Management of blood transfusion services

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Contents

Preface ........................................ xi
Resolution WHA28.72 of the Twenty-eighth
World Health Assembly ........................ xi

Chapter 1.  Formulation of a national blood programme
by J. Leikola .................................... 1
National blood policy .......................... 1
Alternative structures .......................... 3
National blood programme ................... 5
National blood transfusion committee ....... 7
Estimating the need for blood and cellular
products ......................................... 8
Estimating the need for plasma products ... 10
Component therapy ............................ 11
Appendix. A model for a national blood policy 14

Chapter 2.  Development of a national blood transfusion
service
by Susan R. Hollán ............................ 17
Introduction .................................. 17
General considerations ........................ 17
Basic functions of a blood transfusion centre . 20
National blood transfusion centre ............ 22
Regional blood transfusion centres .......... 23
District hospital blood transfusion centres .. 25

Chapter 3.  Calculation of present and projected blood needs
by Cornelia Szilassy ........................... 27
Introduction .................................. 27
Guidelines for calculations .................... 27
Chapter 4. Donor recruitment
by Susan R. Hollán and Cornelia Szilassy . . . 31
Introduction ......................................... 31
General considerations ............................. 31
Guidelines for action ............................... 33
Motivation and propaganda ....................... 34
Assessment of recruitment efficiency ............ 37

Chapter 5. Design of premises for a blood transfusion centre
by Judith Pintér, Cornelia Szilassy and
G. Polner ........................................... 39
Introduction ........................................ 39
General considerations ........................... 40
Functional plan .................................... 43
Designing a blood transfusion centre ............. 47
Preliminary and detailed planning ................ 49

Chapter 6. Basic equipment for blood transfusion centres
by F. Haskó and Ilma Szász ........................ 58
Introduction ....................................... 58
Procurement of equipment ......................... 59
Maintenance of equipment ......................... 61
Safety precautions .................................. 62
Appendix. Suggested list of equipment for
a blood transfusion centre ......................... 66

Chapter 7. Standardization of equipment: calibration
procedures
by Ilma Szász ....................................... 71
Introduction ....................................... 71
Materials and methods ............................ 72
Different approaches for standardizing
equipment ........................................... 81

Chapter 8. Transportation
by W. Wagstaff, Nandran S. de Zoysa and
Masri Rustam .................................... 86
Introduction ....................................... 86
Choice of vehicle type .............................. 86
Special adaptation of vehicles ...................... 88
Transport of blood and blood products .......... 89
Maintenance and breakdown service ............. 91
Transport department staff ....................... 92
Chapter 9. Inventory control, storage and disposal
by E. Brodheim and R. W. Beal ................. 94
Logistics of blood supply ....................... 94
Inventory control concepts .................... 96
Inventory control methods for blood products . 96
Inventory control methods for reagents and materials ......................... 99
Refrigeration and storage ..................... 100
Dispatch ........................................ 103

Chapter 10. Quality control in blood transfusion centres
by G. Medgyesi and J. Kádár ................. 105
General considerations .......................... 105
Premises of blood transfusion centres ........ 106
Quality assurance of equipment ............... 107
Quality control of reagents .................... 111
Quality control of systems and procedures . 113
Monitoring blood component quality .......... 118
Quality control of blood transfusion practice . 124
Appendix. Some international standards and international reference preparations used in the control of blood products and related substances. ......................... 126

Chapter 11. Transfusion and viral infections: prevention of transfusion-transmitted AIDS and hepatitis
by G. Medgyesi ................................. 128
Transfusion and viral hepatitis ................ 128
Transfusion and acquired immunodeficiency syndrome .......................... 130
Conclusions .................................... 134

Chapter 12. Planning the workforce
by Susan R. Hollán and F. Haskó ............... 135
Introduction .................................... 135
Recruitment and selection of staff ............ 136
Staff training ................................... 137
Appendix. Examples of staff categories in the donor department of a blood transfusion centre 142

Chapter 13. Continuing education in the blood transfusion service
by Susan R. Hollán ............................. 143
General considerations ........................ 143
Management of blood transfusion services

Training programmes ........................................ 143
Training of transfusion centre staff .................... 144
Training of hospital staff ................................ 147

Chapter 14. Personnel management
by W. Wagstaff ............................................. 148
Introduction .................................................. 148
Job descriptions .......................................... 149
Pay and allowances ....................................... 151
Motivation and career prospects ....................... 152
Disciplinary procedure ................................... 153
Grievance procedure ...................................... 166
Relationship with hospitals and the general public .................................................. 169
Appendix 1. Example of personal specification for a job (Assistant Area Personnel Officer) ........ 170
Appendix 2. Example of job description (Senior Technician) ............................................. 172
Appendix 3. Sample letter confirming disciplinary hearing ........................................... 174
Appendix 4. Sample letter confirming disciplinary action ............................................. 175

Chapter 15. Legal responsibilities to blood donors and recipients
by A. André ..................................................... 177
Introduction .................................................. 177
Ethical aspects ............................................. 178
Legal aspects ............................................... 178
Informed consent ......................................... 179
Insurance .................................................... 180
Liability ..................................................... 180
Appendix. A code of ethics for blood donation and transfusion .................................. 183

Chapter 16. Basic financial considerations for planning a national blood transfusion programme
by C. R. Duncan ............................................. 187
Capital budgeting ........................................... 187
Cost accounting ............................................. 199

Chapter 17. Use of computers in the blood transfusion service
by F. Olti ..................................................... 215

vi
General considerations ..................... 215
Guidelines for action ...................... 217

Chapter 18. The role of international organizations in blood transfusion
by F. Lothe ............................. 220
International Society of Blood Transfusion . 221
League of Red Cross and Red Crescent
Societies ................................ 222
World Health Organization .................. 223
International Federation of Blood Donor
Organizations ............................ 224
International Society of Haematology ...... 224
International Society of Thrombosis and
Haemostasis ............................ 224
World Federation of Haemophilia .......... 225
International Committee for Standardization in
Haematology ............................ 225
International Organization for Standardization 225
Council of Europe ........................ 226

Selected reading .......................... 227
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 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 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.
Chapter 1
Formulation of a national blood programme

J. Leikola

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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1 Formerly Blood Programme Director, League of Red Cross and Red Crescent Societies, Geneva, Switzerland.
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
may or may not be involved in the preparation of plasma derivatives. Its organization may be loose with independent regional centres (e.g. France, the Netherlands) or coherent with strong centralization (e.g. Finland, Ireland). The nature of the programme varies with the administrative structure and size of the country. Within the United Kingdom, for example, Scotland has an integrated national blood transfusion service whereas there are independent regional centres in England, Wales and Northern Ireland, some of which cover a population equal to, or greater than, the population of Scotland. In contrast, in Liechtenstein there is no need to refer to the small blood transfusion service in Vaduz as a ‘national blood programme’.

Even in very large, federal states where there is no coherent national blood programme, there should not be any competition between different organizations for blood donors within the same territory. In a report from the American Blood Commission it is stated that ‘Territorial conflicts are exacerbated when the relevant blood programmes use conflicting recruitment messages. However, it should be recognized that the problem exists even if one recruitment “philosophy” is held by all programmes involved in a territorial dispute. Whenever there is competition for donors, there will be competitive recruitment messages, even if the philosophical approach remains the same. The net result is that blood must be imported since regional recruitment is simply not adequate to meet blood needs’.

The transfusion of blood and its components is an important part of clinical medicine, but the blood programme per se is unique in that the transfusion service is acting as the intermediary between the healthy donor, who has recognized a humanitarian need, and the patient, who needs blood or one of its many components. The transfusion service therefore has a threefold responsibility:

- to take the best possible care of the donor before, during and after donation;
- to ensure that the best possible use is made of the donor’s gift;
- to ensure that the components required are made available promptly and with a guarantee of both quality and safety.

In order to carry out such a programme the government, the Red Cross or Red Crescent Society, or the organization or institution responsible for these activities must:
• employ appropriately qualified professionals to direct the centres making up the total service;
• provide premises, plant and a technical infrastructure;
• organize donor recruitment, call up donors, and maintain a donor record and register from which donors are regularly called;
• provide a professional management body responsible for the technical supervision of the service;
• ensure that blood transfusion professionals actively collaborate with their clinical colleagues;
• secure adequate financial reimbursement or direct allocation of money for both investment and running costs, to ensure continuity of professional staff, satisfactory plant and equipment, and general financial security for the operation;
• encourage training, development and research in blood-related fields, for which the blood transfusion service provides a unique opportunity.

NATIONAL BLOOD TRANSFUSION COMMITTEE

It is important that the national blood policy is not imposed by the government but that it is agreed upon by all parties concerned. To this end, it is useful to have a national blood transfusion committee on which all relevant parties and interested groups are represented. In addition to the public health authorities and the national Red Cross or Red Crescent Society, the committee should include representatives of the professional community, e.g. haematologists, other clinicians, and hospital administrators. In addition, university medical faculties and health services of the armed forces may provide important inputs to the work of the committee. In some countries, representation of trade unions and political parties may also be useful.

The committee should include a number of influential decision-makers, which will facilitate the implementation of policy. At the same time, it is important to guard against too large a membership or the inclusion of too many people with numerous other commitments, otherwise the practical work of the committee may suffer. In most instances a large committee with broad representation will have a smaller executive body that can meet more often. The subjects to be considered by the committee and the executive should be prepared by the director of the national blood transfusion service; the final outcome
of the committee’s deliberations is likely to depend largely on
the director’s personality and ability.

Blood transfusion policies necessarily change with time as new
health hazards such as acquired immunodeficiency syndrome
(AIDS) are recognized and advances are made in clinical care.
Such changes pose new challenges to blood transfusion services,
which must therefore participate actively in relevant research
programmes. The national blood policy as formulated by the
committee should be flexible enough to meet the new challenges,
but the basic framework should be unchanged in order to provide
continuity. If a good blood policy is wisely implemented, optimal
results can be achieved with minimal wastage of funds and
resources.

ESTIMATING THE NEED FOR BLOOD AND
CELLULAR PRODUCTS (see also Chapter 3)

A country’s need for blood depends upon the stage of
development of its health care structure, its use of substitution or
supportive therapy (e.g. in thalassaemia, haemophilia and
leukaemia), and the type of surgical operations performed.

In well-developed services the supply of blood usually
responds to the clinical demand, not merely to the clinical
need. Nevertheless, good collaboration between transfusion
service medical staff and their clinical colleagues may well result
in a reduction in the use of ‘fresh’ blood, in the number of blood
units transfused in certain surgical operations, and in the use of
whole blood rather than red cell concentrates—that is, in the
consumption of those products that are not always clinically
justified. New treatment regimens, however, such as the use of
platelet or granulocyte concentrates, may present fresh challenges
to the transfusion service.

In advanced health care systems, such as those in the developed
countries, the need for cellular components of blood can be met if
the number of blood units donated annually corresponds to
approximately 5% of the population, although more blood may
be collected for other purposes (e.g. cryoprecipitates, plasma
derivatives). Surplus red cells may be exported to assist less
successful services within or outside the country, used to maintain
a high degree of preparedness in remote hospitals (thus knowingly
taking the risk of outdating), or simply discarded. Prolongation of
the preservation time of red cells and platelets, combined with
efficient inventory control, has all but eliminated outdating of blood in many centres.

The number of blood donors is smaller than the number of units given annually. In an expanding service the number of new donors is relatively high, but in a fully developed system the majority should be regular donors. Taking all blood donors and donations into account, the average number of annual donations should be between 1.5 and 2 per donor in a society where the red cell demand is met. This means that, when about 3% of the population are active blood donors, all the needs for cellular blood products can be satisfied.

