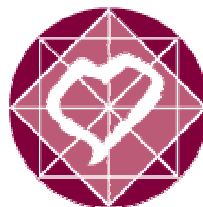




Quality of Life programme

May 2001

**SURVEY ON OPINIONS FROM NATIONAL ETHICS
COMMITTEES OR SIMILAR BODIES, PUBLIC DEBATES AND
NATIONAL LEGISLATION IN RELATION TO HUMAN STEM
CELLS**



QUALITY OF LIFE AND MANAGEMENT OF LIVING RESOURCES

INTRODUCTION

The Swedish presidency has, in collaboration with the European Commission, organised a conference on Ethics and biomedicine – balancing risks and benefits in Umeå on 11-12 June 2001.

The conference will attempt to illustrate the process of handling ethical dilemmas in biomedicine by reviewing the ethical debate on three current examples, which have led to strong opinions in society, new guidelines and in some cases legislative proposals. The three examples considered are xenotransplantation, biobanks and stem cells representing different stages in the process.

In order to feed the debate, the European Commission, DG Research, has prepared a survey concerning the opinions from national ethics committees and national legislation in relation to xenotransplantation, biobanks and human stem cells.

National Ethics Committees or similar bodies in the EU Member States have been contacted during the period from 15 March till 15 May 2001.

The Commission would like to thank the contact persons in each country for providing this information.

This booklet contains the information collected concerning human stem cells.

The survey will be updated on a regular basis. We would therefore like to invite you to provide any comments or new information you may have to Dr. Line Matthiessen (e-mail: line-gertrud.matthiessen-guyader@cec.eu.int, fax: +32.2.299.18.60), who has been responsible for collecting the information.

Bruno HANSEN
(Director for Life Sciences)

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Survey on Human Embryonic Stem Cells research and use

AUSTRIA

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Austrian Reproductive Medicine Act (Fortpflanzungsmedizingesetz, FMedG) states, that cells capable of development may only be used for medical assisted reproduction.

Contact person: Dr. Meinhild Hausreither, Federal Ministry of Social Security and Generations, Department VIII/D/13, Radetzkystr.2, A-1031 Vienna, Phone: +43 1 71100 4387

Concerning processing: Austrian Pharmaceuticals Act (AMG) and the regulations on blood safety.

Contact person: Dr. Hans Kurz, Federal Ministry of Social Security and Generations, Department VIII/D/21, Radetzkystr.2, A-1031 Vienna, Phone: +43 1 71100 4643

There is no national Ethics Committee in Austria, that is involved with human embryonic stem cells.

There is no current legal and / or regulatory framework for human embryonic stem cells research in Austria.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

In the course of the planned amendment of the Austrian Act for Reproductive Medicine (FMedG) the regulation of human embryonic stem cells research is currently under discussion.

Survey on Human Embryonic Stem Cells research and use

BELGIUM

- 1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

- 2. Will (or has) a public debate take(n) place on human embryonic stem cells?**

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

- 3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

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- 4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

Proposition de loi relative à la recherche sur les embryons et à la protection des embryons in vitro (<http://www.senat.be>).

Survey on Human Embryonic Stem Cells research and use

DENMARK

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Please contact The Danish Ethics Council: www.etiskraad.dk, email: etiskraad@etiskraad.dk

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

Please contact The Danish Ethics Council

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The question of research on human stem cells/human embryos is regulated by § 25-28 in the act on Medically Assisted Reproduction: Biomedical research on fertilizes ova and stemm cells intended for reproduction can only be undertaken in the following cases: If the aim is to improve techniques for in vitro-fertilisation in order to induce pregnancy and if the aim is to improve techniques of preimplantation diagnosis.

According to §28 it is forbidden to undertake research with the following aims:

- research where the aim is to develop human reproductive cloning;
- research where the aim is to facilitate the creation of a human identity by melting together genetically unidentical embryos or parts of embryos before the impantation in the womb,

- research where the aim is to create human individuals that are hybrids with a gene-pool that is a mixture of different species,
- research with the aim of developing a human individual inside a non-human womb.

In addition to the Act on Medically Assisted Reproduction, the Act on a Scientific Ethical Committee-system lays down provisions on how to carry out research projects in general – no research project involving humans or stem-cells and fertilized ova can be initiated without permission from a scientific ethical committee. (Act no. 503 of 1992 on Scientific Ethical Committees and the handling of biomedical research projects.)

Reproductive cloning of humans is prevented by law in Denmark. The Danish Law on Medically Assisted Reproduction (Act no. 460 of June 10. 1997 § 4) states that it is forbidden to implant identical unfertilized or fertilized ova in one or more women.

Penalty: According to this legislation, the doctor and the authorized health persons that violates the provisions of the act can be punished with fine and with imprisonment in the form of presence. The persons donating eggs and semen and the couple consenting to artificial procreation cannot be punished according to this legislation.

Furthermore, research on humans is regulated by The Act on a Scientific Ethical Committee System and the Handling of biomedical Research Projects. The system of scientific ethical committees consists of The Central Scientific Ethical Committee and 7 regional scientific ethical committees. All committees have representation of laymen and scientists. All research projects must be approved by a scientific ethical committee and projects on fertilized human eggs and human germ cells with the intention of procreational use must be put before the Central Scientific Ethical Committee.

The scientific-ethical committees are working on two levels -a regional level (8 regional committees) and one central committee working on national level

Penalty: According to this legislation anyone the initiates a project against the regulations can be punished with fine or ordinary imprisonment.

The Ministry of Health is responsible for the legislation dealing with human stem cells: The Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K, email. sl@sum.dk.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

Yes – the Danish Minister for Health is preparing a revision of the legislation on human procreation within the next years –For further information please contact the Danish Ministry of Health.

Survey on Human Embryonic Stem Cells research and use

FINLAND

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

N.B. Opinion on human stem cell research has been given by the Nordic Committee on Bioethics (December 2000). Available on web: www.ncbio.org.

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes, probably not yet

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

After the legislative change in the UK there was some public debate in the media - mostly misinterpreted.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Act on Medical Research (no. 488/1999) covers the preconditions and use of human embryos up to 14 days. No specific legislation on stem cell research.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

The legislation on infertility treatments is under final preparatory stage and will give regulations also on ovocyte donations.

