

OPINION N° 74

**UMBILICAL CORD BLOOD BANKS FOR AUTOLOGOUS USE  
OR FOR RESEARCH**

On April 22, 2002, the *Directeur Général de la Santé* referred to CCNE issues raised by the preservation of autologous cord blood (umbilical or placental), i.e. essentially for the purpose of private therapy, or for research on stem cells.

These autologous cord blood banks represent some of the promises of medical advances using cord, instead of bone marrow stem cells, so that the possibly multipotent properties of stem cells can be put to good use for restorative therapy. Such autologous preservation differs from preservation for “allogenic” uses, that is for a third party, as an anonymous donation to a site accessible to all.

**I. Scientific data**

**1) Current status**

**I – I Bone marrow transplants.**

Since the 70s, a large number of patients have benefited from bone marrow grafts of hematopoietic stem cells. Autologous grafts, involving mostly adults, are performed for certain indications, and in this case, HLA<sup>1</sup> typing is obviously unnecessary. In the year 2000, 62,5% of transplants reported by the IBMTR (International Bone Marrow Transplant Registry) (<http://www.ibmtr.org/newsletter/pdf/2002Feb.pdf>) were grafts of autologous cells, originating in peripheral blood for 95% of adults, and 80% of children. Stimulation with growth factors are used to obtain them. In 50% of autologous grafts, patients are over the age of 50, and patients under the age of 20 represent 10% of that population. Clinical indications for autologous grafts and allogenic<sup>2</sup> grafts are not identical.

Allogenic (non autologous) marrow grafts were originally performed exclusively within a family, between HLA-identical individuals. Then, in particular during the 80s, the procedure was extended to unrelated individuals, with the development of Registries where HLA typing was done when potential donors enrolled voluntarily. The number of registered donors (~110 000 in France in 2002, ~8 million world wide) is still small in comparison with the large number of possible HLA combinations. However, allogenic grafts are limited by the small number of

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<sup>1</sup> HLA : major complex of the immunogenetic compatibility system important in order to diminish graft rejection, and in the graft of hematopoietic stem cells, to reduce the graft's reaction against the host (HLA = Human Leucocyte Antigen). This is a very polymorphic system : some groups are frequent and others very rare.

<sup>2</sup> The most frequent indications for allografts are acute and chronic leukaemia, myelodysplasia, and non -malignant diseases (immunodeficiency, aplasia, genetic metabolic disorders). Those of autologous grafts are generally non - Hodgkin lymphoma, multiple myeloma, Hodgkin lymphoma, and solid tumours.

registered donors in proportion to the great diversity required, and also the need to anaesthetise donors. Treating donors with growth factors largely opens the door to collecting stem cells by taking blood samples, as is done for autologous transplants, instead of having to use bone marrow puncture. Since there is as yet little retrospective data to go on, no assessment of any risk due to stimulation has been made. However with healthy volunteer donors, adverse consequences seem rather unlikely.

### **I – 2 Placental blood graft**

Towards the end of the 80s, placental blood (harvested from the umbilical cord) at birth, emerged as an interesting alternative. Ease of sampling, cryopreservation, and above all the first successful engraftments in 1988 on a child with Fanconi's anaemia using cord blood from a sibling, led to placental blood being viewed as a possible alternative for bone marrow donation, at least as far as children were concerned.

The advantages of cord blood cells over bone marrow stem cells in allogenic transplants are due to their youth, their immature status which reduces the risk of immunologic rejection, even in the presence of imperfect HLA compatibility, and also reduces the severity of graft versus host reactions. However, the number of cells is much more limited than with bone marrow (about ten times less) and therefore, for the time being the procedure is not equivalent to marrow donation.

Placental blood stem cells are mainly promising for so-called allogenic grafts. For that reason, in the last few years placental blood banks have been created in France, elsewhere in Europe, and in the United States, so that registers are being kept and national or international exchanges can be arranged. [<http://WWW.BMDW.ORG/>].

Clinical progress with the help of these banks is already quite promising, particularly as regards children. There could be an increasing number of indications for adults in the future if stem cells in sufficient quantities become available, and all the more so because absolute immune compatibility is less of a stringent requirement.