Whenever the health care system is not fully operational, as is the case in the majority of countries, the need for blood should be related not to the size of the population but to other factors that reflect the quality and extent of health services. In a joint LORCS/WHO study the number of blood donations per 1000 population was found to average 52 in highly industrialized countries but only 10 in middle-income countries and 1 in low-income countries.\(^1\) However, when the number of donations was compared with the number of relevant hospital beds, both the industrialized countries and middle-income countries had an index of about 5, compared with 1.5 in low-income countries. The ratio of donations to hospital admissions was 0.44, 0.33 and 0.25, respectively, in these groups of countries.

A number of variables influence calculations of this type. First, it may be very difficult to obtain reliable health-related statistics and, even if the basic data can be obtained, they may not be comparable for different countries. Second, the official number of hospital beds may not correspond to the real situation: hospitals in some countries can be more or less constantly overfilled by up to 50%. Moreover, some hospitals place emphasis on acute cases whereas in others the majority of beds may be occupied by chronically ill patients who are not in need of transfusions. Third, the extent of haemotherapy depends very much on the availability of competent medical personnel.

The use of platelets and granulocytes is much more variable than that of red cells. The demand for platelets is still increasing in developed countries, probably because of the increasing use of intensive cytotoxic therapy. In 1983, the American Red Cross

issued 2335 012 units of platelets, an increase of 16% compared with the previous year. This represents 38% of the total amount of red cells and whole blood distributed to the hospitals. In Europe the figure is generally lower, between 10% and 20%. Consumption in developing countries varies greatly, according to the ability of the blood transfusion services to prepare platelet concentrates, and no general figures can be given.

Granulocyte transfusions seemed to become popular a few years ago, but results were not quite equal to expectations, probably because the quantities that can be safely and conveniently collected tend to be insufficient for physiological requirements. The worldwide demand for granulocyte concentrates has now declined.

ESTIMATING THE NEED FOR PLASMA PRODUCTS

For planning purposes, two plasma products are quantitatively important—factor VIII and albumin.

Factor VIII is used for the treatment of haemophilia. The prevalence of this disease seems to be relatively constant in different populations although most studies have been done in countries with predominantly white populations. The low incidence of haemophilia reported in some populations may well be the result of many cases remaining undiagnosed rather than a reflection of a true genetic variation. Where data are available from a comprehensive diagnostic service, the prevalence of haemophilia A appears to be about 60, and of haemophilia B about 10, cases per million population.

A WHO study estimated that a patient would need a minimum of 10 000 International Units (IU) of factor VIII annually to prevent the serious consequences of haemophilia.\(^1\) However, an ISBT working party arrived at double that amount, i.e. 20 000 IU annually.\(^2\) From one litre of plasma frozen within 6–8 hours of collection, about 400 IU of factor VIII, i.e. 40% of the total content, can be obtained in the form of cryoprecipitate. If this is further processed to concentrate of either intermediate or high purity, the yield is considerably less. In view of the often limited national blood resources, it seems that sufficient therapy can be

\(^1\) The collection, fractionation, quality control, and uses of blood and blood products. Geneva, WHO, 1981.

given to haemophiliacs if concentrates are used only to supplement the basic cryoprecipitate therapy, i.e. if most of the factor VIII is administered as cryoprecipitate.

From the above, the following calculation can be made and will be useful in national planning:

(1) As estimated by the ISBT working party, a patient with haemophilia needs 20 000 IU of factor VIII per year. On the basis of combined cryoprecipitate and concentrate therapy, the average yield of factor VIII would be 300 IU/litre of fresh plasma. One patient’s needs thus correspond approximately to 70 litres of plasma per year.

(2) If 50 haemophiliacs per one million population require regular treatment, 3500 litres of fresh plasma are needed each year from that population.

(3) 3500 litres of plasma can be obtained from 17 000 donations of a standard unit (450 ml) of whole blood or from 7000 double plasmaphereses.

In a fully developed transfusion service with effective component preparation, this goal should be achieved without much difficulty. However, the demand for supply will be increased by occasional losses of material during processing, by more intensive treatment of haemophiliacs, and by the use of high proportions of factor VIII concentrate rather than cryoprecipitate.

If the demand for factor VIII is high but can be met nationally, the amount of plasma available should also cover the need for albumin. (About 23 grams of albumin can be prepared from one litre of plasma.) The clinical use of albumin varies considerably from country to country, without a reasonable physiological explanation: annual consumption of albumin per million inhabitants is less than 100 kg in the United Kingdom but close to 700 kg in Japan. It seems that much of the demand depends on the availability of the product. In many clinical centres, albumin has been partially replaced by electrolyte solutions and other plasma expanders.

**COMPONENT THERAPY**

An appropriate component preparation programme must be part of the national blood policy. If red cell concentrate is used instead
of whole blood in the great majority of transfusions, the plasma can be used for preparation of factor VIII and other products. The yield of plasma from whole blood donations can be increased still further if additive solutions such as SAG (saline-adenine-glucose) are used for red cell preservation. By employing a high degree of component therapy, with additive solutions and perhaps supplementary plasmapheresis on a relatively minor scale, reasonable national needs for blood and blood products can be met, without red cell wastage, using only voluntary, unpaid donors. There are, however, many practical obstacles and the situation is not perfect in any country.

A high degree of component therapy is expensive. Blood for this purpose is usually taken in multiple plastic bags that are costly and generally have to be imported. Abandoning whole blood transfusions may increase the demand for platelets and various plasma products. Equipment and manpower are needed for intensive component separation, but if this leads to national self-sufficiency, the importation of factor VIII concentrates and other plasma products can be avoided and thus an intensive component programme can become cost-effective.

The degree of component therapy should be tailored to the real needs and resources of a given country. Component production has no inherent value *per se* but is a means to procure those parts of blood that are therapeutically essential. Some degree of component separation is needed in every national blood programme, but where funds are very restricted component therapy should be limited.

The place of unfractionated plasma in the arsenal of modern haemotherapy is often questioned. A WHO working group stated in 1981 that ‘Dried plasma is now generally regarded as obsolete’. However, dried and liquid plasma are still extensively used, even in some countries with highly developed and sophisticated health care systems. To a certain extent whole plasma still has a place in contemporary clinical practice.

Developing countries without access to fractionation facilities should seriously consider using whole plasma preparations instead of importing albumin. In particular, factor VIII-depleted plasma could be used more often, being easy and inexpensive to prepare and store. However, a single unit of plasma carries the same risks for transmission of infectious diseases as whole blood

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or red cell concentrates, and its use may be limited by considerations of blood group compatibility. In contrast to albumin prepared by fractionation, plasma is an individual biological preparation where standard quality control cannot be readily applied. Despite these reservations, however, plasma stored in liquid, frozen or dried form, can bevaluably used in various clinical conditions.
Appendix to Chapter 1
A model for a national blood policy

The gift of blood is a highly personal expression of altruism that should be accorded respect and protection. To achieve this goal, every country should have a national blood policy tailored to meet the needs of the health programme that it serves. The salient features that any such policy should include are set out below. They are based upon recommendations of the International Society of Blood Transfusion, the International Conference of the Red Cross, and the World Health Organization.

National blood policy

In order to conserve unconditional gifts of human blood, there should be a single national blood policy, regulated by the national health authority and integrated into the national health programme.

Responsibility for management of such a policy may rest with the national health authority or be delegated to the national Red Cross or Red Crescent Society or to another non-profit organization of proven integrity.

The aim of a national blood policy should be development and maintenance of a national blood programme that strives to meet, in equitable fashion, all of the perceived needs of the patient population throughout the country on a regular basis, at minimal cost, with minimal waste but with optimal safety and efficacy.

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1 Prepared by the Standing Committee on Ethics and Legislation of the International Society of Blood Transfusion (Dr B. P. L. Moore, Canada (Chairman); Professor A. André, Belgium; Dr A. L. de Bowen, Colombia; Dr J. Leikola, League of Red Cross and Red Crescent Societies; Professor J. P. Soulier, France).
**National blood programme**

Within the framework of a national blood policy, the national blood programme should:

- Collect all blood and plasma donations only from voluntary, unremunerated donors who meet stringent standards of health. The frequency of donation and the volume removed should be such that the health and well-being of the donor are unaffected.
- Be responsible for:
  - collections of whole blood, cellular components and plasma;
  - arranging for all plasma to be processed in the country’s own plant or plants or, if that is not possible, by external agencies under contract;
  - ensuring satisfactory quality and yield of wanted plasma derivatives;
  - distribution of blood, blood components, and plasma derivatives of human origin.
- Be accountable to its blood donors, its funding agency, and to the users of its products, both physicians and their patients, through strong community representation.

**National health authority**

To implement a national blood policy, the national health authority should:

- Ensure that adequate funding is available to maintain the highest possible standards of transfusion practice and quality management throughout the country, commensurate with the state of development of the national health programme.
- Establish a forum for human resources development and for exchange of technical information.
- Actively promote the education of the population, particularly the young, in the need for community support of the blood programme.
- Insist that, should importation of any human blood product prove temporarily necessary, the final container or package insert should clearly state where the plasma was collected and who fractionated it.
Management of blood transfusion services

- Permit the non-profit supply of products surplus to the country's perceived needs to national blood programmes in other countries in the early stages of their efforts towards achieving self-sufficiency.
- Follow, in all legislation and regulations, the Code of Ethics of the International Society of Blood Transfusion,\(^1\) the good manufacturing practices of WHO,\(^2\) and other pertinent recommendations of these organizations.

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Chapter 2
Development of a national blood transfusion service

Susan R. Hollán¹

INTRODUCTION

The organization and operation of blood transfusion services differ from country to country. Some countries have highly developed blood transfusion services, but in a number of economically well-developed countries the operation of blood transfusion centres is a sadly neglected aspect of the health services. In many developing countries there is a serious lack of expertise and facilities for the operation of a transfusion service; in others, well organized transfusion services exist, but serious economic constraints limit their ability to cope with national needs for blood and blood derivatives.

GENERAL CONSIDERATIONS

There has been much discussion in recent years about whether a new blood transfusion service in a developing country should be based on the use of the simplest and least expensive premises, equipment and methods, or should be started as a more sophisticated, and therefore more expensive, service. Most guides to the establishment and operation of a transfusion service in

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Management of blood transfusion services

a developing country recommend the first approach, that is, to start the simplest type of service and develop it step by step. On the other hand, many potential directors of transfusion centres in developing countries, currently being trained in developed countries, disagree with this and would like to start their national blood transfusion services at a more sophisticated level.

The first approach seems to be the wiser and the goal more easily accomplished. However, developing countries do not have to go through every step taken in the past by the long-established centres in the more developed countries: they can benefit from all previous experience.

The establishment of new blood transfusion centres should be based on the most up-to-date scientific and practical principles. However, the use of modern techniques and the purchase of sophisticated equipment should be undertaken only when justified by the workload and when the necessary funds, supporting infrastructure and technical expertise are available locally.

Wherever modern medicine is practised there is a need for highly developed transfusion services, able to provide essential replacement and supportive therapy. Modern technology has produced methods of separating whole blood into components and plasma fractions. If the clinical demands of modern medical therapy are to be met adequately, a variety of blood components will be required and these can be produced only by advanced, soundly based centres. There are essentially four limiting factors in establishing a blood transfusion service in developing countries:

- restricted financial resources;
- limited expertise;
- lack of adequate infrastructure;
- limited availability of donor blood—a problem peculiar to transfusion therapy.

Governments should understand that an up-to-date blood transfusion service needs adequate financial resources. Inefficient, badly controlled blood centres, and misuse of the blood collected, cost more in terms of the total national health budget than well-organized services.

