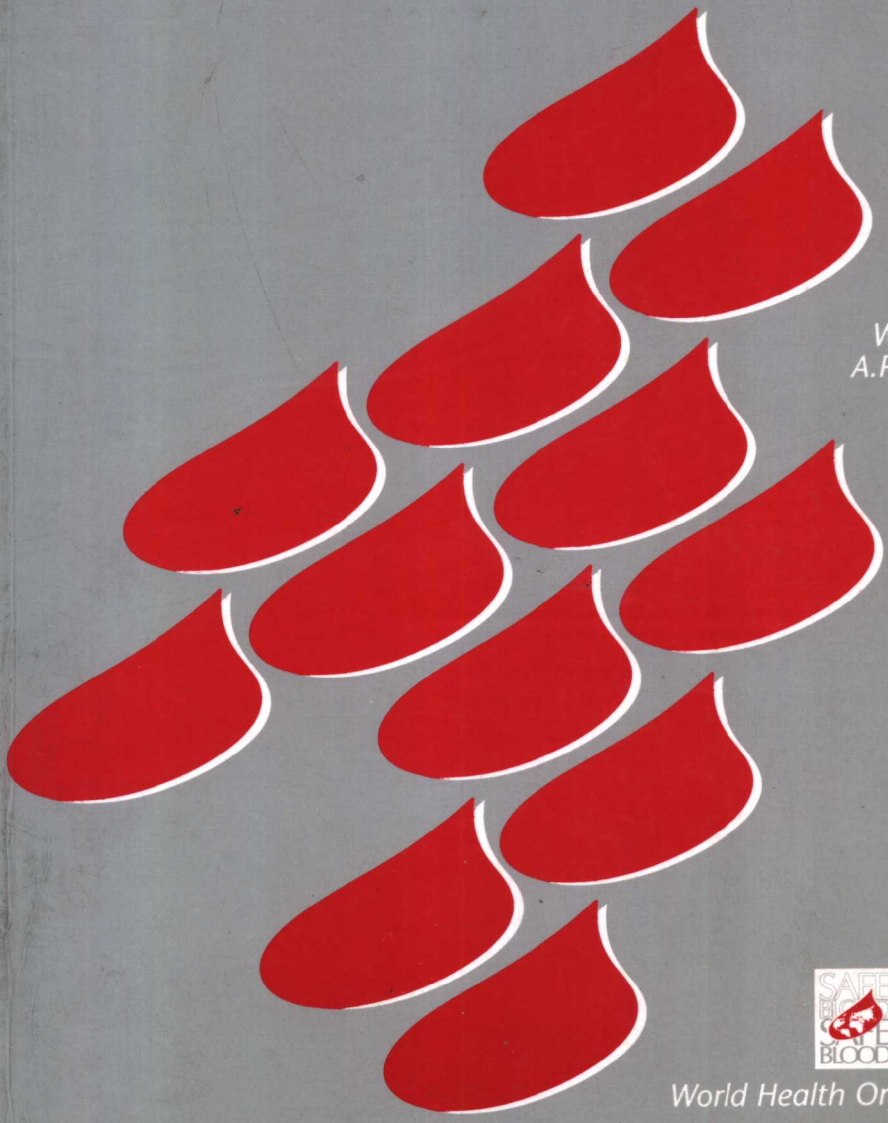
Guidelines for the organization of a BLOOD TRANSFUSION SERVICE



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Preface

This book updates and replaces *Blood transfusion: a guide to the formation and operation of a transfusion service*, which was first published by the World Health Organization in 1971, with an addendum in 1978. Its main objective is to facilitate the organization of blood transfusion services in developing countries, and it is therefore intended primarily for those who are entrusted with the task. Technical details are not included, but extensive guidance may be obtained from the selected reading list at the end of the book. Readers are also referred to the manual *Management of blood transfusion services* (WHO, 1990) for details of some aspects of organizing blood transfusion services, notably personnel matters and cost accounting.

The editors are grateful to all who contributed to this book, both those who wrote the various chapters and those who commented on the material and suggested improvements. However, the editors accept full responsibility for the contents and welcome further comments and suggestions from readers.

