A comparative analysis of the opinions from European national and international ethics committees regarding the collection, storage and use of umbilical cord blood

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Introduction

Since the first cord blood transplant was performed in a patient with Fanconi's anaemia in 1988, umbilical cord blood has successfully been used as a source of stem cells, mostly in children, for haematopoietic reconstitution in allogeneic haematopoietic stem cell transplantation as an alternative to bone marrow or peripheral blood progenitor cells. Related and unrelated umbilical cord blood transplants have been used for children with malignant and non-malignant diseases. Fewer data are available on adult cord blood transplants, with most reported cases involving patients with haemoglobinopathies.

Cord blood as a source of stem cells has important advantages when compared with human leucocyte antigen (HLA)-matched unrelated bone marrow transplants. These advantages include: a lower incidence of Graft-versus-Host disease, absence of risks and pain for donors, immediate availability for access and use, minimal cell manipulation and better long-term immune recovery resulting in a similar long-term survival.

In 1991 the first public cord blood bank was established at the New York Blood Center. Two main cord blood banking options are available: public and private.

Public non-profit accredited cord blood banks receive umbilical cord blood following informed parental consent. Cell count and volume are key parameters for the eligibility of cord blood units for storage. If the unit of blood meets the requisites for therapeutic use it will be screened using a series of tests, registered in international registries and made available to national and foreign transplant centres. In this case the cord blood becomes the property of the public bank for subsequent clinical use. Approximately 20% of all collected cord blood units meet the established criteria for storage. Samples that are not suitable, or that cease to be suitable, for storage for therapeutic purposes may be used for research purposes. In this way society also benefits from discarded blood units.

Most banks co-operate through international registries that list publicly banked cord blood units in searchable databases such as Bone Marrow Donors Worldwide (BMDW), the NetCord Foundation, the National Marrow Donor Program (NMDP) and other national registries, in order to provide access to all patients in need. International accreditation bodies, such as the NetCord Foundation for the Accreditation of Cellular Therapy (FACT) and governmental regulatory requirements are in place to ensure that publicly available cord blood units meet strict quality criteria.

On 21st November 2011 the Bone Marrow Donor Worldwide website reported that a total of 497,501 cord blood units were stored by 43 banking networks in 26 countries. These free and anonymous donations resulted in over 20,000 unrelated cord blood transplantations worldwide.

Private cord blood banks obtain blood samples and store them for individual use by families. In this case the blood remains the property of the child under the guardianship of the parents. Cord blood samples stored in private banks for either autologous or allogeneic transplants (for the infant donor or for a related family member) are not searchable by the public. Indeed, the major criticism of private banks is precisely the non-availability to the public of this blood. Moreover, both scientific and clinical data show that the estimated chance that an individual will develop a disease treatable with his or her own stored cord blood is between 0.04% and 0.005%. More than 780,000 cord blood units are stored in over 130 private cord blood banks worldwide.

Other models of banking (family directed, mixed public-private, and others) also exist. For instance, in the United Kingdom, Richard Branson launched Virgin Health Bank, an innovative experiment in dual
banking (mixed public-private storage): 20% of the cord blood sample is stored for private use, for the child or a family member, and 80% is donated to the public part of the bank, which is accessible to anyone in the world who needs it, at no cost. Virgin Health Bank's challenge is to combine the known potential of public-sector allogeneic storage with the possible, albeit at present remote, applications of autologous storage in specific fields of regenerative medicine.

Numerous research teams continue to investigate the usefulness of cord blood for purposes other than haematological disorders, including in particular: repairing damage caused by heart disease and infarcts, diabetes mellitus, traumatic brain and spinal injuries and stroke. Although the therapeutic usefulness of cord blood for these diseases and pathological conditions has not yet been demonstrated and there are currently very few validated indications for autologous storage, significant advances are being made. In this regard, according to many authors "the possibility for future discovery or additional indications for autologous cord blood transplant" motivates "us to re-examine our attitudes towards private cord blood banking". In particular, "directed-family cord blood banking activities should be encouraged".

