

## Ethics and Medical Laws in Neurorehabilitation

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## Definition of ethics

- **Ethics:** Part of philosophy dealing with morality
- **Moral** is search for an inner standard
- **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  
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 this action can be regarded as general law
- Modern ethics  
Different schools:
  - Value ethics, existentialistic ethics, American bioethics, Marxian ethics, theological ethics

## "Non Western Ethics" partly religious fixed

- 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 Mosalic religion
- Ethical rules in Islamic religion
- Ethical rules in natural religions  
Massai religion, African religious communities,  
Shamanism, etc.

## 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 physician's rules and oath

## Hippocratic oath Obligation for modern physicians

- Curative element: Main demand of physician is to handle everything for the benefit of a patient after best knowledge and best ability, to keep away damages, injustice and risks.
- Obligation to minimize suffering of a patient
- Strict prohibition to apply lethal poison or to give advise to use deadly poison
- A prolongation of suffering has to be prevented
- The basic obligation of a physician is to preserve life.
- The decision about life and death of a patient is not in the hands of a physician

## 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's 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 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

- 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 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 expressed 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 6b – Consent I clinical trial**

Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include the modalities for withdrawal of consent.

## **Declaration of Paris, 2005**

### **Article 6b – Consent II clinical trial**

The consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice.

Exceptions to this principle should be made only in accordance with ethical and legal standards, States adopted by, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

## **Patients unable to consent**

### **related to Paris Declaration 2005, Article 7 Different responsibilities**

- In clinical practice
  - the treating and responsible physician
  - often the true protector of the incapacitated patient
- In research
  - Conflicting interest of responsible physician in the clinical trial with his treatment obligation
  - Protecting the research subject
  - Advancing medical knowledge

**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

**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

**Ethical Obligations**  
**Special conditions**

- Primarily in neurology and psychiatry ethical rules have to be accepted
- Bioethical guidelines fully to transfer and to apply in neurology
- Informed consent in all details to transfer in daily practice and research
- Special guidelines and medico-legal laws for patients unable to consent in daily practice and research
- Special protection of patients with neurological and psychiatric diseases
- Consideration of patient's capability following informed consent

**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.

**Decisions to make during the treatment of**  
**patients with neurological states**

- Decision to start rehabilitation program or to refuse
- Start of rehabilitation program as soon as possible
- Decision to continue or to reduce special medical treatment
- Decision to continue the active rehabilitation program in a special center or to transfer the patient to a nursing home with long term activating program, especially at home care

### 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 to 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 Ethically 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

### Evidence Based Medicine (EBM) Definition I

- Evidence based medicine involves integrating clinical expertise with the best available clinical evidence derived from systematic research.
- Individual clinical expertise is the proficiency and judgment that each clinician acquires through clinical experience and practice.

SE Straus, DL Sackett, 1998

### Evidence Based Medicine (EBM) Definition II

The practice of EBM is a process of lifelong self directed learning in which caring for patients, creates a need for clinically important information about diagnoses, prognoses, treatment and other healthcare issues.

SE Straus, DL Sackett, 1998

### Evidence Based Medicine (EBM) Definition III

- Best available clinical evidence is clinically relevant research which may be from the basic sciences of medicine, but especially that derived from clinical research
- patient centered
- evaluates the accuracy and precision of diagnostic tests and prognostic markers
- efficacy and safety of therapeutic, rehabilitative, and preventive regimens

SE Straus, DL Sackett, 1998

### Evidence Based Medicine (EBM) Critics I

- Among internal bias, economic-based interest may influence the development and diffusion of research and its results.
- difficulty to convert EBM into clinical practice recommendations- it is nearly impossible to make recommendations that are appropriate in every situation.
- EBM cannot be evaluated as the scientific "totem" of the third millennium, neither as the clinical digest of medical literature.

### Evidence Based Medicine (EBM) Critics II

- Cultural and methodological approach
- Converts the abstract exercise of reading and appraising the literature into a pragmatic process
- Internal bias
  - Economic-based interest
  - Inappropriately applied filters of literature
  - Only based on the positive results of evidence
- Epistemological approach identifies external bias
  - EBM can be changed or removed every time by relevant new or emerging evidence
  - Cannot be evaluated as the scientific "totem" of the third millennium

M Timio et al, 2000

### Evidence Based Medicine (EBM) Critics III

- "Evidence" in EBM must be of high quality in order to be useful but is not always the case
- "Real world" trials often do not give the same results as these highly artificial controlled clinical studies.
- EBM may be unreliable, sometimes giving different results to subsequent large randomized trials
- Bias in the hypotheses tested in large trials usually covered by commercially interested companies
- Process of journal review and publication is capricious, slow, may have a selection bias towards positive studies (communication channels for evidence are often unsatisfactory)
- For many rarer conditions there is no "high level" evidence (pediatrics, subspecialty surgery, etc.)
- Usual no trials of old people who are on many pills

DS Celermajer, 2001

S Butterworth, 2004

### Cochrane Library

- Reviews are more systemic and less biased than systematic reviews published in paper journals
- Cochrane Collaboration has taken steps to improve quality of reviews
- Readers of Cochrane reviews remain cautious, especially regarding conclusions that favour new interventions

#### Critics:

- Neurological diagnoses are based on meta analysis of inhomogenous publications (phenomenologically or topically based)
- Experience based medicine gets increasingly unessential

### What is the Cochrane library

- Unique source of reliable and up-to-date information on the effects of interventions in health care.
- Health care relies not only on individual medical skills but also on best information
- Best information is compiled using the technique of evidence-based medicine
- The aim of the Cochrane library is to provide EBM information

Cochrane Website, 2004

### Factors influencing European medicine - 1

- 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

### Factors influencing European medicine - 2

- 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, modern neuro-rehabilitation adjusted to the special condition and best nursing care.
- 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 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.