National blood programmes should be based on detailed and accurate cost-efficiency calculations to make the best use of the available national resources (see Chapter 16). For example, it
would be a waste of money to begin by installing automated
blood-grouping equipment and/or computer-assisted information
systems where these were not justified by the workload. On the
other hand, it is safer to use disposable taking and giving sets and
disposable containers for the processing of blood components, in
spite of the fact that labour costs are relatively low in developing
countries and the cleaning and sterilizing of glass bottles, closures
and other equipment would therefore be less expensive. Attached,
sterilized satellite containers minimize the likelihood of microbial
contamination during component preparation. Moreover, the
production of components is more efficient in plastic bags. Donor
blood is a limited national resource, and the best possible use
should therefore be made of available donations.

Optimal use of blood depends largely on how the blood
transfusion service is organized in a given country. A well-
organized, centralized service is able to plan and continuously
adjust the size of the national blood and blood component
programme. It can concentrate the more sophisticated separation
and, if appropriate, fractionation procedures in one centre or
a restricted number of centres and can organize the exchange of
blood and blood products between the regional centres well
before their expiry dates. From both professional and financial
points of view, centralization of at least some aspects of a national
transfusion service is highly desirable.

A self-sufficient blood transfusion service has to produce
a variety of blood components and plasma protein fractions of
guaranteed biological activity in addition to whole blood. This
can be achieved only if blood transfusion centres have adequate
accommodation, staffing and equipment. The production of some
blood components is relatively simple, but fractionation of
plasma is more complex and time-consuming, and calls for a great
deal of expertise and considerable investment. As mentioned,
careful cost-benefit analysis should be carried out in order to
determine whether the investment in a fractionation plant is
justified. Any country that now depends entirely on imports of
plasma derivatives, often at prohibitive cost, should strive for
realistic and attainable self-sufficiency in the production of blood
components and plasma derivatives. The validity of this is
dramatically underlined by the transmission of acquired
immunodeficiency syndrome (AIDS) by imported blood products
to populations that would otherwise have been at much lower
risk. Nevertheless, there is no justification for setting up
a fractionation plant unless at least 250 litres or 1000 donor pools
of plasma are available for Cohn fractionation at regular intervals of less than one month (smaller amounts are appropriate for other fractionation techniques). Even this would be a small-scale operation but it could serve as the basis for later expansion to a much larger project, or be used for specialized national services cooperating with neighbouring countries. If this is not feasible, the plasma can be separated in national transfusion centres and sent to an established fractionation centre in another country. The products would then be returned to the original country. The costs of shipment may be less than those involved in establishing and operating a fractionation plant or in importing plasma products.

**BASIC FUNCTIONS OF A BLOOD TRANSFUSION CENTRE**

The basic functions of a blood transfusion centre may be listed as follows:

- organization of the service;
- recruitment of donors;
- collection, processing, storage and distribution of blood and blood components;
- laboratory investigations;
- participation in the clinical use of blood and blood components.

There is some debate about the last of these functions: in many countries the experts of the blood transfusion centres have no means at all of influencing the clinical use of blood and blood components. Transfusion practice cannot be safe and efficient, nor can the donated blood be used optimally, unless there is close cooperation between the blood centres and the hospitals.

Two other important activities should be added to the above list:

- training and teaching;
- research and development.

Experts in blood transfusion centres have to train all new employees, and give medical undergraduate and postgraduate teaching on good practices in the clinical application of blood
transfusion therapy. Advances in these fields have been made so rapidly that most clinicians find it very difficult to keep abreast of changes in the basic concepts underlying blood transfusion practice. However, they will consult transfusion centre physicians only if they are known to have good scientific reputations. Planned research work is essential to the development, improvement and control of new blood products, for the evaluation of results and for maintaining the interest, competence and morale of the staff.

Possibilities for an active research programme make the blood transfusion service more attractive to well-qualified doctors and science graduates. This in turn facilitates cooperation between clinicians and transfusion centres. In this way the basic principles of organization of the centres influence the safety, economy and efficiency of the use of blood and its derivatives.

The quality of a blood transfusion service can be defined by a number of criteria. The most important of these are the following:

- Does the centre meet the needs of the health programme that it serves?
- Has the centre a realistic and regularly updated plan for its future growth and development to cover projected needs of the national health service?
- Does a feasible programme exist for the implementation of this plan?
- Is the safety of the collection, processing, storage and distribution of blood, its components and derivatives assured by good practices operating under a comprehensive set of quality control programmes?
- Is the wastage of products, reagents and resources minimized?
- Does the centre make optimum use of its resources by carefully assessing the cost-benefit ratio of new establishments and/or procedures, and avoid diverting resources for the benefit of a few at the expense of the many?
- Is the centre able to differentiate between real needs and unjustified demands?
- Does it liaise closely with clinicians to ensure the safe and optimal use of blood and its derivatives, including advising on the use of crystalloids and non-human colloids?
- Does it have a teaching programme for the continuous training of its staff and for the postgraduate teaching of physicians and surgeons?
Management of blood transfusion services

Experience accumulated in many countries has shown unequivocally that the best way of achieving high-quality performance in blood transfusion is to develop a national service that comprises regional and district centres in addition to a central institution. The district centres must represent the peripheral level, since safe operation and good transfusion practices cannot be assured at lower levels of the health service. (The use of crystalloid solutions plus plasma expanders should be encouraged for the management of acute haemorrhage in health clinics in rural areas.)

The organization and development of an adequate national transfusion service needs careful planning with due account being taken of geographical conditions, economic resources, availability of technical expertise, and the actual infrastructure of the national health service.

NATIONAL BLOOD TRANSFUSION CENTRE

The national blood transfusion centre is the central institution of the national transfusion service and serves as a base for development of a network of regional and district transfusion centres. It should also act as regional centre for the region in which it is situated. In a country with no blood transfusion centre at all, the first step should be the nomination of a national blood transfusion committee to evolve development plans and nominate a director for the national service (see Chapter 1). The national transfusion service can be started by building up a regional centre with adequate plans for its future development into a national transfusion centre.

The national transfusion centre should be accommodated in a separate building, preferably near a large general or teaching hospital. Its special responsibilities are the following:

- planning and organizing the centres of the national transfusion service;
- evolving standard procedures and quality control tests for all levels of the national service;
- training the directors and chief technicians of the newly developed centres;
- establishing an active research programme for the development or adaptation of new technologies and for the assessment of the real needs of the country;

22
• maintaining a national reference laboratory for blood group serology;
• preparing standard reagents, solutions, and cell panels for its own use and for other centres in the country;
• performing antenatal testing in collaboration with maternity services and, where needed, the prevention of rhesus haemolytic disease of the newborn on a countrywide basis;
• providing the country with those blood derivatives that are not produced at regional level.

When feasible, the national centre should also:

• perform special haematological and immunological laboratory assays;
• organize and operate haemophilia and haematological care units.

REGIONAL BLOOD TRANSFUSION CENTRES

If geographical factors, available manpower and the structure and organization of the national health service are appropriate, it is recommended that regional centres be established under the direction of the national centre. Regional centres are generally located in large hospitals, but can also be accommodated in separate buildings.

The primary objective of a regional transfusion centre is to ensure a safe, stable and cost-effective supply of blood and blood products to fulfil the needs of patients in the region, and to assist hospitals in their appropriate use. It has also to contribute to the national availability of resources. To this end the national centre should receive reports on the work of the regional centres and should direct them in planning regional blood programmes and in the use of standardized techniques and procedures. Responsibility for the continued training and education of the director and senior staff of the regional centre lies with the national transfusion centre. The regional centre has similar responsibilities towards the staff of its district transfusion centres and for postgraduate teaching of clinicians in the region. Close cooperation and coordination of planning between the regional centre and the hospitals it serves are of paramount importance. The regional
centre should also supervise the district centres in its region and assist them in introducing new standardized techniques and procedures.

The range of activities of the regional centre will be similar to that of the national centre but on a smaller scale. It may even be assigned some special national function, such as a national blood group reference centre.

In addition to meeting the ordinary requirements for blood and components such as red cell concentrates, platelets, cryo-precipitates and fresh frozen plasma, the regional transfusion centre must make special arrangements to meet extraordinary blood needs. It should have a reservoir of blood and its derivatives from which the unexpected demands of emergencies can be met, and should arrange for blood from selected donors to be available for patients sensitized to blood group antigens. It should also have available plasma derivatives such as albumin, clotting factors and immunoglobulins, blood group reagents, electrolyte and other solutions, cell panels, and the basic equipment necessary for hospital blood bank operations. The centre should plan and coordinate the transfusion service in its region to provide an ample but not excessive supply of blood in order to optimize usage, minimize outdated or any other form of wastage, and provide sufficient numbers of important blood components or specialized materials.

The regional centre should also provide consultation services to the hospitals on transfusion and transfusion-related problems—serological, epidemiological or clinical. These services should be available 24 hours a day, seven days a week, with on-call programmes and round-the-clock coverage by medical and technical staff to meet emergency demands.

In many cases regional centres are large urban establishments acting as referral centres for the entire region and also serving sophisticated medical complexes that offer advanced medical and surgical therapy. Sophisticated surgical and medical procedures often require large amounts of blood components and plasma derivatives, and thus make great demands on centres that are not able to meet them fully from local sources. Efforts towards planned resource sharing by regional centres are therefore of extreme importance and should be directed and coordinated by the national transfusion centre. This is the only way to ensure a safe and adequate blood supply of high quality, and its ready accessibility for those in need, independent of their ability to pay.
DISTRICT HOSPITAL BLOOD TRANSFUSION CENTRES

The district hospital transfusion centres constitute the most peripheral parts of the national service. They are located in district hospitals and, in some developing countries, in rural hospitals that undertake surgery and obstetrics. Their fundamental objective is to provide readily available whole blood (also red cells and fresh frozen plasma where circumstances permit) in adequate amounts and of suitable quality. To this end they must recruit donors, establish blood donor panels and arrange blood-collecting programmes. The safety of their procedures (selection of donors, collection and processing of blood, testing, storage and distribution of products) should be ensured by following written procedures; regular control of safety and efficiency should be exercised by the regional centres to which they report. District centres should be supplied by the regional centres with reagents, blood transfusion equipment and other essential material. A supply of freshly distilled water, an autoclave, and refrigerator (+4 °C and, ideally, −30 °C) should be available.

Where communications are well established and facilities for safe storage of blood exist, a district centre should collaborate closely with the nearest larger district centre, or with the regional centre, in the provision of blood. In an ideal arrangement blood is collected in the local community by hospital staff or mobile units from the blood transfusion centre, safely grouped, screened for antibodies and tested for transmissible diseases at the higher level transfusion centre and then returned to the primary level hospital. To accommodate variations in local supply and demand, extra blood may be provided by the larger transfusion centre when necessary, or retained and used by the larger centre when demand at the primary level hospital is low.

When communications with a larger transfusion centre are poor, or distances are too great, blood will have to be collected and processed locally. If no facilities for the safe storage of blood are available, blood will have to be collected from suitable donors in the local community as emergency situations arise, and should be used as soon as possible.

The interest and participation of clinicians using the services of district transfusion centres are the best means of ensuring the continued safety and efficiency of those services. Local and national efforts should be made to ensure that clinicians are knowledgeable and demanding consumers, who actively
Management of blood transfusion services

participate in the proper functioning of both the hospital blood transfusion service and the donor blood-collecting system that supports it. Continuing education of the centre's staff and teaching of the theory and practice of blood transfusion to physicians and surgeons should also be organized at this peripheral level of the national service.
Chapter 3
Calculation of present and projected blood needs
Cornelia Szilassy¹

INTRODUCTION

An important aspect of planning in a national blood programme is assessment of the amount of blood that must be collected to satisfy the needs of the country's health care system. The director of the national transfusion service must discuss with the national blood transfusion committee how demands can be met, and must reassess the need annually. This chapter contains some examples of such calculations for general guidance, but more precise estimates must be based on the circumstances in each country.

