

Management of **BLOOD TRANSFUSION SERVICES**

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Preface

Resolution WHA28.72, adopted by the Twenty-eighth World Health Assembly in 1975, requested the Director-General of the World Health Organization (WHO) to increase assistance to Member States in the development of national blood transfusion services.

The blood transfusion service is a vital but very often neglected part of the national health service, although blood and blood products have become indispensable in medical treatment during the past thirty years. Blood transfusion is a broadly based discipline that overlaps and intersects many other medical, scientific and managerial fields, including haematology, immunology, genetics, histocompatibility, cellular function and metabolism, protein structure and function, cryobiology, disposable equipment, bioengineering, statistics, data processing, public relations, logistics, and standardization.

Coordinated long-range planning is needed for the development and integration of such diverse activities, together with careful consideration of priorities and optimal use of resources. This is particularly important in developing countries where financial and other resources are usually very limited.

Accumulated information has revealed that blood transfusion specialists, especially in developing countries, often need training in various aspects of management, such as planning the development of a national blood transfusion service, or expanding and improving the efficiency of an existing one, calculating the present and projected needs for blood, determining priorities in developing production of essential blood derivatives, and preparing budgets for the development or expansion of such services. Guidance is needed for the planning of the premises and for staff training, for estimating the number of personnel required, and for preparing instructions (including

principles and practice of quality assurance), regulations and job descriptions.

In view of these needs, WHO and the Government of Hungary organized a postgraduate course on management of blood transfusion services for directors and leading experts of national blood transfusion services. The course took place in Budapest, Hungary, from 26 September to 8 October 1983, with the participation of the League of Red Cross Societies (LORCS) and the International Society of Blood Transfusion (ISBT). Financial support was provided by the United Nations Development Programme (UNDP).

The idea for this book, which is intended as a guide for senior staff, particularly in developing countries, arose from the lectures and discussions that took place during the course. Most of the authors are directors of blood transfusion services, and the subjects chosen and the emphasis given reflect their experience.

As there is no universal established general policy on management of blood transfusion services, the chapters of this book should be taken as examples of possible approaches; the proposals made should, in general, be considered as indications that may have to be adapted, and even at times radically changed, to suit local circumstances.

Anyone who needs more detailed information is urged to consult specialized texts; a selected list of further reading material is given at the end of the book.

* * * * *

The editors of the book thank the reviewers for their helpful comments and wish to acknowledge in particular the input of Dr R. A. Lema, Professor of Haematology and Blood Transfusion at the Faculty of Medicine, Dar es Salaam, United Republic of Tanzania.

The editors also wish to acknowledge the important contribution of Dr Ilma Szász, Head of the Clinical Biochemistry Department, National Institute of Haematology and Blood Transfusion, Budapest, Hungary, in preparing the manual for the course in 1983 which formed a useful starting-point for this book.

Resolution WHA28.72 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 plasma-pheresis 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 donations;
 - (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.

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Chapter 1

Formulation of a national blood programme

J. Leikola¹

Transfusion of blood and blood products is an established standard way of treating patients who are deficient in one or more blood constituents, and is therefore an essential part of health care. The organization of blood transfusion services should be an integral part of any national health policy. Where health authorities do not undertake this task, and do not delegate it to organizations such as the Red Cross or Red Crescent, commercial blood banks will be established on an *ad hoc* basis. This is likely to lead to exploitation of both donors and patients, and to increased risks of transferring diseases by blood transfusion.

NATIONAL BLOOD POLICY

A country's blood policy can be defined as the clearly expressed view of the national health authority on how blood donation and transfusion should be arranged in that particular country. It should include details of the following.

- Any established and relevant legislation, plus applicable government rules and regulations.
- Delegation of some or all activities to institutions, hospitals and organizations such as the Red Cross, with a clear division of responsibilities if several institutions or organizations are

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involved. The role of any commercial enterprises involved should be clearly defined.

- The role of a national blood transfusion committee.
- The role of other bodies, such as professional societies.

While it is not necessary for the ministry of health to be directly involved, the formulation of a national blood policy will prevent the uncoordinated and uncontrolled establishment and maintenance of blood banks of dubious quality and ethics.

The exact nature and interpretation of a national policy will be very different in a small country with a population of a few thousand from that in a large country where the population may number several hundred million; however, the general framework should always be recognized and approved by the national authorities. There are few guidelines on how to establish a national blood policy, and indeed the way in which the policies are expressed varies considerably from country to country. Some states have elected to enact extensive legislation covering the whole field and defining in detail the roles of all parties concerned. In other countries where, by tradition, only one organization effectively administers all needs relating to blood and blood products, it has proved unnecessary to express the national policy in lengthy written form. The latter approach has been successful, but only in circumstances where the social infrastructure is stable and the concept of common law is applied to many other functions of society. In general it is preferable to have pertinent legislation on the national blood policy.

Ethical considerations are important. In 1975, the World Health Assembly urged the Member States of WHO '... to promote the development of national blood transfusion services based on voluntary, nonremunerated donation of blood'. Although nonremuneration is no longer a matter of controversy, many blood banks still use paid donors. Moreover, in some of the countries in which payment of donors of whole blood is now unacceptable, the need for plasma products, especially coagulation factor VIII, is still satisfied by plasma obtained from paid donors under strictly controlled conditions. It should be stressed that the risk to the donor and to the recipient is increased when cash provides the motive for the donation. Evidence from several countries has indicated that national self-sufficiency in all blood products can be achieved by using voluntary, unpaid donors.

