Stem Cells Biobanks

Bioethics Consultative Committee

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STEM CELL BANKS

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1. Stem Cells: The Potential

Stem cells have the capacity to multiply indefinitely either into other stem cells with the same potential or to become daughter cells with much more specialised characteristics. This capacity has generated considerable scientific interest leading to much research on their isolation, their long term culture and the establishment of stem cell lines, their ability to control their specialisation into various cell types and tissues, as well as in developing methods which would avoid the problem of transplant rejection. Scientists, thus hope that stem cells and their culture into specific differentiated stem cell lines would lead to considerable advances in fields as diverse as pharmacological studies and toxicology testing; gene therapy, using stem cells as vectors (such as the use of genetically modified, HIV-resistant, haematopoietic stem cells), and regenerative medicine involving the therapeutic transplants of cells and tissues. In order to harvest their potential, however, research needs to move from being sporadic to a more sustained collaborative effort. One way of doing this would be to establish stem cell repositories which would make stem cells or stem cell lines available for scientific study without the need for individual scientists to have the required expertise or to have to go through the laborious process of reliably isolating and producing them. This would also "minimise the use of human tissues, and enable different researchers to work on identical material so that direct comparisons may be made between studies."[1] Even in the case of treatment, however, stem cells may have to be stored for potential future autologous (or allogenic) use. Thus, for both future therapy and current research, a number of stem cell banks have been established, thereby raising a number of ethical, legal and social concerns.

2. Stem Cell Banks, Registries and Libraries

2.1 Stem Cell Banks

Biological material has been collected and used for different purposes for many years, and it is to be expected that the recent sustained focus on stem cell research would bring about the need for collections of stem cells and stem cell lines for both therapeutic and research purposes. These collections, physically stored in facilities today commonly known as banks, vary in nature depending on the specific type of material collection and the purpose

[1] UK STEM CELL BANK, *Code of Practice for the Use of Human Stem Cell Lines,* 2010.

behind their collection and storage, such that the Austrian Bioethics Committee could 'differentiate' biobanks according to a number of criteria.[2] These are listed below, together with some ethical concerns which might arise in each case:

1. The type of biological material collected: e.g. embryonic stem cells, induced pluripotent stem cells, somatic stem cells or umbilical cord stem cells. Ethical issues include the moral status of the human embryo, the dignity of the human person and the status of the tissue derived from the human body.
2. The manner in which samples are obtained: e.g. whether the biological samples are collected purposely, as in the case of umbilical cord blood, or whether the collection is made of residual material, such as amniotic stem cells collected after amniocentesis. The ethical issues over here would be those of consent and participation, including advertising and incentives for participation, and how biological material taken during the course of diagnostic and therapeutic procedures could become material for research.
3. The purpose of the collection: e.g. for therapy, research or both. The main ethical issue would be that of consent and the giving of adequate information which has been understood. This concern becomes even more pressing in the case of commercial cord blood banks.
4. The way the samples are stored: e.g. cryopreserved, or cultured in a media made of animal material. While not raising ethical issues in itself, this became an issue in the USA when President Bush decided that only established embryonic stem cell lines would continue to receive federal funding, with some countering that the established cell lines were cultured on animal media and would not be useful for therapeutic purposes. The storage of biological material also raises issues of quality control and safety.
5. The amount of data linked to the biological material: this leads to serious ethical concerns related to privacy and identifiability, but since stem cell banks usually do not link data to the biological samples, these issues are usually not pressing concerns in the case of stem cell banks. In fact, one usually speaks of stem cell banks, not stem cell biobanks.[3]

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[2] THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

[3] Biobanks are defined as "collections of human biological material (e.g. tissue, cells, DNA, proteins, blood or other body fluids) as the physical medium of information which is typically linked or can be linked to data

6. The size of the sample and data collection: e.g. private banks, or national/international initiatives. Apart from the usual issues of consent and adequate information, the issue of the ownership of the materials, the right of participants to results or profit sharing, and organisational issues come to the forelight. The latter include ethical issues related to funding and bankruptcy; merging or dividing banks; accessing, exporting, selling and destroying samples; as well as ethical and legal oversight of the banks.
7. Whether the establishment of the biobank is disease-related (such as collections of stem cells associated with a specific genetic disease) or population-related (such as a national stem cell bank): which lead to questions of participation and consent (opt in / opt out).
8. Whether the biobank conducts medical research on identifiable human material or identifiable data: leading to ethical concerns related to privacy, confidentiality and ownership.
9. Who operates the biobanks, whether public and/or private organisations: leading to questions of participation and consent as well as issues related to access to health care services and regulation.
10. Whether biobanks are operated for commercial (profit-oriented) or academic (non-profit-making) purposes: which leads to questions of participation and consent as well as the ownership of the biological material and the benefits participants receive from having their samples stored in the bank.

2.2 Stem Cell Registries and Libraries

Stem cell registries and libraries do not collect cell lines. While registries "catalogue stem cell lines and provide certain information about each line, including provenance, subculture, disease characteristics, derivation, ethics approval, storage facility and contact information", libraries "collect detailed scientific information about specific cell lines that comes from research on those lines. Information in libraries is constantly being added to and updated as research progresses and can be thought of as akin to information collected in the human genome project."[4] Examples of registries include: the UK Stem Cell Bank's registry,[5]

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and information of the donor". THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

4 http://www.stemcellnetwork.ca/index.php?page=stem-cell-banks-libraries-and-registries

5 http://www.ukstemcellbank.org.uk/

the International Stem Cell characterisation Initiative,[6] the US NIH Human Pluripotent Stem Cell Registry,[7] and the EU Human Embryonic Stem Cell Registry.[8] Though the focus of existing stem cell registries is on hES lines, the NIH has recently been directed to expand its registry to pluripotent cells. The UKSCB registry also catalogues adult stem cell lines. At present, proposed stem cell registries include a database by the International Society for Stem Cell Research (ISSCR) for published stem cell lines and a national registry for Canadian hES lines from the Canadian Institutes of Health Research (CIHR).[9] An example of a registry would be that announced by McMaster University in 2007, which aimed to be "the first facility in the world to focus on understanding the role played by each gene in hES cells."[10]

3. Intense Ethical Discussion

Biobanks in general have led to a number of ethical, legal and social concerns dealing with issues such as consent; confidentiality and privacy; ownership, commercialisation and benefit sharing; surveillance, regulation and governance. These concerns, most of which are also shared by stem cell banks in particular, have become more pressing as the collections have grown in size, as the research has become more internationalised, and as the commercial asset value of the biological material has become more visible.[11] Consequently, through an insignificant routine practice for almost a century, the storage of human tissue samples has generated increasing concerns. These have been studied by a number of national ethics committees, and have led to a marked increase in (non-binding) recommendations as well as (binding) regulations and law.

