Current ethical challenges in neurological practice

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EFNS TEACHING COURSE IN NEUROLOGY

Eger, Hungary
October 22-23, 2004

Ethics

Altruism
Sense of honour
Justness
Respect for others
Solidarity
Ability to forgive

Ethics:
Part of philosophy dealing with morality.

Moral
is search for an inner standard.

Kant's Categorical Imperative:
The individual should act in a way that his action can be regarded as general law.

Bioethical principles

Medical conduct, physicians obligations
(Belmont criteria, 1979)

- autonomy (of the patient)
- beneficence
- nonmaleficence
- justice
- (trust)

Kant's maxims

Autonomy
Dignity
Individual human rights

Western-Occidental ethics

- Aristotle philosophy – "the pure spirit", without any concept of God based on Plato and on the confrontation with biological-materialist thoughts (Pythagoras, etc.)
- Christian teachers - Saint Augustinus, Thomas Aquinas- introduced Christian elements, principle of one God
- Immanuel Kant postulated European moral and ethical norms in reflection of Aristotle philosophy
- Regional interpretation of ethics in Europe
  Existentialistic ethics (France)
  Value ethics – "Werte-Ethik"(Germany)
  Ethics of Marxism (Soviet Union)
  Theological ethics (East Europe)
- Bioethical rules as the adaptation to the technical development in modern medicine with the basis of principles of human rights
- No inclusion of the ethical rules of Buddhism, Konfucianism and the rules of the Islamic and the Mosaic religion
- No possibility for globalisation in the present state

Definition

Neuroethics is the application of the principles of bioethics in Neurology

World Medical Association Declaration of Helsinki, 1964 Ethical principles

- Ethical principle to provide guidance to physicians and other participants in medical research involving human subjects incl. identifiable material or identifiable data
- International code of medical ethics: The physician shall act only in patients interests when providing medical care which might have the effect of weakening the physical and mental condition of the patient
- 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

The task of neuroethics

1. Ethics in research in Neurology
2. Neuroethics in clinical practice
3. Education in neuroethics
4. International conventions

Patient-doctor relationship

- Expectation of personal attention
- Trust
- Individualized treatment
- Best benefit to risk/ratio

- It is the patient right to finish the cooperation with his physician
- It is the physicians obligation to inform the patient of all the effects to initiate or to stop the running treatment (in written form)

Corpus Hippocraticum

Although it is the duty of the physician to cure patients completely and to reduce the frequency of diseases the physician should never attempt treatment of those who are already overcome by diseases or forthcoming age with somatic and mental reduction

Neuroethics in clinical practice

- New therapies
  - New drugs
  - New therapeutic devices
  - Implantation of human tissue in central nervous system (stem cells, embryonic tissues etc.)
  - Implantation of stimulating systems
- New diagnostic methods
- New neurosurgical methods
- Genetic testing and counselling
- Organ transplantation - selections of patients and donors
- Determination of brain death
- Palliative treatment of moribund patients
- Withholding of therapy in acute incurable conditions
- Withdrawing of life preserving measures in acute conditions
- Discontinuation of life support systems (end of life decision)

Current ethical issues in neurological practice

- Active euthanasia, free willingly, against free will
  medical assisted suicide
- Passive euthanasia, renunciation of acute treatment,
  renunciation of Maximal therapy
- Palliative treatment in terminal or moribund state of
  neurological diseases
- Withholding of Maximal therapy in incurable acute
  neurological conditions (severest brain damage)
- Decision for end of active neurorehabilitation
- End of life decisions in incurable neurological conditions
  (apallic syndrome/vegetative state without remission,
  final state in ALS, Alzheimer disease etc.)
- Resource allocation and adequate medical care (withholding
  of treatment of old patients, incurable cancer, etc.)
- Treatment of patients unable to consent
- Treatment of vulnerable persons (children, psychiatric patients)

Patients unable to consent
Decision making on behalf of patients

- Presumed consent in emergency situations
- Proxy consent by an authorized person,
  legal representative, solicitor
- Living will
  Advanced directives
  Previous expressed wishes
  Written will

Ethical issues in Neurology
New therapies

- Introduction of new drugs
- Introduction of new medical products
- Introduction of new therapeutic devices
- Implantation of human tissue in central nervous system including xenotransplantation
- Gene therapy
- Implantation of stimulating systems (brain, spinal cord)
- Introduction of new diagnostic methods
- Introduction of new neurosurgical methods

- Use of Evidence Based Medicine for diagnostic and therapeutic guidelines
- Use of diagnostic and therapeutic guidelines-COCHRANE library

Patients unable to consent
In clinical practice

The treating and responsible physician is often the true protector of the patient, who is incapacitated.