Because of the recruitment bias observed in adult voluntary bone marrow donors, the full genetic HLA diversity of a population is not represented in the Registries. Placental blood banks would increase diversity, and they are therefore expected to solve two sets of immunogenetic problems :

- 1) since less stringent compatibility is needed, children with a rare HLA group could benefit successfully from a graft when the donor is not perfectly matched, and
- 2) HLA types infrequently represented in Registries may be represented more readily in placental blood banks, because although they occur repeatedly in certain ethnic groups or populations they are only rarely donated to volunteer Registries, although these populations are also concerned by transplantations.

Because of this situation, since the early 90s, placental blood unit banks have become part of the medical environment and indications which are likely to multiply.

Such banks have been set up in France in public hospitals, under the triple supervision of the French Authority for Grafts (*Etablissement français des greffes*), the French Authority for Blood (*Etablissement français du sang*), and AFSSAPS (*Agence française de sécurité sanitaire des*

*produits de santé* – Safety of Health Products Agency), in a limited number of suitably organised and controlled sites.

As regards placental blood banks for allogenic purposes, the correspondence between the child's identity and his frozen placental blood unit is ensured by traceability. In France, the existence of this preservation is recorded in the child's "*carnet de santé*" (medical record). The donation is anonymous, but in this way the bank is made up of traceable units. An advantage of this method is that it is possible, if needs be, to use the placental blood for the child whose cord blood has been preserved.

Collecting placental blood at birth for the purpose of grafting a known sick related child who could benefit from this therapy (see Opinion n° 72) comes under the heading of intra-familial allogenic grafts.

In a certain number of other countries – in particular in the United States – private cord blood banks for autologous purposes are being set up. The aim is to collect and cryopreserve at the time of birth, for a fee, cord blood for the purpose of future possible conjectural treatment, for which there is (or could be) prospective therapeutic benefit in using stem cells in that blood for the same child (or possibly for a relation, as yet unspecified).

Although organising the preservation of cord blood for autologous purposes must of necessity compare favourably with allogenic bank procedures as regards stringency and safety, autologous therapeutic indications are not at all comparable to those of allogenic procedures, and in the present state of scientific progress, are very nearly virtual.

## **2) Indications for autologous cord blood grafts**

Indications are for the moment almost non-existent. The most optimistic view is that there are infinitesimal chances for the clinical indication to occur where transfusion of a child's own umbilical cord blood would be therapeutically effective.

In the case of a genetic disease, it is difficult to understand how such cells could be useful to the patient concerned, since the cells would be carrying the same mutation, unless some presently unknown effective gene therapy were to emerge. For some of these genetic diseases, **allogenic** grafts, from a related or an unrelated donor, could be indicated.

For many haematological diseases, remission or cure also relies much more on allografts than on autografts. For a wide range of leukaemias, the immunological reaction capacity of allogenic cells to factors carried by the leukaemia cells, have a beneficial effect : i.e. the graft versus host leukemic cells reaction. Autologous cells would not have this effect.

Autologous transplant indications are more frequent for adults than for children : the International Bone Marrow Transplant Registry (IBMTR/ABMTR <http://www.ibmtr.org/newsletter/newsletter.asp>) reports that between 1997 and 2000 ~5% of autografts concerned patients under the age of 20, whereas more than 50% were performed on

patients over the age of 50. Furthermore, in an increasing number of cases<sup>3</sup>, autologous stem cells for engraftment are taken from peripheral blood (blood samples taken after stimulation with growth factors).

It is therefore clear that currently, there is no indication for transfusion to a child of stem cells from preserved placental blood derived from that child's own umbilical cord. Advertisements for creating such banks are intentionally ambiguous regarding the absence of indication and the potential future use of the properties of stem cells.

What should also be underlined, as referred to above, is that hematopoietic stem cells used for autologous purposes are mainly drawn from patients' peripheral blood, and that the autologous indications concern adults more often than children. It would seem plausible that scientific progress on the properties of placental blood stem cells make it possible in future to put them to other therapeutic uses than those presently established, then mastering techniques using stem cells from peripheral blood, or from other adult tissues, would also have developed in parallel. In that event, it would seem likely that using the patient's own stem cells would be the preferred method rather than cells in placental blood which had been stored for many years (nothing is known regarding the survival of frozen stem cells for longer than 10 years). In any case, it would seem only reasonable to await convincing scientific assertions before launching into storing placental blood for autologous restorative grafts.

Notwithstanding the above, are there some plausible autologous indications for this kind of collection?