Survey on Human Embryonic Stem Cells research and use

FRANCE

- 1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Research on human embryonic stem cells from left over embryo and cloning embryo has to be encouraged.

Contact person : Axel Kahn, Comité Consultatif National d’Ethique pour les Sciences de la Vie et de la Santé, 71 rue Saint-Dominique – 75007 Paris, website : www.comite-ethique.fr

- 2. Will (or has) a public debate take(n) place on human embryonic stem cells?**

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

- 3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

Forbidden by law in 1994.

- 4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

Yes, by revision of the law in course.

Survey on Human Embryonic Stem Cells research and use

GERMANY

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Contact : Zentrale Ethik-Kommission bei der Bundesärztekammer
Wissenschaftlicher Beirat der Bundesärztekammer
Herbert-Lewin-Strasse 1, 50931 Köln
Hd. Frau Dr. Pfenning, tel.: 49.221.400.44.64

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

Survey on Human Embryonic Stem Cells research and use

GREECE

- 1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

It is under preparation

- 2. Will (or has) a public debate take(n) place on human embryonic stem cells?**

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

- 3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

The only legal framework operating in Greece is the Convention on Human Rights and Biomedicine and the additional protocol on the prohibition of cloning human beings.

- 4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

There is no official available information

Survey on Human Embryonic Stem Cells research and use

IRELAND

- 1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

- 2. Will (or has) a public debate take(n) place on human embryonic stem cells?**

yes no unless it becomes an issue.

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

- 3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

Embryo research is prohibited.

- 4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

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Survey on Human Embryonic Stem Cells research and use

ITALY

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Yes, the recommendation are the following:

The Italian National Bioethics Committee:

deems that the possibility of cultivating in the laboratory stem cells having the capacity to reproduce indefinitely and to specialize in the formation of any tissue of the human body represents a line of research of particular interest as regards therapeutic applications, The use of these cells to repair damaged tissues and, in future, also damaged organs, by means of cells replacement opens up new prospects of treatment for a wide range of frequently occurring diseases that are today difficult to treat and often incurable;

expresses the hope that such a line of research will pursue the optimal objective of succeeding in “reprogramming” mature cells, that is, of deriving stem cells capable of differentiating into the desired tissues directly from the already differentiated cells of the patient whose tissue is intended to regenerate. This would represent a cellular auto-transplant that had the major advantage of tissue compatibility and would thus presumably be used for important therapeutic applications;

is fully aware that the pluripotent stem cells with the greatest potential for differentiating into the widest range of tissues (in animal models as well as in observed human cases) are the stem cells derived from the embryo at the blastocyst stage even when they are derived through the somatic nuclear replacement technique. The alternative attempts at deriving stem cells from umbilical cord blood or from other tissues capable of expanding and differentiating into cells of tissues other than the original ones are still at the early experimental stage;

deems it to be ethically legitimate to derive stem cells from the cells of spontaneously aborted foetuses or those produced by voluntary interruption of pregnancy, provided suitable steps are taken to exclude both causal relations between abortion and stem cell derivation and any collaboration among corresponding operators, and marketability. Some members of the Committee have nevertheless expressed reservations on the possibility of distinguishing de facto the collaboration among the team involved in performing the voluntary interruption of pregnancy and the team using the derived foetuses, even when suitable formal procedures are adopted to distinguish their possible relationship of causality;

points out that several of its members acknowledge and agree with the ban on creating human embryos for the sole purpose of using them for scientific research, as provided for in art.18, paragraph 2 of the *Convention on Human Rights and Biomedicine*. According to other members of the Committee, a thorough evaluation of the experimental results of somatic nuclear replacement may suggest that this new line of

research could produce therapeutic results of great impact for the being without any alternative such as to suggest evaluating the ethical aspects of future applications on a case by case basis;

reiterates the illegitimacy of using the somatic nuclear replacement technique for reproductive purposes (“reproductive cloning”);

points out that part of the Committee consider it ethically allowed to derive stem cells for therapeutic purposes from embryos that are no longer possible to implant, again on condition that they are wittingly donated by the women or the couples concerned. They nevertheless recommend performing rigorous tests and checks on a case basis on the suitability for implantation, the consent to donate and the therapeutic purpose of the experimentation. These should be carried out only ad hoc indicators of a reasonable impracticability of implantation, as well as by following adequate guidelines and ensuring a preventive evaluation is made by an ethical committee. Other members of the Committee are in any case against using supernumerary or spare embryos even when cryopreserved and not required for transfer to the uterus, because they consider such practices to entail the direct and deliberate suppression of the embryos and thus an instrumental use of human beings and on offence to their dignity;

expresses the hope that a topic of such importance for biological and medical research and so significant as regards the possible treatment of diseases of great social impact and today difficult to treat will be the object of accurate information and wide debate. This should be the case not only within the scientific community but also within laymen, so the latter can be made aware of and responsibly address the problems of a chapter of medicine that, while certainly new, it is hoped will also be effective, and to which the name of “regenerative medicine” has been given.

Please note: See also the opinion of the ad hoc commission of the Ministry of Health. The text is available in website www.sanita.it

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The public has been informed by the media. Nevertheless this issue has been discussed in many conferences, and also in some meetings with students.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The regulation under preparation that could be considered connected with this issue is the law on in vitro fertilization (approved only by one chamber of parliament. See the bills in www.parlamento.it, searching the entry “procreazione assistita”). Yet, the Ministry of Health recently produced a rapport about the banks conserving embryos and gametes. The contact person is Prof. Riccardo Poli.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation
none

**ADVICE OF THE NATIONAL BIOETHICS COMMITTEE
ON THE THERAPEUTIC USE OF STEM CELLS**

(27 October 2000)

Introduction and definitions

1. Research on stem cells and their possible therapeutic applications did not begin yesterday. However, in recent times interest in them has increased, among other things as a result of the consulting committee set up on the topic by the British government, of the guidelines published by the US Health Ministry and of the resolution of the European Parliament. On several occasions, the National Bioethics Committee has expressed its opinion on problems related to human genetics in specific documents: *Identity and status of the human embryo* on 21 June 1996, *Cloning* on 17 October 1997, *Declaration on the possibility of patenting cells of human embryonic origin* of 25 February 2000 and *Opinion on the project for a European protocol on the protection of the human embryo and foetus* of 31 March 2000. Furthermore, within the National Bioethics Committee a working group was set up several months ago which has collected a large body of documentation and discussed the problem in detail in its various aspects. The following document is the collective expression of this work: it aims to make a timely contribution to the discussion of the scientific, ethical and political questions that the use of stem cells for therapeutic purposes raises for society and government. For the reader's convenience, several preliminary definitions are given, also for the purpose of correcting the ambiguities and distortions introduced into the debate by the association between the expression "stem cells" and the term "cloning", which refers to one of the techniques by which it is possible to produce them.