3.1 Discussions on a National Level

In Europe, a number of national Ethics Commissions have studied the issues relating to biobanks containing human cells, tissue or body fluids and the related medical data and in some cases have published their own reports and opinions.[12] Perhaps the most important of

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6 http://www.stemcellforum.org/isci_project.cfm
7 http://stemcells.nih.gov/research/registry/
8 http://www.hescreg.eu/
See also http://www.hescreg.eu/uploads/media/Code_of_Practice_hESreg_Dec_2009.pdf
9 http://www.stemcellnetwork.ca/index.php?page=stem-cell-banks-libraries-and-registries
10 *Ibid*.
11 Bjørn HOFMANN – Jan Helge SOLBAKK – Søren HOLM, "Analogical reasoning in handling emerging technologies: The case of umbilical cord blood biobanking", in *American Journal of Bioethics* 6/6 (2006) 49–57.
12 THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

these opinions are those of the German National Ethics Council,[13] the French National Consultative Bioethics Committee,[14] and the Bioethics Commission at the Federal Chancellery.[15] An extensive survey on the opinions of national ethics committees as well as national legislation in relation to biobanks has been published by the European Commission Research Directorate-General, based on feedback received from EU Member States, candidate countries, Georgia, Iceland, Israel, Norway, Switzerland as well as Canada and the United States.[16] The setting up of the UK Biobank has also led to a number of important documents.[17] Moreover, one could perhaps also highlight the fact that the European Group of Ethics has also published a report on the banking of human tissue and another one on human stem cell research.[18]

Apart from biobanks in general, a number of national committees and organisations have also discussed the matter of cord blood banking in particular. These include: the French *Comité consultatif national d'éthique pour les sciences de la vie et de la santé*;[19] the Belgian Advisory Committee on Bioethics;[20] the Scientific Advisory Committee of the UK Royal

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[13] NATIONALER ETHIKRAT (German National Ethics Council), Opinion: *Biobanks for research*,17 March 2004; Online: http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf

[14] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 77: *Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks" , "Biolibraries"*, March 20 2003. http://www.ccne-ethique.fr/english/start.htm; http://ec.europa.eu/research/biosociety/pdf/opinion_77.pdf

[15] THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

[16] See EUROPEAN COMMISSION RESEARCH DIRECTORATE-GENERAL, *Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human biobanks*, 2004; Online: http://ec.europa.eu/research/biosociety/pdf/catalogue_biobanks.pdf (Accessed: 1 June 2011).

[17] HUMAN GENETICS COMMISSION, *Inside Information Balancing Interests in the Use of Personal Genetic Information*, London: Human Genetics Commission 2002. http://www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf ; UK Biobank – The WELLCOME TRUST – THE MEDICAL RESEARCH COUNCIL – THE DEPARTMENT OF HEALTH, *UK Bioethics and Governance Framework*, Version 1.0 (24 September 2003). http://www.ukbiobank.ac.uk/docs/egf-comment-version.doc ; UK BIOBANK, *UK Biobank Policy on Intellectual Property ("IP") and Access*, First Public Draft (11 January 2005), http://www.ukbiobank.ac.uk/docs/UKBiobankIPandAccesspolicyfirstpublicdraft11.1.5final2.pdf ; MEDICAL RESEARCH COUNCIL – THE WELLCOME TRUST, *Access to Collections of Data and Materials for Health Research*, London: Medical Reasearch Council 2006). http://www.mrc.ac.uk/pdf-access_report_march_2006.pdf .

[18] EUROPEAN GROUP OF ETHICS, Opinion 11: *Ethical Aspects of Human Tissue Banking* (21.07.1998); Opinion 15: *Ethical Aspects of Human Stem Cell Research and Use* (14.11.2000)

[19] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Avis 74: *Les Banques De Sang De Cordon Ombilical En Vue D'une Utilisation Autologue Ou En Recherche* (2002); Online: http://www.ccne-ethique.fr/avis.php

[20] See Belgian Advisory Committee on Bioethics, Opinion 42 of 16 April 2007 on *Umbilical Cord Blood Banks*; Opinion 43 of 10 December 2007 on *The Problem of Commercialisation of Human Body Parts*; Opinion: 45 of 19 January 2009 on *human biological material banks intended for research*. Online: http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/Opinions/

College of Obstetricians and Gynaecologists,[21] and the Policy Statement of the American Academy of Paediatrics.[22] The European Group of Ethics has also issued a report on the subject.[23]

3.2 Council of Europe

The **Biomedicine Convention of the Council of Europe** (1997) is the first legally binding international code related to biomedical issues, including biomedical research.[24] The Oviedo Convention, as it is perhaps most commonly known, came into force in 1999 and has been signed by the vast majority of member states of the Council of Europe. Though Malta is not yet a signatory to this Convention, one may still highlight some important provisions of this important treaty, namely, that:

> Article 1 – protection of the dignity and identity of all human beings and respect for their integrity and other rights and fundamental freedoms;
>
> Article 2 – the interests and welfare of the human being shall prevail over the sole interest of society or science;
>
> Article 3 – equitable access to health care of appropriate quality;
>
> Article 4 – any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards;
>
> Article 5 – an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

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[21] ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS, Scientific Opinion Paper 2 on *Umbilical Cord Blood Banking* (2006), replacing the previous version published in October 2001. Online: http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf.

[22] AMERICAN ACADEMY OF PAEDIATRICS, in "Cord Blood Banking for Potential Future Transplantation" (Policy Statement), in *Paediatrics* 119/1 (2007) 165-170. This is a revision of the 1999 policy.

[23] EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[24] COUNCIL OF EUROPE, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, (Oviedo, 4 April 1997). http://conventions.coe.int/treaty/en/Treaties/Html/164.htm. See also *Additional Protocol on the Prohibition of Cloning Human Beings* (opened for signature in 1998, entered into force in 2001); *Additional Protocol on Transplantation of Organs and Tissues of Human Origin* (opened for signature in 2002, entered into force in 2006); and *Additional Protocol concerning Biomedical Research* (opened for signature in 2005, entered into force in 2007).

Article 6 – Protection of persons not able to consent;

Articles 15, 16 and 17 outline general rules concerning research;

Article 18 – adequate protection of the embryo when research on embryos in vitro is legal; The creation of human embryos for research purposes is prohibited;

Article 21 – prohibits the commercialisation of the human body and its parts, since "the human body and its parts shall not, as such give rise to financial gain";

Article 22 – indicates clearly the need for appropriate informed consent when storing or using human biological material: "When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures."