### Table I - Opinions on cord blood banking issued by European National Bioethics Committees and other European Institutions.

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<thead>
<tr>
<th>National Bioethics Committees</th>
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<tr>
<td>Denmark: Det Etiske Råd (<a href="http://etsikraad.dk/?sc_lang=da-DK">http://etsikraad.dk/?sc_lang=da-DK</a>); The Danish Council of Ethics (<a href="http://etsikraad.dk/?sc_lang=en">http://etsikraad.dk/?sc_lang=en</a>)</td>
<td>None.</td>
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<td>Finland:</td>
<td>None.</td>
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<td>- Valtakunnallisen sosiaali- ja terveysalan eettiset neuvottelukunnat (<a href="http://www.etene.fi/fi">www.etene.fi/fi</a>); National Advisory Board on Social Welfare and Health Care Ethics (<a href="http://www.etene.fi/en">www.etene.fi/en</a>)</td>
<td>None.</td>
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<td>France: Comité Consultatif National d’Éthique pour les Sciences de la Vie et de la Santé - CCNE (<a href="http://www.ccne-ethique.fr">www.ccne-ethique.fr</a>); National Ethics Advisory Committee for the Life Sciences and Health (<a href="http://www.ccne-ethique.fr/?langue=2">www.ccne-ethique.fr/?langue=2</a>)</td>
<td>None.</td>
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### Opinions on cord blood banking: an overview

National bioethics committees have been established in most European countries since the 1990s. This review considers the opinions expressed by national and international European bioethics committees, comprising all those issued by 27 European Union member countries, one international bioethics committee (embracing 5 European countries) and the relevant institutions at the European Union level (the European Group on Ethics in Science and New Technologies (EGE), the Bureau of European Policy Advisers (BEPA) of the European Commission) and at the European Council level (Committee of Ministers and Steering Committee on Bioethics).

To date the national ethics committees of 9 out of 27 EU member states have published documents concerning cord blood banking, to which the opinions expressed at European level and a Recommendation by the Committee of Ministers must be added. The Committees and the relevant opinions are listed in Table I.