2. The expression "stem cell" is used to refer to a cell capable, in the course of the continuous process of its successive duplications, of differentiating until it becomes a "mature" cell of a specific tissue or generates other stem cells. It had been known for some time that certain bone marrow cells act as "progenitors", that is, as cells capable of differentiating into blood cells which are thus continuously replaced. As late as 1998 it was observed that stem cells extracted from a human embryo may be isolated, cultured in the laboratory and induced not only to differentiate into a single specific type of cell (such blood, muscle, or heart, etc.) but to differentiate into any type of cell whenever the culture conditions are suitable. Stem cells can multiply indefinitely, giving rise to both lines of new stem cells and to specialized "daughter" cells. This property could in future allow completely new forms of cell or tissue therapy to be performed, and allow the creation of both undifferentiated and differentiated cells and tissues. The therapy applied to a diseased or damaged cell or tissue could actually consist of transplanting new cells or tissues, which are added to the diseased or damaged ones and ultimately replace them. In recent research on mice, for example, it was found that embryonic stem cells injected into the heart of an adult mouse were incorporated perfectly into the heart muscle of the adult animal,

that is, they differentiated into heart muscle cells and became perfectly synchronized with the beat of the host heart¹.

3. The capacity of the stem cells to differentiate into specific tissues changes according to the origin of the cells and to the development stage of the organism from which they have been extracted. "Multipotent" cells, so-called because of their capacity to multiply and remain in the culture but without the capacity to be renewed an unlimited number of times, have been identified in foetuses as well as in the adult human being, although in limited numbers.
4. By day 4-5 after zygote formation (fertilization) an embryo consists of identical cells (2 in number after about 30 hours, 4 after about 40 hours, 12-16 after about three days, etc.) that are called "totipotent" insofar as they are not specialized and thus have the property of differentiating into all the cell lines required to form the embryo, including those that will produce the placenta and the surrounding membranes. By day four or five after fertilization (morula stage), the embryo still consists of identical embryonic cells, although these cells can no longer form an embryo. From day five to day six after fertilization (blastocyst stage, some hundred or more cells) a spherical cavity is formed in the morula from the external cell mass of which the cells that will ultimately make up the placenta begin to differentiate, together with the membranes surrounding the embryo, while from the internal cell mass (20-30 cells) the cells that will form the actual embryo itself start to differentiate. The latter cells, isolated from the cell mass of the internal cavity are "pluripotent" stem cells, in the sense that they have the potential to differentiate into any type of adult animal cell but not the property specific to totipotent cells of producing an embryo. Indeed if these cells were transferred into a uterus, they would not have the capacity to become implanted and develop because the development of the embryo cannot take place unless they are synchronized with that of the placenta from which the embryo draws its nourishment. Lastly, "germ" cells are defined as those pluripotent stem cells that have been isolated from the progenitor reproductive cells, those that will subsequently develop spermatozoa and egg cells.
5. In research on stem cells, the term cloning is often used ambiguously. In the first instance it is necessary to make a distinction between cloning by cell division and cloning by nuclear replacement. The former consists in producing several embryos by separating the cells during the early stages of division. It has been carried out successfully on human embryos for the purpose of increasing the effectiveness of in vitro fertilization methods and in pre-implantation diagnosis. The latter, associated with the highly-publicized generation of the sheep Dolly, is performed by removing the nucleus from an egg cell ("enucleated oocyte") and replacing it ("nuclear replacement") with the nucleus of a somatic cell from a patient ("somatic nuclear replacement"). If it were to prove possible to apply this technique to human beings, all the pluripotent stem cells cultured from the embryo formed by transferring the nucleus of a cell of any kind (for example, a blood cell) of a patient affected by any disease (for example, of the cardiac muscle), would be genetically identical to those of the patient him/herself and, if injected into the cardiac muscle, would probably not give rise to any rejection reaction. The production of these stem cells by this technique requires the formation of an embryo, the development of which is arrested

¹ Reinlib L, Field L *Circulation* 2000, 101:e182-e187

at the blastocyst stage and from which the stem cells are isolated for the purpose of growing them indefinitely in vitro. It thus does not consist of the complete development of an embryo from which spare tissues or organs would be taken. If this technique were used in a therapeutic programme, the aim would be to accumulate an adequate source of cell supplies for the patient. It is still not understood how the material contained in the enucleated egg cell succeeds in reprogramming the activity of the replaced adult nucleus, although it has been suggested² that it may be possible to create pluripotent cell lines directly from the patients' replaced cells, thus avoiding the step of the formation of an embryo by means of an actual auto-transplant: however, this option is not available at the present time. The somatic nuclear replacement defined above is also known as "therapeutic cloning", an ambiguous term as it suggests the duplication of completely formed individuals from which tissues or even spare organs are taken. They are instead stem cells derived from the embryo that, when grown in the laboratory, can be induced to differentiate into cells and ultimately into tissues of therapeutic interest.

6. The sheep Dolly is genetically identical to the adult sheep whose mammary gland was extracted, and the nucleus of which was replaced into the enucleated egg cell from which the animal was subsequently born. In this case we are dealing with cloning of an entire organism, not just of a cell, and the term "reproductive cloning" is used to distinguish this complete development process from the previous one, which is partial and not aimed at the reproduction of a human or animal organism which, after insertion in a host uterus, can develop until birth and ultimately evolve into an adult organism. Reproductive cloning applied to man is explicitly prohibited by art. 1 of the Additional Protocol to the Convention on Human Rights and Biomedicine of the Council of Europe. Reference is often made to the latter by the National Bioethics Committee, which shares the same views on prohibition and so reproductive cloning will not be taken into consideration in the present document.