The Council of Europe has also issued some directives and recommendations which, though not legally binding, should be taken into consideration. The Committee of Ministers have issued the following recommendations which are important for the subject matter under consideration:[25]

- Recommendation Rec (2006) 4 of the Committee of Ministers *on research on biological materials of human origin*;
- Recommendation Rec (2004) 8 of the Committee of Ministers on autologous cord blood banks;
- Recommendation R (94) 1 of the Committee of Ministers on human tissue banks;
- Recommendation R (90) 3 of the Committee of Ministers concerning medical research on human beings.

The Parliamentary Assembly of the Council of Europe has also issued the following resolution and recommendations:

- Resolution 1352 (2003) on human stem cell research;
- Recommendation 1468 (2000) on biotechnologies;
- Recommendation 1425 (1999) on biotechnology and intellectual property;
- Recommendation 1240 (1994) on the protection and patentability of material of human origin.

[25] All documents are available under: http://www.coe.int/T/E/Legal Affairs/Legal cooperation/Bioethics/Texts and documents/4Parliamentary Assembly.asp#TopOfPage.

3.3 European Union

The European Union also has important Directives containing specific rules which apply to stem cell banking:

- The Data Protection Directive: Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- The Biopatent Directive: Directive 98/44/EC on the legal protection of biotechnological inventions;
- The Tissue and Cells Directives: Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. This parent directive was followed by two technical directives: Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells; and Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

4. The Importance of Analogies

Modern biobanks have led to a marked increase in discourses on ethics and governance. Some researchers have tried to view "the increased attention paid to ethics as part of a special mode of regulation created through what Wittgenstein called language-games." In so doing, Hoeyer and Tutton focus on four aspects of the language-games of ethics in the Ethics and Governance Framework of the UK Biobank, exploring aspects related to the representation of individual choice, the use of public consultation, the establishment of regimes property exchange and changing conceptions of governance.[26]

Similarly, other authors have tried to understand the discourses on the ethics of biobanks in terms of the analogies used. Hofmann and his colleagues, for example, question

[26] Klaus L HOEYER – Richard TUTTON, "'Ethics was here': Studying the language-games of ethics in the case of UK Biobank", in *Critical Public Health* 15/4 (December 2005) 385–397.

why collections of biological materials are called "biobanks", asking: "What is the rationale behind using the word bank to name these institutions? And to what extent is it justifiable to frame these institutions within a vocabulary of hard currency, i.e., of economical values?"[27] The reason for this, they argue, is that the term 'biobank':

> "captures in a succinct way the ethical core activities of these institutions, i.e., the different activities of exchange and change that take place between donors of biological samples and guardians or curators of such samples as well as between bio-guardians/curators and users of biological samples, i.e., health professionals and researchers."

Hofmann and colleagues do not only argue that "analogies play an extensive role in the debate on how to appropriately understand and manage" biobanks;[28] they argue further that "the selection and promotion of analogies has a normative function in and of itself. Because certain analogies are more suitable to emphasize particular aspects of a technology they will be more efficient in promoting certain conceptions and actions."[29] Analogies, they point out, may be said to have an analytical and an argumentative function. On the one hand, in fact, they "are applied to explore or analyze a certain issue, such as to determine the onto-logic status of biological material, to conceive of the knowledge that stems from it, and to map how we should actually act with respect to such material";[30] on the other hand, "analogies are applied to argue for certain conceptions and ways of handling the issue under scrutiny. That is, analogies may be used to explore the normative terrain of biobanking as well as to make normative claims."[31]

Analogies are thus value-laden, and if one can convince others to accept a particular analogy as a good analytic tool, one may also convince them to accept the valuation implicit in the analogy. "A prime example", they argue, "is the analogy of 'waste', which implies a low valuation of the material denoted as waste and a tendency to hide that some kinds of waste are extremely valuable even to the waste producer." [32]

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[27] Bjørn HOFMANN – Jan Helge SOLBAKK – Søren HOLM, "Analogical reasoning in handling emerging technologies: The case of umbilical cord blood biobanking", in *American Journal of Bioethics* 6/6 (2006) 49–57.
[28] *Ibid.*
[29] *Ibid.*
[30] *Ibid.*
[31] *Ibid.*
[32] *Ibid.*

Analogies also differ with respect to the people who provide the biological samples, who might be referred to in a variety of ways: as donors, human subjects or research subjects, or even as research participants, which is the most popular idiom today.[33]

The analogies discussed by Hofmann have been taken up by Karama Neal in his discussion of umbilical cord legislation in the USA.[34] Basing himself on data from the (US) Cord Blood Registry, Neal identifies four such categories, namely:

(1) Information dissemination and donation promotion, based on the analogy of organ donation or gift;
(2) public biobank establishment or support, based on the analogy of natural resources or waste;[35]
(3) incentives for donation based on the analogy of charitable contribution; and
(4) advisory board creation based on the analogy of natural resources or stewardship.

In 2006, the first analogy was adopted or was being considered in thirteen states, with laws requiring "hospitals, physicians, or others to distribute information on cord blood donation, some of which would directly promote donation. Illinois state law, for example, requires that hospitals notify pregnant patients of their cord blood donation options."[36] The second analogy has been adopted by nine states which either have or are considering laws establishing or supporting existing public cord blood biobanks. The third analogy has been adopted by one state, namely Louisiana, which was considering a bill that would give a tax credit to those families choosing to donate blood cord blood. The fourth analogy has been adopted by three states which have created advisory boards charged with the development and/or administration of cord blood donation programs.

As can be seen from the above, the analogies of donation or gift, based on the concept of generosity, dominate. Interestingly, however, Neal states that legislation focusing on public treatment and research biobanks is best described by analogies which see cord blood as a resource that can either be discarded (waste) or used (natural resource). He concludes,

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[33] While pervasive in the offficial documentation of the UK Biobank, this has also been adopted by many authors. For references, see *Ibid.*

[34] Karama C NEAL, "Analogical trends in umbilical cord blood legislation in the United States", in *American Journal of Bioethics* 6/6 (2006) 49-57.

[35] For example, the South Dakota resolution states, in part: "Whereas, umbilical cord blood may be donated to a publicly accessible certified umbilical cord blood bank rather than be thrown away as medical waste" (South Dakota House 2005). Cited in Karama C NEAL, "Analogical trends in umbilical cord blood legislation in the United States", 49-57.

