COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

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

(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. tumor effect" in hematological 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 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;
- 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.