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Blood and blood components – Safety, Quality, Training and Ethical Matters Concerning Preparation, Use and Quality Assurance

Council of Europe Resolutions, Recommendations and Convention

1st Edition

European Directorate for the Quality of Medicines & HealthCare
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Foreword and Acknowledgements

The Council of Europe was founded in 1949. It is the oldest and largest of all European institutions, having now 47 member states. One of its founding principles is that of increasing co-operation between member states to improve the quality of life for all Europeans.

Within this context of intergovernmental co-operation in the field of health, the Council of Europe has consistently selected ethical problems for study.

The most important of such ethical issues relates to the non-commercialisation of human substances i.e. blood, organs and tissues.

With regard to blood transfusion, co-operation among member states started back in the 1950s. From the onset, the activities were inspired by the following guiding principles: promotion of voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood components and protection of the donor and the recipient.

The first result of this co-operation was the adoption of the European Agreement on the Exchange of Therapeutic Substances of Human Origin (European Treaty Series, No. 26) in 1958. It was followed by the European Agreement on the exchange of blood grouping reagents.

1 Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey, Ukraine, United Kingdom.
Blood and blood components

(European Treaty Series, No. 39) and of tissue-typing reagents (European Treaty Series, No. 84) in 1962 and 1976 respectively.

Since 2007 the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), a Steering Committee of the Council of Europe pursues activities in the field of blood transfusion under the aegis of the European Directorate for the Quality of Medicines and HealthCare (EDQM).

In the frame of its activities the Guide to the Preparation, Use and Quality Assurance of blood components is published by the EDQM (ISBN 978-92-871-7022-4).

To supplement this technical guide, it was thought useful to generate a compilation of all Council of Europe legal instruments relevant to transfusion activities under the title of Blood and Blood Components – Safety, Quality, Training and Ethical Matters Concerning Preparation, Use and Quality Assurance².

The drafting and the publication of the 1st Edition of the book at hand was coordinated by Dr Bernhard Bräunig (Consultant, EDQM), Dr Marie-Emmanuelle Behr-Gross (Scientific Officer, EDQM) and supported by Ms Carole Knaup (editorial assistant, EDQM) under the responsibility of Ms Catherine Nicolas (Scientific Editor, EDQM).

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Resolutions and Recommendations
Resolution (68) 32 on establishment in Amsterdam of a European blood bank of rare groups

(Adopted by the Ministers’ Deputies on 31 October 1968)

The Committee of Ministers,

Considering that the Central Laboratory of the Netherlands Red Cross Blood Transfusion Centre intends to establish a European Blood Bank of Rare Groups in Amsterdam;

Considering the advantages of such a bank and the urgent need to set it up pending the creation in the other Council of Europe member states of national blood banks of a similar type;

Having regard to the methods envisaged for the functioning of the said European Blood Bank and to the blood groups which it is foreseen to include therein, as well as to the estimated credits required for its establishment and the additional costs made necessary by its use, as shown in Appendix I of this resolution;

Noting the means by which the said European Blood Bank is to be supplied and requests for its services transmitted, as shown in Appendix II of this resolution;
Considering that the Government of Finland has expressed the desire to participate in the operation of the above-mentioned European Blood Bank,

Resolves:

i. to contribute Dfl. 45,000 towards the cost of setting up the European Blood Bank of Rare Groups to be provided for in the 1969 budget and to be paid to the Central Laboratory of the Netherlands Red Cross Blood Transfusion Centre in Amsterdam for the acquisition by the said Central Laboratory of a "Union carbide" liquid nitrogen refrigerator;

ii. to grant an annual subsidy of Dfl. 11,000 toward the running and maintenance costs of the said European Bank for a period of 5 years, namely 1969 to 1973, to be provided for in the budgets for the said years and to be paid to the Central Laboratory of the Netherlands Red Cross Blood Transfusion Centre in Amsterdam;

iii. to invite Finland to share, on a basis to be agreed, in the above-mentioned expenses to be met from the Council of Europe budget.
Resolutions and recommendations

Appendix I

A. Methods used by the European Blood Bank of Frozen Blood of Rare Groups

1. The blood is taken in a ACD-A solution (plastic bag or bottle in the country where the donor is available).
2. Storage of the collected blood at + 4°C.
3. Shipment of the whole blood, the same or the next day by air or train to Amsterdam in a proper container, e.g. a carton box with styrofoam insulation, kept at 0°C to + 6°C by melting ice in plastic bags.
4. After arrival at the Central Laboratory in Amsterdam the blood is centrifuged; the plasma is removed, freeze-dried and stored.
5. Addition to the remaining 250 ml red cells of 250 ml of a solution containing per litre: 350 g glycerol, 29 g sorbitol and 6.3 g NaCl.
6. Transfer of these 500 ml glycerolised red cells through a closed system into a sterile stainless steel container.
7. Freezing of the red cells by immersing the filled container in a vertical position in liquid nitrogen (- 196°C).
8. Storage of the container in a biostat kept at - 180°C/176°C by means of liquid nitrogen. The use of a large amount of liquid nitrogen (+ 100 litres) as a coolant in this biostat makes the whole system independent of break-down of electricity supply.
9. After the request for the blood of a certain donor, the corresponding stainless steel container(s) will be taken out of the biostat and thawed in a water bath at + 40°C.
10. Transfer of the thawed glycerolised red cell suspension into a plastic bag. Centrifugation and removal of the supernatant, followed by a washing with a solution containing per litre: 160 g sorbitol and 8 g NaCl and two washings with 0.9 % NaCl solution.
11. After the removal of the supernatant of the final wash, the red cells will be suspended in the dissolved original plasma.

12. Shipment of the reconstituted blood in a container at + 4°C by air or train.

13. In vitro experiments about the tenability of the reconstituted blood, indicate that a period of one week storage at + 4°C may be possible. However, as in the case of normal washed red cells, it is strongly advised to follow the good practice of giving the processed blood within 24 hours, because of possible risk of bacterial contamination during processing.

The in vivo survival of the reconstituted blood as determined with the 51 Cr-double tag method, is completely comparable to the survival of blood before freezing (data from the Central Laboratory of the Netherlands Red Cross Blood Transfusion Centre and the New York Blood Centre).

B. Blood groups to be included in the Blood Bank of Frozen Blood

a. Very rare blood groups, e.g. Bombay, K°, Vel-negative etc.

b. Blood, negative for certain antigens, which occur with considerable frequency and against which immune antibodies are quite frequently formed, e.g. e,k,S etc.

c. Blood, negative for certain combinations of antigens, e.g. c + Fy°, e + Fy° etc.

d. Blood from patients who have developed a haemolytic transfusion reaction and in whose blood no iso-antibodies against red cells have been demonstrated.
C. Estimate of credits for the establishment in Amsterdam of a European Blood Bank of Frozen Blood of Rare Groups

1. Credits required for the establishment of the European Blood Bank:
   
   **Equipment:**
   
   1 union carbide liquid nitrogen refrigerator
   
   LR 1000\(^1\) Dfl. 45,000
   
   **Cost per year:**
   
   Liquid nitrogen
   Dfl. 6,000
   
   Maintenance and supervision
   Dfl. 5,000

2. Additional costs per unit of 500 ml blood at the consumer’s expense:

   - Transport etc.
     Dfl. 15
     (Schiphol Airport - Central Laboratory)
   - Metal container, processing solutions, plastic bag.
     Dfl. 30
   - Process labour
     Dfl. 25
   - Transport by air of 4 units of frozen blood to the country of destination (approx.)
     Dfl. 45

---

1 Capacity: 400-500 units of 500 ml.
2 1 Dfl = 1.364 French francs (as at 1 October 1968).
A. Supplies of frozen blood of rare groups to the European Blood Bank

The European Blood Bank will be supplied by voluntary donors. Where necessary, the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service in Amsterdam may appeal for donations of blood through the National Health Authorities of the member states of the Council of Europe and Finland.

B. Requests to the European Blood Bank for Frozen Blood of Rare Groups

Requests made to the European Blood Bank which emanate from member states of the Council of Europe and from Finland will be transmitted through the national laboratories as prescribed by Article 6 of the European Agreement on the Exchange of Therapeutic Substances of Human Origin, or, if appropriate, through similar institutions designated for the purpose by the National Health Authorities.
Council of Europe
Committee of Ministers

Recommendation No. R (79) 5 of the Committee of Ministers to the member states concerning international exchange and transportation of human substances

(Adopted by the Committee of Ministers on 14 March 1979 at the 301st 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, in particular through common action in social, scientific, legal and administrative fields;

Considering that the substantial increase in recent years in the treatment of patients by transplantation or grafting of removed or collected human organs, tissues or other substances and the increasing demand for such organs, tissues and substances, has also increased the need for wider international co-operation in this field;

Considering that the increasing demand for human substances, as well as information as to the demand for them and their availability, must be further facilitated by common action of the member states in order to make them available in due time and condition;
Considering Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances,

A. Recommends to the governments of member states:

I. to take all appropriate measures:
   1. to facilitate the international exchange and transportation of substances indicated under paragraph II below;
   2. to ensure the safe, speedy and priority transport of these substances. For these reasons all containers of substances shall clearly indicate their contents and purposes, the name and address of the sender and addressee and the name, address and telephone number of the person to whom any query should be made;
   3. to ensure the exchange of information on the demand for and the availability of substances and on all matters pertaining to their preservation, transportation and processing;
   4. to exempt substances and their containers from all duties and taxes at importation and exportation; this exemption shall also extend to the return of used containers;

II. to apply the measures mentioned in paragraph I above to any international exchange or transportation of substances of human origin removed or collected with a view to transplantation or other use for therapeutic or diagnostic purposes for the benefit of persons other than the donor and for research purposes. The international exchange and transportation of human blood and its derivatives, which are covered by the European Agreement on the Exchange of Therapeutic Substances of Human Origin, as well as the international exchange and transportation of embryos, testicles, ovaries, ova and sperm are excluded from the field of application of this recommendation;
III. to require, if they are the sending state, only payment of expenses for removing (or collecting), preserving, processing and transporting the substances mentioned in paragraph II above and, if the substances are sent by a private body, to endeavour to ensure that only payment of those expenses will be requested;

B. Invites the governments of member states to inform the Secretary General of the Council of Europe in due course and at any rate every five years, of the action taken on this recommendation.
Council of Europe
Committee of Ministers

Recommendation No. R (80) 5 of the Committee of Ministers to the member states concerning blood products for the treatment of haemophiliacs

(Adopted by the Committee of Ministers on 30 April 1980 at the 318th 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 public health field;

Considering that ethical and economic reasons necessitate optimal use of blood and all blood components to cater for the needs of haemophiliacs, and aware of the resulting implications with regard to the organisation of blood collection, fractionation and therapeutic use;

Taking note of the fact that the risks of transmission of infectious diseases, in particular viral hepatitis, may vary from one area to another;
Recalling the recommendation of the World Health Organisation, the League of Red Cross Societies and the International Society of Blood Transfusion concerning the promotion of voluntary non-remunerated blood and plasma donations, the Agreements of the Council of Europe Nos. 26, 38 and 84 and the Protocols thereto, as well as the technical recommendations of the WHO Expert Committee on Biological Standardisation and of the Task Force of the International Society for Haemostasis and Thrombosis,

Recommends the governments of member states to:

I. a. establish minimal criteria for the quality, packaging, labelling and control of blood products for the treatment of haemophiliacs;
b. ensure that the available products are put to optimal use from a medical and socioeconomic point of view;
c. inform all concerned in haemophilia therapy of the problems arising from the procurement and rational use of blood components concerned in order to balance the needs and resources;
d. provide, in so far as possible, a national haemophilia register.

II. Pursue the implementation of the recommendations indicated in the appendix hereafter with a view to reaching, as far as possible, self-sufficiency of the member states and their medical professions, both in respect of antihaemophilia products and blood plasma required for their preparation.

Appendix to Recommendation No. R (80) 5

Ethical and economical reasons as well as the medical needs require optimal use of blood and of all its components. This requirement
Resolutions and recommendations

should guide the various responsible organisations of blood collection, fractionation and therapeutic use in the choice of the methods of collection, production and treatment. It also demands a regional, national and international co-ordination policy.

This co-ordination necessitates in particular:

– the combination of whole blood donation and plasmapheresis, so as to achieve an optimal use;
– the increase of whole blood collections and the development of plasmapheresis, according to the needs for plasma derivatives as a source of Factor VIII, albumin and specific immunoglobulins;
– the optimal use of red cell concentrates, albumin and plasma protein solutions, according to the recommendations of previous reports;¹
– a limited use of fresh-frozen and freeze-dried plasma, to take into account the needs of Factor VIII, albumin and plasma protein solutions;
– the use of frozen cryoprecipitates only when other preparations of Factor VIII of controlled potency are not available with satisfactory conditions of efficiency, safety and cost.

The geographical origin and the type of donor population (remunerated or non-remunerated) of the plasma used for coagulation factor concentrates should be indicated on every vial, in view of the fact that the risks of transmission of infectious diseases, in particular viral hepatitis, may vary from one area to another and according to the conditions of recruitment of the donors. From an ethical point of view, with respect to the health of the donor and the recipient, the recommendations of WHO and of the League of Red Cross Societies concerning the promotion of voluntary non-remunerated blood and plasma donations should be followed.

The logistic system of blood collection methods and use of blood and plasma should ensure a maximum availability of Factor VIII. Therefore it is advisable:

1. to separate the plasma from the blood cell components as early and as completely as possible;
2. to rapidly freeze the plasma and to store it at low temperature, if possible below minus 30°C.

The methods of thawing and harvesting cryoprecipitates as final product or as starting material for further purification should yield a product containing an adequate potency of Factor VIII. Rapid thawing appears to be more efficient. The size of the pools should be determined after having considered the necessity of warranting a minimal potency, of avoiding waste by overdose and of ensuring maximal safety. As far as possible, each pool should only contain products from the same centre or area.

Quality control should take into account the recommendations of the Council of Europe, the WHO Expert Committee on Biological Standardisation and the Task Force of the International Society for Haemostasis and Thrombosis. Special efforts should be made to reduce the risk of transmission of hepatitis by controlling each batch and each unit of plasma used for the preparation of coagulation factor concentrates and by using sensitive methods (RIA or equivalent methods for HBsAg, other available methods for other hepatitis viruses).

For individual and small pool (maximum twelve donors) cryoprecipitates (frozen or freeze-dried), controls of potency, solubility and stability should be frequent. It is recommended that the potency of all products in regular use should be confirmed in vivo for several batches in several patients, and for new products a more thorough investigation should be carried out including half-disappearance time.

Factor IX concentrates should moreover be specially controlled for the presence of activated coagulation factors by in vitro or in vivo tests.
Resolutions and recommendations

Information concerning the general method of preparation, added substances, the minimum concentration of the relevant coagulation factors, solubility time of the product and the mean recovery and survival in vivo should be supplied to the user.

Within a rational blood component therapy and a balanced public health policy, the indication for the various types of concentrates might be the following:

a. The less purified Factor VIII concentrates (3-20 I.U/ml reconstituted solution) for usual treatment of haemophilia A and von Willebrand’s disease: these concentrates may be used for home therapy, on demand or in episodic or continuous prophylaxis.

b. The more concentrated preparations of Factor VIII (more than 15 I.U/ml solution) for major surgery and for haemophiliacs with severe inhibitors in case of serious haemorrhage, or risk of serious haemorrhage.

c. The more purified preparations of Factor VIII (more than 0.5 I.U/mg protein) in case of intolerance of less purified preparations.

More purified preparations of Factor VIII should not be used in von Willebrand’s disease, unless it has been ascertained that the product is able to correct the observed abnormalities of the disease.

d. Factor IX concentrates in haemophilia B, severe constitutional deficiencies of Factors II, X (and VII, if sufficient amount of this factor is contained in the preparation).

e. Concentrates containing the four Factors II, VII, IX and X, in acquired deficiencies due to severe lack of vitamin K or overdose of anti-vitamin K, if it is not possible to wait for the effect of vitamin K administration. The risk of transmission of viral hepatitis must be especially emphasised in such patients. Frozen or dried plasma can also be useful in this situation.

In acquired deficiencies due to severe hepatic failure, Factor IX concentrates are not to be advised because of the risk of thrombotic
Blood and blood components

accidents. Platelet-rich plasma, fresh-frozen plasma or freeze-dried plasma are preferable in such cases.

Generally speaking, it seems desirable for each member state:

1. to establish a national inventory of the cases of haemophilia A and B;
2. to attempt to find within its own population the necessary quantities of anti-haemophilic factors, or the required quantities of plasma for their preparation;
3. to establish minimal criteria for presentation and quality;
4. to ensure for users that the available products have a fair price-quality ratio, the most expensive ones being reserved for medically justified situations;
5. to give the necessary information to all concerned in haemophilia therapy regarding the problems arising from the procurement and rational use of products; it must be realised that a balance should be achieved between the available resources and the justified needs of haemophiliacs.
Council of Europe
Committee of Ministers

Recommendation No. R (81) 5 of the Committee of Ministers to member states on antenatal administration of anti-D immunoglobulin

(Adopted by the Committee of Ministers on 17 March 1981 at the 331st 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 public health field;
Recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances, which was adopted with a view to ensuring better protection of donors, prospective donors and recipients of human substances and to enhancing the progress of medical science and therapeutics;
Blood and blood components

Considering that recent findings have shown that the perinatal mortality and morbidity from Rh haemolytic disease of the newborn may be reduced to a low level by postnatal administration of anti-D immunoglobulin;

Taking note of the fact that antenatal administration of anti-D immunoglobulin necessitates obtaining three to four times the quantity of immunoglobulin by plasmapheresis of human volunteer donors with an accompanying increased hazard to such donors as well as an increase in the cost of production of anti-D immunoglobulin,

Recommends to the governments of member states that the attention of the relevant scientific and medical circles be drawn to the advantages which could accrue from the administration of anti-D immunoglobulin under the circumstances mentioned in the appendix to this recommendation.

Appendix to Recommendation No. R (81) 5

1. Except following amniocentesis, version or abdominal trauma, anti-D immunoglobulin should not be given during the antenatal period to Rh-negative expectant mothers.

2. All Rh-negative mothers should be given an adequate dose of anti-D immunoglobulin postnatally following the delivery of a Rh-positive baby or following an abortion.

3. Where possible, each Rh-negative mother’s blood should be examined for transplacental haemorrhage to detect those cases (approximately 1%) in which the amount of anti-D immunoglobulin is insufficient to protect against a transplacental haemorrhage in excess of 10 ml-25 ml; in any such case the dose of anti-D immunoglobulin should be appropriately increased.
Council of Europe
Committee of Ministers

Recommendation No. R (81) 14 of the Committee of Ministers to member states on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives

(Adopted by the Committee of Ministers on 11 September 1981 at the 336th 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 public health field;

Recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to the removal, grafting and transplantation of human substances, which was adopted with a view to ensuring better protection of donors, prospective donors and recipients of
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human substances and enhancing the progress of medical science and therapeutics;

Considering that recent studies carried out in all member states¹ have shown that the transmission of infections through the international transfer of blood, its components and derivatives represents a constant health hazard for recipients and that it is necessary when deciding on transfusion to take account of the epidemiological situation in the country of origin of these substances,

Recommends to the governments of member states that national regulations be established concerning the importation of blood, its components and derivatives with a view to limiting as fully as possible potential health hazards due to the transmission of infectious agents; such regulations should, in particular, provide for the furnishing of data on the donation and the preparation of such substances, that is (in addition to the results of any specific tests which may be considered necessary by the importing state) the name of the country in which the blood was given, the date of the donation or preparation and data concerning the identity of the donor on condition that his anonymity is preserved outside the blood bank at which the donation was made; this information should be available at any time to national health administrations.

¹ See the report of the 1980 Co-ordinated Research Programme on Blood Transfusion on the assessment of the risks of transmitting infectious diseases by the international transfer of blood, its components and derivatives.
Council of Europe
Committee of Ministers

Recommendation No. R (83) 8 of the Committee of Ministers to member states on preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products

(Adopted by the Committee of Ministers on 23 June 1983 at the 361st 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 regulations in the health field;

Considering the growing importance of a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that may be caused by an infectious agent transmissible by blood and blood products;
Recalling the basic principles to minimise the hazard of transmissible infectious diseases by blood or blood products drawn up in the context of the work of the Committee of Experts on Blood Transfusion and Immunohaematology:

1. to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products,

2. to achieve national self-sufficiency in the production of coagulation factor products from voluntary, non-remunerated donors,

3. to avoid the importation of blood plasma and coagulation factor products from countries with risk populations and from paid donors;

Recalling Recommendation No. R (80) 5 concerning blood products for the treatment of haemophiliacs, with special reference to Section II of the operative part, and Recommendation No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives;

Recognising the necessity to provide pertinent information to blood donors, attending physicians and selected recipient groups in order to avoid, as far as possible, donations by persons in risk groups, without inappropriate discrimination and emotive over-reaction amongst recipients,

Recommends the governments of member states:

I. to take all necessary steps and measures with respect to the Acquired Immune Deficiency Syndrome and in particular:

   – to avoid wherever possible the use of coagulation factor products prepared from large plasma pools; this is especially important for those countries where self-sufficiency in the production of such products has not yet been achieved;
Resolutions and recommendations

- to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks;
- to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended);

II. to pursue rapid and full implementation of Recommendations No. R (80) 5 and No. R (81) 14.

Appendix to Recommendation No. R (83) 8

The present information leaflet for donors has been prepared and is used by the American Red Cross; it is given as an example for the convenience of National Blood Transfusion Services wishing to draw up their own information leaflet.

An important message to all blood donors

This information is distributed to all potential blood donors to help prevent the spreading of certain illnesses from donors to patients by blood transfusions.

Please read this statement, and if you think that there is a risk that your blood could cause illness in a patient who might receive it, please refrain from donating blood at this time.

What are these illnesses?

Some persons may feel in excellent health but have viruses or other infectious agents in their blood that could cause illness in persons receiving a transfusion of their blood. If you think any of the following information pertains to you, please do not donate blood today:
Blood and blood components

I. Acquired Immune Deficiency Syndrome (AIDS)
This newly described illness of unknown cause is believed to be spread by intimate personal contact and possibly by blood transfusion. Persons with AIDS have reduced defences against disease and as a result may develop infections such as pneumonia, or other serious illnesses. At this time there is no laboratory test to detect all persons with AIDS. Therefore we must rely on blood donors’ health histories to exclude individuals whose blood might transmit AIDS to patients who will receive that blood.

The Office of Biologics of the Food and Drug Administration has identified groups at an increased risk of developing AIDS. These groups are:

- persons with symptoms and signs suggestive of AIDS. These include severe night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy (swollen glands) or Kaposi’s Sarcoma (a rare cancer);
- sexually active homosexual or bisexual men with multiple partners;
- recent Haitian entrants into the United States;
- present or past abusers of intravenous drugs;
- sexual partners of persons at increased risk of AIDS.

2. Hepatitis
Persons with a past history of viral hepatitis are deferred permanently. Intimate contact with someone suffering from viral hepatitis requires deferral for six months.

3. Syphilis
Potential blood donors with active syphilis are deferred.

4. Malaria
Potential blood donors who have visited countries where malaria exists are deferred for six months after leaving the malarious area or, if anti-
malarial drugs were taken, for three years after cessation of this drug therapy. Natives from countries where malaria exists are deferred for three years; Haiti is one of these countries.

**What should I do?**

If you believe that you may be carrying one of the above-mentioned illnesses, or if you are an individual in a group at increased risk of developing AIDS, we ask that you refrain from donating blood at this time. You may leave now without providing an explanation. Or, if you prefer, you may proceed to be deferred confidentially, without further questioning, by the health history interviewer.

If you would like additional information, Red Cross nurses and physicians will be pleased to answer any questions you may have.
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;

Having regard to the Protocol to the European Agreement on the exchange of therapeutic substances of human origin, Part II, by which "the blood shall not be obtained from a human subject (...) who is not, as far as can be ascertained after medical examination and the study of his antecedents, free from disease transmissible by blood transfusion";
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 and No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives;

Conscious of the fact that an increasing number of people travel to areas where malaria is endemic, with the consequent risk of contracting this disease;

Conscious of the need to ensure the best possible protection of both donors and recipients, and of the necessity to promote a policy of optimal use of blood and blood products;

Considering that appropriate serological techniques are available for the detection of latent malaria,

Recommends to governments of member states that they introduce the following regulations and adopt the following measures for preventing the transmission of malaria by blood transfusion or, if appropriate, invite the relevant blood transfusion centres to do so:

i. Individuals born or brought up in endemic malarious areas can be accepted as blood donors three years after their last visit to an endemic malarious area if the results of an approved immunological test are negative after cessation of the quarantine period; individuals with a history of malaria can be accepted three years after becoming asymptomatic and cessation of antimalarial therapy if the result of an approved immunological test is negative after the quarantine period.

ii. All other persons who have visited an area where malaria is endemic can be accepted as blood donors six months after returning, if they have had no febrile episodes during or after their stay in the malarious area; individuals having had such
Resolutions and recommendations

febrile episodes can be accepted if the result of an approved immunological test is negative six months after becoming asymptomatic and cessation of therapy.

iii. The quarantine periods and immunological tests mentioned above may be omitted for donors whose red cells are discarded and whose plasma is used exclusively for fractionation into blood products, thus rendering it safe from the transmission of malaria; it should be remembered that liquid or frozen untreated plasma and frozen cryoprecipitates cannot be regarded as wholly devoid of the cellular elements of blood and, therefore, of viable malarial parasites.

iv. Since questioning of the donor as to the country (or countries) in which he was born or brought up or has visited is essential for effective detection, every transfusion service should have a map of the endemic zones and an alphabetical list of the countries concerned.
Council of Europe
Committee of Ministers

Recommendation No. R (85) 5 of the Committee of Ministers to member states on a model curriculum for the training of specialists in blood transfusion

(Adopted by the Committee of Ministers on 26 March 1985 at the 382nd meeting of the Ministers' Deputies)

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

Whereas the aim of the Council of Europe is to achieve a greater unity between its members and that this aim can be pursued, among other ways, by the adoption of common action in matters of health;

Calling to mind its Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances;

Further calling to mind its Recommendations Nos. R (80) 5 concerning blood products for the treatment of haemophiliacs, R (81) 5 concerning the antenatal administration of anti-D immunoglobulin, R (81) 14 on preventing the transmission of infectious diseases in the
international transfer of blood, its components and derivatives, and R (83) 8 on the prevention of the possible transmission of acquired immune deficiency syndrome (AIDS) from affected blood donors to patients receiving blood or blood products;

Pointing to the present rapid tendency for the clinical demand for blood products to increase and to the development of biotechnical methods of haemotherapy;

Noting on the basis of a recent study of the situation of health services in all the member states that:

- those services are not always organised so as to be able to meet needs satisfactorily, either because of a lack of co-ordination or of a dissipation of effort, or else because the clinical control of the use of substances of human origin is inadequate or there is a shortage of properly qualified staff;

- these problems, where they exist, may lead either to a shortage of substances or to the improper use or wastage of precious products of human origin, both of which it is imperative to prevent in the interest of donors as well as of recipients;

Observing that the creation of a co-ordinated network of blood transfusion centres at national and/or regional level staffed by qualified specialists and located preferably in general or teaching hospitals can help to resolve the problems described;

Considering too that the recent efforts made by certain member states to train blood transfusion specialists have contributed decisively to the efficient functioning of such a network of blood transfusion centres and hence to the meeting of needs,

Recommends the governments of member states to launch schemes for the training of blood transfusion specialists on the lines of the model appended.
Appendix to Recommendation No. R (85) 5

A. Aim of the training

Blood transfusion specialists should be specifically equipped for the following tasks:

i. Programming and organisation of the collection, preparation, storage, distribution and use of blood and blood products in the light of a periodical evaluation of the needs of the sector in their charge;

ii. Scientific and technical assistance to the transfusion services under them;

iii. Organisation of a quality control system;

iv. Promotion of optimal use of blood and blood products by the organisation, inter alia, of a proper system for the clinical control of their use;

v. Participation in research on blood transfusion, immunohaematology and haemotherapy and circulation of the findings to the subordinate services concerned;

vi. Organisation of courses for future blood transfusion specialists (doctors):
   – basic training,
   – in-service training;

vii. Further training.

B. General remarks

The model training course given below is designed with certain key features in mind, which can be summarised as follows:

1. The model is not intended as a rigid prescription for the training of blood transfusion specialists. It is essential that interpretation should be flexible.
2. This interpretation, however, should not be left to local medical personnel but be the responsibility of a national specialist professional body which would ultimately be responsible for issuing the diploma or specialist accreditation certificate, etc. This body would be advised by a specialist advisory group, the majority of whom would be full-time specialists in blood transfusion.

3. At the heart of the training are specialist qualifying examinations. These would involve written papers on clinical and laboratory aspects of transfusion practice and relevant practical and oral examinations. The trainee specialist would not be permitted to sit the examinations until the national specialist professional body had confirmed that the prescribed period of appropriate training had been completed satisfactorily.

4. Every effort should be made to ensure that no candidate would be permitted to be examined in the institution in which he or she had been trained. Where this is not possible efforts should be made to see that at least one of the examiners is external.

5. The fundamental concept on which the training programme would be based would be in-service training (apprenticeship). The availability of lectures and/or practical courses should be encouraged. However, these may be either obligatory or voluntary.

6. A period of postgraduate (after medical school) general medical training would be obligatory, with particular emphasis on clinical aspects of medical care, prior to the commencement of specialist medical training.

7. All centres in which specialists are trained must be approved, following inspection, by the national specialist professional body. Inspections should be repeated at no more than five-yearly intervals.

8. The national specialist professional body would be responsible for establishing mechanisms whereby trainees can obtain career guidance, if required.

9. Trainees should be encouraged to include a supervised research project, work abroad, etc., as part of their ordinary training.
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However, they should be recommended to seek advice from the national specialist professional body before embarking on such action, as such activities should normally represent a minor fraction of their total training period.

10. A clear distinction should be made between the specialist training programme of haematologists, clinical chemists, etc., and specialists in blood transfusion.

11. A key element in the training programme is the clinical use of the increasingly wide range of blood and blood-related products available and the associated laboratory facilities required to achieve this end. It is recognised that this will include experience in haematology, microbiology and immunology, including transplant immunology.

12. It would be essential that trainees have experience and knowledge in those aspects of blood transfusion concerned with the collection of blood, donation testing and product production.

13. Appointment to a specialist hospital/transfusion centre post would normally require prior acquisition of the specialist diploma/accreditation certificate.

C. Model description

I. Basic medical experience

Most countries require that all doctors, after graduation from university, spend a minimum period in hospital practice (junior hospital practice) prior to full qualification. In some countries this period is extended to twenty-four months and includes a period of general practice (primary care).

It is proposed that a minimum period of twelve months' junior hospital practice should be mandatory. It is recognised that in some countries this basic clinical experience is mandatory prior to graduation from university.
II. Postgraduate medical training of specialists

It is important that trainees in blood transfusion have a period, which would not normally be less than two years, for broadening their general medical training at a postgraduate level. Normally this would be primarily directed towards clinical work, particularly in internal medicine and/or surgery and/or obstetrics and/or paediatrics and/or intensive care. It would, however, be acceptable to spend one of the two years in a pathology laboratory complex to gain experience in basic pathology, clinical chemistry and microbiology. As an alternative to the year in laboratory medicine, it would be acceptable to spend a year in haematology, provided the experience covered both clinical and laboratory aspects.

III. Specialist training

The period of specialist training in blood transfusion would normally last four years. Two years would be obligatory in blood transfusion (see below), one year in haematology (not necessary if included in general postgraduate medical training), and one year in immunology with particular reference to infection, transplantation and immunologically related diseases.

IV. Summary

<table>
<thead>
<tr>
<th>Basic medical experience</th>
<th>1-2 years</th>
<th>&gt; 4 years</th>
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<tr>
<td>Postgraduate medical training</td>
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<td>Specialist training:</td>
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<td>two years' transfusion,</td>
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<td>one year immunology</td>
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<td>(clinical and laboratory)</td>
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Examination I

Examination II

V. Specific aspects of specialist training

It is recognised that at the present time trainees in blood transfusion may have to obtain the required experience (two years in blood
transfusion) outside the transfusion centre because the necessary facilities (services) are not available. It is also recognised that some transfusion centres have the required facilities to provide satisfactory training in those aspects related to the year of immunology. Accordingly, guidance on the required experience is given below:

a. General blood transfusion practice
   - Recruitment and selection of blood donors including psycho-social and ethical aspects;
   - Blood group serology (all aspects of immunohaematology for red cells, platelets, white cells and plasma proteins);
   - Genetics;
   - Blood component production;
   - Blood donation testing;
   - Blood component preservation;
   - Blood transfusion legal aspects;
   - Plasma fractionation (basic principles);
   - Haemotherapy (indications, crossmatching and the use of all cellular and plasma related products);
   - Apheresis (donor and patient applications);
   - Reagent production;
   - Haemostasis;
   - Untoward effects of transfusion;
   - Laboratory management;
   - Computer sciences.

1 Some examples of currently relevant blood components: whole blood, red cell concentrates, white cell concentrates, platelet concentrates, transfer factor, interferon, cryoprecipitate, fresh frozen plasma, albumin, factor VIII concentrates, factor IX concentrates, antithrombin III concentrates, fibrinogen concentrate, normal and specific immunoglobulins. Relevant clinical experience, associated with haemotherapy, would include cardiac surgery, neonatal medicine, transplant surgery, management of congenital and acquired bleeding disorders, traumatology and intensive care, infection and immunologically related diseases.
b. **Haematological aspects of transfusion**

Whilst a background training in general haematology is required, particular emphasis should be placed on the clinical conditions requiring transfusion support. These would include:

i. haemorrhagic disorders,
ii. haemoglobinopathies,
iii. aplastic anaemia,
iv. bone marrow transplantation,
v. haematological malignancies.

c. **Immunological aspects of transfusion**

Those aspects related to transfusion practice would be regarded as particularly relevant. These would include:

i. complement components,
ii. immunoglobulin estimation and sub-typing,
iii. cellular immune response tests,
iv. chemotactic mechanisms,
v. lymphokines,
vi. clinical management of microbial invasion with particular reference to lymphokines and immunoglobulin preparations,
vii. post-transfusion microbial infections,
viii. histocompatibility and transplant immunology,
ix. other laboratory immunology tests,
x. infectious diseases (laboratory, clinical and epidemiological aspects).
VI. Examination

It is assumed that all trainee transfusion specialists will be required to sit an examination to attest their professional competence. It is proposed that specialist examinations should be as follows:

Part 1

This would be a test of the candidate’s knowledge of basic sciences: biochemistry, microbiology, haematology and statistics. It would take the form of a multiple-choice, written examination paper, and would normally be sat at the end of the general postgraduate professional training period. Those medical doctors who had full qualifications (diploma) in internal medicine, obstetrics, paediatrics, clinical chemistry, anaesthetics, would be exempt not only from the examination but from one or two years’ general postgraduate medical experience.