As cord blood banking is a rather specific topic, 9 opinions are a significant number, especially when compared with the number of opinions dealing continued on next page
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<td><strong>Germany</strong>: Deutscher Ethikrat (<a href="http://www.nationalethikrat.de">www.nationalethikrat.de</a> - <a href="http://www.ethikrat.org">www.ethikrat.org</a>); German Ethics Council (<a href="http://www.ethikrat.org/welcome/set_language=en">www.ethikrat.org/welcome/set_language=en</a>)</td>
<td>None.</td>
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<td><strong>Ireland</strong>: Irish Council for Bioethics (<a href="http://www.bioethics.ie">www.bioethics.ie</a>) (As of 1st December 2010, the ICB has ceased to operate)</td>
<td>Mozione del Comitato Nazionale per la Bioetica sulla raccolta e la conservazione di cellule staminali derivate da cordone ombelicale. Approvata nella seduta plenaria del 13 luglio 2007. Motion of the National Bioethics Committee on the collection and storage of umbilical cord-derived stem cells. Approved by the plenary session of 13 July 2007 <a href="http://www.governo.it/bioetica/mozioni/mozione_cordonali.pdf">www.governo.it/bioetica/mozioni/mozione_cordonali.pdf</a>.</td>
</tr>
<tr>
<td><strong>Italy</strong>: Comitato Nazionale per la Bioetica (<a href="http://www.governo.it/bioetica">www.governo.it/bioetica</a>) National Bioethics Committee (<a href="http://www.governo.it/bioetica/eng/index.html">www.governo.it/bioetica/eng/index.html</a>)</td>
<td>None.</td>
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<td><strong>Luxembourg</strong>: Commission Consultative Nationale d'Ethique pour les Sciences de la Vie et de la Santé (<a href="http://www.cne.public.lu/index.html">www.cne.public.lu/index.html</a>)</td>
<td>None.</td>
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<td><strong>The Netherlands</strong>: Gezondheidsraad (<a href="http://www.gezondheidsraad.nl">www.gezondheidsraad.nl</a>); Health Council of the Netherlands (<a href="http://www.gezondheidsraad.nl/en">www.gezondheidsraad.nl/en</a>)</td>
<td>None.</td>
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<td><strong>Norway</strong>: Forskningsetiske Komiteer (<a href="http://www.etikkom.no">www.etikkom.no</a>); National Committee for Medical and Health Research Ethics – NEM (<a href="http://www.etikkom.no/en/in-english/">www.etikkom.no/en/in-english/</a>)</td>
<td>None.</td>
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<td><strong>Slovak Republic</strong>: Etická Komisia (<a href="http://www.health.gov.sk/?eticka-komisia-1">www.health.gov.sk/?eticka-komisia-1</a>) (National Ethics Committee)</td>
<td>None (available in English).</td>
</tr>
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<td><strong>Spain</strong>: Comité de Bioética de España (<a href="http://www.comitebioetica.es">www.comitebioetica.es</a>); Spanish Bioethics Committee (<a href="http://www.comitebioetica.es/?lang=en_us">www.comitebioetica.es/?lang=en_us</a>)</td>
<td>None.</td>
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<tr>
<td><strong>Nordic Countries</strong> (Denmark, Finland, Iceland, Norway, Sweden): Nordisk Kommitté för Bioetik (<a href="http://ncbio.org/nordisk/hemma/">http://ncbio.org/nordisk/hemma/</a>) Nordic Committee on Bioethics (<a href="http://ncbio.org/english/">http://ncbio.org/english/</a>)</td>
<td>None.</td>
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with other, more wide-ranging topics such as organ
donation and transplantation, on which only 8
national bioethics committees have issued documents.

All the opinions regarding cord blood banking
considered here take the most significant scientific
and clinical data as a fundamental basis for any ethical
evaluation.

National bioethics committees are unanimous in
recognising that certain statements, position papers
and declarations on cord blood banking issued by
authoritative scientific societies and associations are
essential points of reference in the debate.

Most of the opinions from European national
bioethics committees on cord blood banking issued
after 2004 repeat (or summarise) the principles listed
by the EGE in its opinion n. 19 "Ethical aspects of
umbilical cord blood banking", published on March
16th, 200431. This document does, therefore, deserve
particular attention. According to the EGE "there are
several fundamental ethical principles and values
which can be considered relevant" for umbilical cord
blood banking:

- "The principle of respect for human dignity and
  integrity, which asserts the principle of non-
  commercialisation of the human body.
- The principle of autonomy or the right to self-
  determination on the basis of full and correct
  information.
- The principles of justice and solidarity, as regards
to fair access to healthcare services.
- The principle of beneficence, or the obligation to
do good, especially in the area of health care.
- The principle of non-maleficence, or the obligation
not to harm, including the obligation to protect
vulnerable groups and individuals, to respect
privacy and confidentiality.
- The principle of proportionality which implies a
  balance between means and objectives"31.

Nevertheless, "there are also some value conflicts.
The values of freedom and free enterprise can conflict
with the principles of solidarity and justice, according
to which access to healthcare should be on an equitable
basis and based on realistic needs, as well as with the
principle of protection of vulnerable groups". A wide-
ranging document accompanying this opinion is also
available32. Table II shows the final recommendations
submitted with the EGE's opinion n. 1931.