How stem cells are isolated

7. Stem cells may be obtained from tissues of different origin and, at the present state of our knowledge, may be distinguished by the greater or lesser facility with which they can be isolated, multiplied and grown in the laboratory and by the variety and types of mature tissue cells that they may be induced to produce. Hitherto stem cells have been isolated in the tissues of adult individuals, foetuses, umbilical cord blood, embryos in the early stages of development and, for the time being, only as a potential possibility, as a conceivable "reprogramming" of the adult cells which are thus already differentiated and specialized into the desired cell type.
8. It has so far been possible to isolate and grow in the laboratory stem cells derived from the cells of adult individuals for the following tissue types: bone marrow, blood, endothelium, nervous system, muscle. Table I shows the results of the most recent results, from which it may be seen that, so far, no stem cells have been found in other adult individual tissues. The use of stem cells derived from the above-mentioned tissues is subject to two main constraints: the difficulty of isolating them, expanding them and maintaining them in an undifferentiated state in the laboratory

² McKay R *Nature* 2000, 406:361-364

(a difficulty that for the time being it seems possible to solve only in the case of bone marrow³) and, once they have been isolated, the difficulty of inducing them to specialize over a wide range of tissues that are different from the one from which they were isolated. So far in man only bone marrow stem cells have successfully been induced to differentiate into other types of cells (see Table I). In rat, one research group has succeeded in getting nervous system stem cells to differentiate into blood cells⁴. The potential offered by this research, which is of vital interest as it would allow genetically compatible cell transplants, will certainly be developed over the long term. This explains why research into embryonic stem cells, which are much easier to isolate, expand, maintain and differentiate, is considered by many researchers a necessary preliminary step to the identification of potential stem cells derived from adult individual tissues, i.e. that which will most likely be used for therapeutic applications.

9. Stem cells can be isolated also from human foetal tissue derived from the reproductive cells of fetuses resulting from spontaneous abortions or voluntary interruption of pregnancy, or else from the blood of the umbilical cord removed at birth. At present it is not known what potential they have for differentiation into different tissues. For example, stem cells from umbilical cord blood currently have the potential to develop certain tissues (bone marrow and blood) but not others, which indicates that the differentiation of these cells into tissues different from those in which they were isolated still has a limited outcome, although mesenchymal progenitor cells have recently been identified in umbilical cord blood⁵. In Italy research in this area is fairly well advanced, although the determination of the degree of multipotentiality of stem cells obtained by this procedure still requires much work before they can be considered alternative to embryonic cell use.
10. The source of pluripotent stem cells that are easy to isolate and culture in vitro in the laboratory is currently the embryo at day five or six after fertilization (at the blastocyst stage). The empirical proof of this claim is obtained by examining the results of numerous experiments carried out animals, in the first place the mouse⁶, but also in guinea pigs, chickens, pigs, primates, etc. In late 1998 a group of US researchers published a preliminary report describing the cultivation of human stem cells derived from 14 blastocysts successfully developed from 36 embryos donated by women who had undergone infertility treatment⁷. This result was confirmed by other researchers who succeeded in isolating and then in maintaining in culture human stem cells derived from four blastocysts, which were then induced to differentiate into progenitor cells of many different types of tissue. However, only in

³ Weissman I.L. *Science* 2000, 287: 1442-1446

⁴ Bjornson C et al. *Science* 1999, 283: 534-547

⁵ Erices A et al. *Br J Haematol* 2000, 109:235-42

⁶ Brook FA and Gardner RL *Porc. Natl. Acad. Sci. USA* 1997, 94: 5709-5712

⁷ Thomson JA et al. *Science* 1998, 282: 1145-1147

mouse has it so far been possible to transplant these progenitor cells into host mouse tissues and to induce them to differentiate and be integrated. For example, hemopoietic stem cells from mouse bone marrow were transplanted into rats affected by the human equivalent of type I hereditary tyrosinemia, a fatal metabolic disease, the target of which is mainly liver hepatocytes: the transplanted stem cells induced regeneration of the liver cells of the diseased mice and thus repaired their genetic defect⁸.

11. The nuclear replacement technique described in section 5 above and tested in sheep, cattle, goats, pigs and mice has shown that it is possible to generate embryos without using spermatozoa. In the case of certain animals (the sheep Dolly, for example), the process was carried out before birth. If however, in the case of man, the process is halted after five or six days (at the blastocyst stage), the stem cells derived from the blastocysts not only behave like the stem cells derived from an embryo generated by the union of sperm and egg, but could also afford the substantial advantage of being genetically identical to the cells of the person from which the nucleus was extracted, thus avoiding all rejection problems of the cell transplant in the case in which the nucleus donor is a patient and the cell transplant is aimed at repairing damage to his diseased tissue (auto-transplant). It should be noted however that animals born as a result of the nuclear replacement technique are not exactly identical to the animals whose cell nucleus was used to generate them. Indeed they inherit the mitochondrial DNA contained in the cytoplasm of the enucleated cell egg and the effects of this mitochondrial inheritance on the immunological compatibility between donor cell and receiving egg cell are still unknown. Another problem that makes nuclear replacement technique a therapeutic option of difficult clinical generalization is the finite number of human egg available cells, which cannot be increased at will. However, somatic nuclear replacement may represent a very promising research tool (although by no means yet of treatment) regarding the possibility of "reprogramming" adult human cells (see following section), which is the most ambitious cell transplant treatment project.

12. There is no doubt that the long-term aim of research on stem cells for therapeutic purposes is to "reprogramme" a mature cell of an adult individual in such a way as to convert it back to its undifferentiated state and then to induce it to differentiate into a specific type of cell different from the type to which it belonged prior to "reprogramming". Once it is understood how the human egg cell, after removal of its nucleus, is capable of controlling the conversion of a differentiated cell into a stem cell not only will it no longer be necessary to form an embryo but also nuclear replacement will probably not be accompanied by the problem of tissue incompatibility and subsequent rejection of the tissues introduced into the individual hosting the transplant. This long-term objective nevertheless means that experiments must be performed on embryonic stem cells, the only ones that are available today at a pluripotent stage. Obviously this experimentation must be performed in animals in the initial stages.