GUIDELINES FOR CALCULATIONS

The following information must be available if the calculations are to be accurate:

- size of the country and the nature of its administration;
- geographical characteristics;
- population size;
- annual growth rate of the population;
- population density in the various regions of the country;

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- present rate of development of the health service;
- number and location of hospitals, total number of hospital beds (including the number of patients accommodated on the floor because of unavailability of beds);
- numbers of beds in specialized departments (e.g. surgery, obstetrics, traumatology);
- average blood demand per hospital bed on the basis of data supplied by public health authorities, hospitals and medical associations;
- planned development of health services in terms of number and location of new hospital beds, and introduction of new techniques with high blood requirements (e.g. open-heart surgery);
- factors that may hinder progress, such as shortage of water and electricity; climatic conditions and transportation facilities should also be taken into account.

There are two distinct facets to the calculation of blood demand:

- the needs of the whole country (present and projected);
- the needs of individual regions within the country.

**Calculation of required number of donations**

In countries with highly developed health services, the blood requirement can usually be met if at least 3% of the population are regular blood donors. According to different calculations in developed countries, seven donations per year are necessary to cover the needs of one acute hospital bed, or a yearly average of 40,000 to 60,000 blood donations per one million inhabitants to cover the demand for red cells. On this basis the required annual number of donations can be obtained by:

- estimating 5% of the country’s population; or
- multiplying the number of acute hospital beds by 7.

**Example**

<table>
<thead>
<tr>
<th>Present population</th>
<th>10 000 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of required donations:</td>
<td>5% of 10 000 000 = 500 000</td>
</tr>
</tbody>
</table>
Calculation of blood needs

Number of hospital beds: 100 000
30% of beds do not usually need blood
Number of required donations: \((100 000 - 30 000) \times 7 = 490 000\)

**Calculation of required number of donors**

According to regulations in force in most countries, donations are accepted up to three or four times a year from each donor, although in some countries donations may be accepted up to six times a year. Regulations should be formulated by the director of the national transfusion service to limit the frequency of donation to a safe maximum for the nutritional and general health status of the population concerned. The number of donors required may be calculated from the estimated annual demand for red cells and the agreed frequency of donation. In order to ensure a regular supply of blood, it may be necessary to increase the number of enrolled donors to compensate for seasonal or climatic factors that might affect an individual’s ability to attend a donor session.

**Example**

Number of required donations: 500 000
Donations from 75 000 donors twice yearly: 150 000
Donations from 25 000 donors three times yearly: 75 000
Donations from 200 000 donors once yearly: 200 000
Total number of donations: 425 000
Deficit: \((500 000 - 425 000) = 75 000\)

For the year in question, 75 000 donors must be recruited. The recruitment programme for future years must be modified correspondingly to take account of donors retiring, moving or leaving the programme for any other reasons.

**Calculation of projected blood needs**

Calculation of projected blood needs must take account of expected changes in the national blood demand; this, in turn, will vary with the development of the health service, with increases in the number of hospital beds and with the annual growth rate of the population.
Example

Present population: 60 000 000
Number of donations required: 5% of population = 3 000 000
Annual population growth rate: 1%
Population after 10 years: 66 300 000
Number of donations required after 10 years: 5% of 66 300 000 = 3 315 000
Increase in number of donations required: 315 000

Calculation of blood needs in individual regions

Calculation of blood needs for an individual region aims to define the sphere of activities of an existing or planned regional transfusion centre. The population density and the number of hospital beds must be considered, bearing in mind that the introduction of traumatology and/or open-heart surgery may increase the demand for blood by 15–20%. Active haematology, oncology and cell-separator units will also dramatically increase demands for blood products. Regional centres in remote areas cannot rely on quick help from other centres, and so must hold larger stocks.

Realistic calculations of the annual total blood collection goal of a region should be based on:

- the medical demands of the region;
- the donor potential of the region, and expected frequency of donor attendance;
- the present or anticipated number of staff in the regional transfusion centre;
- the adequacy of present or projected premises and equipment.
Chapter 4
Donor recruitment

Susan R. Hollán\textsuperscript{1} and Cornelia Szilassy\textsuperscript{2}

INTRODUCTION

In 1948 the XVIIIth International Conference of the League of Red Cross Societies adopted a resolution recommending voluntary donation of blood as the ideal system. Since then the blood transfusion services in a number of countries have successfully switched over from a system of paid donors to unpaid voluntary blood donation. It is strongly recommended that newly established transfusion services make every effort to adopt the voluntary (unpaid) system from the beginning. This chapter discusses basic principles of donor recruitment, methods of donor propaganda and organization, and assessment of efficiency.

GENERAL CONSIDERATIONS

The voluntary, unpaid donation of blood is a humanitarian act. A blood transfusion service based upon such donations is morally obliged to work on a non-profit basis, since blood given free of charge should not be used for profit.

Within a system of voluntary donation it is easier to verify a donor's state of health—voluntary donors are less likely than

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Management of blood transfusion services

paid donors to conceal illness. Financial reward for donation of blood may lead to over-frequent donation and thus to increased risk of illnesses such as anaemia. Paid donors are often already in poor health and may have, or develop, nutritional and other deficiencies. Moreover, the prevalence of alcohol and drug dependence is higher among paid donors than among voluntary donors.

Voluntary unpaid donors fall into two categories:

- regular donors; and
- occasional donors, who are usually, but not invariably, relatives, colleagues or friends of patients.

The donor organization of each regional blood transfusion centre should be headed by a donor panel organizer, responsible to the regional director and with close relationships with humanitarian organizations, such as the national Red Cross Society, which may or may not play a major part in the national blood programme. To carry out their work usefully and correctly, donor panel organizers must be fully aware of the needs and capabilities of the blood transfusion centre. They are the key people in recruiting donors, and have to initiate, maintain and develop recruitment of unpaid voluntary donors, cooperate with the various local community organizers and supply them with facilities to help recruitment in their communities.

Donor panel organizers must be patient, tactful and highly enthusiastic about their work in order to succeed in continuously recruiting new donors and then encouraging them to return to give blood regularly. Organizers also require fluency in the local language.

The tasks of a donor panel organizer can be summarized as follows:

- recruitment of donors and use of various locally appropriate methods to inform the public (talks, films and other media);
- organization and maintenance of a blood (and plasma) donor panel as agreed with the regional director;
- maintenance of appropriate records, including keeping donors’ record cards up to date and communicating with donors;
- organization of a blood-collecting programme (notifying a sufficient number of donors to yield the amount of blood needed), provision of refreshments, and distribution of propaganda material;
• keeping of simple statistical records, e.g. number of donors called, number reporting and bled;
• informing the director about the overall status of the donor panel and carrying out the director’s instructions (e.g. amount of blood to be collected).

Within the various communities there should be local organizers who are deeply dedicated to this work and are highly respected members of the community. They must be willing to recruit blood donors within their area and voluntary helpers to assist with mobile sessions. The principal functions of these organizers are:

• to act as liaison officers between their local community and the national or regional blood transfusion centre;
• to take charge of arranging publicity within their community;
• to maintain regular contact with both regional and national organizers;
• to foster the goodwill of local community leaders;
• to organize educational meetings to keep people informed of current problems and advances in blood transfusion.

GUIDELINES FOR ACTION

The national blood programme determines the area from which each blood transfusion centre recruits its blood donors and the number of donors required to meet its transfusion needs.

Donor panel organizers assess the number of prospective donors in their areas based on the number of schools, universities, firms and other organizations in the communities, and the number of employees and students. They should establish strong relationships with community leaders of all types, seeking their help in appointing local organizers and recruiting blood donors. They also periodically (e.g. annually) prepare schedules for the blood programme, which are approved by the directors of the transfusion centres and by the appropriate community leaders. The expected number of donors can then be estimated.

The sequence of events leading to blood collections in the transfusion centre and during mobile sessions should include the following:

• A few weeks before the collection of blood, donor panel organizers start propaganda work, arranging lectures, personal
interviews, door-to-door campaigns and the preparation and
distribution of posters, leaflets and other propaganda
materials.
- A few days before collection, organizers estimate the number of
donors and voluntary helpers. For mobile sessions, they ensure
that the available facilities, e.g. the site, transportation,
refreshments, will be adequate.

Donor panel organizers arrange for public awards to donors,
initiate regular donor recruitment, and register donors who are
prepared to give blood again (which is especially necessary where
there is a shortage of blood for special programmes, such as heart
surgery or plasmapheresis). They survey the results of donor
recruitment at regular intervals, define future tasks (e.g. the need
for new propaganda methods and materials), and submit reports
to directors of the transfusion centres.
If the country needs more plasma than is available after the
production of blood components from donations of whole blood,
the recruitment of voluntary unpaid plasma donors may be
necessary. In that case donor panel organizers should select
regular donors and inform them about plasmapheresis and its
importance. Plasmapheresis is performed only after obtaining the
donor’s written consent. The organizers maintain separate
records of plasma donors, and schedule procedures as
appropriate to meet demands. They also ensure that the donors
receive appropriate recognition. Plasma donors may be asked to
help recruit other donors.

**MOTIVATION AND PROPAGANDA**

Good propaganda is imperative for the recruitment of blood and
plasma donors and can be described under two headings:
- information and persuasion; and
- consideration shown to donors.

**Information and persuasion**

The dissemination of information is an important aspect of donor
recruitment. Donors are informed about the country’s need for
blood donors, the shortages of blood and the speed and ease of
donation, and that blood collection can be arranged and carried out without delay. This information may be communicated by different means:

**Oral communication**

This is the most important method of recruiting donors, especially in countries where people do not read newspapers, listen to the radio or watch television. It may take place through personal contact and door-to-door campaigns or at meetings.

Local publicity is particularly effective where assistance is lent by associations willing to adopt blood donation as one of their causes; Red Cross and Red Crescent Societies and various civic organizations can render especially valuable service at local level. At meetings of such organizations, lectures on transfusion, perhaps illustrated by films, can be very effective, particularly if they are given by doctors well known to the audience. The speakers must have the persuasive power to appeal to the humanitarian feelings of the audience. Time should be available at the end of these meetings for the audience to digest the information they have received, to ask questions and to be given full, frank and precise answers.

It is also possible to create a competitive atmosphere between donor groups within the same service; public comparisons of the results of blood collection will encourage more donors to come forward. Success is more likely in a community if the leaders set a good example.

**Written communication**

Brochures, posters and information leaflets are all valuable forms of written communication. Material must ‘catch the eye’, be easy to understand, and be attuned to local circumstances.

**Information through the mass media**

Articles on the importance of blood donation and reports on blood transfusion centres should be placed in newspapers. Some transfusion services give donors regular bulletins; in others, donors form associations to maintain their own interest in transfusion and stimulate that of potential donors. Radio and television are suitable media for information on blood donation and for urgent appeals, which should always be based on fact if
Management of blood transfusion services

the public is to feel personally involved. However, advertising to impart general information on the existence and work of the transfusion service may be ineffective unless followed up by local campaigns. Public figures and/or personalities such as sportsmen and political or religious leaders can be helpful in recruiting donors, especially if they themselves can be persuaded to donate.

Educating young people

General education of the public on the need for blood should start in schools and must include a description of the donation of blood and an assurance of the safety of the procedure. The uses made of blood and its products may be stressed.

Educating relatives and friends of hospital patients

By talking to the relatives and friends of hospital patients who have had, or will need, blood transfusions, hospital staff can actively contribute to the recruitment of donors. This is especially important when harvesting of platelets or granulocytes by apheresis is necessary.

Dealing with donors

It is of prime importance to dispel donors' fears. If a new donor is bled skillfully, treated well and convinced by personal experience that blood donation is harmless, he or she will usually return to give blood again. This is the best advertisement for blood donation.

