

EUROPE , THE STATUS OF THE EMBRYO AND THE LAW

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The (human) embryo (E)

- Respect because of its human "potential" and kinship (Warnock and CCNE)
- French loi 94-653 : "respect of the human body and its products"; cautious regulation and changing
- HFE Act 1990: liberal regulation
- German Embryo Protection Act (prohibitive)

Legal E definition

- Austria: "inseminated ova and cells developed from them"
- Germany: "fertilised human egg cell capable of development, from fusion of the pronuclei"
- Spain: pre E (group of cells resulting from the fertilisation of ovum until the implantation and formation of the primitive streak)

fertilisation is complete ,
including an egg in the
process of fertilisation”

ESHRE taskforce ethics and
law (Human Reprod, 16,
1046-1048): term may lessen
the symbolic value of this
entity; E is descriptive

Examples of European variations

- Embryos (E) research, cryopreservation; PGD: observation only in France
- Research: on cells resulting from the fertilisation of ovum until the implantation and formation of the primitive streak; 14 days
- ESHRE taskforce ethics and law (Human Reprod, 16, 1046-1048): created E v supernumary; Council of Europe: No creation (art 18)

HFE Act 1990 Research Objectives

- To promote advances in the treatment of fertility
- To increase knowledge about the causes of congenital disease
- To increase knowledge about the cause of miscarriage
- To develop more effective techniques of contraception
- To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation

Other conditions 2001

- (2) A license may be issued for the purposes of-
 - (a) Increasing knowledge about the development of embryos;
 - (b) Increasing knowledge about serious disease;
 - (c) Enabling such knowledge to be applied in developing treatments for serious disease

Task force 4 Stem cells ESHRE

- **Fundamental ethical principles**
- 2.1 general ethics principles
- 2.1.1 The principle of autonomy
- eg informed consent of cell donors
- specific information: longevity, ? indefinite
- therapeutic use, no ET

Other fundamental ethical principles

- Beneficence and non maleficence: safety and standards
- freedom of research: no undue restrictions by ideological dogmas; all sources should be explored

Specific ethical principles

- These depend on the source of cells
- all possibilities should be explored
- eg: fetal stem cells: respect the separation principle ; specific consent for stem cell research
- eg: umbilical cord blood: standards
- eg: adult cells : consent, explain no direct benefit to donor

Specific concerns, the embryo(E)

- Research: supernumerary v created or research (E)
- (see taskforce 1: create embryos for research is appropriate if no alternative)
- SCNT : no alternative but create de novo
- major problem is the source of oocytes

Creating embryos: source

- Potential abuse of vulnerable women
- (either socially, or enticed to donate oocytes to family members or SCNT)
- limited number of oocytes : ? preferential allocation to donation in POF?
- EGE: SNCT techniques too early

Patenting cell lines

- Patenting policy should not hamper the development of new technologies
- should not slow down the acquisition of knowledge
- population health >> commercial goals
- EU: EGE advice on patents due April/May

European Group on Ethics (EC)

- remote therapeutic perspectives must be balanced.....with the risks of the use and creation of embryos: trivialisation
- and risks of exerting pressure on women as sources of oocytes
- and increasing the possibility of their instrumentalisation

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 - Therefore precaution principle, prudence
 - and proportionality principle were used to assert that SCNT techniques would not be approved
 - recommend EU funding on supernumerary E research

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The UK picture

- A democratic process
- HFEA and HGC joint report 1999
- CMO report Aug 2000
- Parliamentary debate 2 chambers
- Final vote 31-1-2001
- Pro-life court case finally dismissed on appeal Feb 2002

HFE Act E research

- 1990 allowed for research in conditions linked to reproduction (infertility, miscarriage, contraception, PGD)
- Feb 2001, also allowed for research for therapy for serious disease
- Reproductive cloning forbidden

Europe latest

- No research licensed yet in UK for SNCT
- Two applications at HFEA
- French revisions of laws may allow E research on ESC therapeutic applications but not fundamental research on E
- Germany may import ES cells
- All differ from USA saga (NIH v private)

ethical analysis exposes considerations that
require ... attention, balance and prioritisation
(B Dickens)

not necessarily: self-determined conclusion