



Experience of Medical Ethics Committees with projects on embryo research

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Presentation

- based on consultation of the medical ethics committees of University hospitals
- similar experiences / comments / concerns:
 - evolution in the perception of scientific research on embryos
 - gradual extension of legislation, either directly or indirectly applicable to research on embryos
 - evolution from ethical reflections to scientific and legal responsibilities
 - focus on the “ participants”
 - adequate and correct information for those who donate supernumerary embryos or those donating gametes to make research embryos “betrokkenen” “personnes concernées”
 - security

Evolution in the perception of scientific research on embryos

- evolution assessment by the ethics committees of the requests for advice
 - at first:
 - frequent invitation of the researcher for additional explanation during the meeting
 - doubts: expert advice
 - same requests treated in several meetings
 - acceptability limits to scientific research affected the assessments
- evolution content of the opinions of the ethics committees
 - comments first opinions no longer applicable

Extension of legal framework

- responsibilities ethics committees included in:
 1. Coordinated Act on Hospitals of 7 August 1987
 2. Act of 11 May 2003 on research on embryos in vitro
 3. Act of 7 May 2004 concerning experiments on the human person
 4. Act of 19 December 2008 on human body material

- each Act implements specific tasks for the ethics committees

- additionally taking into account
 - Act of 8 December 1992 on the protection of privacy in relation to the processing of personal data
 - Act of 22 August 2002 on Patients' Rights

Tasks of the ethics committees

- a supervisory and advisory role with regard to the ethical aspects of the hospital
 - a supporting role in decisions on individual cases on ethics
 - an advisory role with respect to all protocols on human experimentation (expanded in the Act of 7 May 2004)
- main scope (initially): ethical reflections and scientific value

Tasks of the ethics committees

- assessment of research on embryos in vitro
 - control on research on supernumerary embryos or embryos created for research purposes
 - expansion in Law on assisted reproduction and use of surplus embryos and gametes (July 6, 2007)
- scope: research on embryos

Act of 7 May 2004 concerning experiments on the human person

Tasks of the ethics committees

- assessment of research on the human person
 - single opinion, based on the legal conditions for clinical research in Belgium
 - includes monitoring the compliance with the European legislation in the European Directives and ICH-GCP
- scope: human person

Tasks of the ethics committees

- assessment of use of human tissue in scientific research
 - human tissue includes gametes, embryos, fetuses, as well as the substances taken out, whatever their degree of processing is
 - banks for body material (fertility centers)
- scope: human tissue

Experiences ethics committees

Experiences ethics committees

- within the evolution of the legislative framework
- within the daily practice

Experiences ethics committees

Within the evolution of the legislative framework

- concerns
 - balance between all applicable Acts when assessing requests for advice
 - chronology applicable regulations
 - Act 7 May 2004 main component tasks ethics committees
 - implementation as from day 1 after publication
 - requests for advice from then evaluated within this (strict) legislation
 - but: Act on research on embryos ⇨ 2003
 - increasing importance task lawyer of the ethics committee
 - different deadlines

Experiences ethics committees

- opportunities:
 - decisions based on extended points of view and approaches
 - similar elements within the assessment
 - participant information and informed consent
 - voluntary participation
 - the relevance and design of the study
 - protocol
 - methodology
 - suitability of the investigator and supporting staff

Experiences ethics committees

Within the daily practice

- important (increasing) responsibility of the members
- complexity of the requests requires scientific and legal luggage
- dilemmas
 - acceptability
 - limits to scientific research
- differences between committees
 - angles (supernumerary embryos compared to embryos created for research purposes)
 - interpretation applicable law (need for insurance, opting out ?)
 - focus on other elements: scientific ↔ ethical ↔ legal

Experiences ethics committees

- major concern for all ethics committees is the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent:
 - absence of medical terminology, completeness, clarity (overtallige embryo's ↔ ongeschikte embryo's), absence research related costs, voluntary participation
 - choice participant what kind of research
 - rights participants on the outcome of the research
 - separate permission genetic research

Conclusion:

- evolution in the content of the advices of the local ethics committees
- learning process: comments in previous opinions may no longer be applicable
- absence uniformity in interpretation remains
- many questions still unanswered
- positive achievement: specific informed consent forms approved by the ethics committees

Experiences ethics committees

Reflections:

- Need for interaction between ethics committees and Federal Commission
 - task Federal Commission : “formulate recommendations on the application of the law on behalf of the local ethics committees”.
 - website: item “ focus on local ethics committees”
 - Circular (2008) concerning research on embryo
 - Opinion of the Federal commission on the meaning of the word “research” (2008)
 - extension support ?
 - legal/scientific/ethical counseling
- Need for interaction between local ethics committees
- Need for symposia like today ?