The decisive factor in the success of a transfusion service is that it should have many regular donors. The staff of the service must at all times be courteous, interested and cheerful.

Consideration shown to donors

Incentive schemes

In some circumstances the following privileges could be considered as incentives to donors:

- extra leisure time (e.g. for factory workers, soldiers);
- free medical advice;
- priority in the allocation of medicine and hospital beds.
Awards

It may be appropriate to make small awards to donors, such as the following:

- badges, given after the first donation, indicating clearly why they have been given; these should appeal to the general public and be easy to wear;
- thank-you cards, i.e. attractive and colourful cards on which the blood transfusion centre thanks the donor for giving blood;
- certificates with the donor's personal data and the date of the donation;
- small presents of little intrinsic value, such as glass, decorative objects, pens, books;
- medals, which may be presented at a meeting of an organization to which the donor belongs; these usually bring widespread appreciation, especially if presented by a local personality at a special ceremony. They may be graded in value according to the number of donations made.

ASSESSMENT OF RECRUITMENT EFFICIENCY

Donor recruitment may be regarded as successful if at least 3% of the population are donors (see Chapter 3). Regular and effective donor recruitment may result in as much as 10% of the community donating blood, with 60–70% of those donating regularly. The indicators of efficiency are:

- increases in the number of communities involved in giving blood;
- increases in the number of donors;
- increases in the number of regular donors;
- increases in the average number of donations per person (within the acceptable limits).

Causes of inefficient donor recruitment include:

- lack of support from community leader;
- weak and unconvincing propaganda;
- improper handling of donors;
- fear of the donation process;
Management of blood transfusion services

- fear of *any* medical treatment;
- religious objections;
- fear of being rejected;
- indifference;
- egoism (donors wanting to give blood only to family members);
- poor general state of health of the population.
Chapter 5
Design of premises for a blood transfusion centre

Judith Pintér¹, Cornelia Szilassy² and G. Polner³

INTRODUCTION

A blood transfusion centre can meet the demands made on it only if adequate premises are available. In this chapter, several examples of suitable design are given, but it is fully recognized that many other designs may be equally satisfactory.

The premises must be of suitable size, construction and location to facilitate their proper operation, cleaning and maintenance in accordance with accepted rules of hygiene. They must comply with the Requirements for Biological Substances No. 1 (General Requirements for Manufacturing Establishments and Control Laboratories)⁴ and provide adequate space, lighting and ventilation for the following activities:

- medical examination of individuals to determine their fitness as donors of blood and/or blood components;
- taking blood from donors with minimum risk of contamination or error;
- care of donors, including those who suffer adverse reactions;

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• storage of whole blood and blood components pending completion of processing and testing;
• separate storage of whole blood and blood components, after testing and before distribution;
• laboratory testing of blood and blood components;
• processing and distribution of whole blood and blood components in a manner that minimizes the risk of error;
• performance of all steps in apheresis procedures, where applicable;
• labelling, packaging and other additional operations;
• storage of equipment, reagents and disposable material;
• documentation and recording of data on the donor, the donated blood and, where possible, the recipient.

GENERAL CONSIDERATIONS

The blood transfusion centre should be located where it provides easy access for donors and staff, and allows quick and safe transportation of blood and components to hospitals.

Tasks of the transfusion centre

In planning a new transfusion centre, due consideration should be given to the following:

• the total amount of blood to be taken; and
• the level at which the centre will operate (national, regional or district), which will determine the different tasks requiring different premises, working conditions, equipment and personnel.

The centre must make special provision for space if it is to:

• have an outpatient department for activities such as sampling for antenatal serology or treating patients with haematological diseases;
• produce sterile containers (bags or bottles), blood taking and giving sets and other sterile equipment;
• produce blood grouping reagents.
Hygienic conditions

The best hygienic conditions must be ensured throughout the premises of a transfusion centre since there is a continuous movement of donors, staff, materials, and blood and blood samples. Blood and blood components taken from the centre are used in hospitals, and external contamination of containers should therefore be avoided. All rooms must be easy to clean, with washable floors and walls. The collection and disposal of waste must take place separately from the distribution of clean material, to avoid the spread of infection; provision for the expedient disposal of potentially infective materials by autoclaving and/or incineration must be made. There must be compliance with local by-laws in the disposal of these materials. It is particularly important that special arrangements be made for the disposal of blood samples and, occasionally, of outdated blood: they should not be directly discharged into the public sewerage system.

Air-conditioning is desirable for the greater comfort of donors and staff. Moreover special conditions, including a supply of filtered or sterile air, or low temperature and humidity, may be required for some types of equipment and procedures.

Infrastructure within the transfusion centre

Water supply

The water supply should never be contaminated with any material potentially dangerous to health; it must be suitable for production of pyrogen-free water. Installation of filters is often necessary.

Electricity supply

A reliable electrical supply is essential for lighting and for operation of equipment. A power failure to refrigerators may damage stored blood and blood components, and a transfusion centre must therefore have its own stand-by generator. The cost of damage caused by a power cut will almost certainly exceed the cost of the generator. Special attention should be paid to the possible need for a nonstandard electrical supply and for voltage stabilization, especially when considering the suitability of particular equipment.
Management of blood transfusion services

**Sewage**

Sewage disposal must comply with the sanitary requirements of the local health authority. It should be noted that highly nitrogenous sewage has a high biochemical oxygen demand rating and should therefore never be discharged in an untreated condition.

**Storage**

Whole blood and blood components must be stored separately in a refrigerator, refrigerated room or freezer, as appropriate, which is used only for this purpose. Refrigerated rooms are more economical for larger transfusion centres, where large quantities of blood and components must be accommodated.

**Steam**

If large-scale production of solutions is undertaken, there should be an adequate supply of steam for cleaning of equipment and operation of sterilizers. The steam itself should not cause or leave a contaminating deposit on the equipment or containers to be cleaned or sterilized.

**Distilled water**

A supply of freshly distilled (and usually deionized) water should be available in every blood transfusion centre.

**Gas, high-pressure air and vacuum**

Depending on the tasks undertaken by the transfusion centre, there may be a need for a gas supply, for high-pressure air and for vacuum facilities.

**Communications**

The transfusion centre requires telephones and/or telex facilities to maintain communication with hospitals and other transfusion centres, and to call in donors in special circumstances.
Factors determining adequate floor space

If a transfusion centre is not located within a hospital, the following supporting facilities must be provided:

- sterilizing room;
- laundry;
- garage;
- store rooms;
- changing rooms, toilet facilities and canteen for the staff of the centre;
- workshop for maintenance of the building and equipment.

It is important to plan suitable rooms for all operations; for instance a room containing a laminar air-flow cabinet should be of adequate size for the convenient running and maintenance of the equipment. Where air-conditioning is planned, rooms must be designed with sufficient space to accommodate the equipment.

In the case of multistorey buildings, the floors should have large loading capacity; where floor space is limited, weight distribution must be carefully considered.

The provision of a basement depends on the climatic conditions and the type of ground, and may prove impossible in tropical areas.

It is suggested that a separate room be available for sterilizing equipment and stills (to ensure intensive ventilation and other climatic control).

FUNCTIONAL PLAN

The functional plan of a blood transfusion centre is based on the paths taken by the donors, the blood, blood samples and materials.

Path of the donor (see Fig. 5.1)

The ‘path of the donor’ refers to the rooms in the transfusion centre through which the donors need to pass. The first of these is usually the waiting room, which donors enter and then pass through to the donor-record room, where their cards are filed. From here they proceed to the donor laboratory and then to the
consulting room for examination. If they are accepted as donors, they continue to a second waiting room and await their turns to enter the bleeding room. After donation they go from the bleeding room to the resting room, then to the donors’ cafeteria where food and liquid refreshments are served by staff who also supervise this post-donation period. Finally the donors leave the building. These areas should be so arranged that donors can easily find their way.
Path of the blood (see Fig. 5.2)

After withdrawal, the blood can take one of two different paths. If it is not being separated into components immediately, it is put into a refrigerator and stored until the results of laboratory tests are available, after which it is transferred to another refrigerator and made available for clinical use. If components are to be prepared immediately, however, the blood is taken to the appropriate preparation room. The components are then stored in refrigerators or freezers at prescribed temperatures. If the centre has plasma fractionation facilities, the plasma is delivered to that area. Following fractionation, plasma derivatives are stored at the appropriate temperatures.

The refrigerators, or refrigerated rooms, should be close to the distribution area. The blood and components must be stored in the refrigerator or freezer until issued for use.

![Diagram of blood path]

Fig. 5.2 The path of the blood

Path of blood samples (see Fig. 5.3)

Blood samples are taken in the withdrawal room and delivered to the laboratory for testing. When testing is completed the samples are discarded, preferably after incineration.

Path of materials (see Fig. 5.4)

There is continuous movement of material in a blood transfusion centre, and the arrangement of rooms should be such as to allow
this flow to be economical and rational. The material can be divided into four groups:

- material purchased sterile, or sterilized in the centre before use;
- clean but non-sterile material;
- material to be cleaned;
- waste.

To avoid contamination, the paths of these different materials must be separate from each other.

Before planning the premises, a choice must be made between a central store-room or individual stores maintained by each
functional unit of the centre. In the latter case a separate store-room must be attached to each unit. However, even when there is a central store-room, space must be provided in each unit to store material that must be available at all times. Within the store-room, sterile and non-sterile material must be treated separately. A choice must also be made between a central wash-up area for the treatment of multi-use material or a wash-up area for each functional unit. Where a central store-room and central wash-up area are chosen, they must be within easy reach of all functional units.

Waste must be stored in closed containers and collected daily. Its removal from the building must follow the shortest possible path, avoiding all aseptic areas. Used needles should never be carried in containers that can be punctured.

**DESIGNING A BLOOD TRANSFUSION CENTRE**

The level (national, regional or district) of a transfusion centre determines its design, although certain principles are valid at all levels:

- The building must be designed so that closed working areas (e.g. aseptic rooms) are not exposed to strong sunshine. Climatic conditions such as prevailing winds should always be taken into consideration. If the wind carries dust, ventilation by filtered air may be required in certain working areas to ensure sterility and to protect the equipment from dust.
- The building material and style should comply with the general construction guidelines of the country.
- Donors, blood and outpatients, where applicable, should follow separate paths in their movements through the building. They should use separate entrances on different sides of the building. In multistorey buildings, separate elevators should be available for people and goods.
- The design of doors and windows should ensure natural lighting of rooms where possible, and protection against dust and insects. Aseptic or air-conditioned rooms should have non-opening windows.
- Loading and unloading facilities and areas should be covered for protection against rain and snow.
- Access to an adequate stand-by generator must be ensured.
Management of blood transfusion services

Figs 5.5 to 5.13 show the arrangement of units (departments) in various transfusion centres which are in separate buildings on hospital grounds.

Regional centre

Fig. 5.5 illustrates a two-storey building in which the following functions can be performed: registration, examination and

![Diagram of a two-storey building layout with sections labeled for different functions: Store, Sterilization, Stills, Central wash-up, Production of blood components, Testing, Blood collection, Apheresis, Donor selection, Storage of blood and distribution, Training, Staff, Administration, Quality control.]

Fig. 5.5 Regional centre 1
bleeding of donors, plasmapheresis, testing of blood, production of blood components, quality control, and storage and distribution of blood and blood products. The centre also has storage, central wash-up, sterilizing and distilling rooms, an outpatient department, training centre, staff rooms and offices. This is just one example of the layout of a regional centre. Other designs, based on single or multistorey concepts, may produce a building that is just as efficient. Where appropriate, however, allowance should be made for sufficient expansion to permit a regional centre to assume the role of a national centre.