Part 2

This examination could, for example, include the following:

a. Two three-hour papers covering transfusion, haematology and immunology in the proportion of the course content,
b. Two three-hour practical tests,
c. An oral examination (half an hour).
Council of Europe
Committee of Ministers

Recommendation No. R (85) 12 of the Committee of Ministers to member states on the screening of blood donors for the presence of AIDS' markers

(Adopted by the Committee of Ministers on 13 September 1985 at the 388th meeting of the Ministers’ Deputies)

The Committee of Ministers, under the terms of Article 15.6 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 rules in the health field;

Considering the growing importance of a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that is caused by an infectious agent transmissible by blood and blood products;

Recalling Recommendation No. R (80) 5, concerning blood products for the treatment of haemophiliacs, with special reference to Section II

1 Acquired Immune Deficiency Syndrome.
of the operative part, Recommendation No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives, Recommendation No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion, and in particular Recommendation No. R (83) 8 on preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood and blood products;

Having regard to Assembly Recommendation 985 (1984) on the supply and utilisation of human blood and blood products;

Recalling again the basic principles to minimise the hazard of transmissible infectious diseases by blood or blood products drawn up in the context of the work of the Committee of experts on blood transfusion and immunohaematology:

1. to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products,

2. to achieve national self-sufficiency in the production of coagulation factor products from voluntary, non-remunerated donors,

3. to avoid the importation of blood plasma and coagulation factor products from countries where the incidence of AIDS is increasing, unless these products have been tested for AIDS markers or have undergone virus inactivation;

Noting that most member states are taking steps to introduce screening techniques aimed at identifying the presence of serological markers of AIDS in blood donors;

Aware of the important ethical, medical and social implications of such screening,

Recommends the governments of member states:

I. to adapt the various elements of the strategies against AIDS to the national situation;
II. where they are considering, in the light of the national situation, the introduction of screening procedures for the presence of AIDS markers in blood donors, to take all the necessary steps and measures to ensure that:

- donors are made aware that their blood may be tested for the presence of AIDS markers;
- if a reliable method of evaluating the specificity of the screening test is available, this is applied to confirm a positive result;
- competent counselling facilities are available to any donor who is informed of abnormal serological findings;

III. to arrange for alternative sites for such testing to be established in advance of the commencement of testing in blood transfusion services, in order to avoid attracting persons to blood donation sessions whose motive is to be tested for the presence of serological markers;

IV. in co-operation with the appropriate health authorities, ethical committees, medical and donor associations and blood transfusion experts, to confront and, as far as possible, resolve the wider ethical, social and medical issues raised by the screening of donors for the presence of serological markers of AIDS, particularly whether, when and in what way donors are to be informed of abnormal serological findings;

V. to establish a programme for the production of blood products, in particular coagulation factors for the treatment of haemophilia, which includes suitable procedures for the inactivation of the responsible virus;

VI. to pursue rapid and full implementation of Recommendations No. R (80) 5, No. R (81) 14 and No. R (83) 8 and, notwithstanding the increasing use of screening techniques, to continue to provide all blood donors with information about the syndrome such as that appearing in the appendix to Recommendation No. R (83) 8 so that those in risk groups will refrain from donating.
Council of Europe  
Committee of Ministers

Recommendation No. R (86) 6 of  
the Committee of Ministers to  
member states on guidelines for the  
preparation, quality control and use of  
fresh frozen plasma (FFP)

(Adopted by the Committee of Ministers on 13 March 1986 at the  
394th 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 for the purpose of facilitating their  
economic and social progress;

Considering that this aim may be pursued, inter alia, by the adoption  
of common rules in the health field;

Recalling the ethical and clinical principles of blood transfusion  
and immunohaematology, in particular the need to promote the  
optimal use of blood and blood products, and to achieve national
self-sufficiency in the production of coagulation factor products from voluntary, non-remunerated donors;

Recalling, in particular, its Recommendation No. R (80) 5 concerning blood products for the treatment of haemophiliacs and its Recommendations Nos. R (81) 14, R (83) 8 and R (84) 6 on preventing the transmission of infectious diseases by blood transfusion;

Considering that there is a general shortage of Factor VIII, which is needed for the treatment of haemophiliacs;

Considering that the use of FFP as a blood volume expander not only wastes Factor VIIIc, but also carries a risk of transmitting infectious diseases;

Considering that albumin solutions are equally effective in the expansion of blood volume and do not transmit infectious diseases,

Recommends that the governments of member states take all necessary measures and steps to ensure that the preparation, quality control and use of fresh frozen plasma are carried out in accordance with the guidelines set out in the appendix to this recommendation.

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Appendix to Recommendation No. R (86) 6

**Definition of fresh frozen plasma (FFP)**

FFP is a constituent of blood needed to reconstitute the clotting properties of the patient’s blood (by virtue of the properties of the various coagulation proteins) and very occasionally to restore the plasma volume of the patient. There is no particular problem in preserving the intrinsic properties of albumin, but it is more difficult to preserve those of the coagulation proteins, in particular Factor VIII; great care must be taken both during collection (particular attention being paid to the time it takes) and during freezing.
1. Preparation of FFP

1.1. Plasma collection

FFP may be prepared either from units of whole blood or from material collected by (manual or automatic) plasmapheresis. It is important that the volume of solution used to collect and store the blood should be the same as is normally used for collecting blood, so that the ratio of solution to collected blood is always between about 1:6 and 1:9. This constraint has to be complied with, especially in the case of machine collection, in order to prevent the plasma from becoming too dilute. In order to avoid any tendency to clotting, which would use up a greater or lesser proportion of the coagulation factors, attention should be paid to the following:

- Collection must be perfect, so that the blood flows at the maximum rate allowed by the bore of the needle (at least 16/10 mm). The needle should be properly inserted in the vein at the first attempt, and the flow of blood should be rapid from the start and remain constant until the operation is complete. It is recommended that the total time taken to collect the blood be not more than 10 minutes (at an approximate rate of 40-45 ml/minute).

- The blood and the anti-coagulant/preservative solution should be thoroughly mixed, if possible by shaking combining rotary and rocking motion. Shaking is particularly important at the end of the collection process when donor blood comes into contact with an anti-coagulant that has already been highly diluted in the blood previously collected.

- No donor blood (blood not mixed with the preservative anti-coagulant solution) should remain in contact with blood that has already been mixed: the collection tube should be drained and filled with mixed blood, either by expulsion into the bag or by suction into a sterile vacuum tube.

*No blood that has not been collected under these conditions should be used to prepare FFP.*
1.2. Centrifugation and decantation
Centrifugation should be carried out in such a way as to remove as many platelets as possible (so as to prevent these cellular bodies from initiating clotting). Centrifugation at 5-7°C for 20 minutes at 3 000 g or for 15 minutes at 4 000 g is sufficient to obtain high-quality FFP without damaging the erythrocytes. In the case of plasmapheresis, especially manual, but also machine plasmapheresis (non-filtering), a second centrifugation is necessary if not all the platelets have been removed. It is recommended that, in any event, the residual number of platelets be less than 20-25 x 10⁹/l.
Decantation is carried out in the same way as in the preparation of other blood components, in a closed system under pressure, protected from contamination.

1.3. Freezing
This should be done as soon as possible after collection, and at any rate within six hours (with one hour tolerance).
The complete freezing process should be as short as possible. Experience has shown that it sometimes takes several hours in an atmosphere at -30°C. The time must be reduced to less than two hours, and if possible to one hour, by the following means:
- spreading the plasma in a thin layer (bags laid flat and not arranged vertically);
- freezing in a liquid environment (alcohol at -35°C) or at very low temperature (dry ice, liquid nitrogen cryostat).

1.4. Storage
The aim is to preserve the coagulation factors for a reasonable storage time (up to one year): refrigeration units should be fitted with a recording thermometer with an audible alarm and should maintain a uniformly low temperature within.
Experience has shown that the most labile coagulation factors can be preserved. If the FFP is expected to be stored at sub-zero temperatures for a year, it is recommended that it be kept at a temperature of -30°C or below. Given the cost of efficient refrigerated storage units (maintaining temperatures of -30 or -35°C), a storage temperature of only -25°C to -30°C is permissible if the FFP is to be kept at sub-zero temperatures for no more than six months. It has in fact been shown that at this temperature and over this period of time the loss of activity of Factor VIIIc is negligible. The refrigeration units need to be divided into compartments so as to prevent loss of negative kilo-calories when they are opened, which would cause the ambient temperature to fluctuate. If a refrigeration unit fails and the temperature of the stored products rises to -18°C or above, they should no longer be considered as FFP. Throughout storage in the frozen state, each bag should be placed in a protective cardboard or plastic box to prevent the bags from sticking to one another and splitting during handling.

1.5. Thawing

The formation of cryoprecipitates (containing Factor VIIIc, fibrinogen and fibronectin) should be avoided during thawing, for it would reduce the expected clotting properties of the product to a greater or lesser extent when the temperature reaches about zero to 4°C. The way to avoid it is to thaw the product quickly in a thermostatically controlled bath (35°-37°C) with continuous malaxation of the bag throughout the operation.

The FFP should be administered as soon as possible after thawing, and in any event within two hours. During this time it should be preserved at a temperature not exceeding 10°C and should not be refrozen.

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1 At storage temperatures of -18°C to -25°C, FFP may be kept for no more than three months.
2. Quality control of FFP

2.1. Routine tests
These tests should be carried out on all blood collected, according to national regulations.

Routine weighing of the bag containing FFP: the weight must be written on the label or be within 10% of the weight pre-printed on the label.

2.2. Tests on samples of the finished product
These are carried out every two months on a pool of six units that have been kept for less than a month, and a pool of six units nearing the end of their shelf life.

The most important things to check for in each sample are:
- the absence of flocculates after thawing at 37°C;
- the absence of splits or leaks in the plastic bag;
- the Factor VIIIc content which, in a mixture of six sample units, should not be less than 0.7 IU/ml.

It is important that the procedure for measuring Factor VIIIc should be regularly checked by the laboratory in order to remove the hazards of sample control.

3. Use of FFP

3.1. Precautions to be taken before injection
FFP containing anti-A or anti-B haemolysins, or FFP which has not been checked for these should be given only to patients with the same ABO group, or at least to patients having no A or B antigens matching the haemolysins (the rule being that the compatibility is the opposite of that of the red blood cells). In order to avoid any risk of allo-immunisation against antigen D of the Rhesus system, it is
necessary, especially in patients at risk (girls, women of child-bearing age, persons who have undergone several transfusions), to administer infusions in which patient and donor have the same characteristics with regard to this antigen.

3.2. Usual indications for the use of FFP

FFP is indicated for treating:

- complex deficiencies of coagulation factors, such as consumption coagulopathy, coagulopathy due to severe hepatic failure, and massive transfusions;
- rare isolated deficiencies of Factors V, VII, X, XI or XIII or AT III and deficiencies of C1 esterase inhibitor when specific factors are not available;
- all haemorrhages due to clotting disorders, whether as yet unidentified by specific tests or because a specific factor is unavailable; in the latter case, FFP is to be considered as a temporary substitute for the specific factor.

3.3. FFP as a blood volume expander

FFP produces excellent results when used to restore blood volume, but the results would be just as good in the absence of coagulation factors, and it is precisely in order to preserve these that all the above-mentioned expensive precautions are taken.

In view of the general shortage of Factor VIII, which is needed for the treatment of haemophilia, it seems regrettable that the Factor VIII in FFP should be administered to patients who do not need it.

It should also be pointed out that FFP can transmit viral diseases (hepatitis B, other forms of hepatitis and AIDS), whilst albumin solutions, which are just as effective for blood volume expansion, do not.

The use of FFP instead of albumin as a blood volume expander therefore has two major drawbacks: it carries a risk of transmission of infectious diseases and it wastes Factor VIIIc.
Unfortunately, these considerations are all too often overlooked, and FFP is being used increasingly widely for blood volume expansion, when it ought to be saved for the indications listed above. Accordingly, despite the risk of transmission of the same diseases as mentioned in connection with FFP, plasma which does not contain cryoproteins should, whenever possible, be used instead.
Council of Europe
Committee of Ministers

Recommendation No. R (87) 25 of the Committee of Ministers to member states concerning a common European public health policy to fight the acquired immunodeficiency syndrome (AIDS)

(Adopted by the Committee of Ministers on 26 November 1987 at its 81st Session)

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;

Aware of the growing challenge for public health authorities represented by a new and severe health hazard, the Human Immunodeficiency Virus (HIV) infection, transmissible by sexual intercourse, through the blood, during pregnancy and perinatally, and
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which can induce a variety of conditions such as AIDS, Aids Related Complex (ARC), various cancers, neurological and other disorders, as well as some problems with respect to healthy carriers;

Conscious that there is at present neither vaccine nor cure for AIDS;

Considering that, under these circumstances, HIV infection will dangerously increase and spread in the population if no immediate and effective preventive action is taken;

Considering that such an epidemic will represent a very heavy burden for health services and social security systems, and will have serious economic consequences;

Considering that it may also pose ethical, legal and social problems in terms of stigmatisation and discrimination;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms;

Recalling its Recommendations No. R (83) 8 and No. R (85) 12 concerning the screening of blood donors for AIDS markers;

Judging that the implementation of a harmonised comprehensive preventive policy at European level may effectively limit the spread of the disease,

In the light of present knowledge, recommends the governments of member states to:

I. declare the fight against AIDS an urgent national priority;

II. carefully devise, in the light of socio-cultural contexts, the most appropriate public health policy for the prevention of AIDS by drawing up a comprehensive strategy consisting of programmes and measures which:

- are scientifically justified and expedient to impede the spread of the infection with a view to the protection of the health of citizens, and

- do not interfere unnecessarily with their individual rights to objective information, freedom and private life;
III. follow to this end the guidelines set out in the appendix to this recommendation;

IV. intensify co-operation within Europe in pursuing studies on specific aspects of the control of AIDS with a view to:

1. assisting national health administrations in continuously adjusting their public health policy to actual requirements;
2. optimising the effectiveness of such policies by avoiding duplication of efforts through exchange of information, comparison and assessment of strategies;
3. identifying common areas of research in the field of AIDS prevention, diagnosis and treatment, for which specific funds should be allocated;
4. achieving a concerted harmonised European policy in the fight against AIDS.

Appendix to Recommendation No. R (87) 25

Guidelines for the drawing up of a public health policy to fight AIDS

1. Co-ordinating committees

Those governments which have not yet done so, should urgently set up co-ordinating committees at national, regional and local levels in keeping with the size and administrative structure of the country.

1.1. Task of the committees

The task of the national committee should consist in the drawing up of a public health policy for the prevention of AIDS taking into account...
the complex implications at strategical level (for the essential elements of this policy, see Item 2 hereafter).

The appointment of regional and local committees should serve as a means of ensuring a regular flow of information and vertical and horizontal co-operation in the implementation of the policy and co-ordination of actions.

The national committee should monitor the implementation of the policy by instituting an appropriate feedback system for permanent revision and adaptation of the policy.

Resources should be made available, both in terms of finance and personnel, to implement the nationally agreed policy at regional and local levels.

1.2. Membership of the committees

Membership of the national committee should include, for example, representatives of relevant governmental sectors: health, social affairs, social security, education, research, etc.

The national committee should seek the advice of experts in various fields, interested parties, health staff, associations and organisations, whether public or private, whose work is relevant to AIDS prevention.

The membership of regional and local committees should include the same representatives at the corresponding level so as to reflect all concerned interests.

The committees, whether national, regional or local, should be set up in such a way as to:

- ensure a balanced approach integrating the various aspects and issues involved;
- facilitate the drawing up of a consensus policy taking into account the various interests and allowing for an optimal use of scarce resources.
2. Formulation of a public health policy: essentials

The national AIDS committee should draw up a comprehensive policy based on an agreed strategy consisting of a series of co-ordinated and consistent programmes in a variety of complementary fields, combining:

- prevention:
  - health information programmes directed at the general public,
  - health education programmes targeted on groups at particular risk,
  - health promotion programmes;
- public health regulatory measures;
- strengthening of health care services;
- training of staff;
- evaluation and research.

2.1. Prevention: health information, education and promotion

National health administrations should concentrate their efforts on preventive measures aimed at behavioural change to control the epidemic since these are of singular importance as long as a vaccine and cure have not been found.

To this end, a health communication strategy should be devised at the national level taking account of the views of health education, mass communication and social science experts, professional advertisers, etc.; such a strategy should be based on the following programmes which will respectively bear short-, medium- and long-term effects:

- health information programmes directed at the general public with a view to maintaining awareness, avoiding panic reactions and preparing for targeted health educational activities;
- health education programmes directed at groups particularly at risk with a view to achieving behavioural change;
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- health promotion programmes with a view to helping individuals in choosing healthy life-styles.

2.1.1. Health information programmes directed at the general public

The objective should consist in counteracting misinformation, prejudice and fear by raising the level of knowledge about the modes of transmission, the spread of the infection and the risk associated with behavioural patterns. The public should be informed of measures to prevent infection and, in particular, that sexual transmission may be prevented by careful selection of sexual partners, by avoiding casual sexual contact and by the use of condoms.

Special attention should be paid to the media, whose role in shaping public opinion is crucial; a strategy should be adopted to favour responsible reporting on the subject; to this end dossiers should be regularly prepared and made available to the press.

2.1.2. Health education programmes targeted on groups particularly at risk

Such programmes should be planned on a medium-term basis, as their main objective, behavioural change, cannot be reached overnight.

Three overriding principles should permeate health education activities:

- behavioural change depends on the attitude of the individual;
- the individual is responsible for the outcome of his behaviour towards himself, others and society;
- the individual must be treated with dignity and respect.

No health education programme (primary prevention) should be initiated if not backed up by secondary and tertiary prevention facilities (that is, sites for voluntary testing, counselling, treatment and psycho-social support services).
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Target groups to be considered may vary in size from country to country and programmes and activities should reflect this variability; however, in view of the transmission modes, the following should in any case be taken into account:

- intravenous drug users,
- men with homosexual contacts,
- prostitutes,
- customers of prostitutes,
- "sex-tourists", coming from or travelling to areas where AIDS is endemic,
- haemophiliacs,
- people staying in or travelling to areas with a high prevalence of AIDS,
- the prison population,
- adolescents.

2.1.3. Health promotion programmes

Sex education should be integrated in a wider reflection on life-styles and human relationships. Such programmes should encourage individuals to assume responsibility for their health by becoming aware of risks and benefits inherent in various life-styles.

2.2. Public health regulatory measures

In the light of present knowledge, given the absence of curative treatment and in view of the complexity of the epidemic, the implementation of the following public health measures is to be considered essential to limit the spread of HIV infection.

2.2.1. Screening

- systematic screening programmes should be fully implemented in respect of donations of blood, mothers' milk, organs, tissues, cells and, in particular, semen donation in compliance with the
usual strict requirements of informed consent and regulations for confidentiality of data; for greater security, heat-treatment or other inactivation procedures of plasma products should continue to be enforced; self-exclusion from donation should continue to be strongly recommended to individuals with high-risk behaviour;  
- there should be no compulsory screening of the general population nor of particular population groups;  
- health authorities should instead invest resources in the setting up of sites-when these do not already exist-for voluntary testing fully respecting confidentiality regulations, and for arranging under the same conditions contact tracing of partners of seropositives;  
- voluntary testing should be backed up by counselling services which should be readily accessible or even free of charge;  
- the identification, where necessary, of groups to whom to recommend voluntary testing should be decided upon by health authorities in close co-operation with experts in the field; the identification on the basis of risk factors of cases to whom to recommend voluntary testing should be the task of medical staff;  
- quality of testing should be ensured through the appointment of reference centres.

2.2.2. Other measures  
- public health regulatory measures such as health controls, restriction of movement or isolation of carriers, should as a general rule not be introduced on a compulsory basis;  
- in the light of present knowledge, discriminatory measures such as control at borders, exclusion of carriers from school, employment, housing, etc. should not be introduced as they are not justified either scientifically or ethically.

2.2.3. Information relating to seropositivity  
- individuals, whether donors or not, should be informed of a confirmed positive result of a blood test; they should be referred
to competent medical and counselling services to be informed of precautions to be taken to protect their own health and to avoid spreading the infection to other individuals;

- if they take appropriate measures, health staff can usually avoid contamination; patients should, therefore, themselves be left to advise health staff of their seropositivity unless the patient has specifically authorised a doctor to pass on this information.

2.2.4. For the purposes of gaining insight into the epidemiology of HIV infection

- the reporting of AIDS cases in strict compliance with confidentiality regulations is strongly recommended;
- where implemented, the reporting of seropositivity should also be carried out in strict compliance with confidentiality regulations;
- the setting up of epidemiological studies of representative samples or cohorts of the general population and groups with risk behaviour on a voluntary basis and in compliance with regulations of confidentiality and anonymity is to be considered essential in identifying risk factors associated with seropositivity and changing patterns of the disease.

2.3. Strengthening of health care services

Flexible plans consistent with the epidemiological projections and capable of efficiently meeting increasing needs should be drawn up; in this respect the responsible health authorities should:

- ensure adequate in-patient facilities or reinforce existing in-patient units for the treatment of AIDS and related conditions, staffing them with multidisciplinary teams;
- organise out-patient facilities supported by community care services allowing patients to maintain as much as possible a private and a social community-integrated life;
- organise psycho-social support services for in- and out-patients as well as for asymptomatic carriers, their partners and families.
2.4. Training of staff

Appropriate training programmes should be organised for all categories of health staff, especially for those working in the field of diagnosis, treatment, control of transmission of infections, psychological support and terminal care.

Staff in the social services should be trained in the implementation of policies and regulations, as well as in patient and family assistance and psychological support.

Staff who may have occupational exposure to infected fluids and secretions should be kept informed of sensible hygienic precautions to be taken both for themselves and for their clients.

Training for teachers should be organised to allow them to integrate AIDS prevention in health education.

2.5. Evaluation and research

Development of research and co-operation at European level through the designation of reference centres in all AIDS-related fields is an urgent priority to combat AIDS, would be of great benefit both in terms of effectiveness of programmes and costs, and should therefore be strongly supported by national health administrations.
Council of Europe
Committee of Ministers

Recommendation No. R (88) 4 of the Committee of Ministers to member states on the responsibilities of health authorities in the field of blood transfusion

(Adopted by the Committee of Ministers on 7 March 1988 at the 415th 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 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
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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 transfusions and No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion;

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

Considering that these principles are in line with the ideals upheld by the Council of Europe;

Conscious of the fact that availability of blood products for the benefit of all patients depends on the recruitment of donors and the existence of a co-ordinated network of blood transfusion services;

Considering the need to ensure maximum protection of both donors and recipients and that progress made in the protection of recipients has also revealed its value in promoting the health of the population as a whole;

Considering that self-sufficiency with respect to blood products is one of the basic conditions for minimising the hazard of the transmission of infectious diseases by blood transfusion;

Conscious that the increasing use of blood and blood products as therapeutic substances throughout member states calls for a well-defined policy relating to blood transfusion and that increasing exchanges of blood products between member states calls for their harmonisation,

Recommends the governments of member states to bring their policy into conformity with the principles contained in the appendix to this recommendation.
Appendix to Recommendation No. R (88) 4

Definitions

1. The term "transfusion" is meant to cover all activities in connection with promoting the collection of blood, collecting, preparing, conserving, distributing blood, in addition to its administration.

2. The terms "blood" or "blood products" are meant to include all therapeutic substances derived from blood: whole blood, blood components and plasma derivatives.

Article 1

Health authorities (HAs) should have an obligation to promote the adoption of policies in line with the ethical principles of voluntary, non-remunerated blood donation; these principles ensure maximum security for the health of both donors and recipients.

Article 2

The organisation of transfusion at country level should be the responsibility of the HAs; they should in particular assume responsibility, either directly or indirectly, for the establishment of a country-wide collection, preparation and distribution programme so as to cover all the stages of transfusion and to meet the population’s actual needs regarding blood-based therapeutic substances of human origin.

Article 3

HAs may decide to entrust all or part of the transfusion programme to non-governmental bodies and to supervise their activities; activities in connection with the promotion of donation of blood and plasma should be entrusted only to non-profit-making agencies; where this is not already the case, countries should seek to apply the same principle in respect of the collection of blood and plasma.
Blood and blood components

Article 4
To avoid wastage of blood as well as of technical and financial resources in the form of staff and equipment, HAs should ensure co-ordination of all activities of the transfusion programme, whether under their direct or indirect control.

Article 5
HAs should ensure that patients have access to all blood products in the most favourable conditions for applying the most appropriate treatment; this objective can be achieved either by providing blood products free of charge or through a system of social security or any other appropriate system of insurance of the patient; where the product is governed by reimbursement regulations, its price should be adjusted to cover its cost to the transfusion service, including promotion of blood donation, research and development.

Article 6
HAs should be responsible for regularly assessing the need for blood on the basis of scientific, clinical and technical criteria; it should be possible, by means of the assessment, to organise and co-ordinate transfusion activities in such a way that, as a result of adequate blood donor recruitment, blood products are available throughout the country.

Article 7
HAs should make provision for the periodical assessment of the quality and proficiency of transfusion services through suitable arrangements; to ensure the safety of transfusion for both donors and recipients, HAs should make provision for internal and external quality control throughout all the stages of the transfusion programme.
Article 8
HAs should foster close co-operation between the medical staff of transfusion centres and patient care services in order to enable optimal use of blood and thereby avoid wastage.

Article 9
When there is a shortage of blood, the physician in charge of the transfusion centre may have to decide on priorities in consultation with the attending physician(s).

Article 10
HAs should advocate the establishment of a transfusion and post-transfusion monitoring procedure so as to allow for the identification of possible risk factors involved in the preparation of blood products which are only detectable by epidemiological studies.

Article 11
A programme of self-sufficiency should be organised for blood and plasma. Pending the achievement of self-sufficiency, HAs may decide to authorise the importation of blood products. For ethical and security reasons, it is recommended that blood products are imported from countries where the legislation and practice governing the protection of donors and recipients meet the criteria laid down.

Article 12
Concerning the importation of blood and plasma products, the HAs of the importing countries should ask the competent authorities and/or producers in the exporting countries for the necessary guarantees and details of the means used to ensure the security of both donors and recipients; they should, in particular, ascertain the origin of blood and plasma which have been used as a source in the preparation of the exported products.
Blood and blood components

Article 13
If so requested by the importing country, HAs should not allow the exportation from their country of products which do not comply with their national standards or with the World Health Organisation’s certification scheme on the quality of pharmaceutical products moving in international commerce.

Article 14
HAs should ensure that adequate compensation is provided for in the event of complications directly or indirectly related to the taking of blood; to this end, HAs should establish a system of rapid and appropriate compensation regardless of any action for redress between the parties, with regard for the principle of human solidarity which is the basis of blood donation.

Article 15
A donor should not be held liable for an accident occurring to a recipient following the administration of a product derived from the donation of his blood.

Article 16
Transfusion is a medical activity; as such, it should be covered by legislation and regulations covering liability.

Article 17
HAs should make provision, through the network of transfusion centres, for national and international exchanges of blood if the need arises, for updating donor files, including information to meet histocompatibility problems, and for the establishment of at least one reference laboratory.
Article 18

HAs should secure the help of an advisory body for transfusion matters composed from among their own representatives, blood transfusion specialists and directors of blood transfusion centres; its function should be to consider and co-ordinate all questions concerning transfusion and advise on co-ordination issues.
Council of Europe
Committee of Ministers

Recommendation No. R (89) 14 of the Committee of Ministers to member states on the ethical issues of HIV infection in the health care and social settings¹

(Adopted by the Committee of Ministers on 24 October 1989 at the 429th meeting of the Ministers’ Deputies)

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

¹ When this recommendation was adopted:
- the Representative of Sweden, referring to Article 10.2.d of the Rules of Procedure for the meetings of the Ministers’ Deputies, recorded her abstention and, in an explanatory statement, said that her Government will not consider itself bound by the recommendation;
- the Representative of Iceland, in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers’ Deputies, reserved the right of his Government to comply or not with paragraph 41 of the appendix to the recommendation concerning ‘partner notification’.
2. 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;

3. Aware of the magnitude of the challenge HIV infection represents for public health authorities in the absence of vaccine and curative treatment;

4. Conscious in particular of the ethical issues arising in health care and social settings deriving from the need to balance individual and collective rights and duties in the fight against infection;

5. Believing that respect for the human and social rights of HIV-infected individuals and patients with Aids is crucial for the success of a preventive public health policy;


7. Recalling its Recommendation No. R (87) 25 concerning a common European public health policy to fight the acquired immunodeficiency syndrome (Aids), and in particular the recommendations concerning the implementation of a comprehensive information strategy,

8. Recommends that the governments of member states:

9. – ensure that the principles contained in the appendix to the recommendation, drawn up in the light of present knowledge, are reflected in the application of national public health policies to fight HIV infection;

10. – for this purpose, ensure that the recommendation is brought to the attention of all those individuals and bodies responsible for the drawing up and implementation of policies to fight HIV infection.
Appendix to Recommendation No. R (89) 14

I. Public health policy

11. In this connection, the three main ethical and legal issues to be addressed are:

12. whether to introduce voluntary testing, or various forms of screening;

13. whether to offer infected persons the same guarantees of confidentiality as other patients;

14. whether to introduce restrictive measures.

15. In the light of present knowledge, voluntary testing, integrated into the process of counselling, is the approach which is most effective from the public health point of view, and most acceptable ethically and legally, provided that it is supported by vigorous information campaigns, full respect for confidentiality and the implementation of a nondiscriminatory policy.

A. Voluntary testing and screening

16. It follows from the above that public health authorities are recommended to:

a. In relation to counselling and voluntary testing:

17. ensure that voluntary testing is easily accessible at sites such as STD (sexually transmitted diseases) clinics, primary health care services, in particular general practitioners’ practices, as well as drug treatment centres; that such services respect confidentiality, are always accompanied by counselling and are free of charge (or covered by social security through a confidential system);

18. provide training for counselling allowing for the acquisition of the necessary skills by large numbers of health care and social workers, especially at primary health care level, and by health care volunteers;
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19. – ensure that counselling services are consensual and confidential, provide for continuing psychological and practical support, are respectful of the dignity and autonomy of individuals and assist them in understanding their rights and responsibilities in relation to HIV infection;

20. – promote and regularly evaluate information and education strategies for the general public and those likely to engage in risk behaviour, and promote research on behaviour and attitudes associated with HIV transmission, factors favouring behaviour change and its maintenance;

21. – intensify targeted health information and education programmes for those who are potentially exposed, stressing the importance of risk behaviours;

22. – ensure that those population groups most difficult to reach (such as ethnic minority groups, the sensorily deprived, those with learning difficulties) are effectively informed through targeted outreach campaigns;

23. – consider seriously non-coercive pragmatic approaches (for example, the availability of sterile syringes and needles for drug misusers, the provision of instructions on methods of cleaning needles and the availability of condoms in prison), to reduce probabilities of transmission in relation to high-risk situations; such measures should be part of a comprehensive preventive policy including information, counselling and treatment;

24. – promote the adoption of non-discriminatory policies in all settings concerned and ensure their implementation (see below under V);

b. In relation to systematically offered screening:

25. – carefully examine the advisability of introducing systematically offered screening programmes as a preventive measure in the light of various issues, namely:

26. • the rationale of the proposed programme,
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• the population to be screened,
• specific prevalence rates,
• the test method to be used,
• the intended use of data obtained from screening,
• how results are to be communicated to the person tested and how pre- and post-test counselling is to be accomplished,
• the social impact of screening,
• legal and ethical considerations raised by the proposed screening programme;

27. – delegate to health care staff the task of identifying, in the light of specific prevalence rates, groups and individuals to whom targeted testing should be offered, respecting informed consent and confidentiality of data;

28. – ensure that, in order to fulfil the preventive objective of systematically offered screening programmes, counselling services are offered to all individuals to be screened;

\[c.\textit{In relation to systematic screening (routine):}\]

29. – in the light of present knowledge and in the absence of curative treatment, consider systematic screening unethical and contrary to the rights of individuals, if carried out automatically on population groups without informed consent and without counselling, because it overrides the principles of autonomy and physical integrity, affects the privacy of the individual, and is likely to have serious psychological, social and financial consequences for the individual;

30. – ensure that such procedures are not carried out by drawing the attention of health care staff and services to the ethical unacceptability of these measures;

\[d.\textit{In relation to mandatory screening:}\]

31. – fully implement mandatory screening in respect of donations of blood, and those donating mother’s milk, organs, tissues, cells
and semen, in compliance with the usual strict requirements of informed consent and regulations for confidentiality of data;
32. carefully examine how results are to be communicated to the person tested and how pre- and post-test counselling is to be accomplished;

e. In relation to compulsory screening:
33. consider, in the absence of curative treatment, and in view of the impossibility of imposing behaviour modification and the impracticability of restrictive measures, compulsory screening as being unethical, ineffective, unnecessarily intrusive, discriminatory and counterproductive;
34. ensure that compulsory screening is not introduced for any population group and especially for any given population group such as “captive” populations, for example prisoners, immigrants and military recruits;
35. make available information and counselling to such groups.

B. Confidentiality
36. Public health authorities are recommended to:

In relation to the reporting of cases:
37. ensure that the reporting of Aids cases and, where required by health authorities, of seropositivity is used for epidemiological purposes only and therefore carried out in strict compliance with appropriate confidentiality regulations, and in particular that data are transmitted on a non-identifiable basis:
38. to avoid any possible discriminatory use of sensitive health-related data,
39. to avoid discouraging individuals from seeking voluntary testing;
In relation to the patient-health care worker relationship:

40. – strongly support respect for confidentiality, if necessary by introducing specific policies and by promoting educational programmes for health care workers to clarify confidentiality issues in relation to HIV infection;

In relation to partner notification:

41. – ensure that as a general rule there is no partner notification without the consent of the patient, and consider procedures of consultation in accordance with national codes of medical ethics and regulations for the extreme case where a patient refuses to co-operate in the notification of an unsuspecting third party known to the health care worker;

42. – ensure that the autonomy and the dignity of the patient are fully respected in this context as well as confidentiality;

43. – draw the attention of health care staff to the crucial role extensive counselling plays for successful partner notification;

44. – draw the attention of health care staff to the importance of assisting patients in understanding their responsibility towards partners;

45. – support partner notification within a comprehensive preventive strategy providing accessible services including confidential provider referral where necessary without patient identification.