[36] *Ibid*.

however, that "given that analogies of generosity predominate in existing US cord blood legislation, legislators that are considering introducing bills in support of cord blood donation and use may want to focus on the analogies of generosity, even if their legislation includes creation of public biobanks or advisory boards ... the use of analogies of generosity seems to resonate with the American public and their lawmakers. Consequently, they may be useful in developing and passing cord blood legislation and providing funding to support it."[37]

5. Ethical Issues

5.1 Fundamental Ethical Principles

The rapid increase in biobanking activities has lead to a number of important policy texts, recommendations and even binding treaties (as seen in Section 3). It may be helpful, however, to summarise in a succinct form the ethical principles related to stem cell banking, and this has been done well by the European Group of Ethics in its opinion on umbilical cord banking:[38]

(1) The principle of respect for human dignity and integrity, which asserts the principle of non-commercialisation of the human body;
(2) The principle of autonomy or the right to self-determination on the basis of full and correct information;
(3) The principles of justice and solidarity, as regards to fair access to healthcare services;
(4) The principle of beneficence, or the obligation to do good, especially in the area of health care;
(5) The principle of non-maleficence, or the obligation not to harm, including the obligation to protect vulnerable groups and individuals (e.g. pregnant women who may be coerced into consenting), to respect privacy and confidentiality;
(6) The principle of proportionality which implies a balance between means and objectives.

The European Group of Ethics rightly points out that the values of freedom and free enterprise may conflict with the principles of solidarity and justice, according to which access

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[37] *Ibid*.
[38] EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

to healthcare should be on an equitable basis. This conflict may come to the forefront, for example, in the case of commercial umbilical cord banks which promote banking for possible future autologous use (see section 6).

5.2 Types of Stem Cells

A major issue of stem cell banking is the type of stem cells being banked and the way these cells are obtained.

5.2.1 Embryonic Stem Cells (eSC)

Stem cells derived from embryos pose serious ethical problems related to the creation, use and destruction of human embryos. As embryonic human beings, human embryos share the same dignity and, therefore, should enjoy the same level of protection as any other member of the species *Homo sapiens*. Failing to do so, in fact, would amount to discrimination of the basis of (gestational) age.

There are attempts, however, to create embryonic stem cell lines without the need to destroy human embryos. Kevin Eggan and his team (Harvard University) have attempted somatic nuclear transfer into an existing embryonic stem cell in order to create a new stem cell line.[39] This procedure, however, does not solve the ethical problem related to the destruction of embryos, for it raises the ethical question of cooperation in the destruction of the embryo from which the cell line was developed in the first place.

Robert Lanza and his team (Advanced Cell Technology) have taken a different approach, reporting that they have successfully derived a Stem Cell Line using a process similar to preimplantation diagnosis, in which a single blastomere is extracted from a blastocyst.[40] While Lanza's procedure might seem to bypass the ethical problem of embryo destruction, this approach might still raise some ethical concerns.[41]

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[39] CA COWAN *et al.*, "Nuclear reprogramming of somatic cells after fusion with human embryonic stem cells", in *Science* 309/5739 (August 2005) 1369–1373.

[40] I KLIMANSKAYA *et al.*, "Human embryonic stem cell lines derived from single blastomeres", in *Nature* 444/7118 (November 2006) 481–485.

[41] In this study, multiple cells were removed from each embryo and none of the embryos were allowed to continue development. Subsequently, Lanza and his team reported another study in which the biopsied embryos were grown to the blastocyst stage and frozen, whereas the removed blastomeres were cultured in a way aimed to recreate the inner cell mass niche. Young CHUNG et al., **"**Human Embryonic Stem Cell Lines Generated without Embryo Destruction", in *Cell Stem Cell* 2/2 (February 2008) 113-117.

eSC may also be obtained from Human Admixed Embryos (HAE),[42] whose creation, however, creates serious ethical concerns regarding the violation of the principle of human dignity and integrity.

5.2.2 Induced Pluripotent Stem Cells (iPSC)

Other researchers have tried to reprogramme differentiated cells to an embryonic-like state using a variety of techniques.[43] Each of these might present different ethical concerns, most notably those concerned with the unknown biological impact of the changes caused by the way they were brought about (e.g. teratoma formation). These quality and safety issues should certainly lead to substantial scrutiny prior to any approval for therapeutic uses. Moreover, while autologous iPS offer the promise of avoiding rejection when transplanted, they can have no therapeutic value in the case of hereditary diseases, since they would bear the same genetic defects.

5.2.3 Parthenogenetic Stem Cells (hpSCs)

Some researchers have tried to bypass the ethical concerns related to human eSC by focusing their research on human parthenogenetic stem cells (hpSC) derived from human oocytes. These are parthenogenetically activated by different electrical or chemical stimuli which simulates spermatozoon penetration. Researchers report that these parthenogenetic embryos are capable of reaching the blastocyst stage and that their inner cell mass can give rise to parthenogenetic stem cell lines.[44] Scientifically speaking, these hpSC are similar to eSC and iPSC in terms of pluripotency and proliferation. Moreover, since there is no forced change of gene expression patterns, they are unlikely to present the same safety and regulatory problems faced with ipSC. Ethically, however, one may still question whether the parthenote has the ontological moral status of a human embryo.[45]

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[42] For example, '*Cytoplasmic hybrids'* (replacing the nucleus of an animal egg or cell with a human nucleus, cell, gamete or two pronuclei); '*True hybrid'* (created from human and animal gametes or pronuclei; '*Transgenic human embryo' (*a human embryo with animal nuclear or mitochondrial DNA inserted into any cell); '*Chimeric human embryo'*, (a human embryo that has been altered by the introduction of one or more animal cells).

[43] K TAKAHASHI – S YAMANAKA, "Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors", in *Cell* 126/4 (2006) 663–676.

[44] http://www.internationalstemcell.com/stemcells.htm

[45] S RODRIGUEZ *et al.*, "An obscure rider obstructing science: The conflation of parthenotes with embryos in the Dickey-Wicker amendment", in *American Journal of Bioethics* 11/3 (2011) 20-28; R DISILVESTRO, "The Parthenotes and the Parthenon", in *The American Journal of Bioethics* 11/3 (2011) 35-36.

5.2.4 Adult Stem Cells (aSC)

Adult or somatic stem cells have been isolated from different organs and tissues, and avoid the ethical problems related to the creation, use and destruction of human embryos. Some scientists, however, argue that their lack of pluripotency and their slower proliferation makes them less useful for stem cell research. Be that as it may, almost all stem cell therapies which are either available today or which are currently undergoing clinical trials are based on aSC. While it is not possible to discuss all types of aSC, two in particular should be highlighted.