On 21st July 1998 the EGE issued Opinion
n. 11: "Ethical aspects of human tissue banking"33
which underscored the following values: body
integrity, respect of privacy and confidentiality of
data, promotion of solidarity, fairness of access to
healthcare and informed consent of the donors. With
specific regard to umbilical cord blood, Opinion
n. 11 stipulates that "the information provided to
the woman or to the couple must clearly explain
these prospective new treatments, but stress that
they are still very much at the experimental stage".
The Opinion also provides that "in principle, tissue
bank activities should be reserved to public health
institutions or non-profit-making organisations" but
that "tissue banks set up by industry should be subject
to the same licensing and monitoring requirements
as non-commercial operators". It also insists on the
need for appropriate quality and safety rules and calls
for a European legal framework.

The opinion published by the EGE in 2004 is
consistent with the Recommendation Rec(2004)8
issued the same year by the Committee of Ministers
of the European Council34. The Council recommends
that "if cord blood banks are established, they should
be based on altruistic and voluntary cord blood
donation and used for allogeneic transplantation
and related research; 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; accurate
information should be provided to the population
about the advantages and disadvantages of cord
blood banks; where autologous cord blood banks
are being established, the promotional material or
information provided to families must be accurate,
and fully informed consent to cord blood storage
must be obtained".

The Austrian Bioethics Commission35 refers to
the general principles summarised by the European
Group on Ethics in Science and New Technologies:
the principle of respect for human dignity; the right
to physical and mental integrity; the principle not to
exploit the human body and its parts for financial
gain; the principle of autonomy or the right to self-
determination, specifically: voluntary consent on
the basis of full and complete information (informed
consent); the principle of beneficence, implying the
use of medical procedures for the well-being of the
patient; the obligation not to do harm; the principle
of justice; the principle of proportionality, implying a
balance between the means and the objectives.
### Table II - Recommendations from the EGE.

1. "The legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service, which has, presently, no real use regarding therapeutic options. Thus they promise more than they can deliver. The activities of such banks raise serious ethical criticisms.

2. While some members of the Group consider that this activity should be banned, the majority of the Group considers that the activities of these banks should be discouraged but that a strict ban would represent an undue restriction on the freedom of enterprise and the freedom of choice of individuals/couples. These banks should operate under strict conditions.

3. The Group notes that at least one Member State has already forbidden such commercial cord blood banks. Such banks could be considered illegal and the contracts voidable or unenforceable in other Member States. If commercial cord blood banks are allowed by a State, such activity must be subject to strict regulation. Such regulation should include previous licensing by the competent State Authority and close supervision of the procedures followed both in the public and the private domain.

4. If commercial cord blood banks are allowed, appropriate information should be given to the consumers willing to use their services, including the fact that the likelihood that the sample may be used to treat one's child is currently negligible, that the future therapeutic possibilities are of a very hypothetical nature and that up until now there is no indication that the present research will lead to specific therapeutic application of one's own cord blood cells. Therefore, information has to be particularly explicit that the auto conservation has little value in the current state of scientific knowledge. This information should be made clear on all media, including Internet, and in any contracts linking commercial banks to their customers.

5. Any kind of advertising made by commercial cord blood banks in the media, including on the Internet, must be adequately controlled by public authorities.

6. Commercial cord blood banks have to observe the same quality standards as any other tissue bank. Therefore, the EGE welcomes the Directive of the European Parliament and of the Council adopted on 2nd March 2004 on "setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells", which provides for a legal European framework, namely in terms of authorization, licensing, accreditation, inspections, controls, promotions and publicity and staff experience.

7. Given the possibility of termination of business or bankruptcy of a commercial cord blood bank, information should be provided to the customers and insurances should guarantee the continuity of the storage and the transfer of the samples to another bank, or the indemnity of the customers.

8. The collection of cord blood must not disturb the process of delivery and should not present any risks for the mother and child.

9. At present, in the exceptional cases where cord blood storage for autologous use may be justified for families at risk of specific diseases or with rare HLA types, it should be proposed to them that storage should be by public cord blood banks in order to ensure fair access to healthcare services to everybody needing it.