C. Health controls

46. Public health authorities are recommended to:

47. – refrain from introducing restrictions on freedom of movement through ineffective and costly border procedures, for travellers of all kinds, including migrant workers;

48. – not resort to coercive measures such as quarantine and isolation for people infected with HIV or those who have developed Aids.
II. Health care workers

49. The general rules applying to the workplace (see section V.A) also apply to health care settings; additional recommendations are however needed in view of the specific caring duties of health staff and the ethical and legal consequences involved.

A. Prevention

a. Education and training:

50. – health care workers should receive appropriate education about the human immunodeficiency virus, about infection by the virus, about its psychological and social implications, and about the prevention of infection; such education should also explain the general ethical and legal issues in relation to HIV infection including its possible recognition as an occupational disease; this education should be integrated into basic, in-service and further education;

51. – health care workers directly in contact with patients should in particular be educated in:

52. • routine use for all patients of safe-handling techniques and procedures for the control of infection by blood and such body substances that might transmit infectious diseases and HIV in particular,

53. • epidemiological trends of HIV infection to help them identify those persons to whom voluntary testing should be proposed,

54. • counselling techniques and methods helping to give the necessary psychological support to the patient,

55. • ethical and legal issues in relation to HIV infection;

56. – pre-hospital emergency care providers should also receive basic as well as continuing education on methods to prevent transmission of infectious diseases.
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b. Methods and procedures for the prevention of infection in health care settings:

57. in order to protect health care workers whose job involves exposure to blood, body fluids, or tissues suspected of being infected, permanent and enforceable standards should be adopted as regards standard operating procedures related to the treatment of blood-borne diseases; emphasis should be laid upon precautions designed to prevent needle-stick injuries, and these should be used routinely for all patients;

58. these standards should be elaborated on the basis of an evaluation of the potential exposure of health care professionals to infection, through an examination of their working conditions and the specific tasks which they might encounter;

59. health care workers should consider all patients as potentially infectious and should adhere rigorously to precautions concerning blood, body fluids and tissues or other control of infection procedures;

60. hospitals and other medical facilities should, under the supervision of health authorities, implement a system of control and protective measures (including standard operating procedures); in parallel, health care staff should receive appropriate training, adequate protective equipment should be made available and adherence to recommended control procedures should be monitored; in case of failure, counselling, education and retraining should be made available.

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1 The following classification of risk-related tasks should be recommended:

- Category I: requires protective equipment to be worn during the task;
- Category II: the task belonging to Category I might occur unexpectedly, therefore protective equipment should be easily and immediately accessible;
- Category III: does not require any protective equipment.
c. Medical and psychological support for health care staff:

61. health authorities or other employers concerned should make available (free of charge) to any health care professional who cares for HIV patients and who may be at risk of infection:

62. • medical counselling as a result of the above-mentioned monitoring,

63. • psycho-social counselling to cope with the strain which health care professionals caring for HIV-infected or Aids patients may undergo;

64. following a known or suspected parenteral accidental exposure to blood, body fluids or tissues, serological testing and counselling should be made available; such a monitoring programme should include strict provisions for the protection of the confidentiality of test results.

B. Health care staff infected with HIV

65. should be informed and counselled about potential risks associated with taking care of patients with transmissible infections and about measures to minimise the risk of exposure both for themselves and for their patients;

66. should refrain from undertaking any "medical activities" that might create even a minimal risk of transmission to patients (this approach also applies to seropositive health care professionals working independently);

67. should be counselled, when appropriate, to seek either job restructuring or reallocation of work (if such possibilities exist) or flexible scheduling;

68. should be informed of provisions and procedures allowing for the possible recognition of HIV infection as an occupational disease or accident at work.
C. Duty of health care professionals

69. all health care workers have an obligation to care for people infected with HIV and Aids patients; only when employee protection is clearly insufficient (lack of protective equipment, training, etc.) may the health care professional decline to perform tasks involving risk. Therefore:

70. a health care worker may not ethically and/or contractually refuse to treat a patient whose condition is within his current realm of competence solely because the patient is seropositive;

71. any health care worker who is not able to provide the care and services required by a person with Aids should refer the patient to those doctors or facilities which are equipped to provide such services; until the referral can be accomplished, the doctor must care for the patient to the best of his/her ability;

72. the principle of freedom among doctors to choose whether or not to treat patients has to be implemented in such a way that it does not support discrimination against individuals or groups of patients; it should be consistent with rules governing the doctor-patient relationship;

73. any violation of these principles should be reported to the competent authority which will act according to legislation.

III. Health care and social assistance

74. Discrimination by health care and social services, public or private, should be considered unethical and the interests of social solidarity, where those of the individual and society converge, should be given priority.

75. Public health authorities are therefore recommended to:

In relation to social security:

76. ensure that health care both in- and out-patient, preventive and therapeutic, is either free of charge or that costs are reimbursed in accordance with existing social security systems;
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In relation to health care services:
77. – ensure full provision without discrimination of a comprehensive range of preventive activities and services such as information, counselling, testing, psychological support;
78. – offer a full range of health care services, both in- and outpatient, including terminal care, staffed by multidisciplinary teams, so that preference can be given to those services which are considered to correspond best to the psychological and social requirements of individuals;

In relation to social assistance:
79. – ensure co-operation between social workers and health care workers to help those infected in maintaining an integrated and productive life within the community, and to assist them with psychological, family, social, employment, financial and legal questions;
80. – promote domiciliary health care and home-help services and the setting up of self-help groups by supporting voluntary associations.

IV. Epidemiological research
81. With a view to their possible contribution to the planning of information and education campaigns as well as health care services, the introduction of epidemiological surveys should be considered as a means of assessing the incidence and prevalence of the infection. To balance the ethical and legal issues they raise and to meet scientific requirements, it is recommended that:
82. – before authorising epidemiological studies of seroprevalence on representative samples of the population, authorities should:
   • ensure that such studies are carried out in compliance with ethical and legal requirements,
   • assess carefully the scientific value of the prospective results in terms of public health strategies;
83. – if such studies are authorised, the public should be adequately informed;
84. if national legislation or regulations allow for testing to be carried out without consent, results should be unlinked and consequently anonymous;

85. if testing is to be carried out with consent, linked testing should be done on those who accept and an unlinked test should be offered to those refusing a named testing;

86. counselling and voluntary testing should as much as possible be made easily available in settings where unlinked testing is carried out.

V. Social settings

87. As HIV is not transmitted through normal social contact, because of its long latency period and because there is no evidence that HIV infection implies by itself impaired occupational performance, there is no justification for screening for evidence of HIV infection in the workplace or in educational settings. Similarly, discrimination in relation to accommodation cannot be justified.

A. Employment

88. It is recommended that the competent authorities ensure that:

Before employment:

89. any practice by public or private employers to compel a prospective employee to submit to a test for evidence of HIV infection is vigorously opposed; the prospective employee should not be subjected to pressure to disclose whether he/she is infected with HIV;

90. no sanction is imposed subsequently if evidence later emerges of an HIV-positive test prior to recruitment;

During employment:

91. employees are not compelled to undergo screening for evidence of HIV infection or to reveal detailed information about personal behaviour;
92. – employers see to it that their staff management policies provide HIV-infected employees with the same rights and benefits offered to employees with other predispositions, illnesses and disabilities;

93. – employees with any disease or disability, including HIV infection, are treated fairly and with understanding and are allowed to continue working as long as they are able to do so;

In relation to occupational health services:

94. – occupational health care staff are on no account compelled by an employer to carry out HIV screening on applicants or employees;

95. – occupational health care staff, if informed by an employee of a possible HIV infection, treat the employee’s case with the usual rules of confidentiality and use such information only in the interest of the patient’s health;

96. – on no account the occupational health care staff reassess his aptitude in the light of such information (unless the employee might risk exposure to factors in the workplace potentially detrimental to his health); and on no account should they be required to inform the employer of the condition of any worker who is HIV infected;

97. – employers have a duty to protect the confidentiality of medical information relating to their employees, particularly as concerns HIV infection; therefore, health data should only be handled and stored by authorised personnel who are bound by rules on medical confidentiality;

In relation to staff management policies and information programmes:

98. – employers, top-level management and trade union leadership openly and unequivocally adopt nondiscriminatory employment policies and initiate, support and finance educational programmes about HIV infection, its transmission and preventive measures;
99. – the occupational health doctors co-operate closely in the development of such programmes.

B. Education

100. It is recommended that the competent authorities ensure that:

In relation to screening:

101. – compulsory screening programmes are not introduced for pupils, students and teachers as a selection procedure;

In relation to staff management policies:

102. – all recommendations listed under “employment” are followed with respect to teachers;

In relation to information programmes:

103. – school health education programmes about HIV infection and Aids are an integral part of a more planned and sequential programme of comprehensive school health education which includes education for family life and sex education; they should start before pupils reach the age of puberty;

104. – a vigorous training programme is initiated for the teachers and health educators involved;

105. – such programmes are developed in close co-operation with school health services and health care staff in the community to ensure consistency of information and appropriate follow-up by health care staff (such as counselling, testing);

In relation to confidentiality:

106. – school health staff, teachers and other educational staff all strictly respect the principles of confidentiality;

107. – decisions on whether to inform the school of the presence of an HIV-infected child or adolescent are taken only when in the interest of the person in question on a case-by-case basis and
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after a consultation among, if possible, the infected person, the parents, the teachers and the health care staff.

C. Housing

108. It is recommended that the competent authorities:
109. – contact housing agencies to provide them with information on HIV infection, on the social rights of individuals, on sanctions in case of discriminatory policies;
110. – promote the organisation of suitable housing arrangements integrated within the community for people infected with HIV in need of accommodation.

VI. Insurance

111. National authorities should co-operate with private insurance companies to elaborate a code of practice with a view to ensuring:

• respect for the dignity and private life of the individual;
• the seeking of informed consent with counselling for any form of testing;
• no introduction of screening for group insurance policies;
• protection of health-related data and any other confidential information affecting the privacy of the individual;
• the adoption of unequivocal policies concerning HIV infection.

112. National authorities should consider studying insurance possibilities for HIV-infected individuals.

113. In all the settings and situations where discrimination and violation of civil and social rights of an individual may arise, there should be an appropriate and confidential system providing speedy redress of such discrimination or violation.
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 regulations in the health field;

Recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to 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 (85) 12 on
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the screening of blood donors for the presence of Aids markers, No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion and No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion;

Recalling the principles underlying the above recommendations, namely that, for both ethical and clinical reasons, blood donations should be voluntary and non-remunerated, that optimal use should be made of blood, and that member states should be self-sufficient for blood components and plasma derivatives;

Considering that these principles are in line with the ideals upheld by the Council of Europe;

Considering the particular importance of plasma derivatives in modern haemotherapy and that the need for source plasma for the preparation of coagulation factors is increasing in view of new methods of viral inactivation and higher use of concentrates in modern haemophilia therapy;

Considering that in many member states this need of source plasma is covered through importation from countries not following the principles established by the Council of Europe;

Considering that progress in gene engineering technology does not yet provide a solution for the production of plasma products;

Considering that respect of this principle is also important from a clinical and strategic point of view for the safety of products and especially the prevention of the transmission of infectious agents;

Considering the positive experience of some European countries in attaining self-sufficiency for plasma products through voluntary, non-remunerated donation and the need to harmonise policies in a European context, especially as concerns collection and use of human substances,

Recommends the governments of member states to:

i. promote self-sufficiency for plasma products on the basis of voluntary non-remunerated donation;
ii. improve co-ordination of the collection and production of plasma products, where appropriate in co-operation with other member states, by mobilising the necessary means in terms of finances, equipment and staff;

iii. draw up, in co-operation with other member states, European guidelines for the rational use of products;

iv. follow to this end the principles contained in the appendix to this recommendation.

Appendix to Recommendation No. R (90) 9

Objective: Achieving self-sufficiency for plasma products on the basis of voluntary non-remunerated donation

Health authorities of countries not having achieved self-sufficiency of source plasma should take the necessary measures to reach this goal as soon as possible.

For the collection of source plasma a country should rely exclusively on voluntary, non-remunerated donation for:

- ethical reasons, in order to guarantee full respect of the health of the donor;
- clinical reasons, in order to avoid as much as possible the risk of transmission of infection;
- social justice reasons, in order to ensure participation in donation by all social strata of the population, irrespective of economic status;
- reasons of independence from importation and hence stability in the supply of products and their pricing.
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Methods: Establishing a co-ordinated plasma programme

In connection with promotion of donation, health authorities (HAs) should have an ongoing policy of informing donors that, although some products such as Factor VIII may be manufactured by gene technology, other essential products will continue to be derived from fractionation of human plasma.

In connection with collection HAs should:

- evaluate the needs for plasma products on the basis of scientific, clinical and technical criteria, and for this purpose:
  - promote the collection of relevant statistics to assist them;
  - institute a co-ordinated monitoring system allowing for constant assessment of the balance between needs and resources;

- improve the co-ordination of the collection of source plasma through voluntary, non-remunerated donation setting time limits for specific objectives, and bearing in mind the following factors of singular importance for increasing plasma procurement:
  - whole blood and plasma should not be used when cellular components and plasma volume expanding solutions are equally or more clinically effective and safe;
  - the use of optimal additive solutions should be promoted for suspension and storage of red cells in order to improve the yield of plasma;
  - where sufficient plasma to meet fractionation needs cannot be recovered from whole blood donation, plasmapheresis should be promoted within the framework of blood transfusion services;
  - research to increase Factor VIII yields should be promoted, with investment where appropriate, since essential steps to ensure safety of products have significantly reduced such yields.

In connection with production, HAs should:

- evaluate public and private fractionation capacities;
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– establish co-ordination of fractionation activities at national and/or European level to better use existing facilities.

In connection with use of products HAs should:

– promote the adoption of modern principles of haemotherapy based on scientific and clinical criteria avoiding waste of precious human source material.

In connection with research and development HAs should:

– encourage ongoing programmes for product research and development aiming at the adoption of strict clinical indications;
– due to the very rapid developments in the use of biotechnology for haemotherapy products, blood transfusion services should increase their involvement in this field to ensure a smooth transition from old to new technology;
– consider, in consultation with blood transfusion services, the benefits of distributing biologically engineered haemotherapy products through blood transfusion services.

In connection with finances, HAs should:

– endeavour to identify the costs of cellular components and fractionated products so that pricing imbalances will not adversely affect self-sufficiency.

In connection with European co-operation, HAs should:

– co-operate closely to achieve European self-sufficiency in the framework of the European Community and the Council of Europe and to determine complementary strategies for the collection of source plasma, fractionation and provision of products;
– introduce legislation to require that when products are traded from one member state to another or imported into Europe, these should carry information about the origin of source plasma.
Means: Mobilising the necessary resources

HAs should materialise their commitment to non-commercialisation of human substances by mobilising the necessary means in terms of:

- expertise to formulate a co-ordinated strategy and draft the necessary guidelines;
- financial support for the promotion of donation campaigns and where necessary for plasmapheresis programmes;
- issuing of regulations to implement measures allowing for optimal recuperation of plasma;
- investment, if appropriate, in activities related to production, research and development;
- promoting the setting up of criteria for rational use of products and monitoring of blood use;
- initiating consultation with other member states to set up a calendar of action in order to reach self-sufficiency at European level.
Council of Europe
Committee of Ministers

Recommendation No. R (93) 4 of the Committee of Ministers to member states concerning clinical trials involving the use of components and fractionated products derived from human blood or plasma

(Adopted by the Committee of Ministers on 22 March 1993 at the 490th 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, in particular by the adoption of minimum common rules on matters of common interest;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular its Articles 2.1, 3 and 8; to Article 7 of the United Nations International Covenant on Civil and Political Rights; to the European Convention for the Prevention of
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Torture and Inhuman or Degrading Treatment or Punishment; and to the Declaration of Helsinki, adopted at the 18th World Medical Assembly (1964) and amended by the 29th Assembly in Tokyo (1975), the 35th Assembly in Venice (1983) and the 41st Assembly in Hong Kong (1989), concerning recommendations guiding physicians in biomedical research involving human subjects;

Recalling Recommendation No. R (90) 3 of the Committee of Ministers concerning medical research on human beings as well as Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances, and Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion;

Considering the growing importance of blood products in supportive haemotherapy and the need to subject such products to clinical testing and trials to ensure their safety, efficacy and quality as is the case for medicinal products;

Considering that such products are of human origin and that hence specific ethical and technical principles have to be taken into account in addition to those, national and international, applying to medical research and clinical trials on human beings;

Considering the need for harmonisation of such principles in member states,

Recommends the governments of member states to adopt legislation in conformity with the principles appended to this recommendation and to take any other measures in order to ensure their implementation.
Appendix to Recommendation No. R (93)4

A. Field of application
1. The following articles apply to:
   1.1. the conducting of clinical trials for the purpose of ensuring the safety, efficacy and quality of blood components before their routine clinical use;
   1.2. the conducting of clinical trials for fractionated products before obtaining market authorisation;
   1.3. the testing of collecting systems involved in the donation of whole blood or apheresis for the purpose of ensuring that these are safe for the donor and that the products are of acceptable safety, efficacy and quality before the marketing of such systems.
2. The recommendations do not apply to the practice of therapeutic apheresis.

B. Ethical principles concerning blood donors and recipients taking part in clinical trials

Article 1
All those responsible for clinical trials of blood components and fractionated products, whether they are the investigators in charge of carrying out the trials, or directing the experiment, should take into account the following ethical principles concerning blood donors and recipients as prerequisites to their research activity, as blood components and fractionated products differ from other medicinal products in that their source is a human blood donor.
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Article 2
Blood donors should be voluntary and non-remunerated. Benefits in cash or kind should not be offered to donors of blood or plasma, although direct expenses incurred by the donor may be reimbursed.

Article 3
Selection of donors should be in conformity with the recommendations of the Council of Europe to ensure that the person is in good health, in order to protect the donor against damage to his/her own health, and to protect the recipient against transmission of diseases or against medicinal products and drugs which could be detrimental to him/her.

Article 4
No clinical trial may be carried out without the informed, free, express and specific consent of the person undergoing it. In this context, the relevant principles set out in Recommendation No. R (90) 3 should be observed.

The said principles apply also to the donor:
- when procedures are to be performed which may have relevance to his/her health and well-being;
- when a new procedure is being used to collect his/her blood.

The donor need not be informed when blood or plasma is collected using established procedures and the blood components or fractionated products derived from the donation are being treated in a novel or modified manner to prepare components or products for the purpose of clinical testing or trial respectively.

Article 5
Principle No. 9 (respect of confidentiality) and Principle No. 14 (compensation in case of accident) as set out in Recommendation...

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No. R (90) 3 should be applied to recipients, and to donors, under the conditions defined under Article 4 above.

C. Technical principles

1. Principles common to clinical trials of blood components and of fractionated products

Article 6
Legislation, regulations and both national and international guidelines directed primarily to those who are involved in the generation of clinical data for the purpose of obtaining market authorisation for medicinal products should be applied in clinical trials of blood components and of fractionated products.

Article 7
The preparation of the blood components and fractionated products for the clinical trials should comply with principles of good manufacturing practice and the safety of the components or fractionated products particularly with regard to virology and vis-à-vis transmissible agents, and should be ensured prior to clinical trials; similarly, quality of the product must be ensured prior to the commencement of the trial and throughout the trial.

Article 8
In many instances placebo-controlled clinical trials of blood components; and fractionated products cannot be undertaken since it is unethical to withhold treatment. In such circumstances the new or modified blood component or fractionated product has to be compared with an existing blood component or fractionated product. However, with this limitation, clinical trials can be randomised and carried out double-blind. An alternative may be the comparison of
a new or modified component or fractionated product with well documented retrospective data obtained using an existing blood component or fractionated product.

Article 9

When a new clinical indication for an existing blood component or fractionated product is proposed, the blood component or fractionated product should be subjected to a clinical trial in the same manner as that for a new or modified medicinal product, keeping in mind the specific characteristics of labile products.

2. Principles applying to clinical trials of blood components

Article 10

When a blood component has been subjected to physical or chemical modification which may alter its characteristics it should be subjected to a clinical trial (including autologous survival studies where applicable) following approval by an ethical committee, unless the changes are such that secure in vitro tests demonstrate that there has been no biological change; in such a case the person in charge of preparing such a product assumes responsibility for its safety, efficacy and quality, and the blood component may be administered to patients only with the authorisation of the physician(s) in charge.

Article 11

Whenever feasible, clinical trials should be performed initially by autologous studies to determine adverse reactions and the half-life of the component(s) under test. Group controls should be used.
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Article 12
Since each blood component will constitute a batch, a sufficient number of patients must be included in Phase III trials to ensure that batch to batch variation can be excluded.

3. Principles applying to clinical trials of fractionated products

Article 13
The presence of contaminants, particularly neo-antigens, which may be relevant to the health of the trial subjects, must be assessed prior to the commencement of the clinical trial.

Article 14
In Phase III trials, there may be relatively few patients available in a given centre. In these circumstances, multicentre trials need to be organised and such trials must be continued for a sufficient period to ensure that all possible factors affecting safety and efficacy of the product have been studied.

Glossary
Blood products: products derived from whole blood or plasma; these include both cellular blood components and fractionated products.

Blood component: a labile therapeutic constituent derived by separation from a single donation, an apheresis procedure or a small pool of human blood or plasma (that is, twelve or less donations). This will include the cellular components, plasma or simple derivatives derived from plasma, for example, cryoprecipitate.

Fractioned products: a medicinal product derived by fractionation from human plasma. This will include in particular albumin, coagulation factors and immunoglobulins of human origin.
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Medicinal product: any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

Clinical trial: a clinical trial is any systematic study of medicinal products in human subjects whether in patients or non-patient volunteers in order to discover or verify the effects and/or any adverse reaction to identify investigational products, and/or study their absorption, distribution, metabolism and excretion in order to ascertain the efficacy and safety of the product.

For the purpose of this recommendation, the term "clinical trial" includes studies carried out on human blood components, keeping in mind the specific characteristics of labile products.

Clinical trials are generally classified into Phases 1 to IV. It is not possible to draw distinct lines between the phases, and diverging opinions about details and methodology do exist. Definitions (in brief) of the individual phases, based on their purposes related to clinical development of medicinal products, are given below:

Phase I
First trials of a new active ingredient in man, often healthy volunteers. The purpose is to establish a preliminary evaluation of safety and of the tolerance in respect of the dose and a first outline of the pharmacokinetic/pharmadynamic profile of the active ingredient in humans.
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Phase II
Therapeutic pilot studies. The purpose is to demonstrate activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. The trials are performed in a limited number of subjects and often, at a later stage, in a comparative (for example, placebo-controlled) design. This phase also aims at the determination of appropriate dose ranges/regimens and (if possible) clarification of dose/response relationships, in order to provide an optimal background for the design of wider therapeutic trials.

Phase III
Trials in larger (and if possible varied) patient groups with the purpose of determining the short and long-term safety/efficacy balance of formulations of the active ingredient, as well as to assess its overall and relative therapeutic value. The pattern and profile of more frequent adverse reactions must be investigated and special features of the product must be explored (for example, clinically relevant drug interactions, factors leading to differences such as age, etc.). The design of trials should preferably be randomised double-blind, but other designs may be acceptable, for example long-term safety studies. Generally the circumstances of the trials should be as close as possible to normal conditions of use.

Phase IV
Studies performed after marketing of the final medicinal product(s) containing the active ingredient, although definition of this phase is not completely agreed upon.

Trials in Phase IV are carried out on the basis of instructions given in the marketing authorisation, including post-marketing surveillance, as well as the assessment of therapeutic value or strategies. However, clinical trials (after a product has been placed on the market) exploring for example, new indications, new methods of administration or
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new combinations, should in practice be considered as trials for new medicinal products having similar objectives as pre-marketing trials. Such studies may consequently - according to the circumstances - require trial conditions as described above for Phases I to III.
Council of Europe
Committee of Ministers

Recommendation No. R (94) 10 of the Committee of Ministers to member states on early pharmacological intervention against HIV infection

(Adopted by the Committee of Ministers on 10 October 1994 at the 518th 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 health field;

Aware that early pharmacological intervention programmes for people infected with the human immunodeficiency virus (HIV) are being developed in order to prevent or delay symptoms of the disease as much as possible;

Aware that HIV infection represents a major challenge to public health authorities in the absence of vaccine and curative treatment;
Conscious in particular of the ethical issues in health care and social settings arising from the need to balance individual and collective rights in the fight against infection;

Believing that respect for the human and social rights of individuals living with HIV and patients suffering from an acquired immunodeficiency syndrome (Aids) is crucial for the success of a preventive public health policy;

Bearing in mind the provisions of the Convention for the Protection of Human Rights and Fundamental Freedoms and of the European Social Charter;

Having regard to Recommendation No. R (87) 25 concerning a common European public health policy to fight Aids, and in particular the recommendations concerning the implementation of a comprehensive information strategy, and to Recommendation No. R (89) 14 concerning the ethical issues of HIV infection in the health care and social settings, and in particular the issues on voluntary testing and screening;

Taking account of the fact that drugs which slow down the progression of the infection are already available or will become available in the future;

Considering that such drugs have been of benefit to some patients;

Considering that the risks and benefits of early pharmacological intervention should be carefully assessed for both the individual and society,

Recommends that governments of member states:

i. develop early pharmacological intervention programmes only in addition to primary prevention, which should remain a top priority against the spread of HIV infection;

ii. introduce early pharmacological intervention programmes in the light of the possibilities and benefits of treatment If the benefit is clear, those programmes should be further promoted;
iii. make information accessible to the population at risk, and include in this information possible benefits as well as disadvantages of early pharmacological intervention;

iv. reconfirm their policy against discrimination and social exclusion of people with HIV, in respect of the new possibilities of early pharmacological intervention;

v. support self-help groups at local, regional and national level;

vi. create optimal conditions for early pharmacological intervention, in particular:

a. the provision of general information on the possibilities of early pharmacological intervention, availability of sufficient facilities for pre-test and post-test counselling, anonymous and voluntary testing, and social and psychological support;

b. the availability of professional care-givers who should ensure that before entering an early pharmacological intervention programme individuals are fully informed of all implications of pharmacological intervention including risks and benefits;

c. full guarantees that an individual’s choice not to start an early pharmacological intervention programme should not influence access to other appropriate care and treatment;

d. the full protection of a person’s privacy, as well as full respect for a person’s free choice.
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...
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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.
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.
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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
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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.
Council of Europe
Committee of Ministers

Recommendation No. R (95) 15
of the Committee of Ministers to
member states on the preparation,
use and quality assurance of blood
components

(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 greater
unity between its members and that this aim may be pursued, inter
alia, by the adoption of common action in the health field;

Recalling its Resolution (78) 29 on harmonisation of legislations of
member states relating to 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
Blood and blood components

preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives, No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion, No. R (85) 12 on the screening of blood donors for the presence of Aids markers, No. R (86) 6 on guidelines for the preparation, quality control and use of fresh frozen plasma, No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion and No. R (93) 4 concerning clinical trials involving the use of components and fractionated products derived from human blood or plasma;

Taking into account the Council Directive 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma;

Taking into account Agreement No. 26 on the exchange of therapeutic substances of human origin;

Considering the importance of blood components in modern haemotherapy and the necessity to ensure their safety, efficacy and quality;

Considering that such components are of human origin and that hence specific ethical and technical principles have to be taken into account;

Considering the need for harmonisation of such principles in member states;

Considering that biotechnology does not provide substitutes for most blood products;

Convinced, therefore, of the need to provide health authorities, transfusion services as well as hospital blood banks and clinical users with a set of guidelines for the preparation, use and quality assurance of blood components;

Aware that the Guide to the preparation, use and quality assurance of blood components published by the Council of Europe has already
become the generally-accepted European standard and that it is therefore appropriate to give a legal basis to this guide;

Considering that this guide will be regularly updated by the committee of experts of the Council of Europe,

Recommends that the governments of member states take all necessary measures and steps to ensure that the preparation, use and quality control of blood components are carried out in accordance with the guidelines set out in the appendix1 to this recommendation.

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Council of Europe
Committee of Ministers

Recommendation No. R (96) 11 of the Committee of Ministers to member states on documentation and record-keeping to guarantee the traceability of blood and blood products especially in hospital

(Adopted by the Committee of Ministers on 2 October 1996 at the 574th 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 health field;

Considering that whereas blood transfusion and blood products are given for the purpose of saving life and improving the health of the recipient but that sometimes they may inadvertently lead to transmission of disease or other undesired side effects;
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Considering the importance of taking any necessary measures which will diminish the risk of such transmission, particularly for hepatitis B and C;

Recalling 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 (85) 12 on the screening of blood donors for the presence of Aids markers, No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, No. R (95) 14 on the protection of the health of donors and recipients;

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

Bearing in mind the Council Directive of the European Communities 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma and the associated guidelines together with the requirements for market authorisations;

Bearing in mind Resolution 6936/95 of the Council of the European Union on blood safety and self-sufficiency in the European Community,

Recommends that the governments of member states ensure that measures are taken to ensure traceability of blood and blood products from the donor to the recipient, as well as from the recipient back to the donor, in accordance with the principles set out in the appendix to this recommendation.
Resolutions and recommendations

Appendix to Recommendation No. R (96) 11

A. Field of application

This recommendation applies to:

i. the unit (static or mobile) collecting the blood or plasma;
ii. the blood bank in the hospital;
iii. the operating theatre, ward or clinic where the blood or blood product is transfused.

Note: i. and ii. may be one and the same entity.

B. Principles

National health authorities are responsible for determining the general principles under which blood transfusion operates in each country. The principles of good practice set out below are designed to ensure two-way traceability of blood and blood products from donors to recipients and recipients to donors. Because blood or blood products may cross national boundaries, traceability should also be ensured at the international level.

i. Unit collecting the blood or plasma

1. Details of the donor of any donation should be registered at the unit collecting the blood or plasma. These should include name, address and date of birth. Hard copy or computer records are acceptable.
2. All personal details should remain confidential and be kept in a secure place. Access should only be allowed to those who have a need to know.
3. Each donation should be given a reference number, preferably using a bar code. Each component from that donation should have the same number to which may be given a subsidiary code, if appropriate. Labelling should comply with the relevant national legislation and international agreements and should particularly include the producer’s name and address (see Recommendation
Blood and blood components

No. R (95) 15). Where components from individual donations are pooled to provide the required therapeutic dose (for example platelets), there must be a secure numbering system that allows all components of the pool to be traced.

4. Samples for testing for blood groups and markers of infection should be labelled with the relevant code number of the donation.

5. The detailed results of these tests, together with the relevant donation numbers, should be noted on a results sheet.

6. The blood group, and where appropriate the phenotype, should be given on the vessel containing the donation. Such information should also be entered in the confidential database.

7. The destination of each donation and of each component should be noted in a register. This must state whether the donation was sent for clinical use, for fractionation, for research or whether it was discarded.

8. The register should also give the precise address to which the donation or component was sent together with the person responsible for its receipt.

9. The transfusion unit should be able to identify the donor of any suspect donation.

10. The transfusion unit should be in a position to inform the blood bank quickly in the event that it discovers some problem with a donation. The blood bank should be in a position to identify the recipient.

ii. The blood bank in the hospital

11. The hospital blood bank should keep a register of each donation or component or blood product received. This should state the date and time of receipt and the relevant code or batch number.

12. When the hospital blood bank receives a request for blood or a blood product it should ensure that the request form contains details of the name and date of birth of the intended recipient and ward or clinic where the blood is to be sent. Details of the
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consultant responsible for the recipient should also be included. These details should be entered on a register in the blood bank against the code or batch number for the blood or blood product.

13. The hospital blood bank should also ensure that it has received a sample from the intended recipient for grouping and cross-matching.

14. Where the laboratory responsible for testing the potential recipient is different from the hospital blood bank, it should also document the details of the recipient and the donation, applying the principles given above.

iii. The operating theatre, ward or clinic where the blood or blood products are transfused

15. The physician prescribing the transfusion or the nurse affecting it should ensure that details of the component or product being transfused are entered in the recipient’s hospital notes. These data should include as a minimum the component or product name (for example erythrocytes, platelets, Factor VIII), the donation or batch number and blood group, where appropriate. They may be entered by removing part of the label and sticking it in the notes. In the case of fractionated blood products there is usually no label and so the details must be written in by hand.

16. It is particularly important to record these details in cases of acute emergency where life-saving measures may prevent immediate attention to these points.

17. Any untoward reaction is to be reported as soon as possible to the blood bank giving the donation or batch number involved, for example the occurrence of jaundice, haemolysis or anaphylaxis. These should be investigated at the place of transfusion and the detailed results should be made available to the blood bank and through it to the collecting unit as soon as they are available. Appropriate action should be taken locally and the collecting unit - and through it the blood bank - is to inform those to whom other fractions of that donation or previous donations have been sent if this is necessary.
iv. General

18. The time for which records are kept is determined by local or national requirements. The appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components states that the period should be at least ten years. Samples used for microbiological testing should be retained for a period which takes account of the likelihood of a late report of an adverse reaction and of the amount of freezer space available.

19. Donations, components and products should be visually checked. If there is any indication whatsoever of a physical anomaly the transfusion centre should be informed and the suspect products should be returned to it. This should be noted in the registers at both the hospital blood bank and the transfusion centre.

20. Physicians, medical students and nursing staff should be educated to recognise adverse and unexpected reactions to blood or blood products. There should be an agreed protocol with the haematologist over what action is to be taken and how the event is to be reported.

Fractionated blood products

21. In the case of fractionated blood products, these may go directly from the fractionator or supplier to the physician treating the patient or to the hospital pharmacy or to the hospital blood bank. In these cases records need to be scrupulously kept by each department through which the product has passed. The physician should be able to identify the relevant recipient and the fractionator/supplier should be able to identify the relevant pool and from this information the relevant blood transfusion centre.

22. In the case of fractionated blood products used in home therapy, the hospital clinic needs to keep records of the batch numbers of supplies of blood products given to individual patients. Individual patients should keep a note of the batch number of products and the date when they are used. This is especially important where, for instance, brothers may share the same supply of Factor VIII.
23. For licensed pharmaceutical products it is necessary to follow national legal requirements in respect of responsibility for pharmacovigilance.

24. It also needs to be recalled that some blood products may be added as stabilisers, etc., to other pharmaceutical products.
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 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. R (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 on haematopoietic progenitor cells should implement scientifically recognised state-of-the-art 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 at least twenty years.