⁸ Lagasse E et al. *Nature Medicine* 2000, 6: 1229-1234.

Possible therapeutic uses of stem cells and nuclear replacements

13. Tissues and organs damaged by traumas or disease can recover spontaneously. In some cases, however, treatment consists of repair or even of replacement. For example, the transplant of bone marrow cells has been used with varying degrees of success in the treatment of certain forms of leukaemia and certain genetic diseases. The biological mechanisms underlying their repair would be able to act much more effectively if an adequate supply of undamaged cells was available to colonize the organ or the damaged tissue in such a way as to speed up the repair process and the normal physiological mechanisms. This is the direction currently being followed by research into the therapeutic use of stem cell lines: the laboratory reconstruction of entire organs, such as kidneys or the heart, with their lymphatic and blood vessel systems and their complex tissue architecture or even their parts is still considered too remote a goal for therapeutic applications realistically to be expected in the short term. Available scientific evidence points rather to the possibility that laboratory culture of cells capable of repairing the damage suffered by certain organs may become possible quite rapidly. The following table⁹ lists the diseases that could represent a possible target for the specialized cells generated by inducing the differentiation of stem cells.

Cell type	Disease
Nervous system cells	Stroke, Parkinson's, Alzheimer's, Spinal cord injury, Multiple sclerosis
Heart muscle cells	Heart attacks
Insulin-synthetizing cells	Diabetes
Cartilage cells	Osteoarthritis
Blood cells	Cancer, immunodeficiencies, inherited blood diseases, leukaemia
Liver cells	Hepatitis, cirrhosis
Epithelial cells	Burns, wound healing
Skeletal muscle cells	Muscular dystrophy
Bone cells	Traumas, osteoporosis

One of the socially more significant applications of this innovative therapeutic technology could well prove to be the treatment of diabetes, a multifactorial disease of genetic origin that affects about 3% of the Italian population¹⁰. In this way it would be possible to inject patients with stem cells instead of the current practice of

⁹ From the so-called Donaldson report *Stem Cell Research: Medical Progress with Responsibility*, Department of Health, United Kingdom, June 2000, page 18, available at the web address <http://www.doh.gov.uk/cegc/>.

¹⁰ Source: ISTAT 1998

injecting large quantities of pure insulin; with the same goal, stem cell lines induced to produce human insulin on a permanent basis could conceivably be prepared in the laboratory.

14. The nuclear replacement technique could be used for purposes other than the production of stem cells, for instance, for the correction of genetic defects during the early stages of embryonic development or to treat diseases caused by alteration of the mitochondrial DNA. Furthermore, progress in our knowledge of human cell differentiation would allow animal experimentation to be progressively reduced. These arguments nevertheless lie beyond the scope of the present document and will be further investigated by the Committee.

Technical problems and risks

15. The use of stem cells to produce tissues for treatment purposes raises a number of technical issues, including: a) how "normal" is the resulting tissue in terms of rate of ageing, effects of harmful mutations, contamination of different tissues, immunological tolerance; b) if the stem cells produced by nuclear replacement from adult tissues give rise to as broad a range of differentiated tissues as that derived from the stem cells of an embryo produced by the fusion of sperm and egg cell; c) if it is possible to general the number of cells required for treatment purposes; d) to what extent and in which dosages is the incorporation of healthy tissue derived from stem cells effective in repairing damaged tissue. Obviously answers to these fundamental questions will be provided only after much experimental work has been done initially by using animal models, as customary in all trials for therapeutic purposes.
16. It may be anticipated that the two greatest risks involved in the use of stem cells are: immunological rejection of the nuclear replacement (mentioned above), which is common to all transplants and with respect to which the simplest theoretical solution would be to derive stem cells from the patients themselves, a process that could be defined as cellular auto-transplant; and the risk of tumour formation due to the transplantation of incompletely or anomalously developed stem cells. Also in the latter case only experimentation, in the first instance on animal models, will allow us to understand the probable behaviour of laboratory-cultivated cells after transplantation into an organism, their capacity to perform normal functions, to integrate with existing cells, and the factors that may induce them to develop tumours.

Ethical problems

17. The use of human stem cells raises important ethical issues that essentially concern the origin of the cells and the way in which they are derived. The fact that these cells are currently isolated from human embryos at the blastocyst stage (about day 5 or 6) or from tissues obtained from spontaneous abortions or from voluntary interruptions of pregnancy implies that the ethical problems should be treated very carefully prior to any scientific discussion of the therapeutic potential or research in this sector. Considering the matter in the light of the origin of the stem cells, it would be preferable to divide the arguments according to whether these cells derive: from embryos created ad hoc for the purposes of scientific research; from tissues of fetuses obtained from spontaneous abortions or from voluntary interruptions of

pregnancy; from tissues obtained by means of somatic nuclear replacement; from embryos not used in infertility treatment.

18. The illegitimacy of creating an embryo in vivo or in vitro for the sole purpose of research is a principle on which a strong consensus exists at both the national and the European level. More specifically, the Council of Europe has explicitly banned it in art. 18, paragraph 2 of the *Convention of Human Rights and Biomedicine*. Also the National Bioethics Committee has expressed an opinion in this sense¹¹ and reiterates this position on the previously stated grounds. What remains to be debated are the various ethical issues raised by the other procedures for obtaining stem cells.

19. Although there is no specific legislation in Italy regulating the use of foetal cells, tissues and organs, it is possible to derive rules in this field from international conventions and other laws or regulations. From an ethical point of view, the use of tissues from aborted foetuses has already been taken into consideration by the National Bioethics Committee in one of its previous documents¹² and deemed legitimate whenever warranted by exclusive study, research or treatment purposes. Conversely, the National Bioethics Committee is of the opinion that the decision to interrupt pregnancy must not be conditioned by the expectation of possible economic and therapeutic benefits from using foetal cells, tissues or organs. Likewise, marketing and patenting of the latter must be banned. The National Bioethics Committee deems that the use for therapeutic purposes of stem cells deriving from foetal tissues must be conditioned to the informed consent of the aborting woman, it must consist of a free, uncharged and unconditioned act of disposition and that the physicians performing the abortion have to differ from those using foetal cells, tissues or organs.