5.2.4.1 Amniotic Stem Cells (amSC)

Recently, cells derived from the amniotic fluid for genetic diagnosis have been found to share many biological characteristics of stem cells, with researchers identifying cells of the three embryonic germ layers in the amniotic fluid.[46] It would therefore seem that this approach would offer scientists with different types of cells from one single source while overcoming the ethical difficulty of using eSC. These researchers have thus established Amniotic Stem Cell International as an international non-profit repository of stem cells from the surplus cells remaining after amniocentesis.[47]

5.2.4.2 Cord Blood Biobanks

The most commonly banked aSC today, however, are those found in cord blood which is considered as a tissue, and not as blood, even for regulatory purposes. The reason for this is that what is being stored is the haematopoietic stem cells found in the cord blood.[48] While overcoming the ethical problems associated with eSC, published studies have shown that cord blood stem cells have the capacity to change into other cell types. Advances in cord blood collection and storage, as well as progress in medical technology, have resulted

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[46] R SIMANTOV, "Amniotic Stem Cell International (Short communication)", in *Reproductive BioMedicine* 16/4 (2008) 597-598.

[47] The isolated cells, donated free of charge, will be expanded under xeno-free culture conditions and used to produce homogeneous, specialized and genetically characterized cells.

[48] The Directive of the European Parliament and the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, adopted on 2nd March 2004 covers haematopoietic progenitor cells but excludes blood and other blood products. The *Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin* which applies to tissues and cells, including haematopoietic stem cells but does not apply to blood and blood derivatives. *Directive 2002/98/EC* of 27 January 2003 *concerning the quality and safety of collection, storage and distribution of human blood and components* does not apply to blood stem cells.

in an increased use of these cells, both for treatment and research, and this has lead to a significant number of cord blood banks to be set up globally. A pressing ethical issue, however, is whether such banks should be allowed to operate for profit, or whether they should be private or public. This will be discussed later on in Section 6.

5.3 Consent

5.3.1 Informed Consent

Free and informed consent is an essential ethical principle in the collection of stem cells (be it for therapeutic or research purposes). The information given should be comprehensible, and oral information should be supported by relevant written material. The scope of consent should include the purposes, the nature, the significance and the implications of the collection, such that the participants should be "informed of its purpose, method of treatment, procedure for assignment to treatment, benefits and risks associated with participation, and required data collection procedures and schedule."[49] Moreover, all the Patient Information Forms and the Informed Consent Forms should be approved by an Ethics Committee.

Appropriate consent or authorisation is also necessary in the case of residual biological material (such as amSC) which have been removed from the human body for purposes other than storage for research and, whenever possible, this should be requested before the biological materials are removed.[50]

Appropriate consent and authorisation is also required prior to the removal of stem cells for research from the body of a deceased person and this authorisation should not be given nor accepted "if the deceased person is known to have objected to it."[51]

Though informed consent is a staple requirement in treatment and research, it might be possible to ask whether the standard model of informed consent could be problematic in the case of biobanks. Due to the long term and open ended nature of the research, for example, how can researchers or banks inform participants of all the potential uses to which their biological material and associated data could be put to use? Would it be possible for a biobank to change its purposes retrospectively? Moreover, the ongoing nature of the research means that the aims of the research and the methods used might develop in ways which did

[49] UK STEM CELL BANK, *Code of Practice for the Use of Human Stem Cell Lines*, 2010.
[50] Rec 2006, Article 12.
[51] *Ibid*., article 13.

not exist and which was not foreseen when the biological material was collected. Due to these and similar concerns, the UK Biobank, for example, has departed from the standard model of informed consent, resorting instead to a system of broad consent (sometimes called general, or blanket consent). Notwithstanding this, however, it is difficult to see how a consent with such a diminished content might be really said to respect the principle of self-determination seriously. In fact, any research done on the collected stem cells must fall within the scope of the consent that has been requested and given, the information and consent should be "as specific as possible with regard to any foreseen research uses and the choices available in that respect."[52] Participants may also place restrictions on the use of their biological materials.[53]

Any future research which does not fall within the scope of prior consent should only be undertaken if there is a reasonable effort to obtain consent for use of the identifiable stem cells. When, notwithstanding such a reasonable effort, the participant cannot be contacted to obtain consent, research may still be done on those stem cells as long as there is an independent evaluation which is satisfied that the research addresses an important scientific interest that would otherwise not be achieved by using only those stem cells for which consent can be obtained and that there is no evidence that the participant concerned has expressly opposed such use.[54]

5.3.2 Withdrawal of Consent

The ethical principle of free informed consent implies that persons may freely refuse consent to the use of their identifiable biological material as well as the possibility of withdrawing or altering the scope of their consent without this leading to any form of discrimination against them, especially with respect to their right to medical care.[55] In such a case, the materials may be either destroyed or rendered unlinked anonymised, "in the manner foreseen by national law".[56] The UK Biobank *Ethics and Governance Framework* makes it clear that consent to the use of the sample and data cannot be withdrawn by family members after death or incapacitation of the participant.[57] Moreover, while individual participants could withdraw their samples and data (while competent), they could not consent to the

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[52] *Ibid*., Article 10.
[53] *Ibid*., article 21.
[54] *Ibid*., article 22.
[55] *Ibid*., Article 15.
[56] *Ibid*.
[57] UK Biobank, *Ethics and Governance Framework*, 2003.

donation on the condition that their samples or data should be withdrawn in the event of their death or incapacitation.[58]

5.3.3 Minors and Incompetent Persons

In the case of minors and those who are incompetent to consent, authorisation for the collection of stem cells may be authorised by a parent or legal guardian. Nonetheless, the right to withdraw consent to the storage of identifiable biological material for research purposes may be exercised once the capacity to give consent is attained. In the case of minors attaining majority, one might also consider requiring a 'renewal' of consent or, more precisely, requiring a personal consent to, or withdrawal, of the authorisation to store one's identifiable biological material.

5.4 Data Protection, Confidentiality and Privacy

The biological material in stem cell banks, either alone or together with the data associated with them, may be either identifiable (directly; coded, that is, the user has access to the code; or linked anonymised, that is, the code is under the control of a third party) or not identifiable (that is, unlinked anonymised). Stem cells which are stored with the purpose of future therepeutic purposes which are of benefit to the participants (or their family) should obviously be identifiable, but stem cells which have been stored for research purposes should, "as far as appropriate", be anonymised, with any use in an identified, coded or linked anonymised form having to be justified by the researcher.[59] Even though anonymised, however, biological materials may only be used if their use does not violate restrictions placed by the persons concerned prior to their anonymisation, and the anonymisation should be verified by an appropriate review procedure.[60] Confidentiality and privacy issues mean that data security should be taken seriously.