**District centre**

A district centre will usually be part of, or closely associated with, a hospital. Its design will depend on the closeness of this association, particularly with respect to support facilities and infrastructure. The functions of the centre will determine its structure.

**PRELIMINARY AND DETAILED PLANNING**

It must be emphasized that the examples given in this section are purely illustrative. In many situations, a district or regional centre may not achieve or need to achieve the figures quoted, which should therefore be modified to suit local conditions.

Fig. 5.6 shows the design and arrangement of units within a regional centre, which comply with those shown in Fig. 5.5 but are shown in more detail. The arrangement of rooms within the functional units allows for appropriate paths to be taken by donors, blood, blood samples and materials.

**Standard floor space requirements**

The standard floor space of a transfusion centre depends on the number and type of tasks to be performed. This section suggests standard floor spaces for centres of different sizes performing all laboratory tests, including screening for transmissible diseases, independently of hospital laboratories. The arrangement and size of rooms within the functional units are also discussed. Case study examples are included, based on:
Fig. 5.6 Regional centre 2

Key
1 Sterile store-room
2 Reception of material
3 Store-room
4 Garage with ramp
5-6 Toilets
7 Sterilization
8 Preparatory room
9 Stills
10 Central wash-up
11 Store-room for detergents
12 Reception for washing
13 +4°C refrigerated room
14 -30°C refrigerated room
15 Air-lock
16 Labelling
17 Aseptic room (for blood derivatives)
18 Centrifuges
19 Chemical laboratory
20-21 Laboratory for testing for transmissible diseases
22 Reception of blood samples
23 Laboratory for donors’ blood samples
24 Cross-matching
25 Laboratory for patients’ samples
26 Detection of antibodies
27 Preparation of sera
28 Food store-room
29 Donors’ cafeteria/snack bar
30 Resting room
31 Blood taking
32-33 Toilets
34 Plasmapheresis
35 Sterile room
36 Donor recording
37 Examination laboratory (including urine samples)
38 Changing room
39 Consulting room
40 +4°C refrigerated room
41 -30°C refrigerated room
42 Air-lock
43 Delivery of blood and derivatives
44 Duty room, telex
45 Meeting room (lecture room)
46 Staff rest-room
47-50 Changing rooms and shower
51 Organization department
52 Secretariat
53 Director’s office
54 Library
55 Microbiology
56 Room for thermostats
57 Sterile box
58 Culture media preparation
59 Entrance for donors
60 Entrance for deliveries
61 Main entrance
Design of premises

- a district transfusion centre, not attached to a hospital and serving a limited number of medical units in the close vicinity, taking 50 donations per day (all within the centre) and with limited facilities for blood component preparation;
- a regional centre, not attached to a hospital and serving medical units at varying distances, taking 200 donations per day (more than half by mobile teams) and with facilities for processing 80% of donations to blood components.

**District centre**

The functions of a district transfusion centre are:

- Examination of donors and collection of blood

  Standard floor space depends on the number of donors to be examined and bled daily. Floor space of 120 m² is adequate for 50 donors per day and includes the donors’ waiting room (which should be cheerfully decorated to help donors feel at ease).

- Storage of blood

  If the amount of blood stored by the district centre does not exceed 50 units at any one time, a floor space of 40 m² should suffice for blood storage, distribution and administration.

- Testing of blood

  If the district centre collects 50 units per day it will require a floor space of 30 m² for testing and quality control.

- Store-room and offices

  Another 30 m² of space are required for these purposes.

The additional facilities needed in a district centre performing the functions outlined above and preparing a limited number of blood components, will require the following areas:

- Cleaning and sterilization, 30 m²
- Laundry, 16 m²
- Garage, 20 m²
Management of blood transfusion services

| Store-rooms | 20 m² |
| Changing and rest-rooms, and staff canteen | 2 x 20 m² |
| Maintenance workshop | 20 m² |
| Director’s office | 12 m² |
| Donor organizer’s office | 12 m² |

**Regional centre**

The tasks of a regional transfusion centre are:

- Examination of donors and collection of blood

  If daily bleedings number 200, the donor department should have a floor space of 300 m². This assumes that more than half of the total donations are taken by mobile teams. (The detailed design of such a department is shown in Fig. 5.7.)

- Testing of blood

  This involves the testing of donors’ blood samples (grouping and detection of transmissible diseases), blood-grouping and cross-matching for hospital patients (if it is not performed by a hospital laboratory), as well as preparation of some diagnostic reagents. At least 150 m² of floor space are needed to perform these tasks. (More details are shown in Fig. 5.8.)

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**Fig. 5.7 Donor department — 240 m²**

52
Design of premises

<table>
<thead>
<tr>
<th>Detection of transmissible diseases</th>
<th>Reception of materials</th>
<th>Testing of donors' samples</th>
<th>Cross-matching</th>
<th>Testing of patients' samples</th>
<th>Preparation of reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 m²</td>
<td>20 m²</td>
<td>50 m²</td>
<td>15 m²</td>
<td>30 m²</td>
<td>15 m²</td>
</tr>
</tbody>
</table>

**Fig. 5.8 Testing of blood—150 m²**

- Production of blood components

The plan and size of this unit are determined by the quantity and quality of blood components produced. The following types of blood components may be produced at the regional centre level:

- red blood cell concentrate
- red blood cell concentrate, washed
- red blood cells, frozen
- platelet concentrate
- leukocyte concentrate
- fresh frozen plasma
- cryoprecipitate.

The unit depicted in Fig. 5.9 can process 80% of the 200 units of blood taken daily, and occupies a floor space of 230 m².

<table>
<thead>
<tr>
<th>Cryobiology store</th>
<th>Cryobiology refrigeration</th>
<th>Control laboratory</th>
<th>Store of sterile sets</th>
<th>Cold room + 4 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 m²</td>
<td>20 m²</td>
<td>20 m²</td>
<td>20 m²</td>
<td>25 m²</td>
</tr>
</tbody>
</table>

| Centrifuges 30 m² | Aseptic room 15 m² | Air lock 10 m² | Aseptic room 15 m² | Centrifuges 30 m² | Reception of materials 15 m² |

**Fig. 5.9 Preparation of blood components—230 m²**

53
• Quality control

Microbiological and chemical control of blood, blood components, solutions and reagents is performed here. Floor space should be at least 100 m² (see Fig. 5.10).

• Storage and distribution of blood

The regional centre featured in this example requires a sufficient area to store a maximum 1000 units of blood at 4 °C, and an additional 2000 units of blood components at −30 °C. The unit has telex facilities, offices and a duty-room; the total useful area is 100 m² (see Fig. 5.11).

• Cleaning

This unit contains the central wash-up room (for cleaning laboratory equipment), stills and sterilizing equipment, and requires an area of 150 m² (see Fig. 5.12).
The regional centre should also have a store-room of 30 m², a garage of 100 m² and additional rooms (changing room, toilets) occupying about 70 m².

The total useful area of the regional centre is 1500 m². It could be valuably enlarged, however, to include a training centre (at least 200 m²), management offices (100 m²), staff rooms (150 m²) and an outpatient department (50 m²), thus increasing the total useful area to 2000 m².

If the regional transfusion centre is not attached to a hospital, it will need the following additional facilities:

- Laundry: 30 m²
- Staff canteen: 30 m²
- Maintenance workshop: 30 m²

These can be attached as an additional wing to the regional centre illustrated in Fig. 5.6.

**National centre**

The design of a national transfusion centre will differ from that of a regional centre if it undertakes a larger volume of work or performs additional tasks. More management tasks and laboratories (e.g. if the centre acts as a national reference laboratory) demand more floor space. If plasma fractionation is to be undertaken eventually, the national centre will then have to be enlarged accordingly; a further separate unit may also be required for production of sterile blood containers (see Fig. 5.13).
Flexible construction for expansion of centre activities

The national blood transfusion service must always keep abreast of scientific advances (new techniques, new blood components, etc.) and be actively involved in the planning and development of the various blood centres. In the early stages of a national service the transfusion centres carry out only the basic functions—examination of donors, bleeding, testing, storage and distribution of blood. The scope of activities can then be enlarged by adding the following:

- production of blood components (or increasing production and variety of blood components);
- improvement of quality control;
- care of patients suffering from haematological disorders;
- independent functioning (e.g. local production of blood containers);
- production of diagnostic reagents;
- production of sterile solutions for processing blood components;
- fractionation of plasma;
- automation and data processing.

An existing building can be enlarged by construction of a new wing, by adding a new floor (if the foundations of the building permit) or by making use of spare rooms. It is recommended that more floor space be planned for a transfusion centre than is required initially—perhaps 10% of the total useful area. These extra rooms can first be used as store-rooms but be fitted out later to serve other purposes.

Any enlargement that is expected to take place in the near future should be embodied in the original plans. For example, if the national blood programme provides for a national centre to start plasma fractionation, the original plan should include a separate department for this purpose.

Although it is desirable to accommodate a national transfusion centre in an ideal, purpose-designed building, in most cases it is beyond the available financial resources. Alternatively, an existing building can be adapted or reconstructed for the new purpose, but it must satisfy the following requirements:

- The available floor space must be sufficient for the purposes of the centre, and/or the building must be capable of later expansion by addition of a new wing or a new floor.
• The arrangement of existing rooms must be satisfactory, or it must be possible to rearrange them.

In conclusion, it is worth noting that many experienced designers consider that grandiose projects are more likely to fail than more modest schemes that concentrate on functional efficiency.
Chapter 6
Basic equipment for blood transfusion centres

F. Haskó¹ and Ilma Szász²

INTRODUCTION

The blood transfusion centre should be equipped with machinery and instruments appropriate to its task. The quality and quantity of equipment needed depends on the number of blood units collected and processed, the methods used, and the infrastructure of the centre. These factors, and their economic significance, are discussed in this chapter. Maintenance methods and safety regulations are also described, and lists of equipment for transfusion centres are given as examples. (Calibration procedures and standardization of equipment are dealt with in Chapter 7.)

To ensure the smooth functioning of a transfusion centre, a comprehensive plan for the procurement of basic equipment is essential. Continuing provision is often difficult because of financial constraints and it is therefore advisable for a committee of experts to undertake the planning. Its members should include physicians, scientists, laboratory technicians and members of the maintenance staff.

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PROCUREMENT OF EQUIPMENT

Role of the Infrastructure

The basic operations of a transfusion centre require electricity, good quality water, an efficient sewerage system, cleanable surfaces in the premises, an aseptic environment for some procedures, and provision for transport of blood and other materials. These facilities are often taken for granted in developed countries but, even where conditions are 'favourable', it is essential for a transfusion centre to have an emergency generator and a reserve water supply that can be used if main supplies fail. If a transfusion centre is to have its own electrical power station, allowance should be made in the planning for future expansion. A centre may also need its own well and pump if mains water supplies are not available, preferably with sufficiently large storage tanks to maintain supplies during a breakdown in this supply. Unfortunately, the quality of water is not universally suitable for a transfusion centre; it may be too hard, for example, or contain toxic substances, and a suitable purification system may be necessary.

Wastewater sometimes contains substances such as proteins, chemicals or outdated blood, whose discharge into public sewers is prohibited. The transfusion centre thus also needs a wastewater purification system, which may be costly.

The equipment selected should be compatible with local conditions and infrastructure. The most important factors to be considered are:

- source of electricity (public network, generator or emergency generator), variations in current, phases, voltage, frequency, fuses, cross-sections of wires, types of sockets and plugs, availability of earth connection;
- source of water (public network, spring, groundwater well), variations in pressure, output, quality and temperature, dimensions of supply pipes, availability of hot water;
- sewerage system (public sewers, drainage pit or other draining facilities at disposal sites), dimension of sewerage pipes;
- temperature and humidity of air, availability of air conditioning;
- availability of benches, shelves, floor space and wall sockets; distances between appliances and sockets; dimensions of door openings for transport of equipment.
Role of technology

A written series of methods for producing and/or testing a product is essential; these standard operational procedures should include all the information necessary to complete the tasks and be available at all times to the staff concerned. Early decisions should be reached on basic methods (e.g. blood collection in bags or bottles) that will influence the type of equipment to be purchased later.

