COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (95) 14

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

ON THE PROTECTION OF HEALTH OF DONORS AND RECIPIENTS IN THE AREA OF BLOOD TRANSFUSION

(Adopted by the Committee of Ministers on 12 October 1995 at the 545th 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 a greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common regulations in the health field;

Recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to the removal, grafting and transplantation of human substances;

Recalling also its Recommendations No. R (80) 5 concerning blood products for the treatment of haemophiliacs; No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives; No. R (83) 8 on preventing the possible transmission of acquired immune deficiency syndrome (Aids) from affected blood donors to patients receiving blood or blood products; No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion; No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion; No. R (89) 14 on the ethical issues of HIV infection in the health care and social settings and No. R (90) 9 on plasma products and European self-sufficiency;

Recalling Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components establishing a set of guidelines necessary for health authorities and transfusion services;

Recalling the principles underlying the above recommendations, namely that, for both ethical and medical reasons, blood donations should be voluntary and non-remunerated and that optimal use should be made of blood;

Aware that the availability of blood products for the benefit of all patients depends on the recruitment of donors and that it is necessary to take measures to ensure the safety of both donors and recipients in the area of blood, plasma and cell donation;

Recalling the importance of good donor selection, avoiding any possible discrimination; recognising the necessity to provide pertinent information to blood donors, in order to avoid donations by persons who have a medical history or whose behaviour and/or health status is likely to increase the risk of infection for the recipient;

Believing that the harmonisation of national regulations on the protection of health of donors and recipients in the field of blood transfusion will greatly facilitate the achievement of the above aims and principles,

Recommends that the governments of member states bring their national regulations into conformity with the principles contained in the appendix hereto.

Appendix to Recommendation No. R (95) 14

A. Ethical principles

Article 1

The donation of blood, plasma or cellular components should comply with the ethical principle of voluntary, non-remunerated donation applicable to all removal, grafting and transplantation of human substances.

Article 2

Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.

Article 3

All collections should be effected in such a manner that the donor's health is not harmed and that its therapeutic use in the form of cellular components or plasma derivatives involves minimal risks to the recipient.

Article 4

The human origin of blood and its constituents and derivatives, as well as the ethical principles of voluntary and non-remunerated donation, demand that substances be used optimally so as to avoid all wastage.

Article 5

All potential donors should be informed prior to donation that their blood will be examined for the detection of serological markers of viral or other infections. Transfusion centres should notify the donor, preferably by a physician or any other person medically qualified, if analysis of the blood samples taken has produced evidence of any pathological condition. Confidentiality of these medical data should be respected.

B. Needs related to blood collection

Article 6

The premises used for blood collection should:

– be so designed that they can be used in a rational way;

– meet the hygiene requirements applicable to this type of activity;

– have facilities for carrying out medical checks in strict conditions of confidentiality in order to verify whether individuals wishing to donate blood should be accepted as donors or whether they should be discreetly rejected;

– allow for the collection of blood, plasma or cells from donors in full safety (and, if necessary, for re-injection without any risk to the donor).

Article 7

Each collection centre should have the necessary facilities for dealing with incidents which may arise during blood/plasma/cell donation.

Article 8

Equipment and particularly collection equipment should be visually inspected so as to avoid any complications, in particular involving contamination.

Article 9

The medical and scientific aspects and laboratory functions of a blood transfusion centre should be supervised by a suitably qualified person specifically appointed for that purpose, who should see to it that all operations (in particular the screening of donors and associated medical checks) are carried out properly and efficiently. Collection of blood/plasma/cells should be carried out under the supervision of medically qualified persons.

C. Measures to be taken for the safety of donors

Article 10

Each transfusion centre should have acceptance criteria for selecting blood/plasma/cell donors which conform to the highest applicable standards, as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components.

Article 11

During collection, strict precautions should be observed with regard to hygiene in order to prevent not only contamination of the blood collected, but also any possibility of infection to the donor.

Article 12

The intervals between two donations and the volume collected should comply with the strictest criteria, as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components.

Article 13

After giving blood, donors should be allowed time to recover while under discreet medical supervision.

Article 14

Before each collection session, all donors should be questioned individually and confidentially by a qualified person on the basis of a printed questionnaire in order to identify any risks they may face.

Article 15

Each new donor should undergo a detailed medical assessment which should be repeated if the need arises.

Article 16

Donors should be subjected to haematological tests, as indicated in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components. Current tests do not exclude latent iron deficiency; when such tests are available, it is recommended that they be used.

Article 17

Given that extracorporeal circuits are involved, plasmapheresis and cytapheresis should be subject to additional precautions, as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components.

Article 18

Collection centres should have insurance cover for accidents arising in connection with blood/plasma/cell donation.

D. Donor selection

Article 19

The medical criteria used in donor selection should ensure the quality and safety of the final blood product.

Article 20

Reduction of the risk for the recipient depends primarily on measures to inform and educate donors which should be as clear and comprehensive as possible. Potential donors should be informed of what, in their medical history, in their current behaviour and in their state of health, is likely to increase the risk of infection for the recipient.

Article 21

The medical interview should be regarded as an important element in the selection of potential donors. The following should be excluded (temporarily or permanently as the case may be): persons belonging to categories who by virtue of their medical history or current activities or behaviour present a high risk of transmission of infectious diseases (for example HIV, hepatitis viruses, prions, etc.).

E. Measures to be taken for the safety of recipients

Article 22

Strict precautions should be taken in the collection, production and storage of blood products to prevent transfusion complications.

Article 23

Blood products and plasma derivatives should be stored and transported under strict conditions and in accordance with the most scrupulous criteria as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components, both in transfusion centres and in hospitals.

Article 24

There should be systematic quality control of blood products and plasma derivatives issued by blood transfusion centres.

Article 25

All blood collected from a donor should be subjected to analyses capable of detecting infections transmissible through blood (for example HIV, hepatitis viruses, etc.).

Regional epidemiological surveys can provide data which may be used as a basis for decisions to conduct additional tests for either new infectious agents or surrogate markers.

Article 26

Pre-transfusion laboratory tests should ensure serological compatibility between the unit to be used for transfusion and the recipient, in accordance with the strictest criteria, as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components.

Article 27

Transfusion which is a therapeutic act should be prescribed by a physician and carried out under his or her supervision and responsibility. The physician should inform the patient of any potential side-effects of the transfusion.

Article 28

A final check is needed immediately prior to transfusion to ensure correct identification both of the recipient and of the unit to be transfused.

Article 29

The patient's need for a transfusion should be assessed by pre-transfusion testing; post-transfusion tests are recommended in order to monitor and keep on record the effectiveness of the transfusion on the recipient. Haemovigilance systems should be implemented in order to detect possible adverse effects on the recipient.

Article 30

Transfusion centres should provide written information on the procedures for dispensing the blood products distributed to users (clinics, hospitals, etc.).

F. Quality assurance

Article 31

Transfusion centres should be required to operate quality assurance programmes. Blood products prepared under their responsibility should be subject to regular quality controls. There should be strict compliance with quality assurance provisions as set out in the appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components.