6. Criteria for the collection of haematopoietic progenitor cells should be established in accordance with national law. Distribution should take place in such a 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 procedures for 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 originate from the recipient or from another individual.
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 into account the ethical principles concerning voluntary, non-remunerated blood donation set out in Recommendations No. R (88) 4 on responsibilities of health authorities in the field of blood transfusion, No. R (90) 9 on plasma products and European self-sufficiency and No. R (95) 14 on the protection of the health of donors and recipients in the area of blood transfusion;
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Recalling its Recommendations No. R (93) 4 on clinical trials involving the use of components and fractionated products derived from human blood or plasma and No. R (95) 15 on the preparation, use and quality assurance of blood components;

Bearing in mind the stipulations of the Convention on Human Rights and Biomedicine,

Recommends that governments of member states see to it that:

1. the procurement of raw material for the preparation of oxygen-carrying substances or other medicinal substances based on human blood is organised in a way that does not hamper a steady and sufficient blood supply for transfusion purposes;

2. the procurement of such raw material should be transparent and give the donors sufficient information on the potential use of the blood collected;

3. the principle of voluntary, non-remunerated donation is respected and followed in all donations of blood, independent of the ultimate therapeutic use of the products.
Council of Europe
Committee of Ministers

Recommendation No. R (2001) 4
of the Committee of Ministers to
member states on the prevention of
the possible transmission of variant
Creutzfeldt-Jakob Disease (vCJD) by
blood transfusion

(Adopted by the Committee of Ministers on 7 March 2001 at the
744th 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 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;
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;  

Considering the identification of a new form of Creutzfeldt-Jakob Disease (CJD) that differs from previously recognised types of the disease, known as variant Creutzfeldt-Jakob Disease (vCJD);  

Taking into account that much of the scientific basis concerning transmission routes and mechanisms is uncertain in CJD as well as in the new vCJD;  

Considering nonetheless that there are indications that vCJD may be transmissible by blood or blood products;  

Given that the length of the incubation period will make it extremely difficult to establish scientific certainty within a reasonable time limit;  

Considering that it has been established beyond reasonable doubt that the transmissible agent for vCJD is indistinguishable from that of Bovine Spongiform Encephalopathy (BSE) and that vCJD most probably results from the exposure to bovine products derived from BSE infected cattle;  

Taking into account that at present there is as yet no evidence that vCJD has been transmitted by blood or blood products;  

Taking note of the information provided in the explanatory report to this recommendation,  

Recommends that governments of member states take the following measures in order to prevent the possible transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood transfusion:  

1. Initiatives need to be taken to promote the appropriate use of blood to minimise the unnecessary exposure of patients to blood transfusion.
2. Care should be taken to ensure that any measure proposed will not have a negative impact on the donation and supply of blood necessary to meet patients' needs. Any measures under consideration for the purpose of minimising the theoretical risk of transmitting vCJD to a recipient by blood transfusion must take into account the balance of risk between maintaining an adequate blood supply and minimising the theoretical risk.

3. Member states should have a centralised CJD surveillance system in place, with access to a European CJD reference centre facility, and a system of traceability of donations in order to initiate a recall if necessary.

4. Member states should determine, on the basis of the prevalence of BSE within individual countries, of the endogenous exposure of the population to bovine products imported from countries with a high BSE prevalence and of the incidence of cases of vCJD, what precautionary measures they may need to take to minimise the theoretical risk of transmission of the vCJD infective agent through blood transfusion.

5. Efforts must be made to develop and implement a sensitive and specific test for diagnostic and screening purposes as soon as practically feasible.
Council of Europe
Committee of Ministers

Recommendation No. R (2002) 11 of the Committee of Ministers to member states on the hospital’s and clinician’s role in the optimal use of blood and blood products

(Adopted by the Committee of Ministers on 10 October 2002 at the 811th 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 among its members and that this aim may be pursued, inter alia, by the adoption of common action in the health field;

Considering that whereas transfusions of blood and blood products are given for the purpose of saving life and improving the health of the recipient but that sometimes they may inadvertently lead to the transmission of disease or other undesired side effects;

Considering the importance that the blood and blood products available are used with the greatest care and to their full potential;
Recognising that the unnecessary and inappropriate use of blood and blood products needs to be avoided;

Acknowledging the primary role and responsibility of clinicians in treating patients, including decisions concerning the transfusion of blood components and blood products and the use of alternatives to transfusion;

Acknowledging that development in the field of transfusion medicine should be fostered by the recommendations of the Council of Europe;

Acknowledging that the organisation of health services and the provision of medical care remains the responsibility of the member states;

Acknowledging that member states, in achieving the objectives of the recommendation, must take account of existing statutory and organisational arrangements for the provision of health services;

Recalling its Recommendations No. R (85) 5 on a model curriculum for the training of specialists in blood transfusion, No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion (concerning voluntary, non-remunerated blood donation) and 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 Recommendations No. R (95) 15 on the preparation, use and quality assurance of blood components and No. R (96) 11 on documentation and record-keeping to guarantee the traceability of blood and blood products especially in hospital;

Welcoming the publication of the proceedings of the 1999 European Union conference on “Blood safety in the European Community: an initiative for optimal use” and the World Health Organisation (WHO) initiative on rational transfusion therapy;

Taking into consideration the advice given in the appendix to this recommendation,
Recommends to the governments of member states to apply the following principles through relevant competent authorities as necessary:

1. ensure the development of a national policy for clinical transfusion medicine;
2. promote a national programme of education and training in the clinical use of blood and blood products;
3. ensure that guidelines on the clinical use of blood and blood products are drawn up by transfusion medicine specialists in consultation with other parties involved in the transfusion procedure. These guidelines should contain evidence-based or otherwise approved indications for the transfusion of blood and blood products in order to optimise efficiency and avoid unnecessary transfusion;
4. promote the setting up of appropriate structures with the purpose of ensuring the implementation of national guidelines on the clinical use of blood and blood products;
5. promote the establishment of appropriate local or regional structures for multidisciplinary hospital transfusion committees with a view to implementing a quality management system for the clinical use of blood and blood products;
6. encourage studies on the clinical use of blood and blood products by collecting and comparing indicators of use at regional and national level;
7. encourage the use of alternatives to allogeneic blood transfusion and develop preventive strategies to reduce blood loss;
8. encourage measures to eliminate wastage and loss of blood and blood products due to technical reasons.
Appendix to Recommendation Rec(2002)11

1. Introduction

This appendix gives advice as to how the general principles specified in the Recommendation may be effected. It is recognised that the implementation of this advice must have due regard to the organisation and structures of health care services in the member states and national developments in transfusion medicine.

Blood is given to save the life or improve the health of the patient in need. This priceless gift is not to be wasted in unnecessary or inefficient use. It is a gift, too, that may carry risks of transmission of infectious agents and various other complications. It is thus of primary importance that it be used in the best possible way to maximize benefits and minimize risks.

Major aspects of the optimal use of blood are:

1. promotion of effective logistics and efficient laboratory working practices to eliminate wastage and losses due to technical reasons;
2. evidence based or otherwise approved indications for the transfusion of blood components to optimize efficiency and avoid unnecessary transfusion.

The latter reduces patients’ exposure to risk, and alternatives to transfusion may be more cost-effective. Optimal exploitation of the blood supply should help overcome the difficulties arising through seasonal shortages of blood and plasma and the generally inadequate supply of blood and blood products in various countries.

Present practices leave much scope for improvement. Protocols defining in detail standard practices and operating procedures to be followed at all stages of transfusion are now generally considered to make an essential contribution to quality assurance (QA) and quality management (QM) of blood transfusion. However, policies and
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guidelines on the clinical use of blood and blood products have been developed in few countries, and existing national guidelines exhibit considerable variations.

For the purpose of harmonizing the practices of clinical transfusion medicine in Europe, it is desirable that European recommendations in this respect should be agreed and adopted as widely as possible. In this context, the important role of the hospital and the clinician, irrespective of the level and structure of the country’s health system and blood transfusion system (centralised, regionalised, hospital-based), should be emphasised as a key prerequisite for the optimal use of blood. The hospital and the clinician play an equally important role in systems for monitoring and evaluating clinical blood use.

2. The clinical use of blood and blood products

2.1. The present situation

There exists currently a great variability in Europe in the use of blood and blood products in comparable clinical situations. Adequate documentation of both the process and the outcome is often lacking. Thus current clinical practice fails to satisfy the criteria necessary to ensure quality in use of blood and blood products, which may be defined as the administration of the right quantity of the right blood at the right time to the right patient. Studies carried out by the Council of Europe and other bodies have shown that consumption of erythrocytes, fresh frozen plasma, and other blood products and plasma derivatives, varies within Europe. One reason for this state of affairs is that we lack adequate scientific data on the need for blood and plasma products, as well as on their consumption, in different clinical settings. Thus it is difficult to establish standards for the optimal use of blood resources and for consumption versus availability and production. Furthermore, there is a paucity of information about the use of alternatives to haemotherapy in Europe - with the exception of the preoperative deposit of autologous blood - while medical and surgical means and preventive strategies to reduce blood loss are not
2.2. The framework

The decision to transfuse blood is made by the individual clinician or the clinical team responsible for the care of the patient. Their action should be taken within the framework provided by:

1. the existence of clear national policy and guidelines on the use of blood and blood products at the country level;
2. the supervision and support provided by national, regional or local hospital blood transfusion committees responsible for implementing and reviewing the policy and its actual operation;
3. the availability of alternatives to transfusion, to contribute to minimising the need for transfusion.
4. appropriate training of all clinical and blood service staff;
5. monitoring and evaluation of the country guidelines in the context of a quality assurance system to secure safe and adequate supplies of blood and blood products from the blood services and their effective use by the clinicians.

3. Policy on the clinical use of blood and blood products at the country level

Working within the framework and the strategy of existing country blood programmes, a policy for clinical transfusion medicine should be developed at the country level. The key elements are as follows:

1. optimal use of blood and blood products at country and local level;
2. use of blood and blood products to treat patients only when the clinician's duty of care to his or her patient demands it, taking into account the balance of benefits and risks of transfusion for each patient. Requiring the patient's informed consent may increase the responsibility and awareness of both the clinician and the patient;
3. promotion and availability of intravenous replacement fluids, pharmaceuticals and devices to minimize the need for transfusion;

4. establishment of a suitable mechanism for ensuring the local application of existing guidelines for clinical use of blood and blood products, including implementing total quality procedures (covering pre-transfusion, transfusion and clinical surveillance), haemovigilance at all stages of blood transfusion and monitoring and evaluation of the clinical use of blood and blood products. Systematic data collection and analysis should be performed at local and national level;

5. commitment to continuing education in efficient clinical use of blood and blood products and application of the guidelines for all staff involved in the transfusion process;

6. harmonization of practices in all respects related to the clinical use of blood and blood products;

7. cost-effectiveness, cost/benefit analysis and cost-recovery evaluations should be established in conjunction with the country’s health system.

4. Guidelines on the clinical use of blood and blood products at the country level

Comprehensive guidelines on the clinical use of blood and blood products should be drawn up by transfusion medicine specialists together with the other parties involved in the transfusion procedure (in particular the key blood users (pre-scribers)).

The principal aims are as follows:

1. to lay down guidelines for all stages of the transfusion process;
2. to catalogue the clinical indications for the transfusion of blood and blood products;
3. to promote the alternatives to transfusion and ways of minimizing the need for transfusion;
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4. to require that all transfusion records be kept in such a way as to facilitate haemovigilance and monitoring of use, with the object of continual improvement of the clinical use of blood and blood products;

5. to define pre-transfusion measures for the identification of patient at blood sampling;

6. to require the use of standard blood request forms and blood ordering schedules, which both helps to ensure that all necessary data for monitoring blood use are recorded and at the same time contributes to educating physicians in matters related to transfusion;

7. to draw up protocols for transfusing patients. These will be specific to each situation, haemotherapy of thalassaemia and haemophilia patients, auto transfusion, open-heart surgery, exchange-transfusion and other practices;

8. to draw up protocols for emergencies and crisis management.

5. Structures for implementing policy on the clinical use of blood

It needs appropriate structures for implementing a policy on the clinical use of blood.

A possible approach is the setting up of a Committee on the clinical use of blood with the purpose of ensuring the implementation of a harmonized policy. Its membership, adapted to local circumstances, should be based upon senior representatives of all parties involved in blood provision and blood prescription. However, for effective functioning of the Committee, it is probably desirable for the membership to be below ten.

These may be drawn from among the following:

1. a senior officer of the Ministry of Health (director of public health, director of the department with responsibility for blood transfusion etc);
2. the president or a representative of a National Advisory body on blood transfusion services;

3. representatives of the Haematology Society and Blood Transfusion Societies and professional associations of the most representative transfusion users (e.g. anaesthetists, surgeons, obstetricians, oncologists, paediatricians), nurses, haemophilia specialists and thalassaemia specialists;

4. representatives of hospital transfusion committees;

5. representatives of haemovigilance officers;

6. representative of the National Drug Administration;

7. representatives of relevant NGO’s (Red Cross/Red Crescent Society, blood donor associations, multitransfused patients’ associations).

6. Clinical services provided by blood establishments

A blood service may be set up as a separate unit in all major hospitals, with its own specialized staff, management and funding. However, it operates in collaboration with many others. Transfusion medicine specialists often also have duties in clinics treating patients with acute or chronic haematological disorders and for patients requiring apheresis for therapeutic purposes. They may serve in oncology clinics, anticoagulant therapy outpatient services and bone marrow transplantation departments, and generally offer their expertise in clinics for patients requiring haematological care as well as haemotherapy. Serologists specializing in blood transfusion may also work in immunology and histocompatibility laboratories. Multi-transfused patients with thalassaemia syndromes, other chronic anaemias or haemophilia and other hereditary haemorrhagic disorders are traditionally treated by an experienced haematologist in wards and outpatient departments located in blood services.

Effective co-operation between hospital blood services and transfusion medicine specialists on the one hand, and clinics and clinicians on the other, requires effort on both sides. One area requiring close
collaboration between all parties is the development of the national policy and guidelines on the clinical use of blood.

7. The Hospital Transfusion Committee

7.1. Purpose and tasks

The establishment of a multidisciplinary hospital transfusion committee (HTC) in every hospital that provides a blood service is recommended. If more appropriate, a regional committee could be set up. Its purpose is to implement policy and guidelines, and to monitor local usage of blood and blood products. Its main tasks are:

1. to lay down blood transfusion policies, conforming to national guidelines, adapted to local clinical activities;
2. to conduct regular evaluation of blood transfusion practices;
3. to monitor the clinical use of blood in order to secure its optimal use, and reduce unnecessary transfusion and avoid wastage;
4. to promote the introduction of safer and more cost-effective alternatives to transfusion;
5. to prevent and treat early conditions that could result in need of transfusion;
6. to participate in national programmes for the prevention and management of hereditary conditions resulting in chronic haematological diseases requiring haemotherapy (haemophilia, haemoglobinopathies, etc);
7. to analyse adverse reactions due to blood transfusion, to ensure their reporting to haemovigilance networks and other appropriate authorities, and to take corrective action;
8. to set up continuous training programmes in the clinical use of blood for all physicians and nurses of clinics involved in the transfusion process and for blood service staff.

The HTC’s membership should include senior representatives of the blood services and the clinical departments with significant
transfusion activity, notably, anesthesiology, haematology, surgery, paediatrics and gynaecology/obstetrics. It is recommended that nurses and administrative personnel also be represented. The hospital staff member responsible for the supply of intravascular replacement fluids, pharmaceutical, medical devices and sterile disposable equipment may be included in the HTC. A manager or finance officer as well as patients may also be represented. However, the size of the committee should not be so large as to hinder its effective functioning. HTC should report to the highest level of hospital management.

7.2. Quality management

Various international bodies recommend the nomination of a local transfusion officer whose duties include carrying out the above tasks, supported and supervised by the HTC. If the hospital is already provided with a quality management system, quality management for clinical use of blood products should make up a part of the hospital-wide quality management system.

Further, the transfusion officer and the HTC should define standard operating procedures (SOP’s), mandatory for health care personnel and verify by internal audit the compliance to guidelines and SOPs. Evaluation of effectiveness and safety and feedback to clinicians are also major tasks and responsibilities of the transfusion officer and of the HTC.

Standard operating procedures should cover all of the processes in the blood transfusion chain focusing on:

1. the identification system which links the patient identification, the operator, the blood sample through processing, the blood product and confirms the original patient identification at the time of blood administration. Emphasis must be placed on error recognition;
2. administration of blood and blood products;
3. management and follow-up of adverse reactions;
4. emergency procedures;
Blood and blood components

5. handling of unused blood and blood products units;
6. transportation and storage conditions of blood products outside the blood transfusion service;
7. documentation of the above steps and of the outcomes.

7.3. Education
The effective implementation of national policy demands a national programme of education and training in the clinical use of blood. A comprehensive education policy should cover training in all the following sectors:
1. Undergraduate and postgraduate education:
   a. medical schools, teaching hospitals;
   b. schools of nursing.
2. In-service training:
   a. clinicians of different specialities (priority: anaesthetists, gynaecologists, surgeons, paediatricians, haematologists);
   b. nurses;
   c. blood transfusion staff.
3. Continuing medical education:
   a. hospitals;
   b. seminars, conferences;
   c. publications.
Particular attention should be focused on the regular training and assessment of competency of nursing and junior medical staff who are more directly involved in bedside transfusion practice. The frequency of blood transfusion in many settings is very limited, thus staff are not regularly exposed to blood transfusion and may not be familiar with bedside transfusion protocols.

7.4. Monitoring the clinical use of blood
The National Committee should itself carry out, or request another appropriate body to carry out, studies of the clinical use of blood, by
collecting and comparing indicators of use at regional and national level. HTC’s may carry out similar analyses at the local level. Major indicators widely used include red cells units transfused by number of patients discharged and number of hospital beds. Other possible indicators are shown in the following paragraph. Differences in blood use indicators between clinics, hospitals and regions may provide a general picture of the factors that influence the supply of health services at local, regional and national levels, and may show where improvements are required. Sound analysis requires that factors such as the differences between types of hospital (local, regional and university) be allowed for.

7.5. Annual performance indicators of use of blood and blood products

Note: the following indicators should be computed for plasma and platelet use, as well as red cell use.

1. Evaluation of use of blood at national level

   No of blood units transfused
   No of blood units collected

   No of blood units transfused
   No of blood units issued

   No of blood units cross-matched
   No of blood units transfused

   No of group “O” blood given to group “A” or group “B” patients

2. Evaluation of use of blood at local level

   No of blood units transfused
   No of blood units distributed

   No of blood units transfused
   No of blood units prescribed
Blood and blood components

No of patients / bed
No of blood units / bed
No of blood units / patient
No of blood units transfused / clinical department
No of blood units transfused (mean) / category of clinical indication

3. Use of blood / local / regional / university hospitals

4. Distribution from blood centre to hospital blood bank

No of units distributed
Total no of units transfused

5. Stock management

No of blood units discarded / storage condition
No of blood units discarded / expiry

Total no of blood units discarded / transportation
No of group “O” Rh neg outdated or transfused to Rh positive patients.

6. Cost-effectiveness, cost-benefit analysis, cost-recovery evaluation

7.6. The Hospital Transfusion Laboratory: investigation of adverse reactions

The HTC should ensure that every adverse reaction to blood and blood products is fully investigated by a Hospital Transfusion Laboratory (HTL) and reported to the producing blood centre. The HTL co-ordinates the local investigation of adverse reactions, retrieving units for return to the blood centre, carrying out whatever testing falls within its domain and collaborating with the hospital microbiological laboratory and other laboratories for further testing as required according to the nature of the incident. It excludes possible causes of transfusion reactions such as ABO compatibility and platelet antibodies, and investigates the possibility of defective reagents and blood collection materials.
8. Main clinical indications for transfusion of blood and blood products

- blood loss (acute, chronic);
- anaemia (acute, chronic) (where other therapies have been inapplicable or ineffective);
- surgery and trauma (acute, elective, burns);
- supportive treatment:
  - haemophilia and other congenital haemorrhagic disorders;
  - thalassaemia and other haemoglobinopathies;
  - immunodeficiency disorders (including HIV infection);
  - thrombocytopenia;
  - bone marrow dysfunction;
  - transplantations;
  - oncology (solitary tumours, leukaemias/lymphomas);
- neonatal anaemia;
- haemolytic disease of the newborn;
- exchange transfusion;
- thrombocytopenia;
- vitamin K deficiency;
- paediatric anaemias (nutritional, malaria, infections etc.);
- anaemia in pregnancy (where other treatments have been ineffective);
- major obstetric bleeding;
- disseminated intravascular coagulation;

Alternatives to allogeneic blood transfusion:

- prevention of anaemia (for pregnant women and infants);
- prenatal diagnosis of hereditary haematologic disorders (thalassaemia, sickle-cell disease, haemophilia etc);
Blood and blood components

- administration of pharmaceutical agents, (haematinins, erythropoeitin);
- prevention of haemolysis due to red cell enzymes deficiency;
- optimise the nutritional status, iron supplement.
- autologous blood transfusion:
  - preoperative deposit;
  - immediate preoperative haemodilution;
  - intraoperative blood salvage.
- volume substitutes:
  - crystalloid solutions;
  - colloid solutions.

Preventive strategies to reduce blood loss:

- anticipate the need for replacement of blood loss by treating of existing anaemia not only to restore red cell mass, but also to replete iron stores;
- surgical strategy should allow appropriate measures to prepare the patient for operation;
- medical strategies to reduce blood loss should take into account surgical posture, temperature, anaesthetic mode, the use of anti-fibrinolytics and the reduction of medication known to be associated with excessive bleeding;
- rational monitoring – blood sampling should be timely and to the smallest possible volume e.g. paediatric samples;
- public health strategies should address nutritional anaemia, drug abuse associated with gastro-intestinal bleeding, e.g. aspirin, NSAID, and the treatment of parasites associated with anaemias.
9. Concluding remarks

The existing variations in the use of blood and blood products between countries, and both between and within hospitals in the same country, together with the lack of internationally accepted optimal standards defining quality in terms of appropriate use of blood resources, impose the need of implementing a quality management system with the cooperation and commitment of all parties involved in the blood transfusion chain. In this respect, the role of the hospital and the clinician, as well as the nursing staff and all other healthcare providers, in ensuring the highest level of quality, safety and efficacy of blood transfusion must be emphasized. Within such a system, the organizational, economic, educational and clinical aspects of haemotherapy, alternatives to haemotherapy, and preventive strategies to reduce blood loss, should be analysed and tasks and responsibilities should be defined at national and local level. Underlying this structure is the basic requirement of a sufficient supply of safe blood to be used for the benefit of the patient in need of haemotherapy. The irreplaceable fundamental principle in this remains the recruitment and retention of voluntary non-remunerated donors.
Council of Europe
Committee of Ministers

Recommendation No. R (2003) 11 of the Committee of Ministers to member states on the introduction of pathogen inactivation procedures for blood components

(Adopted by the Committee of Ministers on 19 June 2003 at the 844th 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 actions 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;

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;

Welcoming the report on pathogen inactivation of labile blood products, produced by the European Health Committee (CDSP), setting out the benefit/risk and cost/benefit ratios of these procedures,

Recommends to governments of member states to take account of the following considerations regarding the introduction of pathogen inactivation procedures for blood components, if necessary by the relevant competent authorities:

1. current safety standards of blood components are high;
2. incremental costs of pathogen inactivation procedures are high in relation to the additional safety gained;
3. the cost effectiveness of pathogen inactivation methods and the evidence of health gain for the individual have not been established;
4. pathogen inactivation methods may have a negative impact on the efficacy of blood components and may harbour unexpected long-term adverse effects.
Council of Europe
Committee of Ministers

Recommendation No. R (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,
Resolutions and recommendations

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.
Explanatory memorandum to Recommendation Rec(2004)8 of the Committee of Ministers to member states on autologous cord blood banks and 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 voluntarily 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. tumor effect” in hematological diseases. In cases of congenital disease and in some leukemias 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.
Resolutions and recommendations

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 there is no scientific rationale for the universal storage of UCB. It is not 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 voluntarily 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.
### Resolutions and recommendations

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Council of Europe
Committee of Ministers

of the Committee of Ministers to
member states on teaching transfusion
medicine to nurses

(Adopted by the Committee of Ministers on 15 December 2004 at
the 909th 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 health field;

Taking into account Resolution No. R (78) 29 on harmonisation
of legislation of member states relating to removal, grafting and
transplantation of human substances;

Recalling also its Recommendations Nos. R (80) 5 concerning blood
products for the treatment of haemophiliacs, R (81) 14 on preventing
the transmission of infectious diseases in the international transfer
of blood, its components and derivatives, R (84) 6 on the prevention
of the transmission of malaria by blood transfusion, R (85) 12 on the screening of blood donors for the presence of AIDS markers, R (86) 6 on guidelines for the preparation, quality control and use of fresh frozen plasma (FFP), R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, R (95) 14 on the protection of the health of donors and recipients in the area of blood transfusion, R (95) 15 on the preparation, use and quality assurance of blood components, R (96) 11 on documentation and record-keeping to guarantee the traceability of blood and blood products especially in hospital, and Rec(2002)11 on the hospital's and clinician's role in the optimal use of blood and blood products;

Considering:

– the importance of blood components in modern haemotherapy and the need to ensure their safety, efficacy and quality;

– that such components are of human origin and that hence specific ethical and technical principles have to be taken into account;

– that biotechnology does not provide substitutes for most blood products;

– the need to provide health authorities, transfusion services, hospital blood banks and clinical users with a set of guidelines for the preparation, use and quality assurance of blood components;

– that the safety of blood transfusions (which must be prescribed by doctors) depends largely on the nursing staff involved in transfusions in hospital or at home, or working in blood establishments or in other specialised fields such as autologous blood transfusion and bone marrow transplantation;

– that the majority of serious adverse reactions and untoward events associated with blood transfusion which can result in serious morbidity or mortality are caused by human and system errors in the whole blood transfusion chain;

– that such complications can be avoided or reduced by the application of safety measures before and during transfusion;
Resolutions and recommendations

that adequate training of nurses is a key determinant for ensuring the safety, efficacy, and quality of blood transfusions,

Recommends that the governments of member states take all necessary measures and steps to ensure that:

1. all nurses receive training in blood transfusion;
2. only nurses who have been trained and have specific qualifications in blood transfusion medicine are allowed to practice it;
3. nurse training curricula reflect the requirements of modern transfusion medicine and other specialised fields of medicine such as oncological and haematological disorders, surgical procedures, autologous donation of blood, as well as bone marrow and organ transplantation;
4. implementation and evaluation of continuous training programmes is carried out in order to improve the quality and safety of blood transfusion;
5. mechanisms are developed for the cooperation between nurses, physicians, and other health care workers employed in hospitals, blood establishments, and hospital blood banks;
6. procedures are set up to monitor knowledge of key processes, such as clinical audit, with ongoing feedback and implementation of remedial action, to ensure continuous improvement in performance;
7. guidelines and procedural protocols on blood transfusion medicine for the nursing staff and other professionals are developed in accordance with relevant Council of Europe recommendations.
Explanatory memorandum to Recommendation Rec(2004)18 of the Committee of Ministers to member states on teaching transfusion medicine to nurses

A. Introduction

1. To improve quality and safety in blood transfusion medicine in European countries, harmonization of blood transfusion practices is required.

2. Recent reports on risk assessment in blood transfusion demonstrate that more than 30% of serious adverse reactions and untoward events associated with blood transfusion are due to human errors and system errors in the blood transfusion chain (vein-to-vein). These can be fatal or cause major or minor morbidity to the transfused patient.

3. Most errors occur in blood sampling from the patient, in prescriptions of blood components, in the laboratory of the blood establishment or blood services, during collection of donor blood and in the ward where the blood components are administered.

4. Haemovigilance systems stress that complications of blood transfusion can be avoided or reduced by the application of safety measures before, during, and after transfusion.

5. Blood transfusion safety depends largely on the nursing staff (while the doctors are responsible for prescribing) involved in the transfusion of patients in hospitals or at home, and also on nurses working in many areas: pre- and post-donation counseling procedures in the donor sessions, in blood collection, in the processing, testing, storage and distribution of blood components. Nurses are also actively involved in autologous blood transfusion,
Blood and blood components

as well as in other specialized fields such as bone marrow transplantation, collection, processing, storage and distribution of stem cells, and in organ transplantation.

6. Reports from Europe, the USA and elsewhere on evidence–based practice in the field of blood transfusion stress that inadequate training of nurses is a key determinant of poor transfusion-related knowledge and practice of transfusion safety procedures.

7. Within Europe, there is a wide range of nurses’ responsibilities with respect to clinical and laboratory blood transfusion and therefore in the duties and actions they are allowed to undertake.

8. Similarly, the curriculum for nurses’ education differs considerably between countries and between the various grades of the profession.

9. Therefore, there is a need to determine common basic principles for pre- and postgraduate education of nurses in both the clinical setting and in the blood transfusion establishment and to define a common basis for good transfusion practice.

10. All nurses should receive education in blood transfusion. Only nurses who have been specifically trained and assessed as competent in BT medicine should be allowed to practice it, in cooperation with physicians and other health professionals and within the context of a training programme on new developments of this field.

11. Procedural guidelines for the nursing staff and other professionals working in the clinical and the laboratory setting of blood transfusion medicine should be developed in compliance with the “Guide to the preparation, use and quality assurance of blood and blood components” and other recommendations of the Council of Europe on blood transfusion, to meet national and local requirements and with the aim of ensuring safety in transfusion.
B. Current situation

**Grades of the nursing profession and training in blood transfusion medicine**

Within Europe, most nurses receive pre-registration training in college or university level nursing schools. Two to four years’ training in the various disciplines of nursing contains a variety of curricula in basic blood transfusion, clinical indications and optimal use of blood products in medical conditions and in surgery.

Postgraduate training to promote quality and safety in blood transfusion is usually organized by scientific societies and locally by academic or national health system institutions. Selection criteria, location of training, selection procedure, and conditions of service of nurses undergoing training, and the structure of the training programme (hours, topics, diploma etc), all vary. The responsibilities and duties of nurses in blood transfusion establishments and in hospital blood banks vary both between countries and within a country. In several European countries with established quality systems in blood transfusion, nursing staff receive accreditation for competence in the areas of their responsibility in conjunction with participation in continuous training in the field. A six-month in-training course in a Regional Blood Transfusion Centre is mandatory in Greece for all nurses and technicians working in a hospital blood bank. In several central and eastern European countries, nurses are involved in compatibility testing and other laboratory activities, as well as in blood sessions, pre- and post-donation counselling procedures, and in the organization of programmes for the recruitment of voluntary blood donors.

In the USA, major challenges for the nurse with regard to complications, treatment and resulting nursing care arise in working with immunocompromised and oncology patients, as well as in preparing patients for bone marrow transplantation. A survey of the procedures performed by critical care nurses showed that those performed by the greatest number related to blood component
transfusion, and that critical care nurses frequently performed some of these procedures with little or no supervision by a physician.

In Belgium, a national study assessing blood transfusion practice has concluded that transfusion should be improved by better education of all physicians and nurses involved with transfusion and by improving standardization by better documentation, better reporting and better information to all health care workers involved.

Factors associated with nurses’ poor knowledge and practice in blood transfusion in hospitalised care in France were analyzed in relation to reflecting potential danger and life threat to the patients.

Alarming data from SHOT in the United Kingdom put emphasis on the crucial steps in safe transfusion practice, i.e., patient and pre-transfusion checks, asepsis and apparatus, checking and clerical procedures, keeping vigilant and keeping accurate records. A set of guidelines for checking procedures and potentially adverse signs and symptoms have been drawn up in order to alert registered nurses to safe transfusion practice.

The Council of Europe in the “Guide to the preparation, use and quality assurance of blood and blood components” recommends that before and during transfusion the following measures should be applied:

**Pre–Transfusion**:  
1. Compatibility of identification of patient at blood sampling. The identification system should link the patient identification, the operator, the blood sample through processing, the blood product and should confirm the original patient identification at the time of blood administration. Emphasis must be placed on error recognition;

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1. It may be helpful if nurses responsible for transfusion are provided with a checklist for each stage of the transfusion process to ensure each step is undertaken appropriately.
2. Blood group serological investigation including blood typing, antibody screening and compatibility testing before transfusion of red cell products. The normal procedure shall be to make the investigation in due time before expected transfusion.

3. Preparation/ handling of frozen components

**During and after transfusion:**

1. Safety measures including identification of patient and blood unit and verification of compatibility between patient and blood unit;

2. Clinical surveillance during and after transfusion to include careful observation of the patient, especially in the early stages of the transfusion where significant transfusion reactions are more likely to occur and in the transfusion of any component prepared by an open system;

3. Controlled warming of blood;

4. Avoidance of addition of medical products or infusion solutions in blood components;

5. Handling of frozen units;

6. Vigilance for the risk of air embolism and transfusion complication either in direct relation to the transfusion or with a delay of hours or days.

**C. Elements of nurses’ training curricula**

Restructuring the pre and post-registration nurses’ education curricula, and evaluating and monitoring good transfusion practice of nurses both within the blood establishment and in the hospitals should be considered by the national authorities of the member states. For this purpose, cooperation between the health authorities, nursing schools and academic institutions is required. Information from international

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1 It may be helpful if nurses responsible for transfusion are provided with a checklist for each stage of the transfusion process to ensure each step is undertaken appropriately.
Blood and blood components

bodies and several European countries suggests the inclusion of the following elements in nurses' basic, pre and post-registration education curricula.

**Basic Education:**
1. Physiology of blood and its functions;
2. The concepts of blood component therapy;
3. The principles of blood transfusion;
4. Documentation and record-keeping.

**Pre-registration education:**
General principles of:
1. Physiology of blood and its functions;
2. The concepts of blood component therapy;
3. History of blood transfusion;
4. Organization aspects of blood transfusion;
5. Blood components (red cells, platelets, plasma);
6. Plasma products (albumin, immunoglobulins, clotting factors, etc.);
7. Blood group serology and basics of red cell compatibility;
8. The principles of blood transfusion and alternatives to the use of donor blood;
9. Pre-transfusion and transfusion procedures;
10. Phlebotomy and blood sampling for cross-match. Detailed procedures for patient identification. Introducing systems that allow error detection. One identification system that links patient, sample and blood product and confirms patient ID at the time of blood administration;
11. Basic knowledge of transfusion triggers;
12. Administering blood components and blood products, including special precautions for patients with heart disease, elderly, newborns. Special considerations in massive transfusion;
13. Shelf life of blood components;
14. Blood administration sets and equipment;
15. Patient care and observation during transfusion. Checking of relevant vital signs and their documentation;
16. Infections transmissible by transfusion;
17. Adverse effects of transfusion: recognize symptoms of adverse reactions and initiate standard immediate action if transfusion reaction is suspected;
18. Haematological disorders;
19. Management of haemophilia and coagulopathies;
20. Acquired haemostatic disorders and Disseminated Intravascular Coagulation;
21. Haemolytic disease of the newborn;
22. Documentation and records.