10. Considering that the European population is increasingly multi-ethnical, and in order to allow a fair access to transplantation for any citizen whatever his/her ethnic origin, specific measures should be taken by public authorities to have enough donation from different ethnic groups with different HLA patterns so that for any patient needing a transplantation, an appropriate donor could be found.

11. In the future, should the development 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 but should be taken over by the public sector in order to ensure fair access to healthcare services for everybody.

12. Support for public cord blood banks for allogeneic transplantations should be increased and long term functioning should be assured. However cord blood banks are of limited use as long as networks and registries are not also supported. Indeed, in order to make sure that any patient needing transplantation will find a suitable sample, the development of networks between banks and registries of donors is essential to be able to find rapidly a matching donor and they should be encouraged and supported.

13. A wide European debate on the increasing role of the market in the healthcare system and its advantages and disadvantages should allow European citizens to be aware of the present trends and their implications, in particular on the issues raised in the present opinion”.

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The Austrian Bioethics Commission recommends that in the context of allogeneic transplants, greater support should be given to public and private non-commercial cord blood banks which contribute to public welfare.

The Commission recommends that in accordance with the principle of community welfare justice, potential donors should be informed of the possibility to donate cord blood for purposes of both allogeneic transplantation and research.

However, the Commission does not recommend the storage of cord blood stem cells for autologous transplantation at present.

The Belgian Bioethics Advisory Committee recommends a "coherent legislative framework" and, in particular, "a clarification of the legal status of placenta, umbilical cord blood and the stem cells thereof, in the light of an optimal and responsible use of umbilical cord blood".

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As regards the issue of allogeneic use versus autologous use, the Committee takes note that "at the moment there are no persuasive scientific grounds on which to recommend the storage of umbilical cord blood for autologous use for low-risk families. Autologous use of stem cells from umbilical cord blood in non-haematopoietic indications is still very speculative. Therefore only the storage of umbilical cord blood with an allogeneic purpose for the population in general, and with an autologous use for risk families, can be considered as a service of general benefit".

The Committee underlines that "for the transplantation of bone marrow the organ transplantation model is presented by analogy", while "umbilical cord blood taken from children after birth falls more under the analogy with the model of blood donations for transfusion (of the blood or blood components)".

As regards public versus commercial banks "although not all the members of the Committee are in favour of a ban on commercial private banks, all members nonetheless recommend that storage of umbilical cord blood should always meet internationally applicable quality standards".

The Committee "recommends that a financing system be worked out for the allogeneic storage of umbilical cord blood, both at national level and at European level" and augurs "the development of a system for collection of umbilical cord blood that guarantees that every patient who could receive a transplantation can quickly find a compatible donor".

The Committee underlines the importance of information and emphasises that "the government should offer people comprehensive and accurate information on collection of umbilical cord blood and the various possible intended uses thereof". "Clear and transparent information is needed" also "regarding the cost for patients". The Commission warns against ambiguous commercial advertising: "The advertising carried out by the commercial private firms maintains a two-fold uncertainty, between the different sorts of stem cells on the one hand, and between autologous and allogeneic use thereof, on the other".

The Committee underlines that "the State needs to introduce legal and/or administrative procedures based on which each cord blood bank either public or private, profit-making or non-profit making, will be subject to receiving authorisation for its establishment and operation and will be subject to systematic monitoring by the respective authority. Moreover the cord blood bank will have the obligation to maintain a register". The Committee takes into account that "storage of cord blood for autologous use (...) is of doubtful value, and thus the reliability of the advertising and promotion of this use is challenged". Nevertheless, the Committee "does not intend to recommend the prohibition of the establishment and operation of private profit-making cord blood banks" and lists a series of requirements that commercial banks should meet.

