

### Hippocratic Principles , Helsinki Declaration, Paris Declaration Basic obligations in Neurorehabilitation

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### Definition of Ethics

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

### Ethics

- Altruism
- Sense of Honour
- Justness
- 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
  - Saint Augustinus, Thomas Aquinas  
Christian basic ethics based on the  
10 Commandments to Moses  
Incorporation of Greek ethics  
Attainment of happiness  
God given natural order, State of God
  - Immanuel Kant  
Categorical imperative: the individual shall act in a way, that this action can be regarded as general law
  - Modern western ethics  
Different schools:
    - Value ethics, existentialistic ethics, American bioethics, Marxian ethics, theological ethics

### "Non Western" Ethics

- Ethical rules in Buddhism  
end of rebirth, Nirvana
- Ethical rules in Confucianism  
appreciation of well being of the community  
above the well being of the individual
- Ethical rules in Mosaic religion
- Ethical rules in Islamic religion
- Ethical rules of natural religions  
African religious communities, Massai civilization, Shamanism

### 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 by physicians rules and oath

## Hippocratic Oath

### Commitments for the modern physician

- The curative demand is the obligation of the physician, recommendations have to be given to the benefit of the patient, according to the best knowledge and possibilities, damages and unjustness of the patient have to be avoided.
- Beside the curative element the physician has to minimize harm.
- It is the prohibition for the physician to apply lethal poison as well as to give recommendation in such a direction.
- A prolongation of suffering of dying has to be failed.
- The decision about end of life is not under the responsibility of the physician.
- The basic obligation of the physician is to preserve life.

## World Medical Association, Helsinki Declaration, 1964 Different Amendments, Edinburgh, 2003 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 Bioethics Declaration on Human Rights Paris, September 2005 Aims – Article 2

- Universal framework of principles and procedures to guide states in bioethics
- to guide 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 emphasize the importance of biodiversity

## 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)
- For implementation of every new diagnostic and therapeutic methods clinical trials are indispensable and required

## Informed consent

... is based on:

- Domestic and international law in conformity 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.

## Informed consent patient able to consent

- Content of written information
  - Aims
  - Expected benefits for the subjects and/or others
  - References treatment/placebo
  - Risks and inconveniences
  - If applicable, an explanation of alternative standard medical therapy
- Consent must be documented by either the subject's dated signature or by the signature of an independent witness
- The signature confirms that the consent is based on information, that has been understood and that the subject has voluntarily chosen to participate the treatment program

## Declaration of Paris, 2005 Article 7

Persons without the capacity to consent – I  
concerns medical practice and research

- 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.

In accordance with domestic law, special protections is to be given to persons who do not have the capacity to consent.

## Declaration of Paris, 2005

Article 7

Persons without the capacity to consent - II

- b) Research should only be carried out for his or her 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.

Research which does not have potential 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 to consent 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
- For 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



## **Patients unable to consent**

Decision making on behalf of patients

- Presumed consent in emergency situations
- Proxy consent by an authorised person (legal representative)
- Living will
  - Advanced directives
  - Previously expressed wishes

## **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 responsible physician's

- ability and willingness 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
- Experienced based medicine has to be taken in consideration even without EBM background

### **Summarizing I**

- Every human being has the right to live (Paris Declaration, 2005).
- Every human being has the right to most modern medical treatment, best nursing care and the right to take part in rehabilitation programs.
- A patient has to be cared for according to the base right, basic human rights and the medical principles.
- Every neurological patient has the right of an individual neurorehabilitation program adjusted to the special condition.

### **Summarizing II**

- Economic consideration is not acceptable in treatment and life decision (Hippocratic principles and Universal Declaration on Human Rights (December 10<sup>th</sup>, 1948 ).
- According to Hippocratic principles patients have to be treated in dignity but not to be "over-treated" by all modern possibilities.
- The individual neuro-rehabilitation program has to be continued till rehabilitation potentials are exhausted.