Two independent stages in post registration training are proposed: donor nursing and transfusion nursing.

Post-registration education:
This education can be divided into two stages:

I. Certification in donor nursing: for nurses working in blood establishments
   1. Procedures to select donors;
   2. Detailed procedures for donor identification;
   3. Procedures to an aseptic blood collection;
   4. The importance of the labelling in transfusion chain;
   5. Shelf life of blood components;
   6. Sets and equipments utilised in blood establishments to collect, processing, and analyse blood;
   7. Blood components processing techniques;
   8. Haemapheresis techniques;
Blood and blood components

9. Autologous transfusion techniques, with special relevance for pre deposit autologous transfusion;
10. Storage conditions of blood components;
11. Transportation conditions of blood components;
12. Fundamentals of leukocytes reduction, irradiation, and cryopreservation;
13. Cryopreservation techniques;
14. Infections transmissible by transfusion, including bacterial contamination;
15. Adverse reactions or events in blood donor;
16. Accidents or incidents during blood collection, processing and storage;
17. Blood inventory management concepts;
18. General concepts of the optimal use of blood components;
19. General concepts of major pathologies using blood transfusion (acute anaemia, chronic anaemia, hereditary haemolytic anaemia, coagulopathies, bone marrow and organ transplantation, etc);
20. Haemovigilance concepts;
21. Quality Systems concepts;
22. Documentation and records.

II. Certification in transfusion nursing: for nurses working in blood bank hospitals, wards, anaesthesiology and intensive care units:
1. General concepts of the optimal use of blood components;
2. General concepts of major pathologies using blood transfusion (acute anaemia, chronic anaemia, hereditary haemolytic anaemia, coagulopathies, haematological diseases, bone marrow and organ transplantation, etc);
3. Blood utilization management concepts;
4. Transfusion sets;
Resolutions and recommendations

5. Administration of blood components: measures and cares pre, during and posttransfusion;
6. Procedures to identify a patient:
   a. to collect a blood sample to pre transfusion testing
   b. to transfuse a blood component;
7. Procedures to detect errors in transfusion chain;
8. Pre transfusion testing;
9. Accidents or incidents pre or during transfusion;
10. Blood components: types and clinical indications;
11. Transfusion support in: obstetrics, paediatrics, surgery, and intensive care units;
12. Transfusion in chronic anaemia (oncology patients, hereditary haemolytic anaemia, etc);
13. Transfusion in acute anaemia (emergency, major bleeding);
14. Transfusion in bone marrow and solid organ transplantation;
15. Transfusion in special cases, like Disseminated Intravascular Coagulation, massive transfusion, etc;
16. Precaution measures in patients with heart disease, immune haemolytic anaemia, newborn, elderly;
17. Management of haemophiliac patients or others congenital coagulopathies;
18. Emergencies and disasters;
19. Adverse reaction or events in transfused patients;
20. Near misses;
21. Alternatives to blood transfusion;
22. Autologous transfusion techniques;
23. Storage and distribution of blood components;
24. Infections transmissible by transfusion, including bacterial contamination;
25. Ambulatory transfusion;
Blood and blood components

26. General concepts of collection, processing, and analysis of blood components;
27. Fundamentals of leukocytes reduction, irradiation, and cryopreservation;
28. Haemovigilance concept;
29. Recognition and participation in the management of abnormal reactions after transfusion including "near misses";
30. Quality System concept;
31. Documentation and records;
32. The role of the nurse in hospital blood transfusion committee.

The following section applies if an investigation of training and responsibilities of nurses is intended:

Working methods
1. Determine the spectrum of duties of nurses during blood transfusion, in the clinical setting as well as in the blood collection establishment, in all member states.
2. Assess the pre- and postgraduate training of nurses in blood transfusion in all member states by questionnaire addressed to national representatives who should obtain the relevant information from the health authorities and nursing institutes in cooperation with hospital senior nurses and academic nurses.
3. Determine the differences in training due to differences in responsibilities.
4. Determine common basic principles for good transfusion practice for nurses.
5. Determine common basic principles for training in pre-registration and during practice for nurses.
6. Investigate information available on the curricula recommended by international organizations.
Resolutions and recommendations

Working materials

Inquiry by questionnaire:

1. To Ministry of Health: number of nurses in the clinical setting – number of hospitals where transfusion occurs – number of blood components transfused – number of patients transfused – organization of blood transfusion – number of nurses in the blood establishments.

2. To Ministry of Education or Ministry of Health (as appropriate): official curriculum for basic transfusion medicine training for nurses – official curriculum for transfusion medicine training for nurses in blood establishments – number of nursing schools – number of nursing students.

Assessment of national data and results from the inquiry.

Conclusion

To increase efficiency in blood transfusion medicine, physicians and nurses and other health workers who handle blood or blood components should collaborate on development, evaluation and implementation. Documentation regarding transfusions needs to be simplified and coordinated. Knowledgeable staff is an essential element of safe systems. Basic knowledge should never be assumed: mechanisms to monitor knowledge of key processes along with ongoing feedback and remedial action are necessary to maximize performance. Nurse training curricula and formats at all levels must reflect the requirements of modern transfusion medicine from novice to expert. Working together, nursing and transfusion specialists will improve quality and safety in blood transfusion services.

The Council of Europe’s Recommendation could contribute to the adoption and implementation of training programmes at a national level.
Selected Bibliography

2. Council of Europe Recommendation No. R (95) 15, “Guide to the preparation, use and quality assurance of blood components” 10th
Resolutions and recommendations


24. Walterova L. Overview of clinical indications and optimal use of blood components: role of the Hospital Transfusion Specialist and
Transfusion Committee. ESTM course “The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over”. Sarajevo, October 2001.

Appendix 5

Specific terms of reference of the Committee of Experts on Blood Transfusion (SP-HM)

1. Name of the Committee:
Committee of Experts on Blood Transfusion (SP-HM)

2. Type of Committee:
Committee of Experts

3. Source of Terms of Reference:
European Health Committee (CDSP)

4. Terms of Reference:
Policy Activities
With a view to shaping European policies, based on democratic and ethical principles, the SP-HM shall:

a. examine the factors affecting the availability of blood and blood components;
Resolutions and recommendations

b. study ways to ensure fair access to blood and blood components in periods of blood shortage;
c. consider ethical and human rights issues involved in ensuring safety, quality and health policy aspects of blood transfusion;
d. evaluate the possible impact of new therapeutic and regulatory developments;
e. promote safety and efficacy of blood transfusion at all levels of the blood transfusion chain from the donor to the recipient,
f. examine the emergence of new transmissible diseases;
g. promote continuous education and training in transfusion medicine at all levels
h. follow the developments in the field of European self-sufficiency, in co-operation with the European Commission and other organisations;
i. assist member states in the restructuring and improvement of their blood transfusion services.

To carry out the above, the SP-HM should define a programme of work by identifying a limited number of subjects for short-term study, either by the Bureau of the SP-HM or by consultants. For each subject of study, terms of reference should be drafted, a calendar prepared and an outcome suggested.

Service Activities

a. Promote quality assurance with the latest developments including the up-dating of the technical Appendix to Recommendation No (95) 15 on the preparation, use and quality assurance of blood components.
5. Membership of the Committee:

a. The governments of all member states are entitled to appoint one or two delegates among the experts and the Health authorities responsible for blood transfusion related activities.

b. The following states or organisations may send representatives, without the right to vote or defrayal of expenses, to meetings of the Committee:

Australia, Canada, Holy See, Israel, Japan, Mexico, New Zealand, United States of America, European Commission, World Health Organisation (WHO), International Society of Blood Transfusion (ISBT), International Federation of Red Cross and Red Crescent Societies, and Order of Malta.

6. Working Structures and methods:

a. One plenary spring meeting of two days every two years in Strasbourg or outside, to be decided by the Bureau and approved by the CDSP. The Council of Europe’s budget bears travel and subsistence expenses for one delegate per member state. A Bureau consisting of 10 SP-HM delegates will meet one day before the plenary meeting and separately (autumn) for two days.

Every other year the Bureau will meet in spring for half a day followed by a meeting of one day and a half, to which all SP-HM delegates will be invited at their own expense. The Bureau will meet separately in the autumn for two days.

b. The tasks of the Bureau are the following:

- monitor progress in the implementation of the programme of work,
- deal with urgent questions and take the necessary decisions,
- carry out relevant research work when appropriate,
- prepare the relevant agenda, identify the preparatory work needed and possible follow-up.
c. The Chairperson and the members of the Bureau will be elected for 2 years by the SP-HM plenary.
d. The Bureau will meet in Strasbourg unless the choice of another place can be duly justified.

7. Duration:
These terms of reference expire on 31 December 2006

Appendix 6

Specific terms of reference of the Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS)

1. Name of Committee:
Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS)

2. Type of Committee:
Committee of Experts

3. Source of Terms of Reference:
European Health Committee (CDSP)
Blood and blood components

4. Terms of Reference:

i. Quality Assurance
   – to promote quality assurance with the latest developments
     including the up-dating of the technical Appendix to
     Recommendation (95) 15 on the preparation, use and quality
     assurance of blood components.

ii. Transfusion transmitted diseases
   – review of their incidence and preventive measures, including the
     selection of donors.

iii. Microbiological safety
   – in blood and blood components,
   – in the laboratory,
   – new methods, in particular, molecular biology.

iv. Exchange of sera
   – to improve proficiency testing.

The Committee will submit its report to the Committee of experts on
blood transfusion (SP-HM).

5. Membership of the Committee:

a. The Council of Europe’s budget bears travelling and subsistence
   expenses for one expert per state from:
   Belgium, Denmark, France, Germany, Hungary, Italy, Poland,
   Spain, Sweden, and United Kingdom.
   All other member states are invited to send one expert each at their
   own expense.

b. Qualifications desirable in members: specialists in the fields
   covered by the terms of reference, working within the framework
   of a national and/or regional transfusion centre. Terms in office
   should not exceed three years, unless otherwise decided by the
   National Health Authorities.
c. The following states or organisations may send representatives, without the right to vote or defrayal of expenses, to the meeting of the Committee:

Australia, Canada, Holy See, Israel, Japan, Mexico, New Zealand, United States of America, European Commission, World Health Organisation (WHO), International Federation of Red Cross and Red Crescent Societies, International Society of Blood Transfusion (ISBT).

6. Working Structures and Methods:

One meeting of 4 days every year.

7. Duration:

These terms of reference expire on 31 December 2006.
Council of Europe
Committee of Ministers

Resolution CM/Res(2008) 5 on donor responsibility and on limitation to donation of blood and blood components

(Arrived by the Committee of Ministers on 12 March 2008 at the 1021st meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia,1

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

Taking account of the ethical principles set out in the Committee of Ministers’ Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, and in particular Article 1 on voluntary non-remunerated blood donation;

1 Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and United Kingdom.
Taking into account the requirements set out in Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components;

Considering the inherent risks of human blood and therapeutic substances of human origin,

Recommends that the governments of States Parties to the Convention:

1. ensure that blood components are produced solely from blood collected from safe blood donors;

2. foster co-operation and trust between blood establishments and blood donors, in particular by informing the public about the need and criteria for selection of blood donors;

3. guarantee that blood establishments provide prospective donors with clear and appropriate information, including at least the following:
   3.1. the essential nature of blood, blood donation procedure, testing of collected blood, components derived from collected blood;
   3.2. possible risks to the health of the donor associated with blood donation;
   3.3. possible risks for the recipient of blood or blood components of a given donor;
   3.4. the donor’s duty to provide the blood establishment with all relevant information to the best of his/her knowledge, in particular on factors and activities which may increase risks for the recipient;
   3.5. the right to withdraw from donation at any time during the procedure for any reason, including doubts as to his/her suitability as a donor without any need to explain this decision;
   3.6. the importance for the donor to give the blood establishment post-donation information if the donor has doubts about his/her suitability or in the event of change in health status after donation;
3.7. the consequences of failure to provide the information as specified above during the donor assessment procedure;

3.8. the confidentiality of all personal information given by donors to the blood establishment, notably those related to health and behaviour;

4. ensure that blood establishments are ultimately responsible for the quality and safety of the blood and blood components collected; in particular, blood establishments should:

4.1. be responsible for the final acceptance or deferral of donors on the grounds of a risk assessment based on regularly updated epidemiological data, and bearing in mind the right of blood recipients to the protection of their health, and the resulting obligation to minimise the risk of transmission of infectious diseases. These rights and obligations override any other considerations, including individuals’ willingness to donate blood;

4.2. set up arrangements for fair compensation providing for cases where harm is caused to the recipient and/or the donor of blood and blood components.
Convention
European Treaty Series - No. 164

Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and biomedicine

Oviedo, 4.IV.1997

Preamble

The member States of the Council of Europe, the other States and the European Community, signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the European Social Charter of 18 October 1961;
Blood and blood components

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a convention on bioethics;
Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine,

Have agreed as follows:

**Chapter I – General provisions**

**Article 1 – Purpose and object**

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

**Article 2 – Primacy of the human being**

The interests and welfare of the human being shall prevail over the sole interest of society or science.

**Article 3 – Equitable access to health care**

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

**Article 4 – Professional standards**

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.


Chapter II – Consent

Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

Article 6 – Protection of persons not able to consent

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.
5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7 – Protection of persons who have a mental disorder
Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8 – Emergency situation
When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 – Previously expressed wishes
The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Chapter III – Private life and right to information

Article 10 – Private life and right to information
1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.
Chapter IV – Human genome

Article 11 – Non-discrimination
Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12 – Predictive genetic tests
Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13 – Interventions on the human genome
An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 14 – Non-selection of sex
The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease is to be avoided.

Chapter V – Scientific research

Article 15 – General rule
Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.
Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

i. there is no alternative of comparable effectiveness to research on humans;

ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

   i. the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;

   ii. the results of the research have the potential to produce real and direct benefit to his or her health;

   iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

   iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

   v. the person concerned does not object.
2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii. the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 – Research on embryos in vitro

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.

Chapter VI – Organ and tissue removal from living donors for transplantation purposes

Article 19 – General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.
Article 20 – Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:
   i. there is no compatible donor available who has the capacity to consent;
   ii. the recipient is a brother or sister of the donor;
   iii. the donation must have the potential to be life-saving for the recipient;
   iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;
   v. the potential donor concerned does not object.

Chapter VII – Prohibition of financial gain and disposal of a part of the human body

Article 21 – Prohibition of financial gain
The human body and its parts shall not, as such, give rise to financial gain.

Article 22 – Disposal of a removed part of the human body
When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.
Chapter VIII – Infringements of the provisions of the Convention

Article 23 – Infringement of the rights or principles
The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24 – Compensation for undue damage
The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25 – Sanctions
Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

Chapter IX – Relation between this Convention and other provisions

Article 26 – Restrictions on the exercise of the rights
1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 – Wider protection
None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a
wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

Chapter X – Public debate

Article 28 – Public debate

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

Chapter XI – Interpretation and follow-up of the Convention

Article 29 – Interpretation of the Convention

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

- the Government of a Party, after having informed the other Parties;
- the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-thirds majority of votes cast.

Article 30 – Reports on the application of the Convention

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.
Chapter XII – Protocols

Article 31 – Protocols

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying accepting or approving the Convention.

Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

1. The tasks assigned to “the Committee” in the present article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.

2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.

3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than
five years from its entry into force and thereafter at such intervals as the Committee may determine.

5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.

6. The Committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.
Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

1. This Convention shall be open for signature by the member States of the Council of Europe, the non member States which have participated in its elaboration and by the European Community.

2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present article.

4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 34 – Non member States

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, paragraph d, of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.
Article 35 – Territories

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 36 – Reservations

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2. Any reservation made under this article shall contain a brief statement of the relevant law.

3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35,
paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 37 – Denunciation

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 – Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a. any signature;

b. the deposit of any instrument of ratification, acceptance, approval or accession;

c. any date of entry into force of this Convention in accordance with Articles 33 or 34;

d. any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;

e. any declaration made under the provisions of Article 35;
f. any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;
g. any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.
Explanatory report to Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine (ETS No. 164)

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

This Explanatory Report to the Convention on human rights and biomedicine was drawn up under the responsibility of the Secretary General of the Council of Europe, on the basis of a draft prepared, at the request of the Steering Committee on Bioethics (CDBI), by Mr Jean MICHAUD (France), Chairman of the CDBI. It takes into account the discussions held in the CDBI and its Working Group entrusted with the drafting of the Convention; it also takes into account the remarks and proposals made by Delegations.

The Committee of Ministers has authorised the publication of this Explanatory Report on 17 December 1996.

The Explanatory Report is not an authoritative interpretation of the Convention. Nevertheless it covers the main issues of the preparatory
work and provides information to clarify the object and purpose of the
Convention and to better understand the scope of its provisions.

Introduction

1. For several years now, the Council of Europe, through the work
of the Parliamentary Assembly and of the ad hoc Committee
of Experts on Bioethics (CAHBI), later renamed the Steering
Committee on Bioethics (CDBI), has concerned itself with
the problems confronting mankind as a result of advances in
medicine and biology. At the same time, a number of countries
have done their own internal work on these topics, and this work
is proceeding. So far, therefore, two types of endeavour have been
undertaken, one at a national and the other at international level.

2. Basically, these studies are the fruit of observation and concern:
observation of the radical developments in science and their
applications to medicine and biology, that is fields in which people
are directly involved and concern about the ambivalent nature of
many of these advances. The scientists and practitioners behind
them have worthy aims and often attain them. But some of the
known or alleged developments of their work are taking or could
potentially take a dangerous turn, as a result of a distortion of the
original objectives. Science, with its new complexity and extensive
ramifications, thus presents a dark side or a bright side according to
how it is used.

3. It has subsequently become necessary to ensure that the beneficial
side prevails by developing awareness of what is at stake and
constantly reviewing all the possible consequences. No doubt the
ethics committees and other national bodies and legislators, as well
as the international organisations, have already applied themselves
to this task, but their efforts have remained either restricted to a
particular geographical area or incomplete because of their focus
on a particular topic. On the other hand, common values are more
often than not claimed as a basis for the various texts, opinions
and recommendations. But differences may, nonetheless, become apparent in connection with certain aspects of the problems dealt with. Even simple definitions may give rise to profound differences.

**Drafting of a Convention**

4. It has consequently become apparent that there was a need to make a greater effort to harmonise existing standards. In 1990, at their 17th Conference (Istanbul, 5-7 June 1990), the European Ministers of Justice, following the proposal of Ms Catherine Lalumière, Secretary General of the Council of Europe, adopted Resolution No. 3 on bioethics which recommended that the Committee of Ministers instruct the CAHBI to examine the possibility of preparing a framework convention "setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences". In June 1991, taking up the contents of a report submitted on behalf of the Committee of science and technology by Dr Marcelo Palacios (see Document 6449), the Parliamentary Assembly recommended, in its Recommendation 1160, that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects". In September of the same year the Committee of Ministers, chaired by Mr Vincent Tabone, instructed the CAHBI "to prepare, in close co-operation with the Steering Committee for Human Rights (CDDH) and the European Health Committee (CDSP) ... a framework Convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the biomedical sciences and Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings".

5. In March 1992 the CAHBI, then the CDBI, which has been chaired in turn by Mrs Paula KOKKONEN (Finland), Dr Octavi QUINTANA (Spain) and Mrs Johanna KITS NIEUWENKAMP
née Storm van'SGravesande (The Netherlands), set up a Working Party to prepare the draft Convention, which was chaired by Dr Michael ABRAMS (United Kingdom). Until his untimely death, Mr Salvatore PUGLISI (Italy) was a member of this Group, after having been Chair of the Study Group set up to examine the feasibility of the draft Convention.

6. In July 1994, a first version of the draft Convention was subjected to public consultation and was submitted for an opinion to the Parliamentary Assembly. Taking account of this opinion and of several other positions taken, a final draft was established by the CDBI on 7 June 1996 and was submitted to the Parliamentary Assembly for an opinion. The latter put forward Opinion No. 198 on the basis of a report submitted on behalf of the Committee on Science and Technology by Mr Gian-Reto PLATTNER and for the Committee on Legal Affairs and Human Rights and the Social, Health and Family Affairs Committee by Messrs Walter SCHWIMMER and Christian DANIEL respectively. The Convention was adopted by the Committee of Ministers on 19 November 1996. It was opened for signature on 4 April 1997.

Structure of the Convention

7. The Convention sets out only the most important principles. Additional standards and more detailed questions should be dealt with in additional protocols. The Convention as a whole will thus provide a common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine.

Comments on the provisions of the Convention

Title

8. The title of the instrument is 'Convention for the Protection of Human Rights and Dignity of the Human Being with regard to
the Application of Biology and Medicine: Convention on Human Rights and Biomedicine”.

9. The term "Human Rights" refers to the principles laid down in the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, which guarantee protection of such rights. The two Conventions share not only the same underlying approach but also many ethical principles and legal concepts. Indeed, this Convention elaborates some of the principles enshrined in the European Convention for the Protection of Human Rights. The concept of the human being has been used because of its general character. The concept of human dignity, which is also highlighted, constitutes the essential value to be upheld. It is at the basis of most of the values emphasised in the Convention.

10. The phrase “application of biology and medicine”, was preferred to "life sciences" in particular, which was considered too broad. It is used in Article 1 and restricts the scope of the Convention to human medicine and biology, thereby excluding animal and plant biology insofar as they do not concern human medicine or biology. The Convention thus covers all medical and biological applications concerning human beings, including preventive, diagnostic, therapeutic and research applications.

Preamble

11. Various international instruments already provide protection and guarantees in the field of human rights, both individual and social: the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of the Child, the Convention for the Protection of Human Rights and Fundamental Freedoms, the European Social Charter. Several instruments of a more specific nature prepared by the Council of Europe are also relevant, such as the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.
12. They must now be supplemented by other texts so that full account is taken of the potential implications of scientific actions.

13. The principles enshrined in these instruments remain the basis of our conception of human rights; hence they are set out at the beginning of the preamble to the Convention, of which they are the cornerstone.

14. Starting with the preamble, however, it was necessary to take account of the actual developments in medicine and biology, while indicating the need for them to be used solely for the benefit of present and future generations. This concern has been affirmed at three levels:

- The first is that of the individual, who had to be shielded from any threat resulting from the improper use of scientific developments. Several articles of the Convention illustrate the wish to make it clear that pride of place ought to be given to the individual: protection against unlawful interference with the human body, prohibition of the use of all or part of the body for financial gain, restriction of the use of genetic testing, etc.

- The second level relates to society. Indeed, in this particular field, to a greater extent than in many others, the individual must also be considered to constitute part of a social corpus sharing a number of ethical principles and governed by legal standards. Whenever choices are involved in regard to the application of certain developments, the latter must be recognised and endorsed by the community. This is why public debate is so important and is given a place in the Convention. Nevertheless, the interests at stake are not equal; as indicated in Article 2, they are graded to reflect the priority in principle attached to the interests of the individual as opposed to those of science or society solely. The adjective "alone" makes it clear that care must be taken not to neglect the latter; they must come immediately after the interests of the individual. It is only in very precise situations, and subject to the respect of strict conditions that the general interest, as it is defined in Article 26, would take priority.
The third and final concern relates to the human species. Many of the current achievements and forthcoming advances are based on genetics. Progress in knowledge of the genome is producing more ways of influencing and acting on it. This knowledge already enables considerable progress to take place in the diagnosis and, sometimes, in the prevention of an increasing number of diseases. There are reasons to hope that it could also enable therapeutic progress to take place. However, the risks associated with this growing area of expertise should not be ignored. It is no longer the individual or society that may be at risk but the human species itself. The Convention sets up safeguards, starting with the preamble where reference is made to the benefits to future generations and to all humanity, while provision is made throughout the text for the necessary legal guarantees to protect the identity of the human being.

15. The preamble refers to the developments in medicine and biology which should be used only for the benefit of present and future generations and not be diverted in ways that run counter to their proper objective. It proclaims the respect due to man as an individual and as a member of the human species. It concludes that progress, human benefit and protection can be reconciled if public awareness is aroused as a result of an international instrument devised by the Council of Europe in line with its vocation. Stress is laid on the need for international co-operation to extend the benefits of progress to the whole of mankind.
Article 1 – Purpose and object

16. This article defines the Convention's scope and purpose.

17. The aim of the Convention is to guarantee everyone's rights and fundamental freedoms and, in particular, their integrity and to secure the dignity and identity of human beings in this sphere.

18. The Convention does not define the term "everyone" (in French "toute personne"). These two terms are equivalent and found in the English and French versions of the European Convention on Human Rights, which however does not define them. In the absence of a unanimous agreement on the definition of these terms among member States of the Council of Europe, it was decided to allow domestic law to define them for the purposes of the application of the present Convention.

19. The Convention also uses the expression "human being" to state the necessity to protect the dignity and identity of all human beings. It was acknowledged that it was a generally accepted principle that human dignity and the identity of the human being had to be respected as soon as life began.

20. The second paragraph of the Article specifies that each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention. This paragraph indicates that the internal law of the Parties shall conform to the Convention. Conformity between the Convention and domestic law may be achieved either by applying directly the Convention's provisions in domestic law or by enacting the necessary legislation to give effect to them. With regard to each provision, the means will have to be determined by each Party in accordance with its constitutional law and taking into account the nature of the provision in question. In this respect, it should be noted that the Convention contains a
number of provisions which may, under the domestic law of many States, qualify as directly applicable ("self-executing provisions"). This is the case, particularly, of the provisions formulating individual rights. Other provisions contain more general principles which may require the enactment of legislation in order that effect be given to them in domestic law.

**Article 2 – Primacy of the human being**

21. This article affirms the primacy of the human being over the sole interest of science or society. Priority is given to the former, which must in principle take precedence over the latter in the event of a conflict between them. One of the important fields of application of this principle concerns research, as covered by the provisions of Chapter V of this Convention.

22. The whole Convention, the aim of which is to protect human rights and dignity, is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light.

**Article 3 – Equitable access to health care**

23. This article defines an aim and imposes an obligation on States to use their best endeavours to reach it.

24. The aim is to ensure equitable access to health care in accordance with the person’s medical needs. "Health care" means the services offering diagnostic, preventive, therapeutic and rehabilitative interventions, designed to maintain or improve a person’s state of health or alleviate a person’s suffering. This care must be of a fitting standard in the light of scientific progress and be subject to a continuous quality assessment.

25. Access to health care must be equitable. In this context, "equitable" means first and foremost the absence of unjustified discrimination. Although not synonymous with absolute equality, equitable access implies effectively obtaining a satisfactory degree of care.
26. The Parties to the Convention are required to take appropriate steps to achieve this aim as far as the available resources permit. The purpose of this provision is not to create an individual right on which each person may rely in legal proceedings against the State, but rather to prompt the latter to adopt the requisite measures as part of its social policy in order to ensure equitable access to health care.

27. Although States are now making substantial efforts to ensure a satisfactory level of health care, the scale of this effort largely depends on the volume of available resources. Moreover, State measures to ensure equitable access may take many different forms and a wide variety of methods may be employed to this end.

**Article 4 – Professional standards**

28. This article applies to doctors and health care professionals generally, including psychologists whose interactions with patients in clinical and research settings can have profound effects and social workers who are members of teams involved in the decision making process or in the carrying out of interventions. From the term "professional standards" it follows that it does not concern persons other than health care professionals called upon to perform medical acts, for example in an emergency.

29. The term "intervention" must be understood here in a broad sense; it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment or rehabilitation or in a research context.

30. All interventions must be performed in accordance with the law in general, as supplemented and developed by professional rules. In some countries these rules take the form of professional codes of ethics (drawn up by the State or by the profession), in others codes of medical conduct, health legislation, medical ethics or any other means of guaranteeing the rights and interests of the patient, and which may take account of any right of conscientious objection by health care professionals. The Article covers both written and
unwritten rules. When there is a contradiction between different rules, the law provides the means of resolving the conflict.

31. The content of professional standards, obligations and rules of conduct is not identical in all countries. The same medical duties may vary slightly from one society to another. However, the fundamental principles of the practice of medicine apply in all countries. Doctors and, in general, all professionals who participate in a medical act are subject to legal and ethical imperatives. They must act with care and competence, and pay careful attention to the needs of each patient.

32. It is the essential task of the doctor not only to heal patients but also to take the proper steps to promote health and relieve pain, taking into account the psychological well-being of the patient. Competence must be determined primarily in relation to the scientific knowledge and clinical experience appropriate to a profession or speciality at a given time. The current state of the art determines the professional standard and skill to be expected of health care professionals in the performance of their work. In following the progress of medicine, it changes with new developments and eliminates methods which do not reflect the state of the art. Nevertheless, it is accepted that professional standards do not necessarily prescribe one line of action as being the only one possible: recognised medical practice may, indeed, allow several possible forms of intervention, thus leaving some freedom of choice as to methods or techniques.

33. Further, a particular course of action must be judged in the light of the specific health problem raised by a given patient. In particular, an intervention must meet criteria of relevance and proportionality between the aim pursued and the means employed. Another important factor in the success of medical treatment is the patient's confidence in his or her doctor. This confidence also determines the duties of the doctor towards the patient. An important element of these duties is the respect of the rights of the patient. The latter creates and increases mutual trust. The therapeutic alliance will be strengthened if the rights of the patient are fully respected.
Chapter II – Consent

Article 5 – General rule

34. This article deals with consent and affirms at the international level an already well-established rule, that is that no one may in principle be forced to undergo an intervention without his or her consent. Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person. This rule makes clear patients’ autonomy in their relationship with health care professionals and restrains the paternalist approaches which might ignore the wish of the patient. The word “intervention” is understood in its widest sense, as in Article 4 – that is to say, it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research.

35. The patient’s consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone. Article 5, paragraph 2, mentions the most important aspects of the information which should precede the intervention but it is not an exhaustive list: informed consent may imply, according to the circumstances, additional elements. In order for their consent to be valid the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. This information must include the purpose, nature and consequences of the intervention and the risks involved. Information on the risks involved in the intervention or in alternative courses of action must cover not only the risks inherent in the type of intervention contemplated, but also any risks related to the individual characteristics of each patient, such as age or the existence of other
pathologies. Requests for additional information made by patients must be adequately answered.

36. Moreover, this information must be sufficiently clear and suitably worded for the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause.

37. Consent may take various forms. It may be express or implied. Express consent may be either verbal or written. Article 5, which is general and covers very different situations, does not require any particular form. The latter will largely depend on the nature of the intervention. It is agreed that express consent would be inappropriate as regards many routine medical acts. The consent is therefore often implicit, as long as the person concerned is sufficiently informed. In some cases, however, for example invasive diagnostic acts or treatments, express consent may be required. Moreover, the patient’s express, specific consent must be obtained for participation in research or removal of body parts for transplantation purposes (see Articles 16 and 19).

38. Freedom of consent implies that consent may be withdrawn at any time and that the decision of the person concerned shall be respected once he or she has been fully informed of the consequences. However, this principle does not mean, for example, that the withdrawal of a patient’s consent during an operation should always be followed. Professional standards and obligations as well as rules of conduct which apply in such cases under Article 4 may oblige the doctor to continue with the operation so as to avoid seriously endangering the health of the patient.

39. Furthermore, Article 26 of the Convention, as well as Article 6 concerning protection of persons not able to consent, Article 7 concerning protection of persons who have mental disorders and Article 8 concerning emergency situations, define the instances in which the exercise of the rights contained in the Convention and hence the need for consent may be limited.
40. Information is the patient's right, but as provided for in Article 10, the patient's possible wish not to be informed must be observed. This does not, however, obviate the need to seek consent to the intervention proposed to the patient.

**Article 6 – Protection of persons not able to consent**

41. Some individuals may not be able to give full and valid consent to an intervention due to either their age (minors) or their mental incapacity. It is therefore necessary to specify the conditions under which an intervention may be carried out on these people in order to ensure their protection.

42. The incapacity to consent referred to in this article must be understood in the context of a given intervention. However, account has been taken of the diversity of legal systems in Europe: in some countries the patient's capacity to consent must be verified for each intervention taken individually, while in others the system is based on the institution of legal incapacitation, whereby a person may be declared incapable of consenting to one or several types of act. Since the purpose of the Convention is not to introduce a single system for the whole of Europe but to protect persons who are not able to give their consent, the reference in the text to domestic law seems necessary: it is for domestic law in each country to determine, in its own way, whether or not persons are capable of consenting to an intervention and taking account of the need to deprive persons of their capacity for autonomy only where it is necessary in their best interests.

43. However, in order to protect the fundamental rights of the human being, and in particular to avoid the application of discriminatory criteria, paragraph 3 lists the reasons why an adult may be considered incapable of consenting under domestic law, namely a mental disability, a disease or similar reasons. The term "similar reasons" refers to such situations as accidents or states of coma, for example, where the patient is unable to formulate his or her wishes or to communicate them (see also paragraph 57 below on
emergency situations). If adults have been declared incapable but at a certain time do not suffer from a reduced mental capacity (for example because their illness improves favourably), they must, according to Article 5, themselves consent.

44. Whenever a person is acknowledged to be incapable of giving consent, the Convention establishes the principle of protection whereby, according to paragraph 1, the intervention must be for the direct benefit of the person. Deviation from this rule is possible in only two cases, covered by Articles 17 and 20 of the Convention, on medical research and the removal of regenerative tissue respectively.

45. As indicated before, the second and third paragraphs prescribe that when a minor (paragraph 2) or an adult (paragraph 3) is not capable of consenting to an intervention, the intervention may be carried out only with the consent of parents who have custody of the minor, his or her legal representative or any person or body provided for by law. However, as far as possible, with a view to the preservation of the autonomy of persons with regard to interventions affecting their health, the second part of paragraph 2 states that the opinion of minors should be regarded as an increasingly determining factor in proportion to their age and capacity for discernment. This means that in certain situations which take account of the nature and seriousness of the intervention as well as the minor’s age and ability to understand, the minor’s opinion should increasingly carry more weight in the final decision. This could even lead to the conclusion that the consent of a minor should be necessary, or at least sufficient for some interventions. Note that the provision of the second sub-paragraph of paragraph 2 is consistent with Article 12 of the United Nations Convention on the Rights of the Child, which stipulates that “States Parties shall assure the child, who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child”.

46. Furthermore, the participation of adults not able to consent in decisions must not be totally ruled out. This idea is reflected in
the obligation to involve the adult in the authorisation procedure whenever possible. Thus, it will be necessary to explain to them the significance and circumstances of the intervention and then obtain their opinion.

47. Paragraph 4 of this article draws a parallel with Article 5 concerning consent in general, stating that the person or body whose authorisation is required for the intervention to take place must be given adequate information about the consequences and risks involved.