According to the French National Ethics Advisory Committee for Life Sciences and Health "ethical difficulties arise because the concept of cord blood banks for exclusively autologous use carries a number of perils: (i) 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; (ii) such banks raise hopes of utopia and disguise a mercantile project using assistance to children as a screen; (iii) they jeopardise justice and equity. If any reasonable indications existed, then the offer should be systematic, organised, managed, and supervised by public authorities; cost and broadness of scale then enter the picture. The disproportionate, and for the time being useless, cost of generalised autologous storage is in total contradiction with the obligation to provide public health based on solidarity and awareness of priorities; (iv) management by the private sector may be seen as discrimination based on wealth. However, this would hardly be exceptional in the healthcare sector, and those who use these programmes cannot be blamed for their ingenuousness; and (v) the futility of autologous banks and their cost would be a provocation in the eyes of the very poor, in particular in the Southern hemisphere".

The Committee's "recommendation to decision-makers is that they should encourage a considerable extension of public cord blood banks for essentially allogeneic purposes, rather than subscribing to the creation of private banks for strictly autologous purposes, the potential therapeutic usefulness of which is, as yet, in no way corroborated".

According to the Greek National Bioethics Commission one of the major problems is "how
to ensure the widest possible utilisation" of cord blood stem cells. The Commission underlines that "as things stand today, this purpose is better served by heterologous transplantation which is ensured by networks of collections (for-profit or non-profit) and not by autologous transplantation. Since the potential use of the material exclusively by the donor or his/her family members is negligible (and, conversely, the probability of final destruction of cells very high) the choice of private use cannot be justified on ethical grounds. All the more so considering that this choice would discourage making cells available for common use and would drastically reduce the availability of grafts to those who need them".

The Commission recommends: "The adoption of an explicit provision of law entrusting a public authority with the licensing and supervising of the operation of companies that collect and store umbilical cord blood. In view of relevance with transplants this authority could be the National Organization of Transplantation". The Commission also recommends the "adoption of standards of quality and safety for biological material"; "the development of appropriate public information tools (…) by the Ministry for Health (…) and of consent forms and information documents for prospective users of already operating companies". Moreover "once a public licensing system for these banks is put in place, the content of these documents should be reviewed as a prerequisite for the license. Companies should also register forthwith with the Data Protection Authority, to protect the confidentiality of the sensitive data of blood donors".

On 1st December 2010 the Irish Council for Bioethics ceased to operate "as a result of a Government decision to discontinue funding the operation of the Council". The Council has not published opinions specifically devoted to cord blood banking. Nevertheless, the problem of cord blood banking is mentioned in the more general document "Stem cell research: hope or hype? Exploration of the ethical questions". The Council does not adopt a definite position regarding cord blood banking, but notes that "there is currently a debate about whether storing a child's umbilical cord blood is a worthwhile investment for future healthcare or an expensive procedure, which might never prove beneficial. Concerns have been raised regarding the promises made about the potential for cord blood transplants to treat a number of diseases for which there is, at present, no medical evidence. Therefore, opponents argue that the State should not be paying for storage when there are no proven benefits. Opponents also argue that the chances of umbilical cord blood stem cells ever being needed by all of the families who store it are very small. Therefore, they raise concerns regarding the commercial storage of umbilical cord blood.

They state that allowing parents who can afford to pay for storage to do so would force those who cannot afford to store their babies' cord blood to feel unduly guilty. Proponents argue that given the nature of recent scientific advances there is a reasonable likelihood that umbilical cord blood stem cells will become of significant medical value in the coming years. Some argue that the State should put resources into establishing a national umbilical cord blood bank, similar to the national blood bank, where everyone can donate their babies' cord blood and where cells are shared with patients based on medical need. Others argue that parents who wish to pay commercial companies to store umbilical cord blood should not be prevented from doing so. They state that umbilical cord blood storage is akin to other forms of medical insurance, which might never be needed, and that parents who can afford to do so should be free to make an autonomous decision i.e. a decision free from external influences".