Austrian Society for  
Aerospace Medicine  
Life Sciences in  
Space

## Buchpräsentation

### “Positionierung der österreichischen Forschung in Weltraummedizin und Space Life Science”

F. Gerstenbrand

23. September 2008  
Waidhofen an der Thaya

## ASM

Austrian Society for Aerospace Medicine  
Life Sciences in Space

- Gegründet nach dem erfolgreichen AUSTROMIR-Projekt 1991
- Aufgaben:
  - Auswertung der Forschungsergebnisse des AUSTROMIR-Projektes
  - Fortsetzung der Zusammenarbeit mit der russischen Raumfahrtforschung (IBMP, Moskau)
  - Durchführung eigener Forschungsprojekte in Kreislauf, Muskeltätigkeit, vegetative Reaktionen, Raumfahrt-Neurologie, Strahlenbiologie, etc.
- Auswertung von Spin-off-Ergebnissen

## Inhalt des Buches

- Detailberichte über
  - Biophysik und Biotechnologie
  - Strahlenphysik
  - Physiologie und Medizin
  - Klinische und technologische Umsetzungen
  - Raumfahrtneurologie

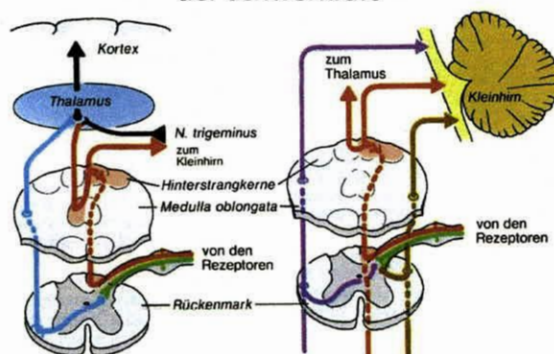
## Raumfahrtneurologie

- Forschung über den Einfluss des propriozeptiven Systems bei Ausfall der Schwerkraft
  - echte Schwerelosigkeit
  - simulierte Schwerelosigkeit (Labor)
- Erforschung des Bedrest-Syndroms
- Verwendung der Forschungsergebnisse in der Neurorehabilitation

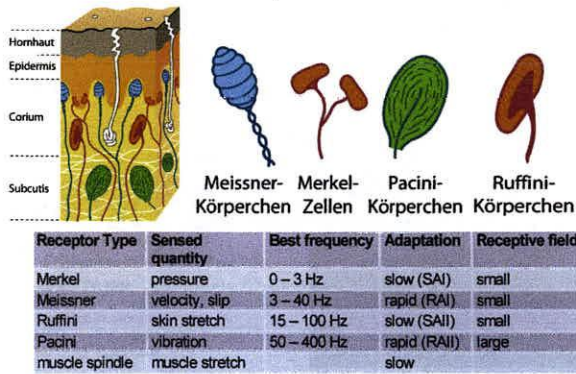
## Folgen des Ausfalls der Schwerkraftrezeptoren in der Schwerelosigkeit (echt, simuliert)

- Beeinträchtigung des propriozeptiven Systems insgesamt
- Beeinträchtigung der Motorik und aller Bewegungsabläufe
- Störung der aufrechten Haltung
- Störung der höchsten Hirnleistungen (Koordination, Assoziation, Kritik, emotionelle Kontrolle)

## Das propriozeptive System, verantwortlich für die Verarbeitung der Schwerkraft



## Mechanorezeptoren der Haut



## Spin-Off-Effekte

- Verwendung in der Rehabilitation von Bewegungsstörungen und Motorik
- Kreislauftraining und Ernährungswissenschaften
- Biotechnologie und Laboratoriumsmethoden
- Strahlenrisiko und Prävention
- Neurorehabilitation

## Störung des propriozeptiven Systems

- Im Bereich der Rezeptoren und des Leitungssystems (Polyneuropathie, Rückenmarksläsionen, Erkrankungen des Systems – funiculäre Myelose, etc.)
- Schäden in den Schaltzentren (Hirnstamm, Thalamus – traumatisch, entzündlich, etc.)
- Schäden in den kortikalen Regionen (lokal, diffus – traumatisch, vaskulär-zirkulatorisch, etc.)

## Verwendung von Stimulationseffekten in der Neurorehabilitation

- Bei neurologischen Erkrankungen
  - Parkinson-Syndrom
  - Rückenmarksläsionen
  - Zustand nach Schlaganfall und Hirnverletzung
  - Hirnabbau – Demenz
  - Bedrest-Syndrom bei Koma, apallisches Syndrom, kardiologischen Erkrankungen, Langzeiterkrankungen
- In der Geriatrie
- Im Wellness-Bereich



**ASM** Austrian Society for Aerospace Medicine /  
Life Sciences in Space

Positionierung der  
österreichischen Forschung  
in Weltraummedizin und  
Space Life Sciences

facultas 