48. According to paragraph 5, the person or body concerned may withdraw their authorisation at any time, provided that this is done in the interest of the person not able to consent. The first duty of doctors or other health care professionals is to their patient and it is also part of the professional standard (Article 4) to act in the interest of the patient. It is, in fact, a duty of the doctor to protect the patient against decisions taken by a person or body whose authorisation is required, which are not in the interest of the patient; in this respect, national law should provide adequate recourse procedures. The subordination of consent (or its withdrawal) to the interest of the patient is in keeping with the objective of protecting the person. While a person capable of giving consent to an intervention has the right to withdraw that consent freely, even if this appears to be contrary to the person’s interest, the same right must not apply to an authorisation given for an intervention on another person, which should be retractable only if this is in the interest of that third party person.

49. It was not considered necessary to provide in this article for a right of appeal against the decision of the legal representative to authorise or refuse to authorise an intervention. In the very terms of paragraphs 2 and 3 of this article, the intervention may be carried out only “with the authorisation of his or her representative or an authority or a person or body provided for by law”, which in itself implies the possibility of appealing to a body or authority in the manner provided for in domestic law.
Article 7 – Protection of persons who have mental disorder

50. This article deals with the specific question of the treatment of patients suffering from mental disorders. On the one hand it constitutes an exception to the general rule of consent for persons able to consent (Article 5), but whose ability to decide on a proposed treatment is severely impaired by their very mental disorder. On the other hand, it guarantees the protection of these people by limiting the number of instances in which they may be subjected to treatment for their mental disorders without their consent, by subjecting such interventions to specific conditions. Moreover, this Article does not provide for the specific emergency situations mentioned in Article 8.

51. The first condition is that the person must be suffering from a mental disorder (trouble mental in French). In order for the article to apply, an impairment of the person’s mental faculties must be observed.

52. The second condition is that the intervention is necessary to treat specifically these mental disorders. For every other type of intervention, the practitioner must therefore seek the consent of the patient, insofar as this is possible, and the assent or refusal of the patient must be followed. The refusal to consent to an intervention may only be disregarded under those circumstances prescribed by law and where a failure to intervene would result in serious harm to the health of the individual (or to the health and safety of others). In other words, if persons capable of consent refuse an intervention not aimed at treating their mental disorder, their opposition must be respected in the same way as for other patients capable of consent.

53. A number of member States have laws about the treatment of patients with mental illness of a serious nature who either are compulsorily detained or have a life-threatening medical emergency. They permit intervention for certain serious situations,
such as the treatment of a serious somatic illness in a psychotic patient or also for certain serious medical emergencies (for example acute appendicitis, an overdose of medication or the case of a woman with a severe psychotic illness who has a ruptured ectopic pregnancy). In such cases the legislation permits a life-saving treatment, so long as the physician concerned believes it is proper to do so. The procedure is covered by Article 6 (Protection of persons not able to consent) or Article 8 (Emergency situations).

54. The third condition is that, without treatment of his or her mental disorder, serious harm is likely to result to the person’s health. Such a risk exists, for example, when a person suffers from a suicidal tendency and is therefore a danger to himself or herself. The article is concerned only with the risk to the patient’s own health, whereas Article 26 of the Convention permits patients to be treated against their will in order to protect other people’s rights and freedoms (for example, in the event of violent behaviour). On the one hand, therefore, the article protects the person’s health (in so far as treatment of the mental disorder without consent is allowed when failure to administer the treatment would seriously harm the person’s health), and on the other hand it protects their autonomy (since treatment without consent is prohibited when failure to administer the treatment represents no serious risk to the person’s health).

55. The last condition is that the protective conditions laid down in national law must be observed. The article specifies that these conditions must include appropriate supervisory, control and appeal procedures, such as mediation by a judicial authority. This requirement is understandable in view of the fact that it will be possible for an intervention to be carried out on a person who has not consented to it; it is therefore necessary to provide an arrangement for adequately protecting the rights of that person. In this connection, Recommendation No. R (83) 2 of the Committee of Ministers of the Council of Europe concerning the legal protection of persons suffering from mental disorder placed as involuntary patients establishes a number of principles which must be

**Article 8 – Emergency situations**

56. In emergencies, doctors may be faced with a conflict of duties between their obligations to provide care and seek the patient’s consent. This article allows the practitioner to act immediately in such situations without waiting until the consent of the patient or the authorisation of the legal representative where appropriate can be given. As it departs from the general rule laid down in Articles 5 and 6, it is accompanied by conditions.

57. First, this possibility is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent. The article applies both to persons who are capable and to persons who are unable either de jure or de facto to give consent. An example that might be put forward is that of a patient in a coma who is thus unable to give his consent (see also paragraph 43 above), or that of a doctor who is unable to contact an incapacitated person’s legal representative who would normally have to authorise an urgent intervention. Even in emergency situations, however, health care professionals must make every reasonable effort to determine what the patient would want.

58. Next, the possibility is limited solely to medically necessary interventions which can not be delayed. Interventions for which a delay is acceptable are excluded. However, this possibility is not reserved for life-saving interventions.

59. Lastly, the article specifies that the intervention must be carried out for the immediate benefit of the individual concerned.
Article 9 – Previously expressed wishes

60. Whereas Article 8 obviates the need for consent in emergencies, this article is designed to cover cases where persons capable of understanding have previously expressed their consent (that is either assent or refusal) with regard to foreseeable situations where they would not be in a position to express an opinion about the intervention.

61. The article therefore covers not only the emergencies referred to in Article 8 but also situations where individuals have foreseen that they might be unable to give their valid consent, for example in the event of a progressive disease such as senile dementia.

62. The article lays down that when persons have previously expressed their wishes, these shall be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient’s opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progress in medicine.
Chapter III – Private life and right to information

Article 10 – Private life and right to information

63. The first paragraph establishes the right to privacy of information in the health field, thereby reaffirming the principle introduced in Article 8 of the European Convention on Human Rights and reiterated in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. It should be pointed out that, under Article 6 of the latter Convention, personal data concerning health constitute a special category of data and are as such subject to special rules.

64. However, certain restrictions to the respect of privacy are possible for one of the reasons and under the conditions provided for in under Article 26.1. For example, a judicial authority may order that a test be carried out in order to identify the author of a crime (exception based on the prevention of a crime) or to determine the filiation link (exception based on the protection of the rights of others).

65. The first sentence of the second paragraph lays down that individuals are entitled to know any information collected about their health, if they wish to know. This right is of fundamental importance in itself but also conditions the effective exercise of other rights such as the right of consent set forth in Article 5.

66. A person’s "right to know" encompasses all information collected about his or her health, whether it be a diagnosis, prognosis or any other relevant fact.

67. The right to know goes hand in hand with the "right not to know", which is provided for in the second sentence of the second paragraph. Patients may have their own reasons for not wishing to know about certain aspects of their health. A wish of this kind must
be observed. The patient’s exercise of the right not to know this or that fact concerning his health is not regarded as an impediment to the validity of his consent to an intervention; for example, he can validly consent to the removal of a cyst despite not wishing to know its nature.

68. In some circumstances, the right to know or not to know may be restricted in the patient’s own interest or else on the basis of Article 26.1, for example, in order to protect the rights of a third party or of society.

69. Therefore, the last paragraph of Article 10 sets out that in exceptional cases domestic law may place restrictions on the right to know or not to know in the interests of the patient’s health (for example a prognosis of death which might, in certain cases if immediately passed on to the patient, seriously worsen his or her condition). In some cases, the doctor’s duty to provide information which is also covered under Article 4 conflicts with the interests of the patient’s health. It is for domestic law, taking account of the social and cultural background, to solve this conflict. Where appropriate under judicial control, domestic law may justify the doctor sometimes withholding part of the information or, at all events, disclosing it with circumspection (“therapeutic necessity”).

70. Furthermore, it may be of vital importance for patients to know certain facts about their health, even though they have expressed the wish not to know them. For example, the knowledge that they have a predisposition to a disease might be the only way to enable them to take potentially effective (preventive) measures. In this case, a doctor’s duty to provide care, as laid down in Article 4, might conflict with the patient’s right not to know. It could also be appropriate to inform an individual that he or she has a particular condition when there is a risk not only to that person but also to others. Here too it will be for domestic law to indicate whether the doctor, in the light of the circumstances of the particular case, may make an exception to the right not to know. At the same time, certain facts concerning the health of a person who has expressed a wish not to be told about them may be of special interest to a
third party, as in the case of a disease or a particular condition transmissible to others, for example. In such a case, the possibility for prevention of the risk to the third party might, on the basis of Article 26, warrant his or her right taking precedence over the patient’s right to privacy, as laid down in paragraph 1, and as a result the right not to know, as laid down in paragraph 2. In any case, the right not to know of the person concerned may be opposed to the interest to be informed of another person and the interests of these two persons should be balanced by internal law.
71. Genetic science has undergone dramatic changes in recent years. In human medicine, apart from the pharmaceutical field, there are other areas in which it can be applied, namely: genetic testing, gene therapy and the scientific elucidation of disease causes and mechanisms.

72. Genetic testing consists of medical examinations aimed at detecting or ruling out the presence of hereditary illnesses or predisposition to such illnesses in a person by directly or indirectly analysing their genetic heritage (chromosomes, genes).

73. The aim of gene therapy is to correct changes to the human genetic heritage which may result in hereditary diseases. The difference between gene therapy and the analysis of the genome lies in the fact that the latter does not modify the genetic heritage but simply studies its structure and its relationship with the symptoms of the illness. In theory, there are two distinct forms of gene therapy. Somatic gene therapy aims to correct the genetic defects in the somatic cells and to produce an effect restricted to the person treated. Were it possible to undertake gene therapy on germ cells, the disease of the person who has provided the cells would not be cured, as the correction would be carried out on the cells whose sole function is to transmit genetic information to future generations.

**Article 11 – Non-discrimination**

74. The mapping out of the human genome, which is advancing rapidly, as well as the development of the genetic tests which are linked with it are likely to bring substantial advances in the prevention of illnesses and the administration of treatment. But genetic testing also raises considerable concerns. Among these the most widespread is probably the concern that genetic testing, which
can detect a genetic disease, a predisposition or a susceptibility to a genetic disease, may become a means of selection and discrimination.

75. The fundamental principle established in Article 11 is that any form of discrimination against an individual on grounds of his or her genetic heritage is prohibited.

76. Under Article 14 of the European Convention on Human Rights, the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status. Article 11 adds to this list a person’s genetic heritage. The prohibition of discrimination set out thus applies to all areas included in the field of application of this Convention. This notion also includes non-discrimination on grounds of race as understood by the 1965 United Nations Convention on the Elimination of all Forms of Racial Discrimination and as it has been interpreted by the Convention Committee (CERD).

77. Whereas the term "discrimination" has usually a negative connotation in French, this is not necessarily the case in English (where one must use the expression "unfair discrimination"); it has, however, been decided to keep the same term in both languages, as it is in the European Convention of Human Rights and in the case law of the Court. Discrimination here must, therefore, in French as in English, be understood as unfair discrimination. In particular, it cannot prohibit positive measures which may be implemented with the aim of re-establishing a certain balance in favour of those at a disadvantage because of their genetic inheritance.

**Article 12 – Predictive genetic tests**

78. Progress in the study of human genetics has occurred at a remarkable rate over the course of the last ten years. Developments in the field now make it possible to identify with much greater
precision than ever before those who carry specific genes for major single gene disorders (for example cystic fibrosis, haemophilia, Huntington’s disease, retinitis pigmentosa etc) and also those who carry genes which may increase their risk of developing major disorders later in life (for example heart disease, cancer and Alzheimer’s disease). It has been possible to identify those who were destined or likely to develop certain single gene disorders on the basis of a clear mendelian pattern of inheritance or through the identification of phenotypic characteristics (either through clinical observation or through standard laboratory biochemical tests) which permit action to be taken to prevent the onset of clinical disease. Advances in genetics have led to much more sophisticated and precise techniques for testing for some disorders. However, the identification of a particular abnormal gene does not necessarily imply that the carrier will develop the disease nor does it predict the pattern or severity of the disease.

79. Modern techniques have also made it possible to identify genes which contribute to the development of major disorders later in life – and to which other genes and environmental and lifestyle factors also made a contribution. It has also been possible to identify some of these genetically determined risk factors in the past through the identification of phenotypic characteristics. The probability of individuals developing the disease later in life is, however, much less certain than in the case of the single gene disorders, since the probability of doing so depends upon factors which are outside individuals’ control (for example other genetic characteristics) as well as factors which may be modified by individuals in ways which will alter the risk (for example diet, smoking, lifestyle factors etc).

80. Tests which are predictive of certain genetic diseases may offer considerable benefits to an individual’s health by allowing timely preventive treatment to be instituted or by offering opportunities to diminish the risks through modifications in behaviour, lifestyle or environment. This, however, is not possible at present in many genetically determined disorders. The right to know as well as the right not to know and proper informed consent are, therefore, of
particular importance in this field since problems may clearly arise for the individual resulting from tests predictive of genetic disease for which there is currently no effective treatment.

A further complicating factor is that tests predictive of genetically determined diseases may also have implications for members of the family and the offspring of the person who has undergone testing. It is essential that appropriate professional standards are developed in this field.

81. The situation is even more complicated with predictive testing for serious late onset diseases, when there is at present no treatment available. Screening for serious late onset diseases should remain exceptional, even when screening is related to scientific research: it would put too much strain on the free participation and on the privacy of individuals.

82. Because of the particular problems which are related to predictive testing, it is necessary to strictly limit its applicability to health purposes for the individual. Scientific research likewise should be carried out in the context of developing medical treatment and enhancing our ability to prevent disease.

83. Article 12 as such does not imply any limitation of the right to carry out diagnostic interventions at the embryonic stage to find out whether an embryo carries hereditary traits that will lead to serious diseases in the future child.

84. Because there is an apparent risk that use is made of genetic testing possibilities outside health care (for instance in the case of medical examination prior to an employment or insurance contract), it is of importance to clearly distinguish between health care purposes for the benefit of the individual on the one hand and third parties’ interests, which may be commercial, on the other hand.

85. Article 12 prohibits the carrying out of predictive tests for reasons other than health or health-related research, even with the assent of the person concerned. Therefore, it is forbidden to do predictive genetic testing as part of pre-employment medical examinations, whenever it does not serve a health purpose of the individual.
This means that in particular circumstances, when the working environment could have prejudicial consequences on the health of an individual because of a genetic predisposition, predictive genetic testing may be offered without prejudice to the aim of improving working conditions. The test should be clearly used in the interest of the individual's health. The right not to know should also be respected.

86. Insofar as predictive genetic testing, in the case of employment or private insurance contracts, does not have a health purpose, it entails a disproportionate interference in the rights of the individual to privacy. An insurance company will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will it be able to refuse the conclusion or modification of such a policy on the ground that the applicant has not submitted to a test, as the conclusion of a policy cannot reasonably be made conditional on the performance of an illegal act.

87. However, national law may allow for the performance of a test predictive of a genetic disease outside the health field for one of the reasons and under the conditions provided for in Article 26.1 of the Convention.

88. According to Article 5, a genetic test may only be carried out after the person concerned has given free and informed consent. Article 12 adds a supplementary condition which is that predictive tests must be accompanied by appropriate genetic counselling.

Article 13 – Interventions on the human genome

89. The progress of science, in particular in knowledge of the human genome and its application, has raised very positive perspectives, but also questions and even great fears. Whilst developments in this field may lead to great benefit for humanity, misuse of these developments may endanger not only the individual but the species itself. The ultimate fear is of intentional modification of the human genome so as to produce individuals or entire groups endowed with
particular characteristics and required qualities. In Article 13, the Convention provides the answer to these fears in several ways.

90. In every case, any intervention which aims to modify the human genome must be carried out for preventive, diagnostic or therapeutic purposes. Interventions aimed at modifying genetic characteristics not related to a disease or to an ailment are prohibited. As long as somatic cell gene therapy is currently at the research stage, its application can be allowed only if it complies with the standards of protection provided for in Article 15 and the following Articles.

91. Interventions seeking to introduce any modification in the genome of any descendants are prohibited. Consequently, in particular genetic modifications of spermatozoa or ova for fertilisation are not allowed. Medical research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation is only permissible if carried out in vitro with the approval of the appropriate ethical or regulatory body.

92. On the other hand the article does not rule out interventions for a somatic purpose which might have unwanted side-effects on the germ cell line. Such may be the case, for example, for certain treatments of cancer by radiotherapy or chemotherapy, which may affect the reproductive system of the person undergoing the treatment.

**Article 14 – Non-selection of sex**

93. Medically-assisted procreation includes artificial insemination, in vitro fertilisation and any technique having the same effect which permits procreation beyond the natural process. According to this Article, it is not permissible to use a technique of medically-assisted procreation in order to choose a future child’s sex, except where serious hereditary sex-related disease is to be avoided.

94. It is for internal law to determine, according to the procedures applied in each state, the seriousness of a hereditary sex-related disease. In some countries, guidelines are laid down by political or
administrative authorities or by national ethics committees, ad hoc committees, professional bodies, etc. In every case, appropriate genetic counselling of the persons concerned is necessary.
Chapter V – Scientific research

Article 15 – General rule

95. Freedom of scientific research in the field of biology and medicine is justified not only by humanity’s right to knowledge, but also by the considerable progress its results may bring in terms of the health and well-being of patients.

96. Nevertheless, such freedom is not absolute. In medical research it is limited by the fundamental rights of individuals expressed, in particular, by the provisions of the Convention and by other legal provisions which protect the human being. In this connection, it should be pointed out that the first Article of the Convention specifies that its aim is to protect the dignity and identity of human being and guarantee to everyone, without discrimination, respect for their integrity as well as for other rights and fundamental freedoms. Any research will therefore have to observe these principles.

Article 16 – Protection of persons undergoing research

97. This Article lays down the conditions for all research on human beings. These conditions were largely inspired by Recommendation No. R (90) 3 of the Committee of Ministers to member States on medical research on the human being.

98. The first condition is that there must be no alternative of comparable effectiveness to research on humans. Consequently, research will not be allowed if comparable results can be obtained by other means. Invasive methods will not be authorised if other less invasive or non-invasive methods can be used with comparable effect.

99. The second condition is that the risks which may be incurred by that person are not disproportionate to the potential benefits of the research.
Blood and blood components

100. The third condition is the need for an independent examination of the scientific merit as well as of the ethical, including legal, social and economic acceptability of the research project. The examination of the latter aspects have to be carried out by independent multi-disciplinary ethics committees.

101. Paragraph iv underlines the obligation to inform the person in advance of their legal rights and guarantees, for example their right to freely withdraw their consent at any time.

102. Paragraph v reinforces conditions set forth in Article 5 concerning consent. In the sphere of research, implicit consent is insufficient. For this reason the Article requires not only the person's free and informed consent, but their express, specific and written consent. The words "specific consent" are to be understood here as meaning consent which is given to one particular intervention carried out in the framework of research.

**Article 17 – Protection of persons not able to consent to research**

**Paragraph 1**

103. In its first paragraph this Article establishes a principle with regard to research on a person who is not able to consent: the research must be potentially beneficial to the health of the person concerned. The benefit must be real and follow from the potential results of the research, and the risk must not be disproportionate to the potential benefit.

104. Moreover, to allow such research, there should be no alternative subject with full capacity. It is not sufficient that there should be no capable volunteers. Recourse to research on persons not able to consent must be, scientifically, the sole possibility. This will apply, for instance, to research aimed at improving the understanding of development in children or improving the understanding of diseases affecting these people specifically, such as infant diseases or certain psychiatric disorders such as dementia in adults. Such
research can only be carried out, respectively, on children or the adults concerned.

105. Protection of the person not able to consent is also strengthened by the requirement that the necessary authorisation as provided for under Article 6 be given specifically and in writing. It is also stipulated that such authorisation may be freely withdrawn at any time.

106. The research must not be carried out if the person concerned objects. In the case of infants or very young children, it is necessary to evaluate their attitude taking account of their age and maturity. The rule prohibiting the carrying out of the research against the wish of the subject reflects concern, in research, for the autonomy and dignity of the person in all circumstances, even if the person is considered legally incapable of giving consent. This provision is also a means of guaranteeing that the burden of the research is acceptable to the person at all times.

**Paragraph 2**

107. Under the protective conditions prescribed by domestic law, paragraph 2 provides, exceptionally, for the possibility of waiving the direct benefit rule on certain very strict conditions. Were such research to be banned altogether, progress in the battles to maintain and improve health and to combat diseases only afflicting children, mentally disabled persons or persons suffering from senile dementia would become impossible. The group of people concerned may in the end benefit from this kind of research.

108. As well as the general conditions of research on persons not able to consent, a certain number of supplementary conditions must be fulfilled. In this way the Convention enables these people to enjoy the benefits of science in the fight against disease, while guaranteeing the individual protection of the person who undergoes the research. The required conditions imply that:

- in order to obtain the necessary results for the patient group concerned, there is neither an alternative method of comparable
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effectiveness to research on humans, nor research of comparable effectiveness on individuals capable of giving informed consent;

- the research has the aim of contributing to the ultimate attainment of results capable of conferring a benefit to the person concerned or to other persons in the same age category, or afflicted with the same disease or disorder or having the same condition, through significant improvements in the scientific understanding of the individual’s conditions, disease or disorder;

- the research entails only minimal risk and minimal burden for the individual concerned (for example blood sampling – see paragraphs 111 and 113 below);

- the research project not only has scientific merit but is also ethically and legally acceptable and has been given prior approval by the competent bodies;

- the person’s representative or an authority or a person or body provided for by law has given authorisation (adequate representation of the interests of the patient);

- the person concerned does not object (the wish of the person concerned prevails and is always decisive);

- authorisation for this research may be withdrawn at any time throughout a research project.

109. One of the first supplementary conditions is that this research should be likely to significantly improve the scientific understanding of a person’s health condition, disease or disorder and obtain, in the end, results benefitting the health of the person undergoing research or the health of persons in the same category. This means, for example, that a minor may participate in research on an ailment from which he or she suffers even if the minor would not benefit by the results of the research, provided that the research might be of significant benefit to other children suffering from the same disease. In the case of healthy minors undergoing research it is obvious that the result of the research might be of
benefit only to other children. In cases where healthy minors participate in research, clearly it is to obtain results of benefit to other children; however such research may well be of ultimate benefit to healthy children taking part in this research.

110. The research on "the individual's condition" might cover, with regard to research on children, not only diseases or abnormalities peculiar to childhood or certain aspects of common diseases that are specific to childhood, but also the normal development of the child where knowledge is necessary for the understanding of these diseases or abnormalities.

111. While Article 16.ii restricts research in general by establishing a criterion of risk/benefit proportionality, Article 17 lays down a more stringent requirement for research without direct benefit to persons incapable of giving consent, namely only minimal risk and minimal burden for the individual concerned. Indeed, it is only in respecting these conditions that such research may be carried out without constituting an instrumentalisation of these persons contrary to their dignity. For example, taking a single blood sample from a child would generally only present a minimal risk, and might therefore be regarded as acceptable.

112. Diagnostic and therapeutic progress for the benefit of sick children depends to a large extent on new knowledge and insight regarding the normal biology of the human organism and calls for research on the age-related functions and development of normal children before it can be applied in the treatment of sick children. Moreover, paediatric research concerns not only the diagnosis and treatment of serious pathological conditions but also the maintenance and improvement of the state of health of children who are not ill, or who are only slightly ill. In this connection mention should be made of prophylaxis through vaccination or immunisation, dietary measures or preventive treatments whose effectiveness, especially in terms of costs and possible risks, urgently requires evaluation by means of scientifically controlled studies. Any restriction based on the requirement of "potential
direct benefit” for the person undergoing the test would make such studies impossible in the future.

113. As examples, the following fields of research can be mentioned, provided all conditions outlined above are met (including the condition that it is impossible to obtain the same results through research carried out on capable persons and the condition of minimal risk and minimal burden):

– in respect of children: replacing X-ray examinations or invasive diagnostic measures for children by ultrasonic scanning; analyses of incidental blood samples from newborn infants without respiratory problems in order to establish the necessary oxygen content for premature infants; discovering the causes and improving treatment of leukaemia in children (for example by taking a blood sample);

– in respect of adults not able to consent: research on patients in intensive care or in a coma to improve the understanding of the causes of coma or the treatment in intensive care.

114. The above-mentioned examples of medical research cannot be described as routine treatment. They are in principle without direct therapeutic benefit for the patient. However, they may be ethically acceptable if the above highly protective conditions, resulting from the combined effect of Articles 6, 7, 16 and 17, are fulfilled.

**Article 18 – Research on embryos in vitro**

115. The first paragraph of Article 18 stresses the necessity to protect the embryo in the framework of research: where national law allows research on embryos *in vitro* the law must ensure adequate protection of the embryo.

116. The article does not take a stand on the admissibility of the principle of research on *in vitro* embryos. However, paragraph 2 of the Article prohibits the creation of human embryos with the aim to carry out research on them.
Chapter VI – Organ and tissue removal from living donors for transplantation purposes

Article 19 – General rule

117. Organ transplants are current medical techniques helping to save, prolong or greatly facilitate the lives of persons suffering from certain serious disorders. The purpose of this chapter is to establish a framework to protect living donors in the context of organ (in particular liver, kidney, lung, pancreas) or tissue removal (for instance, skin). The provisions in this chapter do not apply to blood transfusions.

118. According to the first principle of the text, organs or tissues should be removed from deceased donors rather than from living donors whenever possible.

Removing organs or tissue from living donors always represents a risk for the donors, if only because of the anaesthesia they sometimes have to undergo. This implies that organs from living persons should not be used where an appropriate organ from a deceased person is available.

119. The second condition in the case of living donors is that there exists no alternative therapeutic method of comparable effectiveness. In view of the risk involved in any organ removal, there is no justification for resorting to this if there is another way of bringing the same benefit to the recipient. The transplant must therefore be necessary in the sense that there is no other solution that would produce similar results, such as "conventional" treatment, or tissues of animal origin, cultured tissues or tissues transplanted from the recipient. In this respect dialysis treatment is not considered to provide results in terms of the patient's quality of life comparable with those obtained by a kidney transplant.
120. In order for an organ to be removed, the express and specific consent of the donor must be given, in accordance with Article 5 of the Convention. Moreover, Article 19, paragraph 2, stipulates that this consent must be specific and given in written form or before an official body, making the conditions set forth in Article 5 more stringent for this particular type of intervention. The official body concerned could be a court or a notary, for example.

121. The removal of organs may only be carried out for the therapeutic benefit of the recipient where the need was known before the removal. Tissue, for its part, can be stored in tissue banks for future needs (it should be stressed that this concerns, in most cases, unused tissue — for example tissue removed after an intervention — see Article 22); in this case the provisions of Recommendation No. R (94) 1 of the Committee of Ministers to the member States on human tissue banks are applicable.

**Article 20 – Protection of persons not able to consent to organ removal**

122. Article 20 deals specifically with the question of the removal of organs or tissue from persons incapable of giving consent. The principle is that this practice is prohibited.

123. Only in very exceptional circumstances may exceptions be made to this rule, and only for the removal of regenerative tissue. Within the meaning of this Article, regenerative tissue is that capable of reconstituting its tissue mass and function after partial removal. These exceptions are justified by the fact that regenerative tissue, in particular bone marrow, can only be transplanted between genetically compatible persons, often brothers and sisters.

124. If, at the present time, bone marrow transplants among brothers and sisters is the most important situation which meets with the condition of this article, the formula "regenerative tissue" takes into account future developments in medicine.
125. Paragraph 2 therefore permits removal of bone marrow from a minor for the benefit of his or her brother or sister. It is the principle of mutual aid between very close members of a family which, subject to certain conditions, can justify an exception to the prohibition of removal which is intended to protect the persons who are not able to give their consent. This exception to the general rule is qualified by a number of conditions set forth in Article 20, designed to protect the person who is incapable of giving consent, and these may be supplemented by national law. The conditions of Article 19, paragraph 1, also apply.

126. The first condition is the absence, within reasonable limits, of a compatible donor who is able to consent.

127. Moreover, the removal is only authorised on the condition that, in the absence of the donation, the life of the recipient is in danger. It goes without saying that the risks to the donor should be acceptable; the professional standards of Article 4 naturally apply, in particular as regards the balance between risk and benefit.

128. It is also required that the beneficiary be a brother or sister. This restriction is intended to avoid both family and doctors going to extreme lengths to find a donor at any price, even if the level of kinship is distant and the chances for a successful transplant are not very likely, because of tissue incompatibility.

129. Furthermore, in keeping with Article 6, the authorisation of the representative of the person not able to consent or the authorisation of the authority or body provided for by law is needed before the removal can be carried out (see under 38 above for withdrawal). The agreement of the competent body mentioned in Article 20, iv is also required. The intervention of such a body (which might be a court, a professionally qualified body, an ethics committee, etc.) aims to guarantee that the decision to be taken is impartial.

130. Finally, the removal may not be carried out if the potential donor objects in any way. As in the case of research, this opposition, in whatever form, is decisive and must always be observed.
Chapter VII – Prohibition of financial gain and disposal of a part of the human body

Article 21 – Prohibition of financial gain

131. This article applies the principle of human dignity set forth in the preamble and in Article 1.

132. It states in particular that the human body and its parts must not, as such, give rise to financial gain. Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital. However, technical acts (sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc.) which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this Article does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such. Further, this Article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalisation).

133. The provision does not refer to such products as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity.

134. The question of patents was not considered in connection with this provision; accordingly the latter was not intended to apply to the question of the patentability of biotechnological inventions.
Such was the complexity of the problem of patents that a detailed study was necessary before any regulations were drawn up. If such a study led to the conclusion that regulations on the subject were desirable, the regulations should include principles and rules suited to the specific nature of the subject. In this respect, it has been noted that the European Community has issued a proposal for a Directive containing the principle according to which "the human body and its elements in their natural state shall not be considered patentable inventions".

**Article 22 – Disposal of a removed part of the human body**

135. Parts of the human body are often removed in the course of interventions, for example surgery. The aim of this article is to ensure the protection of individuals with regard to parts of their body which are thus removed and then stored or used for a purpose different from that for which they have been removed. Such a provision is necessary in particular, because much information on the individual may be derived from any part of the body, however small (for example blood, hair, bone, skin, organ). Even when the sample is anonymous the analysis may yield information about identity.

136. This provision thus establishes a rule consistent with the general principle in Article 5 on consent, ie that parts of the body which have been removed during an intervention for a specified purpose must not be stored or used for a different purpose unless the relevant conditions governing information and consent have been observed.

137. The information and consent arrangements may vary according to the circumstances, thus allowing for flexibility since the express consent of an individual to the use of parts of his body is not systematically needed. Thus, sometimes, it will not be possible, or very difficult, to find the persons concerned again in order to ask for their consent. In some cases, it will be sufficient for a patient
or his or her representative, who have been duly informed (for instance, by means of leaflets handed to the persons concerned at the hospital), not to express their opposition. In other cases, depending on the nature of the use to which the removed parts are to be put, express and specific consent will be necessary, in particular where sensitive information is collected about identifiable individuals.

138. This article must not be understood to authorise an exception to the principle in Article 19 that removal of organs for transplantation purposes may be carried out only for the benefit of the recipient. However, in a case where the organ appears not to be suitable for transplantation purposes, because of its condition, it may then exceptionally be used for research in transplantation medicine specifically related to the particular organ.
Chapter VIII – Infringements of the provisions of the Convention

Article 23 – Infringement of the rights or principles

139. This article requires the Parties to make available a judicial procedure to prevent or put a stop to an infringement of the principles set forth in the Convention. It therefore covers not only infringements which have already begun and are ongoing but also the threat of an infringement.

140. The judicial protection requested must be appropriate and proportionate to the infringement or the threats of infringement of the principles. Such is the case, for example, with proceedings initiated by a public prosecutor in cases of infringements affecting several persons unable to defend themselves, in order to put an end to the violation of their rights.

141. Under the Convention, the appropriate protective machinery must be capable of operating rapidly as it has to allow an infringement to be prevented or halted at short notice. This requirement can be explained by the fact that, in many cases, the very integrity of an individual has to be protected and an infringement of this right might have irreversible consequences.

142. The judicial protection thus provided by the Convention applies only to unlawful infringements or to threats thereof.

The reason for this qualifying adjective is that the Convention itself, in Article 26.1, permits restrictions to the free exercise of the rights it recognises.

Article 24 – Compensation for undue damage

143. This Article sets forth the principle that any person who has suffered undue damage resulting from an intervention is entitled
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to fair compensation. The Convention uses the expression "undue damage" because in medicine some damage, such as amputation, is inherent in the therapeutic intervention itself.

144. The due or undue nature of the damage will have to be determined in the light of the circumstances of each case. The cause of the damage must be an intervention in the widest sense, taking the form of either an act or an omission. The intervention may or may not constitute an offence. In order to give entitlement to compensation, the damage must result from the intervention.

145. Compensation conditions and procedures are prescribed by national law. In many cases, this establishes a system of individual liability based either on fault or on the notion of risk or strict liability. In other cases, the law may provide for a collective system of compensation irrespective of individual liability.

146. On the subject of fair compensation, reference can be made to Article 50 of the European Convention on Human Rights, which allows the Court to afford just satisfaction to the injured party.

Article 25 – Sanctions

147. Since the aim of the sanctions provided for in Article 25 is to guarantee compliance with the provisions of the Convention, they must be in keeping with certain criteria, particularly those of necessity and proportionality. As a result, in order to measure the expediency and determine the nature and scope of the sanction, the domestic law must pay special attention to the content and importance of the provision to be complied with, the seriousness of the offence and the extent of its possible repercussions for the individual and for society.
Chapter IX – Relation between this Convention and other provisions

Article 26 – Restrictions on the exercise of rights

Paragraph 1

148. This article lists the only possible exceptions to the rights and protective provisions contained in all the provisions of the Convention, without prejudice to any specific restrictions which this or that Article may involve.

149. It echoes partially the provisions of Article 8, paragraph 2, of the European Convention on Human Rights. The exceptions made in Article 8, paragraph 2, of the European Convention on Human Rights have not all been considered relevant to this Convention. The exceptions defined in the article are aimed at protecting collective interests (public safety, the prevention of crime, and the protection of public health) or the rights or freedoms of others.

150. Compulsory isolation of a patient with a serious infectious disease, where necessary, is a typical example of an exception for reason of the protection of public health.

151. A person who may, due to his or her mental disorder, be a possible source of serious harm to others may, according to the law, be subjected to a measure of confinement or treatment without his or her consent. Here, in addition to the cases contemplated in Article 7, the restriction may be applicable in order to protect other people’s rights and freedom.

152. Protection of the rights of others may also, for example, justify an order by a judicial authority for a test to be carried out to establish parentage.
153. It may also be justified to use genetic assessments (DNA tests) for the identification of persons in connection with criminal investigation.