The Italian National Bioethics Committee considers that:
- the use of cord blood stem cells can be extended to persons other than those from whom they were taken provided their use does not contravene the ban on obtaining profit from the human body or its parts;
- when private banks are authorised to collect and store cord blood stem cells these must be subject to a system of authorisations that allows the effective exercise of the forms of public controls envisaged in the EC Directive;
- any indemnity offered to donors must be in the form of a reimbursement of the expenses incurred for the donation.

The National Bioethics Committee also hopes that suitable measures will be taken to inform the non-specialist public concerning the realistic therapeutic applications of cord blood-derived stem cells supported by advances in scientific knowledge, and that the public will have access to biobanks,
including through a rational geographic distribution of these facilities.

Finally, the National Bioethics Committee expresses the hope that the new legal regulations concerning the storage and use of cord blood stem cells will be in line with the principles and rules governing transfusions and the production of blood products in Italy, to enable the unequivocally voluntary and free donation of umbilical cord blood following informed consent and verification of the donor's physical fitness and in compliance with the principle of non-commercialisation of the human body".

The *Swedish National Council on Medical Ethics* proposes that a public biobank for umbilical cord blood be established and recommends that the law on biobanks be reviewed and clarified on specific points. Biobanks outside of the health care sector should also be regulated. The National Board of Health should develop specific information material targeted to parents about the storage of umbilical cord blood*.

In the United Kingdom, the *Nuffield Council on Bioethics* published the report "Human bodies: donation for medicine and research". The authors state: "By contrast with blood donation by adults, the idea of obtaining cord blood from the umbilical cord, in order to obtain stem cells from a baby at birth, has been much more controversial, particularly where the cord blood is subsequently stored only for private use. We note the growing evidence as to the potential value of publicly-accessible sources of stem cells, and the procedures recommended by the Royal College of Obstetricians and Gynaecologists to protect the welfare of mothers and babies where donation of cord blood is considered. We conclude that the collection of cord blood in these circumstances for public use is an example of a justified public intervention, and endorse the work of the NHS Cord Blood Bank, Anthony Nolan Trust and others in facilitating the collection of cord blood for this use. We note the recent report from the UK Stem Cell Strategic Forum calling for a significant increase in the UK's 'inventory' of cord blood and recommending that a UK Stem Cell Advisory Forum should be established in order to manage a UK cord blood inventory, along with a UK stem cell registry and a database of patient outcomes following transplantation". The Nuffield Council "endorses these recommendations".

**Opinions on cord blood banking: the issue of public versus private storage**

All the opinions emphasise the importance of public cord blood banks for allogeneic transplantation and underline that at present the autologous use of cord blood is rather limited. Most opinions do not suggest that autologous cord blood banking should be banned, but do suggest that it should be discouraged. Nevertheless, the emphasis on this suggestion varies widely. For example the Austrian committee "does not recommend the storage of cord blood stem cells for autologous transplantation" while the Cyprus committee "does not intend to recommend the prohibition of the establishment and operation of private profit-making cord blood banks".

This section summarises the core opinions of national bioethics committees regarding the issue of public versus private banking.

**Austria**

The Austrian Commission "recommends that in the context of allogeneic transplants, greater support should be given to public and private non-commercial cord blood banks". The Commission "does not recommend the storage of cord blood stem cells for autologous transplantation at present".

**Belgium**

According to the Belgian Committee "only the storage of umbilical cord blood with allogeneic purposes for the population in general and with an autologous use for families, can be considered as a service of general benefit". "Although not all the members of the Committee are in favour of a ban on commercial private banks, all members nonetheless recommend that storage of umbilical cord blood should always meet internationally applicable quality standards".