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Resolution WHA 28.72 of the Twenty-eighth World Health Assembly, 29 May 1975

UTILIZATION AND SUPPLY OF HUMAN BLOOD AND BLOOD PRODUCTS

The Twenty-eighth World Health Assembly,

Conscious of the increasing use of blood and blood products;

Having considered the information provided by the Director-General on utilization and supply of human blood and blood products;

Bearing in mind resolution XVIII of the XXII International Conference of the Red Cross;

Noting the extensive and increasing activities of private firms in trying to establish commercial blood collection and plasmapheresis projects in developing countries;

Expressing serious concern that such activities may interfere with efforts to establish efficient national blood transfusion services based on voluntary nonremunerated donations;

Being aware of the higher risk of transmitting diseases when blood products have been obtained from paid rather than from voluntary donors, and of the harmful consequences to the health of donors of too frequent blood donations (one of the causes being remuneration),

1. Thanks the Director-General for the actions taken to study the problems related to commercial plasmapheresis in developing countries;
2. Urges Member States:
   (1) to promote the development of national blood services based on voluntary nonremunerated donation of blood;

(2) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products;

3. Requests the Director-General:
   (1) to increase assistance to Member States in the development of national blood services based on voluntary donations, when appropriate in collaboration with the League of Red Cross Societies;
   (2) to assist in establishing cooperation between countries to secure adequate supply of blood and blood products based on voluntary donation;
   (3) to further study the practice of commercial plasmapheresis including the health hazards and ethical implications, particularly in developing countries;
   (4) to take steps to develop good manufacturing practices specifically for blood and blood components in order to protect the health of both donors and recipients; and
   (5) to report to the World Health Assembly on developments in these matters.

Contents

Chapter 1

Organization of a blood transfusion service

IMPORTANCE OF THE BLOOD SUPPLY

The life-saving properties of transfused blood became clear during the Second World War, and thereafter blood transfusion quickly became a routine hospital function. Without blood transfusion, the treatment of severe haemorrhage is difficult or impossible and many surgical procedures cannot be safely attempted. Haematological conditions such as thalassaemia, haemophilia, leukaemia, and aplastic anaemia cannot be treated effectively without support from the blood transfusion service. No general hospital can be effective unless it can perform blood transfusions, and if blood is not available from an outside source, the hospital itself is obliged to undertake the task of blood collection.

The recruitment and selection of blood donors are critical to the success of a blood programme, and every effort must be made to ensure both the safety of the donor and the safety of the transfusion for the recipient. The process of donor selection is reliable only when information provided by donors can be trusted, and experience has shown that this is most likely when there is no material gain from donation. Problems in donor selection are considerably reduced when a blood transfusion service is founded upon the principle of voluntary, unpaid blood donation.

When donors are remunerated, they are often overused by the transfusion service, and there is an increased risk of disease transmission. Recruitment of patients' families as donors ("replacement" or "family" donation) frequently places undue

pressure upon these families, which may force them to pay professional donors to serve as surrogates. The risk of blood donation and transfusion creating new health hazards necessitates the maintenance of the strictest standards, and rigorous quality control is therefore essential.

Because of the importance of blood transfusion services, and the many problems inherent in their organization, the World Health Assembly adopted resolution WHA28.72 (see page ix) in 1975. This remains the basis of the policy of the World Helath Organization as regards blood transfusion services.

The goal

The goal of blood transfusion services is to provide effective blood and blood products, which are as safe as possible, accessible at reasonable cost, and adequate to meet patients' needs.

The amount of blood collected varies greatly from country to country—from more than 100 donations per thousand inhabitants per year to less than 1 donation per thousand. An adequate amount is that which is required to satisfy the needs within a particular health care system. Adequacy, however, depends not only on absolute amounts but also on quality and on the range of products that can be made available. An adequate service should be able to provide at least whole blood, red blood cells, plasma,[1] platelets, and cryoprecipitate.

ORGANIZATION OF BLOOD TRANSFUSION SERVICES

The national blood transfusion service is ultimately the responsibility of the national government. This responsibility may be carried out by government agencies or delegated wholly or in part to other organizations, such as the national Red Cross/Red Crescent Society.