154. Certain legislations provide for court-ordered psychiatric treatment of an accused person who, failing such treatment, would be unfit to stand trial, with the object of enabling the accused to make a proper defence. Such court-ordered treatment, with attached appropriate safeguards, may be considered as relevant within the scope of Article 26, which refers namely to necessary measures for the fair administration of justice ("prevention of crime") which, in a democratic society, include the defence of the accused.

155. The protection of the patient’s health is not mentioned in this paragraph as one of the factors justifying an exception to the provisions of the Convention as a whole. In order to clarify its scope, it seemed preferable to define this exception in each of the provisions expressly alluding to it. Article 7, for example, specifies the conditions on which individuals suffering from mental disorders may, without their consent, be given treatment if their health might seriously suffer otherwise.

156. Moreover, defending the economic well-being of the country, public order or morals and national security are not included amongst the general exceptions referred to in the first paragraph of this article, unlike Article 8 of the European Convention on Human Rights. It did not appear desirable, in the context of this Convention, to make the exercise of fundamental rights chiefly concerned with the protection of a person’s rights in the health sphere subject to the economic well-being of the country, to public order, to morals or to national security.

157. The economic aspect is however referred to in Article 3 by the words "available resources"; however, within the meaning of this article this notion does not represent a reason for allowing for an exception to the rights secured in other provisions of the Convention.
158. War and armed conflict were also ruled out as possible grounds for exceptions. However, this is not meant as preventing the law from taking specific measures in the military aiming at protecting public health in that particular context.

159. The reasons mentioned in Article 26.1 should not be regarded as justifying an absolute exception to the rights secured by the Convention. To be admissible, restrictions must be prescribed by law and be necessary in a democratic society for the protection of the collective interest in question or for the protection of individual interests, that is the rights and freedom of others. These conditions must be interpreted in the light of the criteria established with regard to the same concepts by the case-law of the European Court of Human Rights. In particular, the restrictions must meet the criteria of necessity, proportionality and subsidiarity, taking into account the social and cultural conditions proper to each State. The term “prescribed by law” should be interpreted in accordance with the meaning usually given to it by the European Court of Human Rights, that is a formal law is not required and each State may adopt the form of domestic law it considers most appropriate.

**Paragraph 2**

160. The restrictions set out in the first paragraph of the Article shall not apply to the provisions mentioned in the second paragraph. It concerns the following provisions: Article 11 (Non-discrimination), Article 13 (Interventions on human genome), Article 14 (Non selection of sex), Article 16 (Protection of persons undergoing research), Article 17 (Protection of persons not able to consent to research), Articles 19 and 20 (Organ and tissue removal from living donors for transplantation purposes) and Article 21 (Prohibition of financial gain).
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Article 27 – Wider protection

161. In pursuance of this article, the Parties may apply rules of a more protective nature than those contained in the Convention. In other words, the text lays down common standards with which States must comply, while allowing them to provide greater protection of the human being and of human rights with regard to applications of biology and medicine.

162. A conflict may arise between the various rights established by the Convention, for example between a scientist's right of freedom of research and the rights of a person submitting to the research. However, the expression "wider protection" must be interpreted in the light of the purpose of the Convention, as defined in Article 1, namely the protection of the human being with regard to the application of biology and medicine.

In the example quoted, any additional statutory protection can only mean greater protection for a person submitting to research.
Chapter X – Public debate

Article 28 – Public debate

163. The purpose of this article is to prompt the Parties to create greater public awareness of the fundamental questions raised by the application of biology and medicine. Society’s views must be ascertained as far as possible with regard to problems concerning its members as a whole. To this end, appropriate public discussion and consultation are recommended. The word “appropriate” leaves the Parties free to select the most suitable procedures. Where appropriate, for example, States may organise ethics committees and have recourse to the teaching of ethics in the field of medicine, biology and health to health care professionals, teachers and the general public.
Chapter XI – Interpretation and follow-up of the Convention

Article 29 – Interpretation of the Convention

164. This article allows the possibility of requesting the European Court of Human Rights’ advisory opinion on legal questions concerning the interpretation of the Convention. The opinion shall be without direct reference to any specific proceedings in a court.

165. This Convention does not itself give individuals a right to bring proceedings before the European Court of Human Rights. However, facts which are an infringement of the rights contained in this Convention may be considered in proceedings under the European Convention of Human Rights, if they also constitute a violation of one of the rights contained in the latter Convention.

Article 30 (Reports on the application of the Convention)

166. According to the model of Article 57 of the European Convention of Human Rights, this Article stipulates that any Party, on the request of the Secretary General of the Council of Europe, shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.
Chapter XII – Protocols

Article 31 – Protocols

167. The Convention establishes principles valid for all applications of biology and medicine in human beings. This article makes provision for the immediate drawing up of protocols containing rules on specific fields. As the purpose of the protocols is to develop further the principles contained in the Convention, their provisions should not depart from those therein. In particular, they cannot lay down rules affording human beings less protection than that resulting from the principles of the Convention.

168. To be able to sign or ratify a protocol, a State must have simultaneously or previously signed or ratified the Convention. On the other hand, States which have signed or ratified the Convention will not be obliged to sign or ratify a protocol.
Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

169. Amendments to the Convention shall be examined by the CDBI, or by any other committee designated by the Committee of Ministers. Accordingly, each member State of the Council of Europe, as well as each Party to the Convention which is not a member of the Council of Europe, will have the right to vote concerning the proposed amendments.

170. This article provides that the Convention shall be re-examined no later than five years from its entry into force and thereafter at such intervals as the Committee in charge of the re-examination may determine.
Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

171. Other than the member States of the Council of Europe, the following States, which took part in its preparation, may sign the Convention: Australia, Canada, the Holy See, Japan and the United States of America.

Article 35 – Territories

172. Since this provision is mainly aimed at overseas territories, it was agreed that it would be clearly against the philosophy of the Convention for any Party to exclude parts of its main territory from the application of this instrument, and that there would be no need to lay this down explicitly in the Convention.

Article 36 – Reservations

173. This article, on the model of Article 64 of the European Convention of Human Rights, permits reservations in respect of any particular provision of the Convention, to the extent that any law in force is not in conformity with the provision.

174. The term law does not imply that a formal law is required (for example, in some countries, the professional bodies issue their own deontological rules which are applicable to their members to the extent that they do not contradict State norms). However, according to paragraph 1, a reservation of a general character, that is couched in terms too vague or broad for it to be possible to determine its exact meaning and scope, is not permitted.

175. Furthermore, according to paragraph 2, any reservation made shall contain a brief statement of the law concerned; this statement constitutes an evidential factor and contributes to legal certainty,
and is not a purely formal requirement but a condition of substance (see European Court of Human Rights, Belilos Case, sections 55 and 59).

176. It was agreed that any declaration, even described as interpretative, made by the State or the European Community relating to any provision of the Convention, which seeks to modify for the declaring State the obligations deriving from such provision should meet, in order to be valid, the requirements set out in Article 36.
Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as “Convention on Human Rights and Biomedicine”),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity
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and identity of all human beings and guarantee everyone, without
discrimination, respect for their integrity and other rights and
fundamental freedoms with regard to the application of biology and
medicine;
Considering that progress in medical science, in particular in the
field of organ and tissue transplantation, contributes to saving lives or
greatly improving their quality;
Considering that transplantation of organs and tissues is an established
part of the health services offered to the population;
Considering that, in view of the shortage of organs and tissues,
appropriate action should be taken to increase organ and tissue
donation, in particular by informing the public of the importance
of organ and tissue transplantation and by promoting European
co-operation in this field;
Considering moreover the ethical, psychological and socio-cultural
problems inherent in the transplantation of organs and tissues;
Considering that the misuse of organ and tissue transplantation may
lead to acts endangering human life, well being or dignity;
Considering that organ and tissue transplantation should take place
under conditions protecting the rights and freedoms of donors,
potential donors and recipients of organs and tissues and that
institutions must be instrumental in ensuring such conditions;
Recognising that, in facilitating the transplantation of organs and
tissues in the interest of patients in Europe, there is a need to protect
individual rights and freedoms and to prevent the commercialisation
of parts of the human body involved in organ and tissue procurement,
exchange and allocation activities;
Taking into account previous work of the Committee of Ministers and
the Parliamentary Assembly of the Council of Europe in this field;
Resolving to take such measures as are necessary to safeguard human
dignity and the rights and fundamental freedoms of the individual
with regard to organ and tissue transplantation,
Have agreed as follows:

**Chapter I – Object and scope**

**Article 1 – Object**

Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

**Article 2 – Scope and definitions**

1. This Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.
2. The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells.
3. The Protocol does not apply:
   a. to reproductive organs and tissue;
   b. to embryonic or foetal organs and tissues;
   c. to blood and blood derivatives.
4. For the purposes of this Protocol:
   - the term “transplantation” covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage;
   - subject to the provisions of Article 20, the term “removal” refers to removal for the purposes of implantation.

**Chapter II – General provisions**

**Article 3 – Transplantation system**

Parties shall guarantee that a system exists to provide equitable access to transplantation services for patients.
Subject to the provisions of Chapter III, organs and, where appropriate, tissues shall be allocated only among patients on an official waiting list, in conformity with transparent, objective and duly justified rules according to medical criteria. The persons or bodies responsible for the allocation decision shall be designated within this framework.

In case of international organ exchange arrangements, the procedures must also ensure justified, effective distribution across the participating countries in a manner that takes into account the solidarity principle within each country.

The transplantation system shall ensure the collection and recording of the information required to ensure traceability of organs and tissues.

Article 4 – Professional standards
Any intervention in the field of organ or tissue transplantation must be carried out in accordance with relevant professional obligations and standards.

Article 5 – Information for the recipient
The recipient and, where appropriate, the person or body providing authorisation for the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention.

Article 6 – Health and safety
All professionals involved in organ or tissue transplantation shall take all reasonable measures to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ or tissue for implantation.

Article 7 – Medical follow-up
Appropriate medical follow-up shall be offered to living donors and recipients after transplantation.
Article 8 – Information for health professionals and the public
Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissues, including matters relating to consent or authorisation, in particular with regard to removal from deceased persons.

Chapter III – Organ and tissue removal from living persons

Article 9 – General rule
Removal of organs or tissue from a living person may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

Article 10 – Potential organ donors
Organ removal from a living donor may be carried out for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body.

Article 11 – Evaluation of risks for the donor
Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor.

The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 12 – Information for the donor
The donor and, where appropriate, the person or body providing authorisation according to Article 14, paragraph 2, of this Protocol,
shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks.

They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 13 – Consent of the living donor

Subject to Articles 14 and 15 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body.

The person concerned may freely withdraw consent at any time.

Article 14 – Protection of persons not able to consent to organ or tissue removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 13 of this Protocol.

2. Exceptionally, and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:
   i. there is no compatible donor available who has the capacity to consent;
   ii. the recipient is a brother or sister of the donor;
   iii. the donation has the potential to be life-saving for the recipient;
   iv. the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body;
   v. the potential donor concerned does not object.
Article 15 – Cell removal from a living donor
The law may provide that the provisions of Article 14, paragraph 2, indents ii and iii, shall not apply to cells insofar as it is established that their removal only implies minimal risk and minimal burden for the donor.

Chapter IV – Organ and tissue removal from deceased persons

Article 16 – Certification of death
Organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.

The doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures, or having responsibilities for the care of potential organ or tissue recipients.

Article 17 – Consent and authorisation
Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained.

The removal shall not be carried out if the deceased person had objected to it.

Article 18 – Respect for the human body
During removal the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.
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Article 19 – Promotion of donation
Parties shall take all appropriate measures to promote the donation of organs and tissues.

Chapter V – Implantation of an organ or tissue removed for a purpose other than donation for implantation

Article 20 – Implantation of an organ or tissue removed for a purpose other than donation for implantation
1. When an organ or tissue is removed from a person for a purpose other than donation for implantation, it may only be implanted if the consequences and possible risks have been explained to that person and his or her informed consent, or appropriate authorisation in the case of a person not able to consent, has been obtained.
2. All the provisions of this Protocol apply to the situations referred to in paragraph 1, except for those in Chapter III and IV.

Chapter VI – Prohibition of financial gain

Article 21 – Prohibition of financial gain
1. The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.
   The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:
   – compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;
   – payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
   – compensation in case of undue damage resulting from the removal of organs or tissues from living persons.
2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Article 22 – Prohibition of organ and tissue trafficking
Organ and tissue trafficking shall be prohibited.

Chapter VII – Confidentiality

Article 23 – Confidentiality
1. All personal data relating to the person from whom organs or tissues have been removed and those relating to the recipient shall be considered to be confidential. Such data may only be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

2. The provisions of paragraph 1 shall be interpreted without prejudice to the provisions making possible, subject to appropriate safeguards, the collection, processing and communication of the necessary information about the person from whom organs or tissues have been removed or the recipient(s) of organs and tissues in so far as this is required for medical purposes, including traceability, as provided for in Article 3 of this Protocol.

Chapter VIII – Infringements of the provisions of the Protocol

Article 24 – Infringements of rights or principles
Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Protocol at short notice.
Article 25 – Compensation for undue damage
The person who has suffered undue damage resulting from transplantation procedures is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 26 – Sanctions
Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

Chapter IX – Co-operation between Parties

Article 27 – Co-operation between Parties
Parties shall take appropriate measures to ensure that there is efficient co-operation between them on organ and tissue transplantation, inter alia through information exchange.

In particular, they shall undertake appropriate measures to facilitate the rapid and safe transportation of organs and tissues to and from their territory.

Chapter X – Relation between this Protocol and the Convention, and re-examination of the Protocol

Article 28 – Relation between this Protocol and the Convention
As between the Parties, the provisions of Articles 1 to 27 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of that Convention shall apply accordingly.

Article 29 – Re-examination of the Protocol
In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of
the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI – Final clauses

Article 30 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31 – Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 30.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 32 – Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.
Article 33 – Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 34 – Notification

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:

a. any signature;

b. the deposit of any instrument of ratification, acceptance, approval or accession;

c. any date of entry into force of this Protocol in accordance with Articles 31 and 32;

d. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, this 24th day of January 2002, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.
Explanatory report to additional protocol to the Convention on human rights and biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186)

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

I. This Explanatory Report to the Additional Protocol to the Convention on Human Rights and biomedicine, concerning transplantation of organs and tissues of human origin, was drawn up under the responsibility of the Secretary General of the Council of Europe, on the basis of a draft prepared, at the request of the Working Party, by Dr Peter Doyle (United Kingdom), member of the Working Party.

II. The Committee of Ministers has authorised the publication of this Explanatory Report on 8 November 2001.

III. The Explanatory Report is not an authoritative interpretation of the Protocol. Nevertheless it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the Protocol and to better understand the scope of its provisions.
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Introduction

1. This Additional Protocol to the Convention on Human Rights and Biomedicine on the Transplantation of Organs and Tissues of Human Origin amplifies the principles embodied in the Convention, with a view to ensuring protection of people in the specific field of transplantation of organs and tissues of human origin.

2. The purpose of the Protocol is to define and safeguard the rights of organ and tissue donors, whether living or deceased, and those of persons receiving implants of organs and tissues of human origin.

Drafting of the Protocol

3. In 1991 in its Recommendation 1160, the Council of Europe Parliamentary Assembly recommended that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects". The same year, the Committee of Ministers instructed the CAHBI (ad hoc Committee of Experts on Bioethics), re-designated the CDBI (Steering Committee on Bioethics) "to prepare, … Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings".

4. At its 14th meeting (Strasbourg, 5-8 November 1991), the CAHBI appointed the Working Party on Organ Transplantation, responsible for preparing the draft Protocol (1). The CAHBI-CO-GT1, later the CDBI-CO-GT1, chaired by Mr Peter THOMPSON (United Kingdom), held its first meeting in January 1992 and began its activities concurrently with the CDBI’s work on the Convention.

5. At the second meeting of the CDBI in April 1993 the Working Party submitted a draft Protocol on Organ Transplantation and in June 1994, the Ministers’ Representatives agreed to declassify this document. However, as CDBI focused its efforts on the preparation
of the Convention, the work on the draft Protocol was postponed until January 1997.

6. The Convention on Human Rights and Biomedicine was adopted by the Committee of Ministers on 19 November 1996 and was opened for signature on the 4 April 1997 in Oviedo (Spain). The CDBI, at its 11th meeting in June 1996, decided to give the CDBI-CO-GT1 (2), chaired by Dr Órn BJARNASON (Iceland), extended terms of reference to examine the draft Protocol on transplantation in the light of the Convention provisions.

7. This Protocol extends the provisions of the Convention on Human Rights and Biomedicine in the field of transplantation of organs, tissues and cells of human origin. The provisions of the Convention are to be applied to the Protocol. For ease of consultation by its users, the Protocol has been drafted in such a way that they need not keep referring to the Convention in order to understand the scope of the Protocol’s provisions. However, the Convention contains principles which the Protocol is intended to develop. Accordingly, systematic examination of both texts may prove helpful and sometimes indispensable.

8. The draft Protocol, which was examined by the CDBI at its 15th meeting (7-10 December 1998), was declassified by the Committee of Ministers at its 658th meeting (2-3 February 1999, item 10.1) for the purposes of consultation. Those consulted, including member States, relevant European non-governmental organisations and particularly the Parliamentary Assembly (specifically the Social, Health and Family Affairs Committee, the Committee on Science and Technology and the Committee on Legal Affairs and Human Rights) have contributed to the development of the text. After re-examination, the CDBI finalised the text of the Protocol during its meeting from 5 to 8 June 2000.

9. The Protocol was approved by the CDBI on 8 June 2000 under the chairmanship of Dr Elaine GADD (United Kingdom). The Parliamentary Assembly gave an opinion on the Protocol, Opinion N° 227 (2001) of 25 April 2001, Professor Jean-François MATTEI
being the Rapporteur. The Protocol was adopted by the Committee of Ministers on 8 November 2001.

10. The Protocol is accompanied by this explanatory report, drawn up under the responsibility of the Secretary General of the Council of Europe on the basis of a draft prepared, at the request of the Working Party, by its member Dr Peter DOYLE (United Kingdom). It takes into account the discussions held in the CDBI and its Working Party entrusted with the drafting of the Protocol; it also takes into account the remarks and proposals made by Delegations. The Committee of Ministers has authorised its publication on 8 November 2001. The explanatory report is not an authoritative interpretation of the Protocol. Nevertheless it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the Protocol and make the scope of its provisions more comprehensible.

Comments on the provisions of the Protocol

Title

11. The title identifies this instrument as the "Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, concerning Transplantation of Organs and Tissues of Human Origin".

12. The expression "of human origin" underlines the exclusion of xenotransplantation from the scope of the Protocol.

Preamble

13. The Preamble highlights the fact that Article 1 of the Convention on Human Rights and Biomedicine protecting the dignity and the identity of all human beings and guaranteeing everyone respect for their integrity, forms a suitable basis on which to formulate additional standards for safeguarding the rights and freedoms of donors, potential donors and recipients of organs and tissues.
14. In November 1987 the Third Conference of European Health Ministers convened in Paris dealt with organ transplantation, and a number of guidelines on the subject were adopted as a result. This Preamble echoes the main introductory paragraphs of their Final Declaration: while the transplantation of organs and tissues is an established part of the health services offered to the population, helping to save lives or improve their quality, emphasis is placed on the need to take specific measures to promote organ and tissue donation but also to prevent misuse of transplantation and the risk of commercialisation.

15. In addition, the Preamble stresses that it is important to take into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe on transplantation of organs and tissues, in particular Committee of Ministers Resolution (78) 29 on harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances and on the management of organ transplant waiting lists and waiting times, Recommendation no. REC (2001)5.
Chapter I – Object and scope

Article 1 – Object

16. This article specifies that the object of the Protocol is to protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

17. The term "everyone" is used in Article 1 because it is seen as the most concordant with the exclusion of embryonic and foetal organs or tissues from the scope of the Protocol as stated in Article 2 (see paragraph 24 below). The Protocol solely concerns removal of organs and tissues from someone who has been born, whether now living or dead, and the implantation of organs and tissues of human origin into someone else who has likewise been born.

Article 2 – Scope and definitions

18. This article sets out the scope of the Protocol and defines the main terms used.

Scope

19. The Protocol applies solely to the transplantation of organs, tissues and cells of human origin (see paragraph 22 below). Organs, tissues and cells used for implantation are normally obtained from any one of the following three sets of circumstances:

a. a living person may, under certain conditions, consent to the removal of an organ or tissue for the purpose of implantation into another person; Chapter III was therefore drafted with the aim of protecting living donors from the psychological and physical risks and the consequences of implantation, particularly
with regard to confidentiality and burdens arising from the requirements of traceability;

b. organs or tissues may be removed from a deceased person and implanted into another person; Chapter IV was designed to regulate the various stages of removal from deceased persons and to guarantee in particular that no removal is carried out if the deceased person had objected to it;

c. a person who is undergoing a procedure for his/her own medical benefit may consent to any removed organ or tissue being implanted into another person; Chapter V was designed to specify the conditions under which such organs or tissues may be implanted, in particular by stipulating that specific information must be provided and informed consent or appropriate authorisation obtained.

20. The second paragraph of Article 2 states that the provisions of this Protocol applicable to tissues shall also apply to cells. Indeed Chapter VI of the Convention enunciates the fundamental principles with regard to removal of organs and tissues from living donors for the purpose of transplantation, but none of these provisions mention the term “cells”. However, in many respects, transplantation of cells poses problems, particularly the consequences of testing and traceability, which are the same as those relating to the transplantation of tissues. Therefore, subject to Article 15, the Protocol applies the same regulations to the transplantation of cells as it does to the transplantation of tissues. In particular, the provisions concerning informed consent or authorisation by or on behalf of the donor, confidentiality, health and safety, and the prohibition of profit apply as for tissues.

21. The transplantation of haematopoietic stem cells, whatever their origin, comes within the scope of the Protocol, as does the transplantation of any kind of cells other than those that have been specifically excluded (see paragraphs 23 to 25 below). It should be emphasised that Recommendation No. R (98) 2 of the Committee of Ministers to member States on provision of haematopoietic progenitor cells is also relevant.
22. This Protocol does not apply to organs or tissues, whether genetically modified or not, removed from animals. These types of treatment are largely theoretical or at best experimental in the present state of scientific knowledge, and raise particular ethical problems. One should note that it is moreover foreseen that the issue of xenotransplantation will be addressed in another instrument presently under preparation. Thus it was agreed to place xenotransplantation outside the Protocol’s scope.

23. Reproductive organs and tissues (comprising ova, sperm and their precursors) are excluded from the scope of the Protocol because organ and tissue transplantation is deemed to have different implications from those of medically assisted procreation and therefore should not be governed by the same rules. Therefore ovaries and testes are excluded but the uterus is not.

24. Transplantation of embryonic and foetal organs and tissue, including embryonic stem cells are also excluded from the scope of this Protocol. It is foreseen that these subjects will be addressed in another Protocol now being prepared on protection of the human embryo and foetus.

25. Blood and its derivatives covers blood and the products derived from blood for use in transfusion medicine. Blood and such products are thus subject to specific regulations, or specific standards, such as Recommendation R(95) 15 on the Preparation, use and quality assurance of blood components. Blood and its derivatives are therefore excluded from the scope of the Protocol. However, haematopoietic stem cells, whatever their origin, are within the scope of this Protocol as noted in paragraphs 21 and 109.

26. Implantation, in its traditional sense, does not include utilisation of tissues of human origin in the form of medical devices or pharmaceuticals; nevertheless, it was agreed that professional standards imply that the principles contained in this Protocol regarding namely safety, traceability, information and consent for such uses should be applicable mutatis mutandis.
Definitions

27. It is not a simple matter to decide what terms to use to signify the grafting or implantation of organs and tissues. In normal usage organs are "grafted" and tissues "implanted", or we refer to the "implantation of a graft". For the purposes of this Protocol it was agreed that in English "implantation" best described the surgical procedures involved.

28. There is also difficulty in agreeing on a scientifically precise definition of "organ" and "tissue". Traditionally an "organ" has been described as part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. In 1994 the Committee of Ministers adopted a definition of tissues as being "All constituent parts of the human body, including surgical residues, but excluding organs, blood, blood products as well as reproductive tissue such as sperm, eggs and embryos. Hair, nails, placentas and body waste products also excluded" (Recommendation No. R (94) 1 of the Committee of Ministers to member States on human tissue banks). These were useful definitions in the early days of transplantation when only a few solid organs were transplanted e.g. kidney, heart and liver. However, developments in transplantation have given rise to difficulties of definition. For example, only a part of an adult liver may be removed and transplanted into a child and the residual liver will re-grow and the transplant will grow to adult size. This is a liver transplant but is clearly not an "organ" transplant according to the traditional definitions. Conversely, if a whole bone is removed and transplanted, the body cannot replicate the bone, but bone is normally considered to be a tissue not an organ.

29. The Protocol sets out to overcome this difficulty by using the terms "organs" and "tissues" throughout the text, except in Article 10 (see paragraphs 30 to 32 below), so that all provisions apply to all parts of the body. The distinction between the removal of "tissues" and "cells" is also difficult. In effect, more than one cell may be considered to be a tissue. Similarly, the Protocol sets out to
overcome this difficulty by stating that the provisions applicable to tissues shall also apply to cells. In the same way, unless specifically stated, explanations relating to tissues in this explanatory report also apply to cells.

30. It is nevertheless possible to distinguish between vascularised grafts that is organs or parts of organs which need re-connection of their blood supply, e.g. heart, lungs, liver, kidney, pancreas, bowel, from non vascularised tissue grafts and cells. The former, once removed from the body, normally only remain viable for relatively short periods and need to be transplanted within a few hours. Thus they cannot currently be processed and stored as can most tissues and cells. For this reason the rules relating to transplantation of vascularised “organs” may differ from those applying to tissues and cells.

31. Live organ donation is currently confined primarily to kidneys, lobes of either liver or lung, and isolated sections of small bowel. Their removal is a major procedure which carries a high risk. On the other hand, removal of tissues from a living donor generally carries a low risk of harm, and removal of cells might in certain cases involve an even smaller risk (see paragraph 90 below). These differences justify different rules; for this reason Article 10 deals with the specific case of organ removal from a living person and Article 15 with the case of cell removal from a living person.

32. For the purposes of this Protocol, the term “organ” is accordingly applied to vascularised organs or parts of organs which require a major surgical procedure for removal and which need to be transplanted rapidly. The terms “tissues” and “cells” cover all other parts of the body except those specifically excluded.

33. Transplantation is defined as the whole process starting with removal of an organ or tissue from one person and ending with implantation of that organ or tissue into a different person. The person from whom the material is removed is generally designated by the word donor and the person into whom the material is implanted by the word recipient. Furthermore tissues such as bone
may be processed and the resulting products implanted into more than one recipient. Similarly, cells may be cultured to supply more than one recipient. Increasingly livers removed from a deceased person are split so that even in the case of organ transplantation there may be more than one recipient. The safeguards in the Protocol apply to all possible steps in the transplant process and to all possible recipients. Moreover, they apply to the entire process of each step in transplantation; for example the word “removal” refers to all the medical interventions necessary for the removal, including investigation and preparation of the donor.

34. The provisions of this Protocol concerning removal apply if its purpose is transplantation. Removal of tissue carried out for any other purpose is not covered by the Protocol. Nevertheless, as stated in Article 20, when in the course of an intervention an organ or tissue is removed for a purpose other than donation for implantation, it may be suitable for implantation but may only be so used if the consequences and possible risks have been explained to that person and informed consent or, in the case of a person who is not able to consent, appropriate authorisation, has been obtained (see paragraphs 108 to 111 below). Besides, the protection afforded to recipients by this Protocol applies to all transplanted human material irrespective of why it was removed.
Chapter II – General provisions

Article 3 – Transplantation system

35. Parties to the Protocol undertake to ensure that a transplant system exists in their State within which transplant services operate. The nature or organisation of the system is not defined in this Protocol; it rests with individual States to decide whether to use local, regional, national or international organisations to meet the requirements of this article. As indicated in the 9th paragraph of the Preamble, institutions must be instrumental in ensuring that conditions protecting the rights and freedoms of donors, potential donors and recipients are observed.

36. The requirements of this article are that access to a transplant service is equitable – that is, all people, whatever their condition or background, must be equally able to be assessed by whatever transplant services are available. The concern is to ensure that there is no unjustified discrimination against any person within the jurisdiction of the Party who might benefit from a transplant. It has to be emphasised that there is a severe shortage of most organs and some of the tissues which can be transplanted. Scarce organs and tissues should be allocated so as to maximise the benefit of transplantation. The State-recognised system will be responsible for ensuring equitable access to assessment for transplantation and to transplant waiting lists.

37. The criteria by which organs and tissues are allocated should be determined in advance but be capable of amendment, be evaluated regularly and modified if or when circumstances change. The system governing transplantation may lay down different criteria according to the type of graft because of the particular characteristics and availability of the different organs and tissues. Organs and tissues should be allocated according to medical criteria. This notion should be understood in its broadest sense,
in the light of the relevant professional standards and obligations, extending to any circumstance capable of influencing the state of the patient's health, the quality of the transplanted material or the outcome of the transplant. Examples would be the compatibility of the organ or tissue with the recipient, medical urgency, the transportation time for the organ, the time spent on the waiting list, particular difficulty in finding an appropriate organ for certain patients (e.g. patients with a high degree of immunisation or rare tissue characteristics) and the expected transplantation result.

It should be noted that the transplantation of organs removed from a living donor takes place generally between persons having a close personal relationship; for this reason, the general provision in Article 3 is subject to the specific provisions contained in Chapter III, Articles 10 (Potential organ donors) and 14, paragraph 2, subparagraph ii (Protection of persons not able to consent to organ or tissue removal).

Organs removed from deceased persons should only be allocated to patients registered on an official waiting list. As to the tissues, there may be or there may not be an official waiting list.

Patients may be registered only on one official transplant list, be it regional, national or international so as not to prejudice the chances of others. However this principle does not preclude a system where a patient is registered on a local waiting which is part of a national waiting list (see Recommendation Rec (2001) 5 of the Committee of Ministers to Member States on the management of organ transplant waiting lists and waiting times).

The most important factor is to maximise equality of opportunity for patients and to do so by taking into account objective medical criteria. The allocation system should be as far as possible patient-oriented.

In case of international organ exchange arrangement, the procedures for distribution across participating countries should take into account the principle of solidarity within each country.
38. In order to ensure the allocation rules are transparent and well founded, they should state clearly who, within the system recognised by the member State, has the responsibility for the determination and the application of these rules. The person(s) or body(ies) responsible for organ and tissue allocation should be accountable for their decisions. Parties should bear in mind the provisions of Recommendation Rec (2001)5 on the management of organ transplant waiting lists and waiting times.

39. Traceability means being able to track all organs or tissues from donor to recipient and vice versa. It is required because it is impossible to eliminate entirely the risks of transmission of disease from donor to recipient and contamination of preserved material. Furthermore, new diseases or disease risks may emerge. Therefore for both public health reasons and the need to inform donors or recipients of potential problems that come to light following transplantation, it is important that any transplant material can be traced forward to recipients and back to the donor. For example, bone may be processed and turned into a variety of products with a long storage life available to treat multiple recipients. If a transmissible disease had been detected not at the outset but later in a recipient, donors would have to be traced to identify the one who transmitted the disease and unused products withdrawn. When seeking consent, both donors and recipients should be warned of such long-term consequences of transplantation and the possible need for prolonged surveillance. In addition, it may be necessary to analyse how organs and tissues were used to detect illegal or unethical use of such material, prevent organ and tissue trafficking and to validate allocation systems. For these reasons the transplant system must ensure a comprehensive system to enable all transplant material to be traced, without prejudice to the provisions on confidentiality set out in Article 23 (see paragraphs 122 and 123).

40. The question of methods for verifying the effectiveness with which the Parties implement systems for applying the various principles set out in article 3 is related to the general issue of Parties’ honouring of the obligations in the Convention on Human
Rights and Biomedicine, or any of its Protocols. In this context, reference should be made to i) the second paragraph of Article 1 of the Convention, which stipulates that "Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention", ii) Article 28 of this Protocol, according to which Articles 1 to 27 are regarded as additional articles to the Convention, and iii) Article 30 of the Convention, which empowers the Secretary General to request any Party to "furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention".

Article 4 – Professional standards

41. The provisions here use the wording of Article 4 of the Convention and apply to all health care professionals whether involved in the decision-making process or in performing a transplant. The text of the explanatory report of the Convention also applies in general, but some further explanation is required for the purposes of this Protocol.

42. The term "intervention" must be understood here in a broad sense. It covers all medical acts performed in connection with transplantation of organs or tissue for purposes of treating a patient. An intervention carried out in connection with experimental transplantation must furthermore comply with the rules governing research.

43. The relevant professional obligations and standards in accordance with which all interventions must be performed, are those laws, specific or general and any codes of practice or rules of conduct in force in the member State. Such codes or rules may take various forms such as health legislation, a code of professional practice or accepted medical ethical principles. Specifically, transplants should only be performed in accordance with the agreed allocation criteria. The rules and criteria may differ somewhat between countries but the fundamental principles of medical practice apply in all countries.
44. The competence of a doctor or other health care worker to take part in a transplant procedure must be determined in relation to the scientific knowledge and clinical experience appropriate to transplantation of organs or tissue at a given time. However, it is accepted that medical knowledge is rarely absolute and while acting according to the highest professional standards more than one therapeutic option may be perfectly justified. Recognised medical practice may therefore allow several alternative forms of intervention leaving some justified clinical freedom in the choice of methods or techniques. However, the choice of technique may affect the risk of inducing disease in the recipient, e.g. lymphoma or graft versus host disease, and such considerations should also be taken into account and the safest transplantation technique used.

45. Professional standards also require that organ and tissue implantation is only performed in accordance with a clear and specific medical indication for the recipient and not for any other reason such as a perceived social benefit. The recipient must have a defined medical problem which should be improved by a successful transplant before a transplant can be performed. The potential benefit of the procedure to the recipient must outweigh any risk. At all times, a decision to transplant must be taken only in the best interests of the patient.

46. Professional standards related to live transplantation require that, even if there is only one transplant team, different clinicians take responsibility for the care of the donor and the recipient, to ensure that the clinical needs of each party are properly and independently managed. In addition, it may be advisable to offer donors systematic long-term follow-up.