The Code of Ethics for Blood Donation and Transfusion, as formulated by the International Society of Blood Transfusion

(ISBT) and later adopted by the highest bodies of the Red Cross movement, gives useful guidelines for national policies. In 1984 the ISBT drafted a model for a national blood policy outlining certain principles that should be taken into consideration (see Appendix, page 14).

In some countries, funds to cover the costs incurred by the blood transfusion service are provided directly by the government. In others, the service charges a processing or handling fee for the different blood products. Whatever the method of financing, the national blood policy should include the framework of funding, type of budgeting and financial control. In many countries, whether industrialized or developing, the costs (capital and recurrent) of the blood programme constitute 0.7–1.2% of the total costs for all hospital care.

Transfusion services in developing countries may occasionally be offered support by organizations in the more industrialized countries, in the form of gifts, for example of laboratory equipment, machinery and vehicles. Such support should be accepted with caution, with due regard to the integration of the gift into the existing system, to the availability of the expertise required to use the equipment and, above all, to local availability of spares and maintenance services. It is not unknown for such a gift to remain unused simply because the necessary electricity supply does not exist.

ALTERNATIVE STRUCTURES

Blood collection, storage, processing and distribution can be arranged by different organizations—Red Cross (in Islamic countries, Red Crescent) blood programmes, government blood transfusion services, hospital blood banks, non-profit organizations other than the Red Cross, and commercial enterprises. All five types of organization may coexist in one country. In fact, there is only a small number of countries in which the national blood programme is maintained by just one organization.

Blood collection, processing and distribution have been entrusted to the Red Cross or Red Crescent Society as a national responsibility in more than twenty countries. Large, well-developed blood programmes of this type effectively take care of all the national needs in countries such as Australia, Belgium,

Canada, Finland, Japan, the Netherlands and Switzerland. The technology in these blood transfusion services is well advanced and characterized by a high proportion of component therapy compared with the use of whole blood.

Other Red Cross and Red Crescent blood programmes are more modest in scope or in the technology they employ, although they also fulfil national needs. Examples of such blood programmes are found in Hong Kong, Indonesia, the Republic of Korea and Thailand.

Finally, in some developing countries of small size and population, even a relatively modest Red Cross or Red Crescent programme is able to cover the whole nation. Such countries include Burundi, Nepal, Nicaragua, Papua New Guinea, Rwanda and Somalia.

In a number of countries the network of blood transfusion services is the direct responsibility of the health authorities. Typical examples of well functioning blood programmes are found in France, Hungary, Ireland, New Zealand and the United Kingdom.

Some countries, in accordance with their general economic structure, have adopted a relatively centralized, state-run organization. Government blood transfusion services also exist in a number of developing countries; some of them are well organized and making good progress despite severe economic constraints. Examples include Barbados, Cuba, Egypt, Islamic Republic of Iran, Kenya, Jamaica, Malaysia, Myanmar, Senegal, Singapore, Sri Lanka, Uruguay and Venezuela.

In general the government services are supplemented by an input from national Red Cross Societies and other voluntary organizations. Donor associations play an important role in the recruitment of new donors in many countries. In order to be effective this has to be carefully coordinated with the technical activities of the transfusion centres: a reliable and adequate supply of blood throughout the year is more important than a very large number of donations annually.

Many countries have chosen not to create national blood programmes but to leave the hospitals to solve the problem directly. The reasons for this are usually historical, such as the independence of some leading hospitals or the wish to avoid giving a 'monopoly' to any organization. In some cases, however, especially in developing countries, a national policy is created but ignored; unfortunately there are numerous examples of this. Nevertheless, a few countries such as Denmark and Sweden have

succeeded in arranging efficient systems based entirely on hospital blood banks.

Hospital blood banks have the advantage of dealing with both donors and patients and can undertake investigations of both in the same laboratory. They are closer to clinical development trends and thus able to respond quickly to changing needs. Duty rosters for personnel are usually easier to arrange in hospitals than in isolated blood transfusion services. However, there are also serious disadvantages and these have stimulated the development of independent services. First, blood donor recruitment is often not sufficiently appreciated in the hospital atmosphere. Second, the hospital premises may make the voluntary healthy donor apprehensive. Third, the existence of numerous, independent, small blood banks results in competition for donors and in unbalanced collection of blood, which is less satisfactory than the carefully coordinated activities of a medium-sized or large transfusion service. The advantages of centralization and the possibility of concentrating activities that are needed only on a national basis (such as reference laboratories, fractionation, or rare blood) are lost when there are several independent small blood banks.

In countries with a traditionally high respect for private initiative, voluntary, nonremunerated blood donations may be arranged by community-based, non-profit organizations other than the Red Cross. In the United States, there is a large number of such organizations. They also exist in some developing countries, for example Brazil and Zimbabwe. Provided that the principle 'not for profit' is honoured, the donors are voluntary and unpaid and the activity complies with the ethical principles established by the ISBT, the private organizations render a commendable service to the society.

NATIONAL BLOOD PROGRAMME

A national blood programme, which should not be confused with the concept of a national blood policy, can be defined as an administrative entity that covers the national needs for blood and blood components. If only one organization is involved, the blood programme is often called a blood transfusion service or blood service. The definitions are not entirely clear and the terms are sometimes used interchangeably. The national blood programme