Some special cases might be conceivable : for example storing placental blood when the HLA groups are so rare that there would be some difficulty in locating an allogenic donor if the need arose. However, HLA groups are generally unknown except in the medical circumstances in which they are typed by laboratories of the public sector with official license to do so (more often than not in the context of allogenic graft indications). It would only therefore be in the case of previous knowledge that a rare group exists in a given family that storage would be considered, and that most probably for intra-family allogenic use. This would in fact be a return to the usual situation of intra-family allogenic grafts, with the single variant of cell source. Storage for autologous use in the case of rare HLA groups would seem to be exceptional.

Although a rare group is a prize for allogenic purposes, the probability of it being needed is small, so that the chances are that it will be used within its own family if the medical need arises. Storage of placental blood could be suggested to certain families, although not routinely; such a procedure could be initiated on admission to public health institutions for treatment. Such cases would come under the heading of variants to existing placental blood collection indications, with a view to immunogenetic diversification of banks. Since both autologous use and use within a family would be provided for, they would in no way compare with schemes involving systematic offers of storage for exclusively autologous purposes.

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<sup>3</sup> (95% of autologous grafts in adults, and more than 80% in children in the year 2000 were performed using peripheral blood cells. The remaining cases used either bone marrow or a mixture of cells taken from blood and marrow).

In fact, whereas allogenic grafts are a very promising development at this time, indications are rare compared to the size of the general population for autologous grafts of placental blood, and confidence is limited regarding the ability to control differentiation based on the multipotency of the cells, for uses where such capacity would be required.

There must therefore be no confusion between the two concepts – allogenic and autologous – and all the more so because autologous use implies at the outset a systematic offer, i.e. turning the collection of umbilical cord blood into a para-obstetrical procedure.

In conclusion, collecting and storing cord blood can have three purposes :

- 1) Allogenic graft for the community for proven medical indications, which justifies as extensive collection as is feasible by public banks.
- 2) Intra-family allogenic use for which indications are authentic but exceptional, in particular for rare HLA groups.
- 3) Exclusively autologous use, the recognised possible indications of which are rare and uncertain. Indeed, in most cases, indications concern adults, for whom collecting autologous marrow or peripheral blood stem cells would perhaps be preferable; indications for restorative therapy are at this point totally hypothetical and have not progressed beyond the research phase. From a scientific point of view, proposals for systematic collection of umbilical cord blood are groundless.

This Opinion is not concerned so much with indications as such, since they are always under constant review as science progresses, but more with the conditions and repercussions of collection for autologous purposes.

### **3) Research on placental blood stem cells**

This is obviously useful and necessary and is already happening. Existing banks provide the possibility of carrying on research using stored blood units which are not fully acceptable for therapeutic purposes (for instance if the volume or quantity of cells is insufficient). This possibility of use for research must be pointed out on the consent form signed by the mother, who may have objections. The context of banks created for autologous use is not suitable for research purposes.

The transfer of stem cells for the purpose of restorative medicine of various tissues, other than blood, is for the moment entirely within the realm of research, and controlling these cell lines is no more than a hope for the future. At this time, oncogenicity is thought to be a serious risk, but has not been evaluated with any precision. Although it seems essential to promote research on the properties of stem cells and the conditions in which control over the course of their differentiation is achieved, using these properties therapeutically is not to date a working proposition. There is certainly no justification at present for creating any structures for this purpose.

It appears that placental blood cells for research are available in sufficient quantities from existing sources.

This Opinion will therefore focus on the conditions and consequences of preserving units of placental blood for autologous therapeutic purposes.

#### 4) Technical aspects

If placental blood sampling is thought to provide some benefit, there would need to be suitable structures and reliable arrangements for the provision of therapy.

##### - Preservation

The cord blood which is collected must be safely frozen and stored. The lack of immunogenetic identification, as would be the case for autologous use, in any case deprives it of any usefulness whatsoever to the community. Immunogenetic identification (HLA group) would be costly<sup>4</sup>, as this type of test is only done when such immunological criteria are necessary to select stem cells (as in the case of allogenic transplants), when these cells are made available to the community. As regards preparation and preservation, the standards of laboratories would have to be as good as those of a blood transfusion facility.

- If systematic sampling is described as a need or a recognised benefit for children, organising the procedure could have an effect on the birth environment, or even on the conditions of, and the technique used for delivery. To the process of delivery would be added an act of therapy for the child's future, so that bringing the child into the world would no longer be the only aim pursued. Such an addition could complicate the act of delivery. On the contrary, in the case of banks for purely allogenic use, only trouble-free deliveries are selected for sampling and since there are many of them, it is possible to only sample in cases where there is no risk of complicating delivery.