In many countries, funds for health services are restricted, resulting in limited funding for transfusion services. Provision of adequate financing, however, is a prerequisite for satisfactory transfusion services (see Appendix 1 to this chapter, page 12), for which there should be a separate budget,

[1] These guidelines do not deal with the provision of plasma, obtained by plasmapheresis, as source material for plasma fractionation.

generally equivalent to between 0.5% and 1.5% of the total costs of hospitals.

National blood transfusion committee

The task of meeting the country's needs for blood and blood products requires cooperation between the blood transfusion service, health authorities, hospitals, medical associations, the mass media, and the general public. In large countries, there may be considerable regional differences in blood needs, which must also be taken into account. The creation of an effective national transfusion committee, with broad representation from all the above groups, will increase the possibility of cooperation. One of the functions of such a committee should be the formulation of national blood policy, which will include rules and regulations for the import and export of blood and blood products, the collection, processing, storage, transport, and distribution of blood within the country, and the administration of blood and blood products to patients.

National blood transfusion service

Personnel

The organization and operation of a national blood transfusion service requires both management and medical skills, ideally provided by one medically qualified director with appropriate postgraduate training. A large transfusion service may also require the appointment of a manager (see Appendix 2 to this chapter, page 14). Regardless of the scale of operations, however, the director alone has ultimate responsibility for the operation of the service. Other personnel requirements are outlined in Appendix 2.

Organizational systems

The organization of blood transfusion services has evolved differently in different countries, according to their size, climate, history, culture, political structure, and level of economic development. An island nation with a population of, say, 75 000, with only two hospitals, does not need the same organization as an industrialized country with 50 million inhabitants.

A transfusion service may be centralized, regionalized, hospital-based, or some combination of these. Once a system has been established, it is difficult to change. Blood collection may be organized through blood centres, hospitals, or, as in many countries, both. Large countries have found it practical to be organized regionally, with one centre responsible for each region.

There are examples of success in all four systems in developed and developing countries. There are also significant examples of organizational breakdown in some mixed systems, and in some uncoordinated, hospital-based systems. Satisfactory results are most easily achieved with centralized or, in large countries, regionalized systems. Hospital-based systems may be satisfactory if they are centrally regulated and coordinated, particularly in small countries.

Centralized organization. In a centralized system, one national blood transfusion centre operates the services for the whole country, with or without satellite regional centres. Finland and Jamaica are examples of countries with this type of system. The advantages of this arrangement are facilitation of planning, and central control of product availability, quality assurance, and problem-solving. In large countries, however, centralization may be cumbersome: in some cases, the needs of hospitals are not satisfied, and hospitals themselves have very little influence on decisions.

Regionalized organization. Regionalized organization of a transfusion service depends upon a country being divided into regions that enjoy a considerable degree of autonomy (but that may have different mechanisms for achieving national control and logistic coordination). There may be a strong national transfusion centre with direct control of regional blood collection centres, or a loose national coordinating body that exercises little control. The systems operated in some countries fall between these two extremes.

For large countries, regionalization increases the efficiency of administration by ensuring that planning, control, and problem-solving are coordinated at the regional level, and allows close contact to be maintained with local hospitals. Australia and Zimbabwe are examples of countries with regionalized systems. National coordination is sometimes difficult to achieve, however, and efficiency can be weakened where there are too many centres or regions.

Hospital-based organization. Where organization of the blood transfusion service is hospital-based, as in Denmark and Malaysia for example, each hospital runs its own blood-collection programme, with or without central regulation and logistic coordination. This system utilizes existing institutions and does not require creation of separate blood centres. It may operate satisfactorily when there is adequate central regulation, and is suitable for the smallest countries. When there is no central regulation or logistic coordination, however, community organization of blood donation in hospital-based systems is usually unsatisfactory. Replacement or paid-donor programmes often arise. Regulation, coordination between hospitals, inventory balancing, quality assurance, and rational production planning are difficult or impossible to achieve.

Mixed systems. Some hospitals collect blood independently, and some use the services of blood centres. This encourages institutional independence, competition, and ingenuity, but has the same disadvantages as the uncoordinated, hospital-based system. Competition for blood donors may destroy institutional cooperation and undermine public support for the blood transfusion service. The United States of America has a mixed system.

