COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(2004) 8
of the Committee of Ministers to member states
on autologous cord blood banks and explanatory memorandum

(Adopted by the Committee of Ministers on 19 May 2004
at the 884th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the field of health;

Taking into account Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16 - 17 November 1987);

Having regard to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Having regard to the Additional Protocol to the Convention on Human Rights and Dignity of the Human Being with regard to the Application of biology and Medicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Considering that:

The principal current use of blood cells collected at the time of birth from the umbilical cord (cord blood) is the collection of haematopoietic progenitor cells (HPC) that can be transplanted into patients with acquired or congenital diseases of the bone marrow. It is likely that such cells will, in the future, constitute a valuable source of cell therapies for the treatment of a wide range of diseases;

Cord blood stored only for autologous use, that is, by the donor or his or her immediate family, is only very rarely used. Furthermore, there is no scientific evidence that umbilical cord blood can be stored for long enough to be of any use to the vast majority of donors. Such storage could limit altruistic donation and thereby limit the possibility of treating those in need;

The unregulated collection of blood at the time of birth could distract the staff caring for mother and child at a critical time;

Even if it is the case that these children do, in the future, develop diseases requiring an HPC transplant, there is evidence to suggest that it is preferable to use allogeneic transplantation to achieve the "graft vs. tumour effect" in haematological diseases. In cases of congenital disease and in some leukaemias with intrauterine cell mutations, autologous HPC transplantation is contraindicated;

The health services of member states should only provide their citizens with proven clinical and cost effective therapies, as resources are always limited;

With the aim of ensuring the availability of transplant treatments for an increasing number of people,

Recommends to the member states that,

1. 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;

2. The promotion of donations for autologous use and the establishment of cord blood banks for autologous use should not be supported by member states or their health services;

3. Accurate information should be provided to the population about the advantages and disadvantages of cord blood banks;

4. 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;

5. Autologous cord blood banks that are being established must meet the quality and safety standards set out in the council of Europe's Guide to safety and quality assurance for organs, tissues and cells.

EXPLANATORY MEMORANDUM

On autologous cord blood banks

The principal current use of umbilical cord blood (UCB) is the collection of haematopoietic progenitor cells that can be transplanted into patients with acquired or congenital diseases of the bone marrow. In addition, it is known that umbilical cord blood could be a source of stem cells.

Autologous umbilical cord blood banks reserve the use of stored UCB for donors who develop pathologies that can be addressed by haematopoietic progenitor cell (HPC) transplantation. In certain cases, these banks also allow the use of a donor's UCB by his or her relatives.

Some of the reasons given by the industry supporting the creation of these banks are analysed below:

Autologous UCB banks as a source of HPC

Reasoning:

UCB can be stored for possible future use if the child or its relatives develop pathologies that might be curable by HPC transplantation.

Explanation:

Currently, umbilical cord blood is one of the sources of HPC; these cells can be used to treat patients with acquired or congenital diseases of the bone marrow.

The creation of autologous UCB banks and the promotion of donations for autologous use could endanger altruistic and voluntary UCB donations, essential for an important number of patients (in Spain, for example, more than 400 people a year need non-related donations). There is an international system in place for locating compatible donors. There are 8.5 million bone marrow donors in the world and about 141 000 stored units of voluntary donated UCB. Even though the number of donors seems to be increasing, due to the need for HLA compatibility between donor and recipient, only 30-40% of patients

succeed in finding a compatible donor. For that reason, a decrease in altruistic and voluntary donations will make it increasingly difficult to find HLA compatible donors.

The probability that the autologous UCB stored in these banks will be used (in other words the probability that these children will develop a pathologies requiring HPC transplantation) is very low. The vast majority of autologous stored UCB units will never be used.

Even if it is the case that these children do, in the future, develop diseases requiring an HPC transplant, there is evidence to suggest that it is preferable to use allogeneic transplantation to achieve the "graft vs. tumour effect" in haematological diseases. In cases of congenital disease and in some leukaemias with intrauterine cell mutations, autologous HPC transplantation is contraindicated.

However, if UCB is donated to a normal UCB bank it can be located in the future either for autologous or heterologous use.

Autologous UCB banks as a source of stem cells

Reasoning:

UCB could be a source of stem cells for the child in the future. It could be used to obtain cells or even organs for transplantation. For this reason, the storage of UCB of all newborns is justified.

Explanation:

From a scientific point of view, at present, the clinical use of stem cells from UCB is a promising treatment but is still in a research phase. Two ongoing experimental trials in mice demonstrate the potential of stem cells from UCB to regenerate nervous tissue. However, these studies are still in an early experimental phase and no clinical trials have been carried out in humans. Stem cell production from adult tissue is also a possibility and the methodology will probably be improved in the future.

Stem cells are also being used in clinical trials to regenerate heart muscle, but these cells can be harvested from adults. On the other hand, the development of organs from stem cells is not yet a realistic option.

The storage of UCB of all newborns would mean the creation of a significant number of UCB banks (autologous banks), and also the collection, storage and preservation of a very large number of UCB units. Sooner or later, these banks would fall under the auspices of national health systems, resulting in very high costs without any clear benefits.

The other option is private UCB autologous banks. Parents who voluntarily wish to store their child's UCB could do so by paying the bank for the collection, preservation and storage of UCB units. Such banks already exist countries such as the United States, the United Kingdom and Germany, but are prohibited in countries such as Italy.

At present is no scientific rationale for the universal storage of UCB. It is no justified that parents pay for an unproven service without definite therapeutic use. There is therefore a need for controls, to facilitate the provision of accurate information to the family, and to ensure that proper informed consent is obtained. Autologous blood banks should be regulated by the same rules and should meet the quality standards recommended by the Council of Europe.

There is a conflict of interest between parental freedom to invest money as they choose and the obligation of the administration, for public health reasons, to restrict this type of commercialisation.

UCB mixed banks (autologous banks and voluntary banks)

A UCB unit could be divided in two parts, one to be stored for autologous use and the other to be donated voluntary to an allogeneic bank.

It is necessary to take into account that the viability of a UCB transplantation is dependent on the number of HPCs. Using only 50% of the volume of the unit could endanger the success of a transplant.

The other possibility is to collect a UCB aliquot of newborns and create a bank of UCB samples for their use in the future, and donate the rest of the UCB to an allogeneic bank. Currently, cellular expansion techniques are not well developed; therefore the collection of this aliquot is without value as its subsequent growth is not feasible.