20. It is considered that the possibility of deriving pluripotent stem cells from the somatic cells of a patient with a damaged tissue or organ would not raise any particular ethical problem, except for those commonly related to human experimentation, which include the need for adequate preliminary testing on animal models. If such stem cells were found to have the potential to differentiate into the damaged tissue and to integrate with it, they would be able to begin or accelerate the repair process. It would represent an actual autologous cell or tissue transplant, or auto-transplant with the major advantage from the therapeutic standpoint of not causing any tissue rejection. The real problem is that, at the present state of research, human stem cells in optimal conditions of pluripotency, stability (when cultivated in the laboratory) and of indefinite growth, can be obtained only from embryos in the early stages of development.

¹¹ Opinions of the National Bioethics Committee on the "Convention for the Protection of Human Rights and Biomedicine" (Council of Europe) and "Preliminary Draft of the Universal Declaration on the Human Genome and Human Rights" (UNESCO) (21 February 1997).

¹² Identity and Status of the Human Embryo (22 June 1996)

21. Under what conditions and limitations is it possible to allow the formation of embryos specifically intended to be a source of pluripotent cell lines for therapeutic purposes? More than one position is represented in the National Bioethics Committee. Several members identify the formation of the zygote as the beginning of an individual human being that must be guaranteed the same protection as a person. Other members of the National Bioethics Committee consider that the status of person is acquired at a later stage, and that the degree of protection due to the embryo must be balanced by an at least equivalent concern for the treatment of a diseased person. This concern, together with that for the progress of scientific knowledge, would, after rigorous investigation and scrutiny, justify the formation of embryos for therapeutic purposes. As stated earlier, art. 18, paragraph 2 of the *Convention on Human Rights and Biomedicine*, awaiting ratification by the Italian parliament, is relevant in this connection. Lastly, other members consider as compatible with their ethical values only the use of embryonic cells for therapeutic purposes, but not their formation. These different positions are represented within the Committee, which acknowledges their respective ethical legitimacy.
22. However, there is a *de facto* situation with which the Committee cannot come to terms, namely the existence in Italy of embryos not used for implantation and cryoconserved in the various centres in which infertility treatment is carried out. The substantial lack of control over these centres means that the number of these so-called "supernumerary" or "spare" embryos cannot be assessed, although by extrapolating the data from other countries and from personal knowledge, it is believed to be very high. This is not the appropriate place to discuss the reasons for these large numbers, or even to express the obvious desire that they should decrease or disappear, but rather to point out that these embryos, owing to the fact that they were not implanted within a period of time compatible with an acceptable biological risk, are today doomed to be destroyed. Even the likelihood of some of them being donated by married couples to other couples currently involves only a small number of cases. Part of the Committee believe that removal and laboratory culture of stem cells taken from an embryo that cannot be implanted does not mean lack of respect for it, but, if anything, a contribution by the donor couple to search for possible therapy of diseases hard to be treated and often incurable and that such a contribution stems from an act of solidarity. The same part of the National Bioethics Committee are aware that any use of cells derived from supernumerary embryos for research purposes must be measured against the constitutional principles which include the protection of the life of the conceptus, the right to health and the freedom of scientific research. They in any case call for a regulatory mechanism coordinated with the more general and now urgent regulation of *in vitro* fertilization techniques, without prejudice to the fact that it should in any case consist of regulations based on transitory criteria. Another part of the Committee expressed the opinion that the respect due to human beings prevents the instrumental use of embryos leading to their destruction which - at the time of thawing to remove pluripotent stem cells - must necessarily be still alive in order to be used as a source of stem cells. This direct and intentional destruction of "supernumerary" embryos, even though performed for research or therapeutic purposes, is in contrast with the duty to respect human life since the time of conception on. The supporters of this opinion also criticize the practice of freezing and storing human embryos in the so-called embryo banks as this could encourage also other instrumental uses of them.

23. The National Bioethics Committee has not neglected to elaborate on the ethical significance that in research on stem cells is played not only by the embryo's ontological status, not only by the health to be hopefully restored in diseased persons, but also by the autonomy of women in deciding to donate their eggs to make somatic replacement possible and by the freedom of women and couples to decide on the fate of non implanted embryos. For that part of the Committee who consider it acceptable to remove and culture in the laboratory the stem cells of an embryo that cannot be implanted, two points thus become particularly important: the quality of the information available to the woman and the couple concerning the use of their donation, which may involve research in the field of infertility treatment or else therapeutic purposes; and the mandatory need for consent to the donation, in full respect of privacy and of the principles governing the treatment of data, as it is in any case provided for by the laws of those European countries where embryo research is regulated.
24. Some members of the Committee expressed the opinion that, for the time being, the right conditions do not exist to begin trials on human beings and that a lot more information must be gathered in the field of animal experimentation.

Conclusions and recommendations

The National Bioethics Committee:

25. deems that the possibility of cultivating in the laboratory stem cells having the capacity to reproduce indefinitely and to specialize in the formation of any tissue of the human body represents a line of research of particular interest as regards therapeutic applications. The use of these cells to repair damaged tissues and, in future, also damaged organs, by means of cell replacement opens up new prospects of treatment for a wide range of frequently occurring human diseases that are today difficult to treat and often incurable.
26. expresses the hope that such a line of research will pursue the optimal objective of succeeding in "reprogramming" mature cells, that is, of deriving stem cells capable of differentiating into the desired tissues directly from the already differentiated cells of the patient whose tissue it is intended to regenerate. This would represent a cellular auto-transplant that had the major advantage of tissue compatibility and would thus presumably be used for important therapeutic applications.
27. is fully aware that the pluripotent stem cells with the greatest potential for differentiating into the widest range of tissues (in animal models as well as in observed human cases) are the stem cells derived from the embryo at the blastocyst stage even when they are derived through the somatic nuclear replacement technique. The alternative attempts at deriving stem cells from umbilical cord blood or from other tissues capable of expanding and differentiating into cells of tissues other than the original ones are still at the early experimental stage.