5.5 Recruitment of Participants

Informed consent must of its nature be free, that is, there must be no coercion and no deception, both in the case of stem cells stored for therapeutic use and those stored for research purposes. This leads to a series of serious concerns about promoting participation, such as issues related to advertising, truthfulness and safety.

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[58] *Ibid*.
[59] Rec 2006, article 8.2.
[60] *Ibid*., article 23.

While it is true that there can be no banks without participants, the recruitment of participants must be done in a way which is ethical, safe and which respects the participants. This is especially so in the case of commercial banks. Any advertising should be adequately controlled by public authorities, taking particular attention to subtle forms of deceit and coercion. One may ask questions such as: (1) Should advertisting be allowed and, if yes, who should be doing it? Should this be left to professional salespersons, or to health care professionals? What about salespersons dressed up as nurses, or PhD holders who participants might confuse with a physician? (2) Is the information given truthful, or hyped? Does it play with the emotions of possible participants, such as those of guilt or fear? (3) What incentives are offered for participation? While pecuniary incentives are unethical, for they go against the commercialisation of the human body, neither is one to accept other incentives such as those playing on false hope. While one may face these issues with respect to any commercial bank, they seem to be especially true in the case of those offering cord banking for autologous future use (see Section 6).

The safety of participants is another pressing concern. Though stem cell research is very promising, stem cell based therapies are still in their infancy. While it is true that today stem cell based therapies are the clinical standard of care for a few conditions, "such as hematopoietic stem cell transplants for leukemia and epithelial-stem-cell based treatments for burns and corneal disorders,"[61] "the general public may not fully understand how many years of preclinical and clinical research will be required to bring novel stem-cell based therapies to fruition. Unfortunately, some clinics around the world are already exploiting patients' hopes by purporting to offer effective stem cell therapies for seriously ill patients, typically for large sums of money, but without credible scientific rationale, transparency, oversight, or patient protections."[62] "Administering unproven stem cell interventions outside a carefully regulated clinical trial puts individual patients at risk and also jeopardizes the legitimate progress of translational stem cell research."

The seriousness of the issue has led the International Society for Stem Cell Research (ISSCR) to convene an international task force of experts to provide "a framework for the

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[61] Insoo HYUN *et al.*, ISSCR: Commentary, "New ISSCR Guidelines Underscore Major Principles for Responsible Translational Stem Cell Research", in *Cell Stem Cell* 3/6 (4 December 2008) 607-609.

[62] Darren LAU *et al.*, "The Direct-to-Consumer Portrayal of Stem Cell Medicine", in *Cell Stem Cell* 3/6 (December 2008) 591-594.

responsible and timely development of clinically useful therapies based on stem cells."[63] The *Guidelines for the Clinical Translation of Stem Cells* "examine the scientific, clinical, regulatory, ethical and societal issues that must be addressed to ensure that basic stem cell research is responsibly transitioned into appropriate clinical applications". They also establish standards that can be used to judge claims SC clinics make and whether the treatments being offered have been developed responsibly. These guidelines also contain a *Patient Handbook on Stem Cell Therapies*[64] as an Appendix, providing information to patients and their doctors to help them evaluate stem cell therapies.

In a European context, there are a number of directives and regulations related to the safe use of stem cells.

- **Directive 2001/20/EC** of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;
- **Directive 2001/83/EC** of 6 November 2001 on the Community code relating to medicinal products for human use;
- **Regulation (EC) No 726/2004** of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency'
- **Regulation (EC) No 1394/2007** of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

In reading these, it is important to understand that stem cell lines may fall within the EU definition of a medicinal product (Investigational Medicinal Product, or IMP), and that stem cell therapies, regardless of derivation, may be considered advanced therapy medicinal products (ATMP's).

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[63] This panel was made up of experts in stem cell science and clinical research from thirteen countries, led by Dr Olle Lindvall, Sweden, and Dr Insoo Hyun, USA. Insoo HYUN *et al.*, ISSCR: Commentary, "New ISSCR Guidelines Underscore Major Principles for Responsible Translational Stem Cell Research", in *Cell Stem Cell* 3/6 (December 2008) 607-609.

[64] http://www.isscr.org/AM/Template.cfm?Section=PatientHandbook

5.6 Quality and Safety Issues

The ethical issues stem cell banks face are not only limited to the ethical procurement of stem cells. The quality of these stem cells must be ascertained, their storage kept safe, and any future use for research or therapeutic purposes must be conducted safely. The EU Directive 2004/23/EC on "setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" provides a legal European framework in terms of authorization, licensing, accreditation, reliability, inspections, controls, promotions and publicity and staff experience.[65] The (Malta) Human Blood and Transplants Act (2006) also serves to "regulate the collection and testing of human blood and blood components and to establish standards of quality and safety for human tissues and cells intended for human transplants."[66]

Stem cell storing and culture procedures must meet current best practices, such as, for example, those related to testing for infectious agents before storing, while the facilities and equipment used should be qualified and validated according to requirements set down by public authorities which accredit or licence the bank. In order to comply with this, for example, the UK Stem Cell Bank has put in place a Quality Management System covering all these requirments, including an effective document management system; a system of unique identifiers which maintains donor anonymity but still allows for traceability from donor to recipient or vice-versa; the maintenence of records for each cell line; the documentation, review and annual reporting of any errors in procedures, or complaints from users; and a system of internal quality audits conducted by independent and qualified individuals, in addition to compliance reporting; and inspections by the competent authority.

5.7 International Cooperation

Significant progress in stem cell research can only be made through international cooperation, not only because of the transdisciplinary nature of the research, but also because of the need to access different biological samples (e.g. HLA typing, ethnicity, genetic diseases) as well as results (therefore, registries). This leads to issues related to conditions under which researchers can access materials in the bank, problems concerning ownership of

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[65] See also the COUNCIL OF EUROPE *Rec (2006) 4*, article 14, on "Principles applicable to all collections of biological materials".

[66] Laws of Malta, Chapter 483.

biological materials and problems of intellectual property arising from such materials. As a result, "questions of consent, quality assurance (with regard to the taking and storage of samples, data quality and data formats, etc.), data protection, the exchange of data and access to data are increasingly linked and must be raised and resolved in an international context."[67]

5.8 The Ontological Question of Biological Material

Stem cells raise a number of questions related to what can be called the ontological question of biological material. The way this question is answered depends much on the particular use of that material as much as it depends on the analogies used (e.g. gift, natural resource, property, waste). Thus, for example, it is easy to conceive of stem cells deposited into a commercial cord blood bank for autologous purposes as property, whereas having them deposited into a public cord blood bank would be more likely to see them as a gift or a natural resource to be used rather than wasted. As argued previously, the analogy chosen then becomes normative, leading to particular answers to qustions such as those related to ownership, intellectual property, patentability and profit sharing.

