based Medicine
- Loss of Traditional Medicine

Summarizing I

- Every human being has the right to live (Paris Declaration, 2005).
- Every human being has the right to most modern medical treatment and best nursing care (Paris Declaration, 2005).
- A patient has to be cared according to the base right, basic human rights and the medical principles.

Summarizing II

- Economic consideration are not acceptable in treatment and life decision (Hippocratic principles and Universal Declaration on Human Rights (December 10th, 1948).
- According to Hippocratic principles patients have to be treated in dignity but not to be "over-treated" by all modern possibilities.
- In severe defect states of neurological patients without hope of any improvement in upcoming severe complications maximal therapy can be renounced.

Summarizing III

- The renunciation of maximal therapy is acceptable according to the Hippocratic principles.
- According to medical rules a decision for end of life also by legal institutions (Supreme court, etc.) is not acceptable in Austria.
- Such decision cannot to be realized by a physician, even though legal (danger to be accused for active euthanasia).

When medical uncertainty leads to moral uncertainty, it seems preferable, albeit harder, to confront the dual ambiguities than to bury them under either statistical criteria or unrelenting moral certitude.

Rhoden NK, 1994

Wenn medizinische Unsicherheit zu moralischer Unsicherheit führt, ist es vorzuziehen, obgleich schwerer, die Widersprüche gegenüberzustellen als sie entweder unter statistischen Kriterien oder einer unverminderten moralischen Gewissheit zu verbergen.

Rhoden NK, 1994

Successful rehabilitation after AS/VS, traumatic, Fred A., 40^a (A)



- Car accident 1995, 30 years
- Apallic syndrome, full stage, treatment in special center over 6 months
- Treatment in special neuro-rehabilitation center for apallic patients, 2 years
- Continued rehabilitation as outpatient, stepwise improvement
- Full integration in family, father of a 3 years old girl
- Only partially handicapped
- Strict aim to be integrated in a normal professional life