28. deems it to be ethically legitimate to derive stem cells from the cells of spontaneously aborted fetuses or those produced by voluntary interruption of pregnancy, provided suitable steps are taken to exclude both causal relations between abortion and stem cell derivation and any collaboration among corresponding operators, and marketability. Some members of the Committee have nevertheless expressed reservations on the possibility of distinguishing *de facto* the collaboration among the team involved in performing the voluntary interruption of pregnancy and the team using the derived fetuses, even when suitable formal procedures are adopted to distinguish their possible relationship of causality.
29. points out that several of its members acknowledge and agree with the ban on creating human embryos for the sole purpose of using them for scientific research, as provided for in art. 18, paragraph 2, of the *Convention on Human Rights and Biomedicine*. According to other members of the Committee, a thorough evaluation of the experimental results of somatic nuclear replacement may suggest that this new line of research could produce therapeutic results of great impact and for the time being without any alternative such as to suggest evaluating the ethical aspects of future applications on a case by case basis.
30. reiterates the illegitimacy of using the somatic nuclear replacement technique for reproductive purposes ("reproductive cloning").
31. points out that part of the Committee consider it ethically allowed to derive stem cells for therapeutic purposes from embryos that it is no longer possible to implant, again on condition that they are wittingly donated by the women or the couples concerned. They nevertheless recommend performing rigorous tests and checks on a case by case basis on the suitability for implantation, the consent to donate and the therapeutic purpose of the experimentation. These should be carried out by ad hoc indicators of a reasonable impracticability of implantation, as well as by following adequate guidelines and ensuring a preventive evaluation is made by an ethical committee. Other members of the Committee are in any case against using supernumerary or spare embryos even when cryopreserved and not required for transfer to the uterus, because they consider such practices to entail the direct and deliberate suppression of the embryos and thus an instrumental use of human beings and an offence to their dignity.
32. expresses the hope that a topic of such importance for biological and medical research and so significant as regards the possible treatment of diseases of great social impact and today difficult to treat will be the object of accurate information and wide debate. This should be the case not only within the scientific community but also within laymen, so that the latter can be made aware of and responsibly address the problems of a chapter of medicine that, while certainly new, it is hoped will also be effective, and to which the name of "regenerative medicine" has been given.

Table I: Human non embryonic stem cells

<i>adult</i>	<i>tissue/original cells</i>	<i>tissue/final cells</i>
from cadaver	progenitor cells of hippocampus neur	Neurons
	mesenchymal cells of bone marrow	adipocytes, chondrocytes, osteocy
umbilical cord	progenitor hemopoietic cells	Erythrocytes, granulocytes, megal monocytes
	bone marrow	cells expressing neural proteins (r cells)
neuron progenitor pool	progenitor cells of hippocampus neur	Neurons
	olfactory bulb	neurons, astrocytes, oligodendroc
healthy adult volunteers	stromal cells of bone marrow (mesenc derivation)	(non mesenchymal) neuronal cells
	stem cells from bone marrow	Hepatocytes
tissues from autopsies and biops	stem cells from bone marrow	Hepatocytes and cholangiocytes
case report and review	progenitor cells from umbilical cord	"hemopoietic and immunological acute leukaemia patient

Survey on Human Embryonic Stem Cells research and use

THE NETHERLANDS

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Yes, The Health Council has provided an advisory report on Research and Use of Human ES Cells (November 1997). This report does not contain a summary in English, nor has it been translated. However, a summarizing note has been published in our International magazine 'Network' Volume 13 nr 1 (May 1998). Please find this note attached. The report focussed on the need to take account of ES cell research in planned legislation of Embryo research. Recently, the Health Council has been asked by the Minister of Health to prepare a further report on human ES-cells in the context of diverse strategies in celltherapy and transplantationmedicine. An expert committee of the Council will be set up to fulfill this task.

Contact person: dr PA Bolhuis e-mail <pa.bolhuis@gr.nl> Tel +31 70 3407717.

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

No public debate has taken place on this particular subject; however, there has been public debate on the related topic of human cloning, which includes non-reproductive embryo-cloning in the context of stem cell research or therapy (feb 97- oct 99). The conclusions of the debate call for a moratorium on human reproductive cloning but would not rule out non-reproductive embryo-cloning. The debate was organised by the Rathenau Institute. It has led to a publication ("kloneren in de polder") issued by the Rathenau Institute, with a summary in English.

Contact person at the Institute is dr K van der Bruggen e-mail <rathenau.instituut@rathenau.knaw.nl> tel +31 703421542.

website: www.rathenau.nl

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

At present there is no formal legal framework. However, the Minister of Health has asked IVF-centers and the relevant scientific groups to submit all protocols involving embryoresearch for review to the CCMO (see below). She also asked CCMO to use a 1995 Government memorandum on embryoresearch as a framework when carrying out this task. Both requests are without legal basis, but there is a factual agreement between the parties involved that this is how things will be handled for the moment (awaiting the outcome of the debate on new legislation; see under 4.) The meant 1995-Memorandum contains a limitative list of acceptable fields of embryoresearch not including celltherapy or transplantationmedicine. This effectively precludes ES-cell research (except using already existing cell-lines). The Memorandum also forbids the special creation of embryo's for nonreproductive purposes.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

The Bill on the handling of Human Gametes and Embryos was presented to Parliament in September 2000. The envisaged legislation (The Bill is still in the first phase of the parliamentary process), will also govern research involving human ES cells. The Bill contains provisions for the donation of embryos for research, including stemcell research. It limits the fields of application to health purposes (including medical research and medical education). It also stipulates that all protocols in the field of embryo research must be reviewed by the Central Committee (CCMO), which is set up in the context of the Medical Scientific Research Involving Human Subjects Act (as an additional task of that committee). This latter requirement applies to research involving the creation of ES-cell lines from human embryos, but not to research using already existing ES cell lines. Research involving the creation of new embryos not intended for transfer (which is the case if stemcellresearch or therapy is combined with nonreproductive embryo cloning) falls under a three year moratorium. The Bill already contains provisions that will apply after lifting the ban. Among the conditions under which 'therapeutic cloning' will then be allowed is that this may only be done for transplantationpurposes which cannot be achieved through other means (eg: use of adult stem cells). An English version of the Bill and a summarizing brochure is on the website of the Ministry of Health: www.minvws.nl under the 'international'-button. The head of the bureau of the CCMO is dr Marcel Kenter; e-mail <ccmo@ccmo.nl> Website: www.ccmo.nl Tel +31 70 3406700.