The applied techniques and the suitability of equipment are also influenced by the level of training of staff members. Capabilities of the maintenance staff must also be considered: untrained people are obviously not able to handle complicated equipment. When staff are not highly trained, investment in sophisticated, automatic equipment is ill-advised; equipment that is as simple and robust as possible is a much wiser purchase in these circumstances.

It is good practice to keep spare parts in stock, especially when the manufacturer has no service agents in the country. All equipment is likely to need replacement parts at some time, despite the contrary claims that are often made.

Specifications for equipment should be precise. In the case of centrifuges, for example, the types of container to be used should be specified, including dimensions; the required capacity for each operation should be specified, together with the type of centrifuge head, the required temperature in the centrifuge chamber, and the necessary centrifugal force; the need for any ancillary equipment and for automatic timing of centrifugation should be determined. In the case of refrigerators a decision should be taken on whether they should be operated by electricity, gas or petrol; this will depend on available facilities. Their dimensions, storage capacity and operating temperatures should also be defined.

The final choice between apparently equally satisfactory items of equipment depends largely on the price and on the guarantee offered. The experience of other institutions with the equipment may be a valuable consideration.

Estimating the amount of equipment

In estimating the amount of equipment required, the heaviest daily workload for each department and operation is divided by working hours, which indicates the basic calculated workload
(workload per hour). The number of items of equipment to be purchased is obtained by dividing the basic calculated workload by the capacity of the equipment. To allow for the fact that donations are not distributed evenly during working hours—for example, a mobile team may bring in 200 to 300 units at once on an otherwise ‘quiet day’—the basic calculated workload should be increased by 50–100%. The calculation may sometimes involve only one piece of equipment, but provision must be made for a back-up system.

Requirements for freezers, refrigerators and refrigerated rooms are calculated differently. The necessary capacity of each should be derived from the number of units of blood or of fresh frozen plasma or cryoprecipitate that must be stored. Allowance must be made for separating units of different blood groups, to permit easy access. Refrigerated rooms should also be equipped with reserve compressors, which activate automatically when necessary.

MAINTENANCE OF EQUIPMENT

Regular maintenance of equipment includes continuous performance testing and replacement of worn parts. Particular attention should be paid to the following:

- replacement of frayed or damaged power cables, and broken plugs or socket-outlets;
- limiting the length of supply cables to no more than 4 metres;
- avoiding the use of extension cables and adaptors;
- regular testing for current leakage, in accordance with accepted standards;
- regular checking of the earthing of equipment;
- regular checking of the neutral-to-earth impedance of all power supply points, socket-outlets and metal in the environment.

A planned preventive maintenance programme should be based largely on the expertise of local engineering staff. In some cases service contracts may have to be arranged with engineers outside the hospital or transfusion centre; this approach may be more reliable and/or economical, but generally has the disadvantage of longer down-times. Proper maintenance of equipment should be integrated with quality control procedures (see Chapter 10).
A comprehensive schedule should be developed for the regular maintenance of equipment. Non-technical staff members must familiarize themselves with the electronic and mechanical features of the equipment, while technical staff responsible for maintenance must acquire a basic knowledge of the medical consequences of malfunction or inappropriate use of the equipment, as well as a thorough understanding of the equipment design and construction. They must be able to calibrate the equipment or supervise its calibration by others, and must collaborate on short instruction programmes for the medically qualified staff of the transfusion centre.

SAFETY PRECAUTIONS

Safety of medical electrical equipment encompasses the intrinsic safety of the equipment, the safety of its installation, and the safety with which it is operated. It is most important that the operator and surroundings are protected as far as possible without restricting the normal function of the equipment. Studies of accidents involving medical equipment have shown that the greatest number are caused by improper use of the equipment, and a significant proportion by a failure to install it correctly or maintain it satisfactorily.

It is recommended that safety committees should be formed in blood transfusion centres. ISBT has issued a guide outlining safety precautions for blood transfusion laboratories.¹ Excerpts from this guide concerning recommendations on hazardous instruments found in transfusion centres are given below.

Safety of electrical supply

When a laboratory is planned, the estimated consumption of electricity should be multiplied by a factor of at least three in order to ensure that there will be sufficient capacity to meet future needs. Overloading represents the most common potential hazard in the use of electrical equipment.

Ample electrical outlets above or at the rear of benches are essential. Four or more outlets may be needed for each technician. Two or more circuits, each capable of carrying between 1700 W and 2000 W, may be needed to avoid overloading. More outlets

and more circuits will be required in certain areas devoted to cell washers, centrifuges, and water-baths. Extension cords and multiple adaptors fitted to a single outlet should be forbidden.

All electrical socket-outlets must be of the three-pin type, incorporating an earth (or ground) wire. All apparatus must be fitted with three-pin plugs and the connections should be inspected regularly to detect frayed or loose wires.

Colour codes for electrical wiring vary in different countries, as the following table shows:

<table>
<thead>
<tr>
<th>Wire</th>
<th>UK</th>
<th>Europe</th>
<th>N. America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live (hot)</td>
<td>Brown</td>
<td>Red</td>
<td>White</td>
</tr>
<tr>
<td>Neutral</td>
<td>Blue</td>
<td>Black</td>
<td>Black/Blue</td>
</tr>
<tr>
<td>Earth (ground)</td>
<td>Green/Yellow</td>
<td>Green/Yellow</td>
<td>Green</td>
</tr>
</tbody>
</table>

Circuit-breakers are mandatory. When fuses are used instead, there may be the temptation to use an inappropriate fuse; this can result in a fire through overloading of the circuit.

Heavy-duty electrical equipment should not be installed without confirming that its electrical requirements will not overload the available power supply.

**Safe operation of centrifuges**

Centrifuges are particularly hazardous for two reasons:

- Mechanical failure, metal fatigue in the rotor, an improperly placed trunnion ring, or an unbalanced load can cause serious injury.
- Most centrifuges discharge a high-velocity current of air. If infected droplets are released within the bowl through use of uncapped tubes or because of breakage, widespread aerosol dispersion of infected material will result. Sparking from electric motors may cause volatile materials such as ether to explode; such materials must not be centrifuged.

**Selection and use**

Only centrifuges with lids that latch firmly should be selected. A safety interlock to prevent the motor rotating if the lid is insecure is desirable.
Management of blood transfusion services

Trunnion cups must be properly seated in the centrifuge head. The load must be carefully balanced using dry balancing materials that will not damage either the load or the cups.

The lid must not be opened when the machine is running: a safety interlock that prevents the lid being opened while the head is turning is an excellent feature.

If saline is spilled into centrifuge cups they should be washed out with water immediately, and the cups carefully dried, to avoid metal corrosion.

Maintenance

Daily inspection of centrifuge bowls and lids is essential. Once each week, all centrifuges in the laboratory should be thoroughly cleaned with detergent. Heads and cups should be removed and soaked in detergent. The inside of centrifuge bowls and lids should be thoroughly swabbed with detergent. Rubber gloves should be worn during this cleaning process.

Tubes with wet rims or nearly-filled tubes in an angle centrifuge head will produce aerosols when centrifuged. They may be closed with stoppers or some suitable proprietary material.

If glassware breaks during centrifugation, the centrifuge should be stopped and 10 minutes allowed to elapse for aerosols to settle. Rubber gloves should then be worn to remove the centrifuge cup carefully. The contents should be placed in an autoclavable plastic bag, which is then autoclaved. The centrifuge cup and cushion should be soaked in 2% glutaraldehyde containing detergent for at least 1 hour before being rinsed in tap water and dried.

Safety precautions for other equipment

Refrigerators and freezers should be defrosted periodically and the walls, shelves and floor thoroughly cleaned with detergent solution. Rubber gloves should be worn during this process.

Water-baths, incubators, and test-tube racks should be regularly cleaned at intervals of no more than one month.

Containers made of expanded polystyrene and used for the transportation of blood units are porous and should be used only with a disposable plastic liner. If the containers themselves become soiled with blood or blood derivatives, they should be discarded. Nonporous, reusable mailing containers should be
cleaned weekly, or whenever soiled, with hypochlorite detergent. The maintenance and quality control of high-pressure steam sterilizers is an extremely complex process that should be undertaken only under the guidance of a competent, qualified engineer.
Management of blood transfusion services

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laminar air flow boxes</td>
<td>4</td>
</tr>
<tr>
<td>Plasma extractors</td>
<td>20</td>
</tr>
<tr>
<td>Tube sealers</td>
<td>4</td>
</tr>
<tr>
<td>Platelet shaker with incubator (+20 °C)</td>
<td>1</td>
</tr>
<tr>
<td>Balance (5 kg)</td>
<td>3</td>
</tr>
<tr>
<td>Balance (2 kg)</td>
<td>1</td>
</tr>
<tr>
<td>Pull-spring scales</td>
<td>5</td>
</tr>
<tr>
<td>Deep-freezer (-40 °C, 500 litres)</td>
<td>4</td>
</tr>
<tr>
<td>Cold room (+4 °C)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Sterilization, processing of equipment and solutions**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic autoclaves</td>
<td>3</td>
</tr>
<tr>
<td>Oven (40–250 °C, 50 litres)</td>
<td>1</td>
</tr>
<tr>
<td>Automatic washers</td>
<td>2</td>
</tr>
<tr>
<td>Water still (60 litres/h)</td>
<td>2</td>
</tr>
<tr>
<td>Water softener</td>
<td>3</td>
</tr>
<tr>
<td>pH meter</td>
<td>1</td>
</tr>
<tr>
<td>Polyethylene film sealer</td>
<td>1</td>
</tr>
<tr>
<td>Stainless steel sink</td>
<td>4</td>
</tr>
<tr>
<td>Refrigerator (240 litres)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Blood group serology department**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plates for blood grouping</td>
<td>40</td>
</tr>
<tr>
<td>Automatic blood group analysers¹</td>
<td>2</td>
</tr>
<tr>
<td>Bench centrifuges</td>
<td>5</td>
</tr>
<tr>
<td>Two-pan balance</td>
<td>1</td>
</tr>
<tr>
<td>Incubators (37 °C)</td>
<td>2</td>
</tr>
<tr>
<td>Refrigerators (+4 °C, 400 litres)</td>
<td>2</td>
</tr>
<tr>
<td>Deep-freezer (-30 °C, 350 litres)</td>
<td>1</td>
</tr>
<tr>
<td>Automatic washer (for glassware)</td>
<td>1</td>
</tr>
<tr>
<td>Auto-Coombs analyser¹</td>
<td>1</td>
</tr>
<tr>
<td>Incubator (37 °C)</td>
<td>1</td>
</tr>
<tr>
<td>Water-bath</td>
<td>1</td>
</tr>
<tr>
<td>Refrigerator (+4 °C, 300 litres)</td>
<td>1</td>
</tr>
</tbody>
</table>

Examination of blood samples from donors

Antibody screening
Refrigerated centrifuges 2
Auto-Coombs analyser¹ 1
Incubator (37 °C) 1
Refrigerator (+4 °C, 400 litres) 2
Deep-freezers (−30 °C, 350 litres) 2

Bench centrifuges 3
Auto-Coombs analyser¹ 1
Incubator (37 °C) 1
Refrigerator (+4 °C, 400 litres) 1
Deep-freezers (−30 °C, 350 litres) 2

Quality control department

Chemical laboratory

Precision balance 1
pH meter 1
Spectrophotometer 1
Refractometer 1
Polarimeter 1
Conductometer 1
Bench centrifuge 1
Gas burners 2
Water pumps 2

Microbiological laboratory

Microscope, binocular 1
Dishes for culture fluid 2
Autoclave 1
Incubators (38 °C) 1
Laminar air-flow box 1

¹ At a highly automated stage of development.
² If applicable.
Management of blood transfusion services

Ultraviolet (bactericidal) lamp 1
Water-bath 1
Refrigerator (+4 °C, 400 litres) 1

**Hepatitis B laboratory**

Bench centrifuges 4
Microtitration plates 50
Automatic pipettes (with tips) 15
Incubators (+37 °C) 3
Autoclave 1
Refrigerators (+4 °C, 400 litres) 2
Chapter 7
Standardization of equipment: calibration procedures

Ilma Szász

INTRODUCTION

According to the International Committee for Standardization in Haematology (ICSH), *calibration* is defined as the determination of a bias conversion factor of an analytical process under specified conditions, in order to obtain accurate measurement results. The accuracy over the operating range must be established by appropriate use of reference methods, reference materials and/or calibrators.