The extreme degree of attention devoted to the cord, how the ligature is applied, concern over the amount of blood collected, may draw attention away from the birth itself : these considerations could become overriding in the context of ensuring the best possible therapeutic efficacy for the child in the future. It is generally considered that 80 ml and  $0.37 \times 10^8$  cells/kg are necessary for a unit of placental blood to be useful for therapy. The effects on the child could be greater than expected because unless sufficient care is taken to avoid it, the amount of blood required and the need to collect a maximum number of stem cells, could lead to hypoxia in the new born, all for the sake of improving preservation of placental blood.

For this reason, in extreme cases, caesarean section might be suggested without obstetrical necessity.

If the placental blood unit obtained was not sufficient for therapeutic purposes, the mother might suffer from feelings of guilt or inadequacy because she was unable to protect her child during delivery from some future threat. This also should be considered.

Obviously, placental blood sampling should not be viewed in too dramatic a light since, more often than not, this extremely commonplace procedure gives rise to no harmful consequences.

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<sup>4</sup> Procedures required for registering a new donor in the voluntary donor's registry are priced at 170 € by France Greffe de Moelle (Bone Marrow Graft organisation). This amount breaks down into 18 € for the medical interview and serological tests, 71 € for serological typing HLA -A, B and 80.6 € for generic molecular typing HLA -DR, DQ.

The issue lies in its purpose. Instead of being an ordinary act of litigation, it becomes a medical action for therapeutic reasons, and could detract from the exclusive attention owed to the child.

### 5) Legal aspects

In France, cord blood collection is not covered by law. At present, collection for allogenic purposes is the responsibility of three official organisations, the French Authority for Grafts (*Etablissement français des greffes*), the French Authority for Blood (*Etablissement français du sang*), and the Safety of Health Products Agency (*Agence française de sécurité sanitaire des produits de santé*). However it is legally classified as a waste product, and therefore its collection could lead to all kinds of interpretation and abuse.

- Were it to be covered by regulations applying to blood, it would become a product that can only be donated anonymously, voluntarily, and free of charge. It is true that autotransfusion was devised with the intention of avoiding a hypothetical viral risk, but collection is performed with the same draconian standards as those prevailing for blood donation. For example, a patient cannot be reinfused with his own blood if it contains pathogenic markers. Blood stored for personal use, can never be donated to someone else, for any reason whatsoever. Its management is completely under the control of the French Authority for Blood.

- Were it to be covered by regulations applying to bone marrow donation, cord blood collected for purely autologous purposes would come under the exclusive control of the French Authority for Grafts, and the scientific and ethical constraints governing organ donation would apply.

## II) Ethical considerations

Preserving placental blood for the child itself strikes a solitary and restrictive note in contrast with the implicit solidarity of donation. It amounts to putting away in a bank as a precaution, as a biological preventive investment, as biological insurance, whereas the true usefulness of the action in the present state of scientific knowledge, may be negligible.

CCNE is not taking the view that dedicated preservation of placental blood (autologous or within a family) is morally reprehensible as such. It could be offered as a possibility, exceptionally and not routinely, if an HLA group is known to be rare. Nor is it justifiable to oppose systematically a stated request from parents who wish to preserve all their options for potential autologous stem cell therapy in the future, even though in the present state of the art, this precaution is utopian. However, CCNE does wish to draw attention to certain points which motivate a position of, to say the least, extreme reserve.

1) There is major divergence between the concept of preservation for the child decided by parents and that of solidarity with the rest of society.

- Systematic auto-preservation, unless for exceptional medical reasons, is a denial of donation and an obstacle to the creation of banks for others which would require very costly prior immunogenetic identification. Furthermore, the probability of autologous use before the age of 20 is infinitely smaller than the likelihood of an allogenic indication, so that children whose cord

blood had been stored would still be potential users of the allogenic banks. As a result, they would benefit from others without any reciprocity if their HLA group remained unidentified.

Quantities of placental blood collected are such that they cannot be separated into two aliquots : one for autologous use, and one for allogenic use. It should be noted, as stated above, that existing public placental blood allogenic banks are composed of traceable samples so that they could be used if required for children whose cord blood was stored, unless that sample has in the meantime been used for someone else.