**Article 5 – Information for the recipient**

47. This article sets forth the recipient’s right to be properly informed prior to implantation. Even though a transplant is intended to improve the health or even save the life of the recipient, the fact remains that the recipient shall be informed beforehand of the
purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention. This information must be as exact as possible and couched in terms which the recipient can understand. Information should be provided in a format appropriate to the needs of the recipient. In addition to proper discussion, written information which the recipient can study when there is adequate time may be particularly helpful. When the recipient is too ill to be able to give informed consent, in particular in emergency cases, the information shall also be given to the person or body providing the authorisation to the implantation, as foreseen by Article 6 of the Convention of Human Rights and Biomedicine.

Article 6 – Health and safety

48. This article deals with the health and safety aspects of the transplant process. It places an obligation on all those involved in the transplant process of organ and tissue to do everything that can be reasonably expected of them to ensure that organs and tissues are healthy and undamaged, that they are handled, transported and where appropriate preserved and stored by means that maximise their viability and minimise the risk of contamination. These measures will ensure that when grafted into a recipient, the risk to the health of the recipient has been minimised. However, it recognises that the risk of transmission of disease cannot be entirely eliminated. Exceptionally, circumstances may arise when some risk of transmission of disease to the recipient, or of failure of the organ or tissue graft, is acceptable if the consequence of not grafting is more serious, in particular, if the alternative is certain death. An assessment of the risks and benefits should be made on a case-by-case basis.

49. The expression ”transmission of any disease” covers also the transmission of a pathology to the recipient which may or may not later develop into the disease (for instance, in the case of hepatitis C virus, the recipient might be infected but never develop overt disease).
50. The ultimate responsibility for deciding whether to use a particular graft lies with the recipient’s implant team. However, it is essential that, in deciding whether to proceed with a graft, the practitioner has access to all the relevant information pertaining to the likely viability of the graft and the risk of transmission of disease. It is the responsibility of everyone involved to ensure that accurate information about the donor and the graft are collected, recorded and accompany the graft. The practitioners responsible for the removal of an organ or tissue have a duty to ensure that the donor is properly screened for transmissible diseases, both infectious and malignant. They are responsible for ensuring that a proper medical history has been obtained and that appropriate tests have either been performed or the necessary samples collected for testing.

51. However, organ transplantation sometimes has to be carried out in difficult circumstances as a matter of extreme urgency without having all the necessary information or knowing whether there is a risk for the recipient. In such circumstances, the doctor in charge should balance the risks and benefits and consequently, the implant should only be performed if the benefits to the recipient outweigh the risks and consent or authorisation has been given after information appropriate to the circumstances has been provided.

52. Moreover, because of the shortage of organs and some tissues, even when a disease risk is detected, it may not be appropriate to reject the donor without first checking whether there is a suitable recipient. The more urgent the type of transplant, the more essential it is to assess the risk and check whether there is any recipient who could benefit. For example in fulminant liver failure, the patient may only have a few hours to live and even a high risk organ may be considered preferable to almost certain death. In the case of tissue transplants which, except for bone marrow, are rarely if ever life saving, donor screening and testing should be more rigorous and disease transmission as far as possible prevented. Consequently, it may still be reasonable to bank tissues, i.e. keep them in quarantine, awaiting the outcome of further investigations such as a post mortem or retesting of a living donor.
53. It is the responsibility of the persons involved in the removal of organs and tissues to use the highest standards of removal, preservation and, where appropriate, storage. They shall also take reasonable steps to ensure the continued quality and safety of the organs and tissues to minimise the risk of damage to the graft and to maximise its viability. In the case of organs this also means ensuring transport is available to minimise delays.

54. Those involved in the transport, preservation and storage of grafts are also responsible for ensuring that all relevant information has been obtained, checked, and accompanies the graft to the recipient, albeit nothing in this provision overrides the obligation of confidentiality as stated in Article 23.

55. Parties should also take account of other relevant national or international instruments in the field of health and safety, for example, guidance on the avoidance of transmission of infectious or malignant diseases during transplantation produced under the auspices of the European Health Committee (3).

**Article 7 – Medical follow-up**

56. Article 7 of the Protocol states that a medical follow-up must be offered to living donors and recipients after transplantation. This is also a further specification of a principle of professional standards. The nature and duration of such follow-up should depend on the nature of the intervention and its potential impact on the individual’s health. Short term follow up is essential to ensure recovery from the procedure. Life long follow up is essential for recipients requiring immunosuppressive therapy. Such follow-up is also desirable for living organ donors to enable any long term effects of the donation to be identified. However, living donors and even recipients cannot be forced to accept long term follow up.
Article 8 – Information for health professionals and the public

57. It is for Parties to the Protocol to ensure that appropriate information about organ and tissue transplantation is made available to health professionals and to the general public. The information should cover all the relevant medical, legal, social, ethical and other issues concerned, particularly sensitive issues such as the means of certifying death. In view of the organ shortage it is seen as advisable to inform all health care workers about the success and benefits of transplantation because of their ability to inform the general public. Parties should also use every opportunity to inform the general public directly of those same benefits and successes. Informing the general public is important in promoting organ and tissue donation but it is also important that people make up their minds on the issues in full knowledge of the facts. Information for the public should be available on donation both from the living and the deceased (however, the provision of this general information should be without prejudice to that which is given to living donors in accordance with Article 12). The information should include the consequences and risks of organs or tissues being implanted into another person. Testing may reveal unrecognised diseases which may have implications for any living donor and possibly for the relatives of deceased persons from whom organs and tissues are removed. The need to ensure traceability should also be explained as the consequences may not be realised until some time in the future. It is particularly important that such information is made available for people who may opt to become organ donors.

58. There is a very specific duty for the Parties, that is to ensure that the rules on consent and/or authorisation for organ or tissue retrieval and transplantation are well known and acceptable to the society. It is important to establish a relationship of trust between potential donors and the transplantation system. Transplant issues are constantly changing so the provision of information is an ongoing responsibility, not just an occasional one.
Chapter III – Organ and tissue removal from living persons

Article 9 – General rule

59. According to the first principle set out in the text, organs or tissues should be removed from deceased persons rather than from living donors whenever possible. Removing organs or tissues from living donors for implantation purposes always has consequences and may carry some risk for that donor. This implies that organs and tissues from living persons should not be used where an appropriate organ or tissue from a deceased person is available.

60. The second condition in the case of living donors is that there exists no alternative therapeutic method of comparable effectiveness. In view of the risk involved in any organ and tissue removal, there is indeed no justification for resorting to this if there is another way of bringing the same benefit to the recipient, such as the use of artificial skin for instance. The transplant must therefore be necessary in the sense that there is no other treatment that would produce similar results. In this respect dialysis treatment is not considered to provide results in terms of the patient’s quality of life comparable with those obtained by a kidney transplant.

61. However, if the results of a living donor transplantation are expected to be significantly better than those expected utilising a graft removed from a deceased person, live donation may be the preferred therapeutic option for a particular recipient.

Article 10 – Potential organ donors

62. This article is specific to the removal of organs as defined in Article 2. It does not apply to the removal of tissues or cells. It defines the conditions under which, in addition of those of Article 9, living donation of an organ may be performed.
63. Those conditions would normally require that a close personal relationship, based on the principle of mutual aid, exists between the donor and recipient. The exact nature of the relationship is a matter for national law to determine and may depend on cultural or other local factors. Those with a close personal relationship with the recipient may include for instance members of the recipient's immediate family, parents, brothers, sisters, spouses or long-standing partners, godparents or close personal friends. Most countries have laws defining the nature of the relationship which is required to exist between donor and recipient and which makes live donation acceptable. The intention of such laws and this Article is to prevent undue pressure to donate being brought to bear on people without a strong emotional relationship with the recipient.

64. However, not all national laws define close personal relationship, and where relationships are defined, the question of donation by a person not in such a relationship may be proposed. As there is some evidence that, despite the risks incurred, there may be perceptible long-term psychological benefit to organ donors who, even if not closely related, have helped improve the health or even save the life of a recipient, this Article allows such circumstances to be taken into account. But they may only be considered when the national law sets out the conditions under which such circumstances may be considered. Those conditions include the provision of an appropriate independent body, for example an ethics committee, to consider each case. The body is responsible for ensuring that the other conditions required by law have been met, and that, for example, no coercion or inducement is involved. These provisions are thus an important safeguard against potential organ trafficking or the use of inducements.

65. The independent body required under this Article is not the same as the official body identified in Article 13 before which the living donor can give his/her consent. However, the law may provide for the independent body provided for by Article 10 to be the same as the competent body identified in Article 14, even if their responsibilities are different (see paragraph 87 below).
The reason for excluding tissues from this Article is that the therapeutic interests of a recipient who may not be known at the time of removal have to be taken into account. Here, the principles of Recommendation No. R (94) 1 of the Committee of Ministers to member States on human tissue banks are relevant.

**Article 11 – Evaluation of risks for the donor**

67. This article deals with evaluation of risk to the donor, which must be kept to a minimum. The health care professional's role here is twofold: to carry out whatever investigations may be required to evaluate the donor's state of health and therefore the potential risk of donation and, second, to take all reasonable measures to limit the risks to the donor without compromising the quality or viability of the organ or tissue removed for transplantation. The principal risks for the donor are the physical risks arising for the surgical procedure. However, there are also short and long-term psychological risks that also need to be fully assessed.

68. Whereas the word "investigation" covers all the examinations or tests to be performed, the word "intervention" is to be understood in a broad sense as covering all relevant medical acts.

69. The article places a ban on removal from a living donor where there is serious risk to the donor's life or health. This raises questions as to what a serious risk to the donor is and who judges the risk to be a serious one. Essentially there are three possible parties who may deem it a serious risk, the donor, the recipient or the medical team. For the purposes of this article, the decision about the risk is a matter for the transplant medical team looking after the donor or the body authorising the donation. The medical team should not propose a removal which they think presents an unacceptable risk even if the donor (for example, because he/she is a relative of the recipient) is ready to consent. In judging the risks involved, the donor’s interests must take precedence, although in some circumstances the balance of risk to the donor compared to potential benefit to the recipient may be taken into consideration.
The donation being acceptable or not depends not just on the physical risk associated with the procedure but must include psychological factors. Thus, the donor’s emotional status should be independently assessed. An example of psychological harm is if the donor develops an undue sense of ownership towards the recipient or the recipient feels unduly obligated to the donor. If, following full assessment, the medical team looking after the donor judge there to be a significant risk of death or long term severe disability to the donor, the donation procedure should not go ahead.

**Article 12 – Information for the donor**

70. This article sets out the donor’s right to be given appropriate information. In the case of donation of regenerative tissue, the most common instance is bone marrow transplantation between brothers and sisters, where the donor may be a minor. It is specifically to cater for this type of donation that the article requires the supply of information also to the representative, authority, person or body providing authorisation according to Article 14.2 of this Protocol.

71. There are two main requirements in the first part of the article. The information should be appropriate to explain the purpose and nature of the proposed removal as well as its consequences and risks, and the need for appropriate testing prior to the removal. It must be given prior to consent or authorisation and removal. Thus the information has to be as accurate as possible and given in terms the donor can understand, e.g. comparing the risks of a complication with other risks encountered in everyday life. In particular, in cases where the donor is a very young child, the content and form of the information presented must be adapted to his or her age and capacity for understanding. The donor must be given adequate time to fully consider the information provided and discuss it with friends and/or relatives. In addition to proper discussion, written information which the donor can study when there is adequate time may be particularly helpful. If the donation requires an authorising party under Article 14.2 those discussions will normally include the potential donor.
72. The second paragraph defines a more specific right for the donor in that it requires all concerned to inform the potential donor of his/her rights and safeguards under domestic and international law. In particular, it states that the donor shall be informed of the right to have access to a source of independent advice about the risks of the removal procedure. This source of information, who may be a doctor or other suitably qualified health care worker, must be independent of the team or teams involved in the transplant. However, that person must have appropriate experience of the risks associated with donation and transplantation to be able to give proper advice. This advice can be requested by the donor if he/she wishes. An authorising party under Article 14.2 should have the same access to independent advice.

**Article 13 – Consent of the living donor**

73. This article is based on Article 5 of the Convention and requires that interventions in the field of organ and tissue transplantation can only be performed after a person has given free and informed consent which can be freely withdrawn at any time. In order to avoid undue pressure on the donor, he/she should be assured that he/she can refuse to donate or withdraw his/her consent at any time in complete confidence. To that end, the donor should be interviewed in private and helped to cope with the consequences of his/her decision.

74. In seeking the consent of the donor it is essential to discuss what should happen if for any reason the proposed recipient can not accept the donation. Any possible alternative use for the donated organ or tissue should be considered prior to the donation.

75. This article does not apply to persons who do not have capacity to consent to the removal of an organ, such persons being protected by the provisions of Article 14 and 15 of this Protocol.

76. The first paragraph of this article is more stringent than Article 5 of the Convention in that, for organ or tissue removal, the donor’s consent must also be specific and given in written form or before an
official body, a court, a judge or an official notary for example. The responsibility of this body is to ensure that consent is adequate and informed.

77. The second paragraph provides the freedom to withdraw consent to the removal at any time. There is no requirement for withdrawal of consent to be in writing or to follow any particular form. The donor need simply say no to the removal at any time, even if a procedure performed under local anaesthetic has commenced. Article 14 affords the same protection to donors of regenerative tissue lacking capacity to consent to their removal. However, professional standards and obligations may require that the team continue with the procedure if not to do so would seriously endanger the health of the donor.

78. This article concerning consent of the living donor is included in Chapter III "Organ and tissue removal from living persons". The consent, as well as withdrawal of consent, therefore only applies to the removal process. If, exceptionally, the donor seeks to withdraw consent to the agreed implantation after removal, national law or professional standards should provide a means of resolving such problems.

Article 14 – Protection of persons not able to consent to organ or tissue removal

79. Provisions relating to consent to organ or tissue removal for implantation apply in the case of live donors having the capacity to consent. Those relating to authorisation apply where a potential donor cannot formally give consent on account of incapacity.

80. Article 14 deals specifically with the question of the removal of organs or tissues from a living person not having the capacity to give consent. The principle is that this practice is prohibited. Article 14 follows the wording of Article 20 of the Convention.

81. Only in very exceptional circumstances may derogations be made to this rule and only for the removal of regenerative tissues. Within the meaning of this article, regenerative tissue is that capable of
reconstituting its tissue mass and function after partial removal. These exceptions are justified by the fact that regenerative tissue, in particular bone marrow, can only be transplanted between genetically compatible persons, often brothers and sisters. Furthermore, Article 15 provides that Article 14, paragraph 2, indents ii. and iii. might not be applied, only in cases in which cell removal implies minimal risk and minimal burden for the donor.

82. If at the present time bone marrow transplants among brothers and sisters is the most important situation which meets the condition of this article, the formula "regenerative tissue" takes into account future developments in medicine.

83. Paragraph 2 therefore permits removal of bone marrow from a minor for the benefit of his or her brother or sister. The principle of mutual aid between very close members of a family and the possibility for psychological benefits to the donor arising from donation can justify, subject to certain conditions, an exception to the prohibition of removal which is intended to protect the persons who are not able to give their consent. This exception to the general rule is qualified by a number of conditions designed to protect the person who is incapable of giving consent, and these may be supplemented by national law. The conditions stated in the general rule of Article 9 also apply.

84. The first condition is the absence, within reasonable limits, of a compatible donor who is able to consent.

85. It is also required that the beneficiary be a brother or sister. This restriction is intended to avoid both family and doctors going to extreme lengths to find a donor at any price, even if kinship is distant and the chances for a successful transplant are not very likely because of tissue incompatibility.

86. Moreover, removal is only authorised on the condition that, in the absence of the donation, the life of the recipient is in danger. It goes without saying that the risks to the donor should be acceptable; the professional standards of Article 4 naturally apply, in particular as regards the balance between risk and benefit.
Blood and blood components

87. Furthermore, in keeping with Article 6 of the Convention, the authorisation of the representative of the person not able to consent or the authorisation of the authority or person or body provided for by law is needed before the removal can be carried out.

88. The agreement of the competent body is also required. The intervention of such a body (which might be a court, a professionally qualified body, an ethics committee, etc.) aims to guarantee that the decision to be taken is impartial. When the donor is an adopted person, it is for this body to verify that there has not been any misuse of the adoption process to enable a removal which would otherwise be forbidden. In this respect, it is important to note the important guarantees established in Article 14 for the protection of incapable persons and reinstated in the above paragraphs 80 to 86.

89. Finally, the removal may not be carried out if the potential donor objects in any way. This opposition, in whatever form, is decisive and must always be observed.

Article 15 – Cell removal from a living donor

90. Although transplantation procedures for cells generally pose problems similar to those related to the transplantation of tissues, there may however be a significant difference with regard to the risks arising from the removal of cells in comparison with removal of tissues. In certain cases such as obtaining a limited number of cells from the skin, the procedure itself may not involve more than minimal risk and minimal burden for the donor. In such cases, and only in such cases, it is foreseen that the Parties to the Protocol can choose not to apply the provisions of Article 14, paragraph 2, indents ii. and iii. The purpose of those provisions is to protect the donor from physical risks and from instrumentalisation contrary to their dignity, but where the risks and burdens are minimal it may not be appropriate to prohibit, for example, a minor donating cells to a family member other than a sibling.
91. One should also emphasise that the requirements of Article 14, paragraph 2, indents i., iv. and v. remain applicable. If compatibility is not medically required, it will always be possible to obtain a donor with capacity to consent. It is therefore not envisaged that cell removal be carried out on persons not able to consent outside of the immediate family circle.

92. This provision is an option for States, not an obligation; States can make use of this option at the time of ratification of the Protocol or at a later stage, depending on scientific and technical developments. Moreover, having in mind that technical developments in the future could permit the reconstitution of tissue in the laboratory from a limited number of cells, the inclusion of this option in the Protocol alleviates the potential need to amend it later if these foreseeable developments become reality.

93. Moreover, in recognition of the need to monitor the appropriate use of this provision, it was decided during the adoption of the draft Protocol by the CDBI that the States utilising this option would be requested to inform the other Parties by a notification addressed to the Secretary General.
Chapter IV – Organ and tissue removal from deceased persons

Article 16 – Certification of death

94. According to the first paragraph, a person’s death must have been established before organs or tissues may be removed “in accordance with the law”. It is the responsibility of the States to legally define the specific procedure for the declaration of death while the essential functions are still artificially maintained. In this respect, it can be noted that in most countries, the law defines the concept and the conditions of brain death.

95. The death is confirmed by doctors following an agreed procedure and only this form of death certification can permit the transplantation to go ahead. The retrieval team must satisfy themselves that the required procedure has been completed before any retrieval operation is started. In some States, this procedure for certification of death is separate from the formal issuance of the death certificate.

96. The second paragraph of Article 16 provides an important safeguard for the deceased person by ensuring the impartiality of the certification of death, by requiring that the medical team which certifies death should not be the same one that is involved in any stage of the transplant process. It is important that the interests of any such deceased person and the subsequent certification of death are, and are seen to be, the responsibility of a medical team entirely separate from those involved in transplantation. Failure to keep the two functions separate would jeopardise the public’s trust in the transplantation system and might have an adverse effect on donation.
97. For the purposes of this Protocol, neonates including anencephalic neonates receive the same protection as any person and the rules on certification of death are applicable to them.

Article 17 – Consent and authorisation

98. Article 17 bars the removal of any organ or tissue unless the consent or authorisation required by national law has been obtained by the person proposing to remove the organ or tissue. This requires member States to have a legally recognised system specifying the conditions under which removal of organs or tissues is authorised. Furthermore, by virtue of Article 8, the Parties should take appropriate measures to inform the public, namely about matters relating to consent or authorisation with regard to removal from deceased persons (see paragraph 58 above).

99. If a person has made known their wishes for giving or denying consent during their lifetime, these wishes should be respected after his/her death. If there is an official facility for recording these wishes and a person has registered consent to donation, such consent should prevail: removal should go ahead if it is possible. By the same token, it may not proceed if the person is known to have objected. Nonetheless, consultation of an official register of last wishes is valid only in respect of the persons entered in it. Nor may it be considered the only way of ascertaining the deceased person’s wishes unless their registration is compulsory.

100. The removal of organs or tissues can be carried out on a deceased person who has not had, during his/her life, the capacity to consent if all the authorisations required by law have been obtained. The authorisation may equally be required to carry out a removal on a deceased person who, during his/her life, was capable of giving consent but did not make known his wishes regarding an eventual removal post-mortem.

101. Without anticipating the system to be introduced, the Article accordingly provides that if the deceased person’s wishes are at all in doubt, it must be possible to rely on national law for guidance as
to the appropriate procedure. In some States the law permits that if there is no explicit or implicit objection to donation, removal can be carried out. In that case, the law provides means of expressing intention, such as drawing up a register of objections. In other countries, the law does not prejudge the wishes of those concerned and prescribes enquiries among relatives and friends to establish whether or not the deceased person was in favour of organ donation.

102. Whatever the system, if the wishes of the deceased are not sufficiently established, the team in charge of the removal of organs must beforehand endeavour to obtain testimony from relatives of the deceased. Unless national law otherwise provides, such authorisation should not depend on the preferences of the close relatives themselves for or against organ and tissue donation. Close relatives should be asked only about the deceased persons expressed or presumed wishes. It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved. Parties should make clear whether organ or tissue retrieval can take place if a deceased person’s wishes are not known and cannot be ascertained from relatives or friends.

103. When a person dies in a country in which he/she is not normally resident, the retrieval team shall take all reasonable measures to ascertain the wishes of the deceased. In case of doubt, the retrieval team should respect the relevant applicable laws in the country in which the deceased is normally resident or, by default, the law of the country of which the deceased person is a national.

**Article 18 – Respect for the human body**

104. A dead body is not legally regarded as a person, but nonetheless should be treated with respect. This article accordingly provides that during removal the human body must be treated with respect and after removal the body should be restored as far as possible to its original appearance.
Article 19 – Promotion of donation

105. Because of the shortage of available organs, this article makes a provision for Parties to take all appropriate measures to promote the donation of organs and tissues.

106. The “appropriate” measures are not defined but will include the provisions on information to be provided to health professionals and to the public (Article 8), the need to set up a transplant system (Article 3) and to have recognised means of giving consent or authorisation (Article 17).

107. It is also appropriate to remember that organ and tissue removal from deceased persons has to be given priority if living donation is to be minimised, in conformity with Article 9. However, organ and tissue removal from deceased persons must itself carry safeguards and these are set out in Chapter IV.
Chapter V – Implantation of an organ or tissue removed for a purpose other than donation for implantation

Article 20 – Implantation of an organ or tissue removed for a purpose other than donation for implantation

108. In principle, this Protocol applies to the removal of organs or tissues for transplantation purposes. There are particular circumstances, however, in which those organs or tissues are removed for another purpose than donation for implantation but will nevertheless be donated at a later stage. The classic situation is the so-called “domino” transplant. When for instance a person needs a heart, or more often a lung transplant, it may be technically easier to remove their heart and lungs en bloc and replace them with a donor heart/lung block. Depending on the reason for the transplant, it is possible that the explanted heart, or at least the heart valves, will be in good condition and suitable for transplantation into another recipient. In this way the first recipient becomes a live donor for the second recipient. In the case of a “domino” heart transplant, the heart valves might be harvested from the second recipient’s heart and be transplanted into a third person.

109. This article is also applicable where, in the course of a medical intervention, tissues are removed then processed and re-implanted into someone else, even if they are regarded as discarded tissues at the time of the intervention. In this respect, one could mention the following examples: the use of bone from femoral heads removed during hip replacement; the implant of a kidney removed for medical reasons; the use of vessels obtained from placentae or haematopoietic stem cells from cord blood.
110. The first paragraph of the article stresses the need to inform a person from whom organ or tissue have been removed for a purpose other than donation for implantation of the consequences associated with implantation of the organ or tissue into another person, namely the need for appropriate testing and recording of information which ensures the traceability of the organs or tissues; the information must include potential risks, for instance any modification, even minor, of the surgical procedure needed to retrieve the organ or tissue in the best possible condition for implantation. The first paragraph also stresses the need to obtain the informed consent of the person from whom organ or tissue have been removed or appropriate authorisation for the use of the organ or tissue for implantation. The first recipient of a heart can for instance be a child. In turn his/her heart or the valves which are removed can be implanted in another child, if the persons providing authorisation have agreed after being duly informed.

111. As indicated in Article 2, the second paragraph of Article 20 provides that all the provisions of this Protocol, except for those in Chapters III and IV, which concern issues relating to removal for implantation purposes, apply to the situations referred to in paragraph 1. Indeed, the general provisions of the Protocol that guarantee fundamental rights (with regard namely to safety, confidentiality, non-commercialisation) will apply to the cases referred to in this article.
Chapter VI – Prohibition of financial gain

Article 21 – Prohibition of financial gain

112. This article applies the principle of human dignity as laid down in Article 1 of this Protocol.

113. It states in particular that the human body and its parts must not, as such, give rise to financial gain or comparable advantage. Under this provision, organs and tissues should not be bought or sold or give rise to direct financial gain for the person from whom they have been removed for a third party. Nor should the person from whom they have been removed, or a third party, gain any other advantage whatsoever comparable to a financial gain such as benefits in kind or promotion for example. A third party involved in the transplant process such as a health professional or a tissue bank may not make a profit from organs or tissues or any products developed from them (but see paragraph 115 below).

114. However, Article 21 states that certain payments that a donor may receive are not to be treated as financial gain within the meaning of this article. Essentially, apart from the last indent, these provide examples of expenses that may be incurred during or as a result of donation or other parts of the transplant process. This paragraph does not make exceptions to the principle laid down but gives examples of compensation to avoid possible financial disadvantage which may otherwise occur. In the case of the donor it allows for compensation for loss of earnings and other justifiable expenses.

115. The second indent of the first paragraph refers to payment of a justifiable fee for medical or technical services performed as part of the transplant process. Such acts might include the cost of retrieval, transport, preparation, preservation and storage of organs or tissues, which may legitimately give rise to reasonable remuneration.
116. The third indent allows donors to receive compensation for undue damage resulting from the removal. By undue damage is meant any harm whose occurrence is not a normal consequence of a transplant procedure. This provision refers to the compensation provided for in Article 25.

117. The second paragraph of this article makes it clear that any attempt to advertise anything to do with organ or tissue transplantation with a view to financial or equivalent gain for any party is prohibited.

118. This article refers solely to organs and tissues covered by the Protocol. The provision does not refer to such products as hair and nails for example, which are discarded tissues, and the sale of which is not an affront to human dignity.

**Article 22 – Prohibition of organ and tissue trafficking**

119. As stated by Article 21 of the Convention, the human body and its parts shall not, as such, give rise to financial gain. Any trade in organs and tissues for direct or indirect financial gain, as defined by Article 21 of this Protocol is prohibited. Organ trafficking and tissue trafficking are important examples of such illegal trading and of direct financial gain. Organ or tissue traffickers may also use coercion either in addition to or as an alternative to offering inducements. Such practices cause particular concern because they exploit vulnerable people and may undermine people’s faith in the transplant system. This is why the prohibition of trafficking in organs and tissues is specifically referred to in Article 22.

120. This does not in any way reduce either the seriousness of infringements of other rights and principles enshrined in the Protocol, or the force of the prohibition of infringements of these rights and principles, as laid down in Articles 24 and 26.

121. In conformity with Article 26 of this Protocol, Parties shall provide for appropriate sanctions to deter organ and tissue trafficking or any attempt at commercial trade in organs or tissues.
Article 23 – Confidentiality

122. Article 23 lays down the principle of confidentiality. Preserving the anonymity of the person from whom organs or tissues have been removed may be impossible in certain circumstances, for example because of the requirement of an appropriate relation between the latter and the recipient in the case of living organ donation. However, personal data concerning persons from whom organs or tissues have been removed and recipients must nonetheless be treated as confidential and handled in accordance with the rules on professional confidentiality (4) and personal data protection. Here, the principles laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 (ETS 108) must be observed. In particular, Article 5.b of Convention 108 provides that personal data are "stored for specified and legitimate purposes and not used in a way incompatible with those purposes". Parties should take account of other national or international instruments, such as Recommendation (97) 5 of the Committee of Ministers to the member States on the protection of medical data and, where applicable, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on free movement of such data.

123. In transplantation, it is nevertheless essential that the principle of confidentiality should not prevent the medical team involved in any transplant process from obtaining the necessary information on the person from whom organs or tissues have been removed and the recipient, and keeping track of the exchange of organs or tissues between them, subject to appropriate safeguards to ensure adequate data protection. One such person may in fact supply several organs or tissues to be implanted in more than one
recipient. If a disease is subsequently detected in that person, the recipients must be traceable. Equally, if a recipient of a transplant develops a disease which may have been transmitted, the person from whom organs or tissues had been removed must be identified, again to trace any other recipients. The rules applicable to traceability of organs and tissues are as set out in Article 3 paragraph 3 of this Protocol.
Chapter VIII – Infringements of the provisions of the Protocol

Article 24 – Infringements of rights or principles
124. This article requires the Parties to make available a judicial procedure to prevent or put a stop to an infringement of the principles set forth in the Protocol. It therefore covers not only infringements which have already begun and are ongoing but also the threat of an infringement.
125. The requisite judicial protection must be appropriate and proportionate to the infringement or the threats of infringement of the principles. Such is the case, for example, with proceedings initiated by a public prosecutor in cases of infringements affecting several persons unable to defend themselves, in order to put an end to the violation of their rights.
126. Under the Protocol, the appropriate protective machinery must be capable of operating rapidly as it must ensure that an infringement is prevented or halted at short notice. This requirement can be explained by the fact that, in many cases, the very integrity of an individual has to be protected and an infringement of this right might have irreversible consequences.
127. The judicial protection thus provided by the Protocol applies only to unlawful infringements or to threats thereof.

Article 25 – Compensation for undue damage
128. This article sets forth the principle that the person who has suffered undue damage resulting from a transplantation is entitled to fair compensation. Like the Convention, the Protocol uses the expression “undue damage” because there can be damage which is inherent in the transplantation itself.
129. The due or undue nature of the damage will have to be determined in the light of the circumstances of each case. The cause of the damage must be either an act or an omission during the transplantation procedure. In order to give entitlement to compensation, the damage must result from the transplantation. Potential donors might be wronged during investigations to determine their suitability, as might recipients. In view of the altruistic nature of live organ donation, particular attention should be paid to the rights of donors and potential donors to an adequate compensation for damage resulting from transplantation.

130. Compensation conditions and procedures are not prescribed in this Article. In many cases, the national law establishes a system of individual liability based either on fault or on the notion of risk or strict liability. In other cases, the law may provide for a collective system of compensation irrespective of individual liability.

131. On the subject of fair compensation, reference can be made to Article 41 of the European Convention on Human Rights, which allows the Court to afford just satisfaction to the injured party.

132. Article 21 of this Protocol makes reference to the aforementioned compensation in such terms as to exclude it from any payments constituting a financial gain or a comparable advantage.

Article 26 – Sanctions

133. Since the aim of the sanctions provided for in Article 26 is to guarantee compliance with the provisions of the Protocol, they must be in keeping with certain criteria, particularly those of necessity and proportionality. As a result, in order to measure the expediency and determine the nature and scope of the sanction, domestic law must pay special attention to the content and importance of the provision to be complied with, the seriousness of the offence and the extent of its possible repercussions for the individual and for society.
Chapter IX – Co-operation between Parties

Article 27 – Co-operation between Parties

134. International co-operation in transplantation matters is important for two main reasons. The first is that information about the organisation and effectiveness of services, successful methods of e.g. informing and educating the public or procuring organs, success rates and new developments should all be freely exchanged to help all States achieve the most effective transplant services possible within the resources available.

135. Secondly, difficulties of tissue matching or the urgency of the clinical condition may require access to a large or very large population if the transplant is to be successful. For example, matching for unrelated bone marrow transplants requires a very large pool of donors. People with fulminant liver failure may need a suitable organ within a few hours if they are to survive. If an organ becomes available in a country which has no suitable patient on its waiting list, there must be arrangements in place to allow that organ to be offered rapidly to patients on other transplant waiting lists if the organ is not to be wasted. States Party to this Protocol are expected to set up transborder links so as to facilitate the exchange of information and the transportation of organs and tissues between States but without prejudice to public safety as specified in Article 6 and the need for confidentiality as specified in Article 23.
Chapter X – Relation between this Protocol and the Convention, and re-examination of the Protocol

Article 28 – Relation between this Protocol and the Convention

136. As a legal instrument, the Protocol supplements the Convention. Once in force, the Protocol is subsumed into the Convention vis-à-vis Parties having ratified the Protocol. The provisions of the Convention are therefore to be applied to the Protocol.

137. Thus, Article 36 of the Convention, which sets out the conditions under which a State may make a reservation in respect of any particular provision of the Convention, will also apply to the Protocol. Using this provision States may, under the conditions set out in Article 36 of the Convention, make a reservation in respect of any particular provision of this Protocol.

Article 29 – Re-examination of the Protocol

138. This article provides that the Protocol shall be re-examined no later than five years from its entry into force and thereafter at such intervals as the Committee in charge of the re-examination may determine. Article 32 of the Convention identifies this Committee as the Steering Committee on Bioethics (CDBI), or any other Committee so designated by the Committee of Ministers. The provisions of the Protocol to be re-examined would especially concern aspects of transplantation where scientific developments would give rise to particular ethical or legal issues; for example, it is conceivable that the question of removing cells from a living person will need to be reconsidered after a few years.
Chapter XI – Final clauses

Article 30 – Signature and ratification

139. Only States which have signed or ratified the Convention may sign this Protocol. Ratification of the Protocol is subject to prior or simultaneous ratification of the Convention. Under the provisions of Article 31 of the Convention, a State which has signed or ratified the Convention is not obliged to sign the Protocol or, if applicable, to ratify it.
Notes

1. Membership of the CAHBI-CO-GT1: Dr Örn BJARNASON (Iceland), Dr Radkin HONZÁK (Czechoslovakia), Ms Sophie JACQUOT-DAVID (France), Dr Jaman ÖRS (Turkey), Dr Daniel SERRÃO (Portugal) and Mr Peter THOMPSON (United Kingdom).

2. Membership of the CDBI-CO-GT1: Dr Christiane BARDOUX (European Commission), Dr Örn BJARNASON (Iceland), Dr Peter DOYLE (United Kingdom), Ms Isabelle ERNY (France), Dr Radkin HONZÁK (Czech Republic), Dr Blanca MIRANDA (Spain), Dr Lars-Christoph NICKEL (Germany) and Mr Ergün ÖZSUNAY (Turkey).

3. A draft text on health and safety from the medical point of view is being prepared by the European Health Committee.

4. In this respect, it has been agreed that the wording "professional confidentiality" in English conveys the same meaning as the wording "secret professionnel" in French.
The EDQM is a Directorate of the Council of Europe, an international organisation founded in 1949 that covers almost the entire continent of Europe. The Council of Europe aims to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.