**Cyprus**

According to this country's Committee "the State needs to introduce legal and/or administrative procedures based on which each cord blood bank, whether public or private, profit-making or non-profit making, will be subject to receiving authorisation for its establishment and operation and will be subject to systematic monitoring by the respective authority. Moreover the cord blood bank will have the obligation to maintain a register".
"Storage of cord blood for autologous use (...) is of doubtful value, and thus the reliability of the advertising and promotion of this use, is challenged. Despite the above the Cyprus National Bioethics Committee does not intend to recommend the prohibition of the establishment and operation of private profit-making cord blood banks. However, the Committee wishes to draw attention to "a series of requirements" (listed in the opinion)\textsuperscript{37}.

**France**

The National Ethics Advisory Committee for Life Sciences and Health's "recommendation to decision makers is that they should encourage a considerable extension of cord blood public banks for essentially allogeneic purposes, rather than subscribing to the creation of private banks for strictly autologous purposes, the potential therapeutic usefulness of which is, as yet, in no way corroborated"\textsuperscript{38}.

**Greece**

The Commission suggests "the adoption of an explicit provision of law entrusting a public authority with the licensing and supervision of the operation of companies that collect and store umbilical cord blood"\textsuperscript{39}.

**Ireland**

The Committee does not give recommendations. It merely takes note of the current debate on cord blood banking: "Concerns have been raised regarding the promises made about the potential for cord blood transplants to treat a number of diseases for which there is, at present, no medical evidence. Therefore, opponents argue that the State should not be paying for storage when there are no proven benefits. Opponents also argue that the chances of umbilical cord blood stem cells ever being needed by all of the families who store it are very small". "Proponents argue that given the nature of recent scientific advances there is a reasonable likelihood that umbilical cord blood stem cells will become of significant medical value in the coming years. Some argue that the State should put resources into establishing a national umbilical cord blood bank, similar to the national blood bank, where everyone can donate their babies' cord blood and where cells are shared with patients based on medical need. Others argue that parents who wish to pay commercial companies to store umbilical cord blood should not be prevented from doing so"\textsuperscript{41}.

**Italy**

The Committee recommends that "where private banks are authorised to collect and store cord blood stem cells this must be subject to a system of authorisations that allows the effective exercise of the forms of public controls envisaged in the EC Directive"\textsuperscript{42}.

**Sweden**

The Council "proposes that a public biobank for umbilical cord blood is established and recommends that the law on biobanks is reviewed and clarified on specific points. Biobanks outside of the health care sector should also be regulated"\textsuperscript{43}.

**United Kingdom**

The Nuffield Council on Bioethics concludes "that the collection of cord blood in these circumstances for public use is an example of a justified public intervention"\textsuperscript{44}.

**Conclusions**

The collection and storage of umbilical cord blood pose a number of ethical problems\textsuperscript{45}. Current scientific evidence suggests discouragement of private commercial autologous storage and support of collection and storage provided that the cord blood has been altruistically donated for haematopoietic stem cell transplantation or that it is stored for a family affected with, or known to be at risk of, a disease treatable with a haematopoietic stem cell transplantation\textsuperscript{46}.

All the documents published by national bioethics committees devote particular attention to the issue of public versus private banking. All of them encourage the establishment of accredited public not-for-profit cord blood banks collecting anonymous allogeneic donations and operating as part of national and international networks.

The national bioethics committees recognise that while there are currently very few validated indications for autologous storage, other potential indications can be envisaged and might offer new possibilities in the future. Moreover, in addition to
haematopoietic stem cells, cord blood contains a high number of non-haematopoietic cells, which explains the increasing interest in possible uses of cord blood for regenerative medicine. For this reason, family-directed cord blood banking should be promoted.

Most Committees underline that accurate information should be provided to the population about the advantages and disadvantages of the different models of cord blood banks. The promotional material and information provided to families must, therefore, be complete and accurate.

The majority of national bioethics committees recommend particular attention to the informed consent process: fully informed consent to cord blood storage must always be obtained.

A few Committees explicitly discourage a complete ban on autologous cord blood banks. Most of them recommend that any autologous cord blood banks that are established should meet the quality and safety standards established by international institutions.

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**References**