It is precisely because blood donation is anonymous and “earmarking” the gift is strictly prohibited that it has prospered. The recent practice of auto-transfusion for viral protection is in fact a breach of the logic behind blood donation. Storing placental blood for solely autologous purposes would paradoxically deny the benefits that placental blood banks for anonymous and allogenic use can contribute.

It appears that systematic storage of placental blood for exclusively autologous uses, in the present state of medical science, would be illusory, and more closely connected to market objectives than to therapy.

2 – The process of organ grafting has always been based on absence of profit, and the principles of gratuitousness, transparency, and ethical rules.

Is it acceptable to allow such principles to be violated by encouraging the preservation for a fee of placental blood for an unlimited length of time, in conditions of increasingly doubtful safety as time passes, for such probably limited uses that it becomes a product stored according to an unreasonable extension of the principle of precaution ?

Giving private banks the task of storing placental blood may be viewed as an expression of individual freedom of choice and free enterprise. However, it is important to remember that such banks cannot be integrated into the allogenic system and will therefore remain within the scope of trade and dubious promises.

3 – Would tasking a public organisation with the management of autologous blood be more ethical?

Ethics imply that within the limits of available health resources, the interests of people concerned, and therefore those of the community, prevail.

From the point of view of solidarity and efficiency, there is here a blatant discrepancy between the State's level of financial commitment and the benefit individuals may draw from it. It would hardly be justifiable in moral terms for the State to invest public resources into such a questionable project. It is the State's responsibility to take informed decisions regarding public health. Large amounts of money spent on encouraging selfish interests would obviously become unavailable to deal with collective problems caused by proven pathologies.

Therefore, devoting public resources to these projects would be futile at this point and if private individuals were to pay for them, their commitment would be based on a hazardous illusion of therapeutic promise for the future, so far devoid of any scientific foundation.

4 – Allograft programmes represent for the whole world the promise of fruitful exchange between banks. This would not be the case with autologous blood banks whose activities only benefit the richer countries.

## Conclusion

In conclusion, CCNE has misgivings concerning excessively utilitarian, utopian, and commercial visions of autologous conservation of placental blood.

Uncertainties of a scientific nature, in the absence of existing indications, and legal uncertainties since there is no legislation covering such programmes, are not however sufficient for adopting a cautious attitude regarding autologous cord blood banks. Science is always uncertain, and law can always be revised.

However, ethical difficulties arise because the concept of cord blood banks for exclusively autologous use carries with it a number of perils:

- 1) 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.
- 2) Such banks raise hopes of utopia and disguise a mercantile project using assistance to children as a screen.
- 3) They jeopardize 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.
- 4) 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.
- 5) The futility of autologous banks and their cost would be provocation in the eyes of the very poor, in particular in the Southern hemisphere.

Apart from these major points, other dangers – for children and for their parents – are worthy of note.

- dangers for the child during collection of blood, since mother and child cease to be the sole concern of doctors throughout delivery ; the need to collect in the approved manner an adequate quantity of cord blood, could focus medical attention on the task in hand (possibly for financial reward ?) to the detriment of mother and child.
- dangers for parents. In the context of private commercial activities, and in present circumstances, such parents can be viewed as the victims of deceitful advertising. This private offer might give them the extremely stressful feeling, should they reject it, that they have not done all they could for their child.
- There could also be reason to believe that paradoxically, a situation created to alleviate the anxiety of parents, might itself generate further anxiety. By focusing attention on possible pathologies, anxiety and guilt feelings on the part of parents could be increased by the fear that storage of the sample might fail, be defective, or be spoilt accidentally.

Parents should be informed of the lack so far of any scientific or medical justification for systematic collection of cord blood for exclusively autologous purposes. They should be encouraged to participate in the necessary development of public allogenic and anonymous

placental blood banks, by telling them that since the sample can be traced, should it be needed and still be available, it could be used for their own child.

Were the management of an autologous bank left to State management, the very high expense of implementing an unnecessary technique at a time when public health budgets are, of necessity, limited, would be ethically wrong. Promoting cord blood banks for allogenic purposes must not be allowed to create confusion between autologous and allogenic banks.

Should scientific progress produce encouraging data in future, which is not the case so far, then political authorities will need to organize matters so that equal access to healthcare prevails, and so that the mismatch between selfishness and solidarity is reduced to a minimum. Solidarity needs to be relentlessly reinvented.

In conclusion, CCNE's recommendation to decision makers is that they should encourage a considerable extension of cord blood public banks for essentially allogenic 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.