Annex

Developments identified which could affect new legislation

Research using embryonic stem cells

On 26 November 1997, the Health Council submitted a report on research using embryonic stem cells to the Minister of Health, Welfare and Sport. In the report the Council highlights certain important developments taking place in the field and urges the government to take account of these developments when drafting the planned bill on procedures involving human reproductive cells and embryos

Embryonic stem cells are the undifferentiated precursors of the many different types of cell from which the tissues and organs of the growing embryo are made. Scientists have succeeded in isolating and cultivating ES cells; in the laboratory, ES cells can be used to grow more stem cells, or, through controlled differentiation, to form cells of various types. Such procedures create enormous scope for research into embryonic development processes and into the emergence of certain diseases. Far-reaching practical applications also look likely in fields such as pharmacology and transplantation.

To date, only animal ES cells have been studied. However, in anticipation of research into possible human applications, the question arises: is it ethically acceptable to use human embryos to establish the necessary cell lines? Human ES cells could be obtained from embryos which, having been created by in vitro fertilization (IVF), can no longer be used for their original purpose, i.e. to initiate pregnancy. The government's planned act on procedures involving human reproductive cells and embryos will clarify whether and, if so, under what conditions it is permissible to use these "surplus" IVF embryos for research or therapeutic ends. The Minister of Health, Welfare and Sport has already outlined the content of the bill in a memorandum to the Lower House. According to this document, the government intends to outlaw research involving the use of human embryos, except where the object is to benefit scientific understanding of (in)fertility, artificial reproduction or hereditary or congenital medical conditions.

The Health Council endorses the view that research involving the use of human embryos is only acceptable if it serves an important medical purpose. However, the Council believes that the restrictive definition of conditionally acceptable research fields could prevent other, equally important research.

Survey on Human Embryonic Stem Cells research and use

PORTUGAL

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Dra. Helena P. Melo
Serv. Bioética e Etica Médica
Fac. Medicina do Porto, Al. Prof. Hernâni Monteiro
PT – 4200-319 Porto
Fax : 351.22.55.73.469

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

There is no legal and/or regulatory framework for human embryonic stem cells research and use.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No legal and/or regulatory framework for human embryonic stem cells and use is under preparation.

Survey on Human Embryonic Stem Cells research and use

SPAIN

- 1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

There is a National Commission of Hematopoietic progenitors Transplant. In 1997 a document about the use of Umbilical cordon blood transplant has been elaborated.

- 2. Will (or has) a public debate take(n) place on human embryonic stem cells?**

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

- 3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

It is regulated in the Royal Decree 411/96, it can be found in the ONT web page <http://www.msc.es/ont/esp/legislacion/flegislacion.htm>. Contact person: Dra. Mayte Nega ONT email: mnaya@msc.es.

- 4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

none

Survey on Human Embryonic Stem Cells research and use

SWEDEN

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

both the NEC and the Medical Research Council is working on it.

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

Very divided views – catholics on one side (only adult stem cells OK for research).

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

See enclosure

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

Not any new.

Survey on Human Embryonic Stem Cells research and use

UNITED KINGDOM

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:
The Council published a short discussion paper called 'Stem cell therapy; the ethical issues' in 2000. This can be obtained in full from the Council's website; <http://www.nuffieldfoundation.org/bioethics/publication/index.html>
The paper was prepared by Professor Martin Bobrow CBE, Professor Tom Baldwin, Lady Hornby, Professor Alexander McCall Smith and Dr Anne McLaren DBE FRS. The members can be contacted via the Council.

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

Much public debate in this country was generated by patient groups, including:

The Association of Medical Research Charities.

Chief Executive: Mrs Diana Garnham. www.amrc.org.uk

The Parkinson's Disease Society; www.parkinsons.org.uk

The Alzheimer's Disease Society; Mr Harry Cayton, www.alzheimers.org.uk

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

Details of the current legal framework and future changes can be obtained from the Department of Health – www.doh.gov.uk. The House of Lords has just established an Ad Hoc Committee on Human Cloning and Stem Cell Research. The contact person is Tony Rawsthorne, email: rawsthornet@parliament.uk

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

see question No. 3

Survey on Human Embryonic Stem Cells research and use

ICELAND

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

No organised public debate has taken place but the issue is being discussed, in particular by professional groups.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The only provisions relevant for embryonic stem cells research are provisions in the Act on Artificial Fertilisation Act no. 55/1996, where *Research on embryos* is dealt with in Art. 11 and 12:

Art. 11: All research, experiments and operations on embryos is prohibited.

Nevertheless, it is permitted to carry out research on embryos:

- a) if it is part of an *in vitro* fertilisation treatment, b) if the intention is to diagnose hereditary diseases in the embryos themselves, c) if the purpose is to advance the treatment of infertility, or d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages.

Art. 12: It is prohibited to:

- a) cultivate or produce embryos solely for research purposes, b) cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared, c) transplant human embryos into animals, and d) perform cloning.

In Regulation no. 568/1997 on Artificial Fertilisation it is further stipulated in Art. 22 that it is prohibited to carry out research on embryos based on Act no. 55/1996, Art. 11, as defined in c) and d) (c) *if the purpose is to advance the treatment of infertility,*

and d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages), unless the research fulfills the criteria of a scientific study as defined in Art. 1, paragr. 8 of the regulation (*A scientific study means research conducted with the aim of achieving further knowledge, making it possible, among other things, to improve health and cure diseases*), and has been granted approval by the National Bioethics Committee or an institutional ethics committee, according to the Act no. 74/1997 on Patients Rights.

The Artificial Fertilisation Act no. 55/1996 , the Regulation no. 568/1997 on Artificial Fertilisation and the Act no. 74/1997 on Patients Rights are available in English on the homepage of the Ministry of Health and Social Security.
<http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/lawsandregs>

Contact: Gudridur Thorsteinsdottir, Director Legal Department, Ministry of Health and Social Security, Laugavegur 116, 150 Reykjavik, Iceland.
E-mail: gudridur.thorsteinsdottir@htr.stjr.is

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No change in legislation or regulations regarding "Human Embryonic Stem Cells Research" is being prepared, according to information from the Ministry of Health and Social Security.