Notwithstanding the general guidelines prohibiting financial gain from or commercialisation of the human body or its parts, these are at present only selectively regulated. Participants participate in biobanks through a process of informed choices, however, "what they provide through their participation shifts into the domains of property transfer and involves the potential commodification of the human body." This has led to considerable attention to be given to ways of establishing morally legitimate systems of exchange for body parts.[68] The question is a matter of what can and cannot be commercialised, and who can and cannot benefit from research on human tissue. Usually, a distinction is made betwen the tissue samples and the information derived from them which leads to a boundary between what Tutton has called two economies: a non-commercial donation of tissues and cells and a commercial economy of biological information that can be transformed into intellectual property.[69] One may question therefore how it could be ensured

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[67] "With regard to this problem of internationalisation it should be noted that such "cross-border questions" of a legal nature raise (extremely) difficult problems in terms of Conflict of Laws and international private law. However, an exploration of these highly problematic issues is not the subject of this Opinion." THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

[68] Klaus L HOEYER – Richard TUTTON, "'Ethics was here': Studying the language-games of ethics in the case of UK Biobank", in *Critical Public Health* 15/4 (December 2005) 385–397.

[69] *Ibid*.

that discoveries are used for the good of society and that secrecy does not prevent their dissemination.

A related concern is that of the patentability of stem cells. This is regulated by the EU Biopatent Directive (Directive 98/44/EC on the legal protection of biotechnological inventions), transposed into Maltese Law by the Patents and Design Act (2002).[70] The UK Patent Office has decided not to grant patents for processes of obtaining stem cells[71] from human embryos, as well as not granting patents for human totipotent stem cells. It will, however, grant patents for inventions involving human pluripotent stem cells provided they satisfy the normal requirements for patentability.

5.9 Relationship between National and Private Banks

If stem cell research requires cooperation on an international scale, this is even more so in terms of cooperation between private and national banks. Such cooperation, however, could be destroyed due to conflict of interest which might arise between the two, especially if the law requires that some or all of the samples of private banks be deposited into the national bank. This, for example, is the case in the UK, where private banks and researchers are obliged to deposit samples of eSC/lines they produce.[72] In order to avoid conflicts of interest, the following steps have been taken: the UK Stem Cell Bank has been located in an independent national institution, and it does not receive nor store human embryos. Moreover, though it may pursue research aimed at improving banking, characterisation, safety testing and preservation of stem cell lines, it does not conduct discovery research on the banked stem cell lines nor carry out research into stem cell biology. Furthermore, all UK Stem

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[70] "A patent shall not be granted in respect of: ... (*b*) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, Provided that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element; (*c*) processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes". Chapter 417 of the Laws of Malta, 4 (5) b-c.

[71] THE BIOETHICS COMMISSION AT THE FEDERAL CHANCELLERY (Vienna), Opinion: *Biobanks for Medical Research*, 9 May 2007.

[72] "*All UK researchers deriving human embryonic stem cell lines are required, as a condition of their HFEA licence, to lodge samples of their embryonic stem cell lines in the UK Stem Cell Bank.* This is not a requirement for iPSC and somatic cell lines, although appropriately derived lines may also be deposited in the UK Stem Cell Bank"; italics original. UK STEM CELL BANK, *Code of Practice for the Use of Human Stem Cell Lines*, 2010.

Cell Bank staff are required to refrain from activities that might represent a conflict of interest with the operation of the UK Stem Cell Bank as an independent organisation within the stem cell field and are required to submit information about their conflicts of interest.[73]

5.10 Institutional Ethics

A number of ethical issues related not to the procedures to be adopted by the banks, but with the bank as an institution. Under what conditions can the bank be sold, merged, or divided, exported or destroyed? What happens if a commercial bank goes bankrupt? What happens to its samples? Should it 'donate' them to the national or public bank, if available?[74] Should the bank store all its samples in one physical location, or should it store different aliquots in different locations? These issues have been addressed by Directive 2006/17/EC of 8 February 2006.

6. Cord Blood Banks

Cord blood banking shares many of the ethical issues related to stem cell banking. One can differentiate between the autologous use of this blood, that is, the use of these stem cells by the same donor, and its allogeneic use, that is, the use of these stem cells by a recipient (of the same species) other than the donor.

6.1 Cord Blood for Autologous Use

The commercial banking of stem cells for autologous use presents further serious ethical issues of its own. These commercial banks signal a shift from the traditional concepts of a free donation based on an act of generosity contributing to social cohesion, to a model based on an analogy of private "banking" for personal profit. Now, even though one might perhaps increasingly accept a role of the market in the health care system, commercial cord banks are not one such solution. In fact, commercial cord blood banks have been criticised from a number of quarters, with some countries even going so far as to ban them.

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[73] *Ibid*.

[74] The EGE is of the opinion that information should be provided to customers about the possibility of bankruptcy, and insurances should guarantee the continuity of the storage and the transfer of the samples to another bank, or the indemnity of the customers. EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

Commercial cord blood banks "raise hopes of utopia and disguise a mercantile project using assistance to children as a screen."[75] In fact, the probability of needing an autologous transplantation has been estimated as approximately 1 in 20,000 during the first 20 years of life,[76] while the possibility of using one's own cord blood stem cells for regenerative medicine is currently purely hypothetical. Not only is research in this field still at a very early stage, but even if scientists were to learn how to control the differentiation of stem cells efficaciously and safely, while being able to store them for decades and then to expand them when necessary, it is still not clear that the autologous use of cord blood would be preferable to the autologous use of bone barrow or to well matched allogeneic stem cells from donation.[77] Indeed, the uselessness of autologous banking is such that the French Consultative Committee could state that "Should the management of an autologous bank be left to the State, the high cost for a currently useless technique would be unethical."[78] A draft recommendation on autologous blood banks adopted by the European Health Committee of the Council of Europe, in fact, states that "The promotion of donation for autologous use and the establishment of cord blood banks for autologous use should not be supported by member States or their health services."[79]

Apart from being useless, however, commercial cord blood banks may actually be harmful. According to the French National Committee, "The gravest danger is for society in so far as setting up such banks is likely to contradict the principle of solidarity, without which no society can survive."[80] Moreover, even though there is no scientific justification to autologous storage, the advertising employed by private banks might play on the parents' feelings, such as fear and guilt,[81] and the collection of the cord might interfere with the delivery at the moment of birth, possibly increasing the risk to mother and child during

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[75] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 74: *On umbilical cord blood banks for autologous use or for research* (2002).

[76] George J ANNAS, "Waste and Longing – The Legal Status of Placental-Blood Banking", in *New England Journal of Medicine* 340 (1999) 1521-1524. Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004) as Annas, NEJM 2000; 340: 1521.