December 12, 2002

## **Annex : Autologous cord blood banks : international aspects**

### **1. Current situation**

Commercial cord blood banks for autologous use have existed for about 10 years. The earliest of them were created in the United States (e.g. *Cryo-Cell*, *Viacord*, *Cord Blood Registry*). They are all accessible on internet. As of December 2001, there were 11 such banks in the United States.

The more enterprising firms have set up subsidiaries in other countries (Mexico, Venezuela, Poland, New-Zealand, South Korea, to mention a few countries apart from Europe). *Cryo-Cell* is represented in a majority of countries in Western Europe. Cost for parents is approximately \$1500 on enrolment, plus \$95 a year for a 20 year period of storage.

**Germany** : A private bank offers these services in Leipzig at 1800 € for 20 years of storage.

**United Kingdom** : the *UK Cord Blood Bank* was the first private bank created (1995) in the United Kingdom as a subsidiary of its parent bank, the *New England Cord Blood Bank*. The company claims that it receives samples from several countries in the American, African, and Asian continents and from the Middle East, and also from the following European countries : Austria, Cyprus, Germany, Greece, Norway. Prices : processing, freight, and storage for the first year : £395, after which the annual fee is £50. Two other private banks operate in the United Kingdom : [www.cordblood.com](http://www.cordblood.com) and [www.cryoc.com/cryo-care/](http://www.cryoc.com/cryo-care/).

**Mexico, Venezuela** : The private banks are subsidiaries of the *New England Cord Blood Bank*.

**Poland** : The public sector cord blood allogenic bank cooperates with a private firm called *Acti Vision-Life SA* to store infant cord blood for autologous use.

**New-Zealand** : There is no public allogenic bank in the country. The private bank *Cordblood* began operating in June 2002.

**South Korea** : *Lifecord*.

### **2. Legislation and regulations in Europe**

**Very few countries have rules governing commercial banks. Only Italy, since January 2002, has a ruling which prohibits the creation of cord blood banks by private companies. The Belgian parliament is due to examine a draft bill submitted on March 13<sup>th</sup> 2001, and also a draft Royal Ruling which should lead to such banks being banned. In Spain, a royal decree on the use of human tissues sets out a certain number of criteria to be followed, in particular non-profitability, which would suggest that a commercial bank could not be incorporated.**

(In the **United States**, all cord blood banks need approval by the Food and Drug Administration and have to supply data on the safety and efficacy of their procedures. Accreditation by the *American Association of Blood Banks* (AABB) is recognised by consumer associations as providing some guarantee of the quality of their procedures.)

Some details :

**Spain** : All cord blood banks must comply with the Royal Decree 411/1996 as regards the use of human tissues, and also the specific directive on this subject that the Autonomous Region is due to draft in the near future. In the Royal Decree, there are no objections to the creation of cord blood autologous banks. However, they will be obliged to respect the conditions and demands

listed in the Royal Decree (infrastructure, staffing, procedures, quality control...). Also noteworthy is that article 16.3 of the Royal Decree specifies that banks should be set up on a non-profit basis.

**Italy** : The ruling dated January 11, 2002, bans private banks. “ *Art. I. The creation of banks for the preservation of umbilical cord blood is prohibited in private sector healthcare facilities, including those with official accreditation, except those structures described in art. 18 of Law n° 107/1990*”.

**Belgium** : Two draft laws are under discussion.

- 1) Following the first launch of a commercial bank, probably *Cryocell*, a draft bill submitted on March 13<sup>th</sup>, 2001, aims to prohibit this type of bank. In the list of motives, parliamentarians insisted on the fact that the particular status of umbilical cord blood is not defined in the law dated July 5<sup>th</sup>, 1994 on the subject of blood and derivatives of human blood, so that the conclusion could be drawn that such blood is not covered by the law. Thus, a new article is needed for the creation of an exception to that law, i.e. article 11bis conferring special status on umbilical cord blood. Article 6 of that same law rules that the Minister sets the price at which blood and blood derivatives are used and delivered, so as to exclude any kind of profitable activity. This draft bill has yet to be voted upon.
- 2) There is also a draft Royal Ruling for the purpose of modifying the Ruling dated 14/04/88 which deals with tissue banks, and in which cord blood is classified as a tissue. The draft in article 2, prohibits “*3. the use of tissues for deferred preventive intentions*”. It also provides further data on the accreditation and approval of banks.

