Assessing the ethics of medical research in emergency situations: how to do international regulations work in practice?

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Emergency

- patient in a critical, life-threatening condition
- patient often unconscious, not able to give consent
- immediate measures needed
- decision making
  - who decides
  - who consents for the patient
Emergency

- traffic accidents
- cardiac arrest
- resuscitation
- complications of systemic bacterial infections
Informed consent

- the individual is adequately informed
- he/she understands the treatment or the procedures of the clinical investigation
- voluntarily participates and is not coerced
- has adequate mental capacity
- has reached the age of legal competence
Is informed consent possible in an emergency setting?

- adequate information?
- adequate understanding?
- voluntariness? coerced?
- emotional, upsetting situation also to family members
Children

● 50-90% of medicine of the children not tested in scientifically optimal settings
  ▶ dose may not be effective enough
  ▶ medicine may be harmful (different side effects)

● medicines used in neonatal units: up to 90% not investigated in clinical trials
Newborn

- neonatal units distant from obstetric units
- seriously ill newborn require rapid measurements
- mothers often only legal representatives
- how to assure satisfactory information
Nürnberg 1947

- 23 medical doctors accused of crimes against humanity
- 16 convicted
- 7 death penalties
Nürnberg declaration 1947

- Accepted clinical trials
  - voluntary informed consent
  - Benefit that cannot achieved by other means
  - Based on animal tests and other pieces of information
  - unnecessary suffering must be avoided
  - Risks < benefits
  - qualified researchers
  - Right to withdraw consent
International regulations

- Declaration of Helsinki
- CoE Convention on Biomedicine (CETS 164)
- Additional Protocol on Biomedical Research (CETS 195)
- EU Directive on Clinical Trials (20/2001/EU)
- UNESCO, CIOMS
• research in emergency conditions possible
• must be stated in the protocol and approved by review committee
• consent to remain in the research should be obtained as soon as possible from the individual or a legally representative
CoE Convention on biomedicine (CETS 164)

- General rule: appropriate information and prior free and informed consent
- In emergency situation medically necessary intervention may be carried out for the benefit of the health of the individual concerned without prior consent
Additional protocol concerning biomedical research (CETS 195)

- law shall determine whether…
- Research approved for emergency situations
- consent or authorisation for continued participation shall be requested as soon as reasonably possible
CIOMS

- waiver of informed consent regarded as uncommon and exceptional
- must be approved by an ethical review committee
UNESCO declaration of bioethics

- prior, free, express and informed consent
- exceptions only by law
EU Directive on Clinical Trials (20/2001/EU)

- written, dated and signed, informed consent prior to the initiation of trial
- if person is unable to consent, by his or her legal representative
- legal representative: existing national law: may include natural or legal persons, an authority and/or a body provided for by national law
EC proposal on better medicines for children

• public consultation of draft proposal 4/2004

• General objectives
  ► increase the development of medicines for children
  ► high quality research
  ► appropriate authorisation
  ► improve information available
Danish model

- EU directive 20/2001/EU: existing national law...
- legal representative: may be in acute situations a unit of two doctors independent on the research project
- law in force April 1, 2006
Research and ethics

Justice

Respect of autonomy

Respect of dignity

Medical research

Avoiding harm

Making good

Maximizing benefits

Avoiding harm

Maximizing benefits

Respect of autonomy

Respect of dignity

Making good

Justice
Ethics in clinical trials

- not only laws and regulations
- ethics is above and in the basics of legislation
- law is the minimum of ethics; recommendations and declarations ideal
Ethics in clinical trials

- ethical principles
  - benefits and harms
  - justice
  - respect of autonomy
- basic human rights
- values and morals
- culture
  - language
  - religion
  - other values of the society
Ethical evaluation of research

- co-operation between parties

- purpose:
  - better research
  - trust to medicine and medical research
  - welfare of human being