COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No (98) 2

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON PROVISION OF HAEMATOPOIETIC PROGENITOR CELLS

(Adopted by the Committee of Ministers on 12 February 1998, at the 620th meeting of the Minister's 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 health field;

Taking account of the ethical principles set out in Recommendation No R (88) 4 on responsibilities of health authorities in the field of blood transfusion concerning voluntary, non-remunerated blood donation;

Taking account of the ethical principles set out in Recommendation No R (94) 1 on human tissue banks;

Recalling its Recommendation No R (95) 14 on the protection of the health of donors and recipients in the area of blood transfusion;

Recalling the guidelines and principles defined in Recommendation No R (95) 15 on the preparation, use and quality assurance of blood components;

Recalling also its Recommendation No R (97) 5 on the protection of medical data;

Considering that, in the procurement and distribution of haematopoietic progenitor cells, the ethical principles concerning organ transplantation as set out in Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, and confirmed at the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), should be respected under all circumstances and that consent is required for the removal of tissues and their proposed use, whether therapeutic, diagnostic or research;

Taking account of World Health Organisation Resolution WHA 42.5 condemning the purchase and sale of organs of human origin;

Taking note of the definition provided for in the appendix to this recommendation;

Bearing in mind the Convention on Human Rights and Biomedicine as well as the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data,

Recommends to the governments of member states the principles set out in the appendix to this recommendation.

Appendix to Recommendation No (98) 2

1. The activities relating to the provision of haematopoietic progenitor cells can be divided into the following separate functions:

   - donor selection;
   - organisation;
   - collection;
   - processing;
   - preservation;
   - internal quality control;
   - storage and release/issue from storage;
   - distribution;
   - quality assurance and good laboratory practice (GLP).

2. The functions described under paragraph 1 should be carried out by institutions which are officially licensed by national health administrations, or recognised by the competent authorities. These institutions should not make any gain from their activities as such.

3. The organisations involved in haematopoietic progenitor cells should ensure that donors of haematopoietic progenitor cells be tested for transmittable diseases, in compliance with the law and practice of the country concerned.

4. The organisations involved in work or haematopoietic progenitor cells should implement scientifically recognised state-of-the-techniques (such as CD34 positive cell numbers, cell viability and sterility) and respect the criteria established by general medical and laboratory practice, and implement an effective quality assurance system (such as GLP).

5. Records of all haematopoietic progenitor cells retrieved and issued should be kept by the organisations involved in haematopoietic progenitor cell transplantation in such a way that their source and their destination are clearly identifiable, providing always that access to such records will be restricted to the extent necessary to protect confidentiality of information and individual privacy; donors and recipients should be followed up for least twenty years.

6. Criteria for the collection of haematopoietic progenitor cells should established in accordance with national law. Distribution should take place in such way as to permit optimal use of haematopoietic progenitor cells on an equitable basis in accordance with national law, rules and practice and objective selection criteria. Cells for transplantation should be released only to those centres, which according to national law are qualified to perform autologous or allogenic progenitor cell transplantations.

7. Close mutual co-operation between different professional groups such as those working in bone marrow transplantation and blood banks should be pursued by all officially recognised organisations concerned with activities involving haematopoietic progenitor cells, and follow-up data on donor/recipient combinations should be shared between relevant institutions within the framework of national guidelines and legislation, provided always that the privacy of the person concerned is fully respected.

8. Close mutual co-operation between different professional groups such as those working in bone marrow transplantation and blood banks should be pursued by all officially recognised organisations concerned with activities involving haematopoietic progenitor cells with the aim of agreeing common minimum quality standards for haematopoietic progenitor cells and the handling haematopoietic progenitor cells outlined under paragraph 1.

9. All family and unrelated donors of haematopoietic progenitor cells, and the mothers of infants donating cord blood, are to be given appropriate information on known risks about the methods of donation, from a physician who is independent of the Bone Marrow Transplant team. Mothers of infants donating cord blood must give their consent prior to collection which must be non-remunerated.

10. Cord blood banks should observe ethical standards and such banks should achieve the standards recommended under paragraph 5 from their inception.

Definition of haematopoietic progenitor cells:

11. For the purposes of this recommendation, haematopoietic progenitor cells (HPC) are primitive pluripotent cells capable of self-renewal as well as differentiation and maturation into all haematopoietic lineages. They are found in bone marrow, foetal liver, in the mononuclear cells of circulating blood and in umbilical cord blood.

12. Haematopoietic progenitor cell preparations (from all four sources) are intended to provide a successful engraftment of haematopoietic stem cells leading to a restoration of all types of blood cells to a normal level and function in the recipient. The infused haematopoietic cells may from the recipient or from another individual.