Opinion n° 11 of the National Consultative Ethics Committee, dated December 20, 1999, on the subject of sampling organs and tissues of healthy live donors for transplanting, can be consulted. This Opinion puts some emphasis on the legal status of cord blood.

To the best of our knowledge, no supranational European body has, as yet, stated its opinion on such banks, but the **European Group on Ethics (EGE)** is expected to make a pronouncement within the next few months. Current thinking is focused on tissue banks for allogenic grafts. The two following reference documents should be consulted : an **opinion of the EGE published in 1998 on the Ethical aspects of human tissue banking** (Opinion n°11) and a **draft European directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells**, September 2002. The two bodies classify cord blood as tissues (for the European directive, see the Official Journal of the European Communities, September 24 2002 (C 227 E, pages 505-521).

### 3. Official pronouncements

Although very few countries have made any pronouncements as yet, many medical associations and groups connected to public banks have expressed, in the majority, very reserved opinions. The following are a few examples.

**France : Académie nationale de médecine**, an Opinion on *Cord blood autologous banks*, dated November 19, 2002 : *In the present state of the art : there is no therapeutic indication. In future, it is not impossible that some indications may emerge... It has not been demonstrated so far that cryopreserved stem cells stored for several decades remain functional. Furthermore, the cost of creating such banks would be exorbitant. However, in order not to be deprived of possibly useful*

*material, one solution would be to reserve cryopreservation of cord blood for autologous purposes to targeted populations (...) The Académie furthermore wishes “to prohibit the creation of private commercial banks for the purpose of collecting and storing cord blood for strictly autologous purposes and, consequently, to prohibit any form of advertising in maternity homes offering for a fee, to collect and preserve placental blood for the possible future needs of a child”.*

**Spain : The National Commission for Grafts** announced its opposition to the creation of such banks in 1997.

**Belgium :** At the end of 2001, the **Conseil supérieur d’hygiène** announced that it supported the prohibition of “*autologous therapeutic uses for deferred preventive intentions*”. Officials in charge of the **public cord blood bank** ([www.ordomedic.be/braf/sangcordon.html](http://www.ordomedic.be/braf/sangcordon.html)) stated : “*So far, autologous cord blood has never been used. Indications would be very limited... The cost of a programme for the cryopreservation of autologous cord blood is totally prohibitive compared to the probability of uses for cord blood... using autologous cord blood is of no benefit except that of private firms who obviously see a potential for financial profit*”.

**United States :** the **National Marrow Donor Program** has approved the position adopted by the **American Academy of Pediatrics** (1999) which stated “*Given the difficulty of making an accurate estimate of the need for autologous transplantation and the ready availability of allogenic transplantation, private storage of cord blood as “biological insurance” is unwise. However, banking should be considered if there is a family member with a current or potential need to undergo a stem cell transplantation* ». **The Cord Blood Donor Foundation** warns potential clients about commercial companies, but does not censure them.

**The American Medical Association, Working Group on Ethical Issues in Umbilical Cord Blood Banking.** 1997. Considers that using cord blood is an unproven treatment. (*Jama*, vol. 278(11), pp 938-943).

**Australia :** The **Australian Cord Blood Bank** (public) “*does not offer this service because there is no proven role and such cord blood is unlikely to be used*”. (<http://www.sch.edu.au/departments/acbb/donate.asp>).

**United Kingdom :** The **Royal College of Obstetricians and Gynaecologists** ([www.rcog.org.uk](http://www.rcog.org.uk)) : “*Routine directed commercial cord blood collection and stem-cell storage cannot be recommended at the present time, because of the insufficient scientific base to support such practices and the attendant logistic problems of collection for NHS providers*”.

**Switzerland :** The Central Ethics Commission of the **Académie Suisse des Sciences Médicales** reserves its position regarding the harvesting and use of human stem cells for scientific research (*Bulletin des médecins suisses*, 2002 ; 83 : Nr 3, p. 85-88). “*One of the problems is storage in a bank of umbilical cord blood. There is on the one hand, the possibility of private storage – exclusively for personal use and for a fee – and on the other, that of creating public blood banks available to the general public. Women/parents should be informed of those two possibilities*”. However, Expert’s Opinion n° 10 of the **Société de Gynécologie et Obstétrique** is opposed to commercial banking (May 10, 2002).

**Japan :** An opinion issued by medical experts expressed disapproval.

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