COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(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 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 fully established. More controlled clinical trials are needed whose results may be assimilated and interpreted by meta-analysis.

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 c linical 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;

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, au to 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 implemen ting 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 specialis ts 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 re port 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 h ospital 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 o perating 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 transfus ion 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;

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

$$\frac{\text{No of blood units transfused}}{\text{No of blood units collected}}$$

$$\frac{\text{No of blood units transfused}}{\text{No of blood units issued}}$$

$$\frac{\text{No of blood units cross-matched}}{\text{No of blood units transfused}}$$

No of group "O" blood given to group "A" or group "B" patients

2. Evaluation of use of blood at local level

$$\frac{\text{No of blood units transfused}}{\text{No of blood units distributed}}$$

$$\frac{\text{No of blood units transfused}}{\text{No of blood units prescribed}}$$

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);

- 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 no t 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.