[77] EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[78] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 74: *On umbilical cord blood banks for autologous use or for research* (2002).

[79] The European Health Committee of the Council of Europe adopted a draft Recommendation on autologous blood banks. At the time of adoption of this opinion the recommendation has however not been adopted yet by the Committee of Ministers. Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[80] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 74: *On umbilical cord blood banks for autologous use or for research* (2002).

[81] *Ibid*.

birth.[82] The matter also evokes special attention due to gender aspects, since the collection takes place within the delivery process, when mothers might be more vulnerable to pressure. Moreover, even if autologous use were to prove to be useful, strong concerns related to justice and equity, as well as discrimination would arise. A draft Royal Decree prepared by the Belgian Ministry of Public Health not only bans the use of umbilical cord blood cells "for deferred preventive intentions", but also forbids "all *discrimination* aiming at favouring a person's access to therapeutic possibilities linked to tissues of human origin, any form of publicity and the research of profit."[83]

6.2 Cord Blood for Allogeneic Use

Cord blood banks for allogeneic transplants, however, might be useful. Researchers attempting to estimate the lifetime probability of undergoing (autologous or allogeneic) hematopoietic stem cell transplant (HSCT) in the US, have reported that the incidences of such treatment increases with age, rising strongly after 40, and that after 40, incidences are higher for men than for women. They estimate that the lifetime probabilities of undergoing HSCT range from 0.23% to 0.98% under the various scenarios, concluding that the lifetime probability of undergoing autologous or allogeneic HSCT is much higher than previously reported and could rise even higher with increases in donor availability and HSCT applicability."[84]

Even so, however, the success of HSC treatments would only be possible if banks contained a great diversity of cells with different genetic and HLA types from different populations in order to be able to find an acceptable donor for any recipient in need. Thus, if in the future scientific development should get to the point where the use of one's own cord blood cells may be of value, the storage should not be a service left to commercial banks. Rather, the principles of solidarity, justice and equity should predominate and autologous storage should become routine,[85] being taken over by the public sector in order to

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[82] *Ibid*.; EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004). According to the European Group of Ethics, the pressure to perform the collection to satisfy a pressing request from the parents may be heavier than when the cord blood collection is a ssystematic procedure in the context of donation. EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[83] Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004). Italics added.

[84] JJ NIETFELD *et al.*, "Lifetime probabilities of hematopoietic stem cell transplantation in the U.S.", in *Biology of Blood and Marrow Transplantation* 14/3 (2008) 316-322.

[85] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 74: *On umbilical cord blood banks for autologous use or for research* (2002).

ensure fair access to healthcare services for everybody.[86] With routine autologous storage, donations would increase, thereby increasing choice in terms of genetic and HLA types. Moreover, considering the multiethnic societies of today, specific measures should be taken by public authorities to have enough donation from different ethnic groups with different HLA patterns.[87] Networking with EUROCORD[88] or NETCORD[89] should be considered.

6.3 Commercial against Public Banks

The presence of commercial banks, however, might lead to public banks having a shortage of donors, for parents might prefer to store their child's cord blood for future autologous use rather than to donate it to a public bank. This would lead to less diversified types of stem cells in public banks with less chances of finding a compatible donor in cases of need. Thus, it would be preferable to have sufficiently supplied public cord blood banks with good networking with other banks and the development of registries to facilitate sharing of biological materials in case of need.

Due to these concerns, some are prone to argue that commercial cord banks for autologous use should be out rightly banned. The Belgian Health Council, for example, has argued that "each cell or tissue bank has to be approved by the Minister after a report of the relevant service and after the opinion of the Health Council and that this approval can only be granted for ... non-profit-making organisms."[90] The same Council argued forcefully that "the therapeutic autologous uses for deferred preventive intentions have to be prohibited."[91] Italy, for example, has banned commercial banks, allowing those who wish to store umbilical cord blood to do so only in public health structures, or else to do so abroad, having first obtained the necessary permit from the Ministry of Health. Moreover, no form of advertising is allowed to take place.[92]

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[86] EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[87] *Ibid.*

[88] http://www.eurocord.org

[89] http://www.netcord.org/index.cfm

[90] Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[91] The Belgian Health Council gave on 7th December 2001 an opinion on the revision of tissue banks' legislation. Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[92] Ordinanza del Ministero della Salute, dated 13 April 2006 and published on the *Gazzetta Ufficiale* on 9 aprile 2006. Cited in http://www.cittadinolex.kataweb.it/article_view.jsp?idCat=99&idArt=38535.

Banning such banks, however, would seem to go against the spirit of free enterprise and scientific research, and a number of countries have chosen to regulate them. This should include (1) licensing and close supervision by public authorities as to the procedures adopted; (2) appropriate and correct information, including explicit information that the autoconservation of cord blood has little scientific value today; and (3) adequate control of any kind of advertising, including on the internet, by public authorities. The best choice, however, would be to promote altruistic and voluntary cord blood donation to public cord blood banks for allogeneic transplantation, perhaps aggresively, so as to diminish the demand for the services of private banks and the ethical problems associated with them. In fact, the French National Ethics Committe recommends that public authorities promote the development of public banks which store umbilical cord blood for allogeneic purposes,[93] and the same recommendation is made by the European Health Committee of the Council of Europe,[94] and the European Group of Ethics.[95]

Moreover, public stem cell banks could be set up which would accept other types of somatic cells apart from cord blood stem cells (e.g. amSC), and any intellectual property which results from any research done on those samples could go to help partly finance the public bank, taking the UK Biobank as an example.[96]

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[93] COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE, Opinion 74: *On umbilical cord blood banks for autologous use or for research* (2002).

[94] The European Health Committee of the Council of Europe adopted a draft Recommendation on autologous blood banks. At the time of adoption of this opinion the recommendation has however not been adopted yet by the Committee of Ministers. Cited in EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[95] EUROPEAN GROUP OF ETHICS, Opinion 19: *Ethical Aspects Of Umbilical Cord Blood Banking* (16 March 2004).

[96] "Any intellectual property arising from research and development activities carried out pursuant to the UK Stem Cell Bank's operation will be assigned to MRC [Medical Research Council] for the purposes of protection and exploitation. Net revenues generated from exploitation of such intellectual property will be used solely for supporting the operation of the UK Stem Cell Bank." UK STEM CELL BANK, *Code of Practice for the Use of Human Stem Cell Lines*, 2010. http://www.ukstemcellbank.org.uk/_db/_documents/Code_of_Practice_for_the_Use_of_Human_Stem_Cell_Lines_(2010).pdf