In research in case of conflicting interests
Protecting the research subject
Advancing medical knowledge

Patients unable to consent
(temporary-permanently)

» Basical legal prerequisite for every medical intervention: "Informed consent", better "valid consent"

» Values to be protected in decision making
Patients rights
Integrity
Dignity

Protection of vulnerable persons
Inability to consent in routine medical practice (reduced capacity)

- Children - parents or guardians as proxy
- Patients with cognitive impairment
  (Aphasia, etc.)
- Patients with progressive or terminal diseases
  (Alzheimer disease, MS, etc.)
- Patients in intensive care unit
- Apallic patients/vegetative state - full state or early remission

Ethical problems in neurorehabilitation

- End of active neurorehabilitation
  Transfer to nursing care, to home care
- Withholding of emergency care in acute complications in hopeless conditions,
  no "Maximal therapy"
- No research programs possible
  laboratory programs, etc.
- No use in donor's program
  plasma, etc.

Treatment of moribund patients

- W. Strauss, 1968: "To cure – sometimes; to relieve - often, to comfort - always".
- H. Küng, 1982: "Fighting death at any expense makes no sense, help becomes torture".
- T. Helme, 1996: "Ordinary terminal care involves a balance of sometimes conflicting "prima facie" duties to preserve life, to protect liberty, respect patients autonomy and to prevent suffering".

Brain death
European position

- Symptomatology, exact details
- Clinical course
- Clarification of the basic pathological process
- Additional examinations (EEG, TCD)
- Team of independent specialists
  neurologist-clinical symptoms
  anaesthesiologist-respiratory arrest
  EEG-specialist
- Exclusion of members from the transplantation team
- Minimal standard for developing countries
  WFN Guidelines

Evidenced Based Medicine

- 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 de-emphasizes intuition and unsystematic clinical experience as grounds for medical decision-making

Euthanasia
Eu-Thanatos = Easy Death

- Active euthanasia
  free willingly
  without free will,
  assisted suicide
- Passive euthanasia
  Withdrawal of therapy
  Withholding of therapy (active therapy, Maximal therapy)
  Discontinuation of life preserving measurements
- Voluntary euthanasia ("Zwangseuthanasie")

Evidence Based Medicine
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
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
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
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
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, subspeciality surgeon, etc.)

DS Celermajer, 2001

- Usually no trials of old people who are on many pills

S Butterworth, 2004

Evidence Based Medicine
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

- Clinicians are looking for new strategies to apply to diagnostic and therapeutic pathways and for the steps where EBM could be addressed when showing the full validity.

M.Timnio, D.Antiseri
Ital. Heart Journal (2000),1; 411-414

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 and topically based)
- Experience based medicine gets more and more unessential

What is the Cochrane library

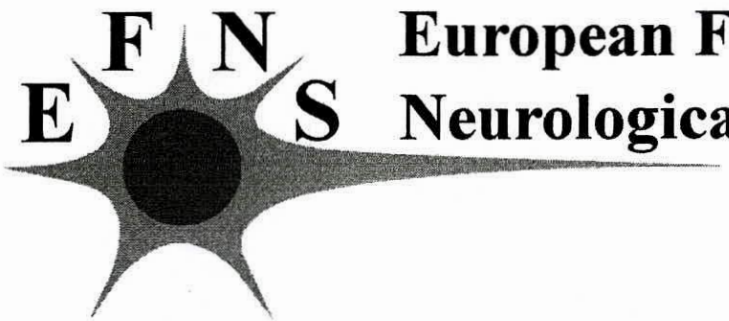
- Unique source of reliable and up-to-date information on the effects of interventions in health care.
- Health care relies not only on individual medical skills but also on best information
- Best information is compiled using the technique of evidence-based medicine
- The aim of the Cochrane library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

Cochrane Website, 2004

Factors influencing European medicine

- Progress in research of biology and genetics
- Progress in basic research
- 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



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