FUNCTIONS OF NATIONAL BLOOD TRANSFUSION SERVICES

Ultimate responsibility for a national blood transfusion service lies with the national government, even when its operation is delegated wholly or partially to organizations such as the Red Cross or Red Crescent Society. Management and operation of the services should be delegated to suitably qualified professionals.

The scope of the transfusion service can vary widely, depending upon local circumstances and resources. Table 1 outlines the targets for transfusion services at levels of development from basic to sophisticated. The basic requirement for any transfusion service is a quality assurance scheme that is applicable to all of its operations (see Chapter 8), which should include good manufacturing and laboratory practice, with adequate internal quality controls. The amount of blood collected should satisfy national needs, and appropriate storage facilities must be available. The national blood transfusion

Table 1. Evolution of blood transfusion services

Stage of development	Products	Screening for transmissible infectious agents	Blood-grouping	Cross-matching	Storage	Other
1. Inadequate	Whole blood only	None	ABO	None or slide room temp.	Uncontrolled	—
2. Basic, adequate	Whole blood (WB) (CPD-A1 preferred) Red cells (RBC)	Syphilis, HBsAg, HIV, and others as determined by national blood policy	ABO, D (tube or microplate)	Major 37°C (AHG)	Controlled	—
3. Basic, full-range	WB, RBC (0–30%) plasma, platelets, cryoprecipitate	As in 2	As in 2, plus antibody screening (donor)	As in 2, plus antibody screening (patient)	As in 2	Antibody screening and identification Reagent production
4. Highly productive	As in 3, plus RBC (30–100%) using additive solutions	As in 2	As in 3	As in 3	As in 2	As in 3
5. Advanced	As in 4, plus frozen RBC, washed RBC, special products, cytapheresis	As in 2	As in 3	As in 3	As in 2	As in 3
6. Sophisticated	As in 5	As in 2	As in 3	As in 3	As in 2	As in 3, plus automation, computers, plasma fractionation, basic research, etc.

Comments
Stage 1 is unsatisfactory and must be rectified.
Stage 2 is adequate for peripheral hospitals; a transfusion service at this level should progress as soon as possible to Stage 3.
Stage 3 should be regarded as a minimum for referral centres.
Stage 4 or 5 is essential for advanced haematological centres.
Stage 6 is discretionary for countries with adequate resources.

service must also develop the capability to screen for transmissible infectious agents, as determined by the national blood policy.

One of the major responsibilities of a national blood transfusion centre, or of a regional centre in a country in which the transfusion service is organized regionally, is motivation and recruitment of donors (see Chapter 2). The centre is also responsible for blood collection (Chapter 3), testing and screening of donor blood (Chapters 4 and 6), preparation of blood components, and storage and distribution of blood and components to hospitals. A national transfusion centre should organize training, prepare reagents (see Chapter 5), and act as a reference laboratory; it may be involved in more specialized functions such as autologous donation, histocompatibility services, or blood coagulation studies. Most countries are able to prepare at least some of the immunohaematological reagents they require (e.g., anti-A, anti-B). National or regional centres should also be involved in setting policies for transfusion of blood and blood products (Chapter 9).

Detailed arrangements for collection, processing, distribution, and compatibility testing of blood and blood components will depend upon factors such as geography and communications, as well as the availability of trained personnel. There may be collection centres in hospitals, from which all blood is sent to blood centres for processing and then redistributed to hospitals according to their needs. Compatibility testing is then performed at the hospitals (see Chapter 6). On the other hand, some or all of the compatibility testing may be done in the blood centres. Depending upon its size, and its function within the national health service, a hospital may also be involved in some of the functions outlined for blood transfusion centres, such as preparation of blood components, training of personnel, and collecting plasma for fractionation. Blood and blood components are usually transfused in hospitals (see Chapter 9).

Estimation of the donor requirement

The driving force for blood collection is usually the need for red cells. Estimates of need may be based on a fixed percentage of the population, but this assumption ignores the disparity that exists in many countries between the size of the population and the number of hospital beds. It is therefore more realistic