A *calibrator* is defined as a substance or device that is used to calibrate an apparatus or to adjust an instrument in order to obtain accurate results. It could be a reference material based on an international reference preparation, a physical device, or a physical or chemical specification.

*Calibration procedures* for specific instruments differ because of differences in operation, and are described in individual operating manuals. Commercially available calibrators can be used, but they should be traceable to internationally accepted reference materials. When an instrument is new and being set up for the first time, it must be calibrated according to its operating instructions, standardized with standards or reference materials if possible,

1 Head of Clinical Biochemistry Department, National Institute of Haematology and Blood Transfusion, Budapest, Hungary.
and, if appropriate, checked against known samples to verify that test results are correct. Thereafter, its performance should be checked regularly by performing calibration and/or standardization and control procedures. If an instrument does not behave in a linear fashion throughout its measuring scale, material with a mid-scale value will not be suitable for calibrating the instrument for accurate measurement at the extremes of the scale.

MATERIALS AND METHODS

The following sections provide examples of the steps to be taken in the calibration or standardization of equipment commonly found in blood transfusion centres, but the list is by no means exhaustive.

Calibrators and/or reference material

One example of reference material is a haemiglobincyanide preparation to which values have been assigned by the manufacturer in accordance with ICSH recommendations. Another example is thromboplastin, commercial brands of which should be standardized to appropriate WHO reference preparations. A pulse generator is an example of a physical device, and absorbance at a given wavelength is an example of a physicochemical specification.

Several materials have been tried as blood cell standards (for blood counters) including (a) natural fresh blood (collected into EDTA—ethylenediaminetetraacetic acid); (b) blood preserved by acid citrate dextrose or citrate phosphate dextrose, sometimes with addition of inosine or adenine; (c) glutaraldehyde-fixed blood cells; and (d) artificial particles such as latex polymers. At present monosized latex particles are considered to be the best primary reference materials for the calibration of blood counting and sizing by haematology analysers, but fresh blood should be used as a secondary reference in standardizing the whole procedure.2

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Methods of calibration (see also Chapter 10)

Calibration of thermometers

Thermometers should be calibrated at operating temperature against a standard thermometer. The procedure is as follows:

- Place the uncalibrated thermometer and the calibrator thermometer in the medium in which the uncalibrated thermometer is to be used (e.g. 10% glycerol, distilled water, air).
- Adjust the temperature of the medium to the temperature at which the uncalibrated thermometer will be used.
- Record the temperature reading of both the uncalibrated thermometer and the calibrator thermometer.
- Affix a piece of tape to the uncalibrated thermometer indicating the difference in temperature reading between it and the calibrator thermometer, the medium used and the date of the calibration. For example, if the calibrator thermometer reads 9 °C and the uncalibrated thermometer reads 10 °C in a 10% glycerol medium, the tape should read ‘−1 °C, glycerol’ plus the date.
- If the thermometer is to be used for a range of temperature, it must be calibrated at the highest and lowest temperatures of that range. Thus, if the range is 1–10 °C, calibration should be at 1 °C and at 10 °C.

Calibration of photometers

When photometers are calibrated, Lambert-Beer’s Law (i.e. that absorbance is proportional to concentration) must be tested on the instrument. This is best done by preparing a calibration curve. A series of dilutions of the analytical solution in arithmetic progression must be prepared and the absorbance measured against the reagent blank.

A graph should be plotted of the results, with a straight line drawn through the points. It may be worth comparing this with a mathematical analysis in which the equation of the curve is

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deduced from the regression equation, and the standard deviation and correlation coefficient are calculated.\(^1\)

If the calibration line does not pass through the point of origin of the graph, it is advisable to check the blank value. It may be possible to make the calibration pass through the point of origin by changing the order of addition of the reagents. If it is not possible to achieve coincidence of zero absorbance with zero concentration there will be an unavoidable complication in calculation.

Linearity must also be considered. If absorbance is directly proportional to concentration, and if the correlation coefficient exceeds 0.98, the instrument is appropriate for measuring the analytical samples of the selected method. Any deviations from Lambert-Beer's Law may be either chemical or physical in nature; most are due to the fact that the light used for the measurement is not monochromatic.

A deviation from Lambert-Beer's Law does not necessarily indicate that the instrument cannot be used for the selected method, but some limitations have to be taken into account. Frequently, the relationship is linear up to a certain concentration and deviates from linearity only at higher concentrations. Accordingly, the analytical sample should be diluted so that the absorbance falls in the linear range. If this does not improve the procedure, the sole remaining course of action is to include at least five standards in every series of determinations and to prepare a standard curve each time. The closer the concentration of the standard is to the concentration of the unknown, the more reliable the results will be.

In general the result should be calculated from the reading for a closely related standard and only in special cases directly from absorbance.

Methodology. Photometers for haemoglobin determination should be calibrated by an ICSH haemiglobincyanide (HiCN) reference preparation. The value of 150 g/litre usually assigned to this reference preparation refers to 150 g/litre haemoglobin mass concentration in the original blood specimen diluted 1:250 by the haemoglobin transformation reagent. The dilutions given in Table 7.1 are recommended for calibrating a photometer.

Absorbance of the 50, 100 and 150 g/litre samples should be read in spectrophotometers against the blank at 540 nm

Table 7.1 Calibration of photometers

<table>
<thead>
<tr>
<th>Hb concentration in whole blood</th>
<th>(g/litre)</th>
<th>Blank</th>
<th>50</th>
<th>100</th>
<th>150</th>
</tr>
</thead>
<tbody>
<tr>
<td>HiCN standard</td>
<td>(ml)</td>
<td>—</td>
<td>2.0</td>
<td>4.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Hb-transformation reagent</td>
<td>(ml)</td>
<td>6.0</td>
<td>4.0</td>
<td>2.0</td>
<td>—</td>
</tr>
</tbody>
</table>

wavelength, or in filter photometers with the appropriate green filter (S 53). At 540 nm a so-called ‘absolute’ photometer gives an absorbance value of 0.408 with the undiluted reference preparation.

Many simple and less costly photometers meet the Lambert-Beer criteria up to the range of practical use, but only ‘relative’ values of absorbance (i.e. values slightly shifted from those defined by the absorption coefficient) are warranted. Consequently, when haemoglobin concentrations of unknown samples are measured by the HiCN method, the absorbances obtained should be related to that of the simultaneously measured HiCN reference material, and concentrations should be calculated from the following formula:

\[
\frac{A_{\text{sample}}}{A_{\text{ref}}} \times C_{\text{ref}} = C_{\text{sample}}
\]

where \( A_{\text{ref}} \) is absorbance of the reference material at 540 nm and \( C_{\text{ref}} \) is the concentration value assigned to the reference material.

Calibration of centrifuges for platelet preparation

At the time of donation, collect blood from a donor into an EDTA tube, in addition to the clotted specimen routinely drawn for testing. Perform a platelet count on the EDTA specimen. If the count is below approximately 130 \( \times 10^9 / \text{litre} \), this unit of blood should not be used for calibration. Calculate the number of platelets in the unit of whole blood (WB):

\[
\text{platelet count (per litre)} \times \text{volume (litres) of whole blood} = \text{number of platelets in whole blood}
\]

Preparation of platelet-rich plasma (see Fig. 7.1). To prepare platelet-rich plasma (PRP), centrifuge the collection bag containing the donor’s blood at a selected speed and for a selected time, and proceed as follows:
Fig. 7.1 Preparation of platelet-rich plasma and platelet concentrate

- Place a temporary clamp (A) on the tubing so that satellite bag X is closed off. Express platelet-rich plasma into satellite bag Y. Seal close to the collection bag (clamp B) and disconnect the two satellite bags.
- Strip the tubing several times so that it contains a representative sample of platelet-rich plasma.
- Seal a segment of the tubing (at C) and disconnect it, so that satellite bag Y, containing the platelet-rich plasma, remains sterile.
- Perform a platelet count on the sample of platelet-rich plasma in the tubing segment, and calculate the number of platelets in satellite bag Y:

  Platelet count (per litre) \times \text{volume (litres)} \times \text{of PRP} = \text{number of platelets in PRP}

- Calculate the percentage yield:

  \frac{\text{number of platelets in PRP}}{\text{number of platelets in WB}} \times 100 = \text{percentage yield}

- Repeat the above procedure three or four times with different donors, using different speeds and times for centrifugation, and compare the yields for each set of centrifuge conditions.
- Select the shortest time and lowest speed that result in the highest percentage yield of platelets in platelet-rich plasma.

*Preparation of platelet concentrate* (see Fig. 7.1). Centrifuge the platelet-rich plasma (satellite bag Y) at a selected speed and for a selected time, and proceed as follows:
• Remove the temporary clamp A. Express the platelet-poor plasma into the second attached satellite bag (X) and seal the tubing (at D), leaving a long section of tubing attached to the platelet concentrate bag (Y).
• Strip the tubing several times, mixing its contents well with those of satellite bag Y. Let the concentrate flow back into the tubing.
• Seal a segment of the tubing so that the platelet concentrate bag remains sterile.
• Perform a platelet count on the platelet concentrate. Calculate the number of platelets in the platelet concentrate (PC):

\[
\text{platelet count (per litre)} \times \text{volume (litres) of PC} = \text{number of platelets in PC.}
\]

• Calculate the percentage yield:

\[
\frac{\text{number of platelets in PC}}{\text{number of platelets in PRP}} \times 100 = \text{percentage yield}
\]

• Repeat the procedure, centrifuging the platelet-rich plasma using different speeds and times of centrifugation. Compare the yields for each set of centrifuge conditions.
• Select the shortest time and lowest speed that result in the highest percentage yield of platelets in the platelet concentrate.

Figure 7.2 shows a nomogram for computing relative centrifugal forces and rotational speed in revolutions per minute. Typical centrifugation parameters for preparing platelet-rich plasma and platelet concentrate with the most widely used centrifuge types are given in Table 7.2.

**Calibration of centrifuges for serology**

Use serum containing an antibody that produces 1+ agglutination macroscopically. Select one sample of red cells positive for the appropriate antigen and one negative sample. Prepare a fresh suspension of red blood cells in the concentration routinely used in each laboratory (e.g. 2–5%).

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Management of blood transfusion services

EXAMPLE

To find the relative centrifugal force at a radial distance of 11 cm from the centre of rotation when operating the centrifuge at a speed of 4000 r/min, place a ruler on the chart connecting the 11 cm point on the Rotating Radius Scale (A) with the 4000 r/min point on the Speed Scale (B). Read the point at which the ruler intersects the Relative Centrifugal Force Scale (C) — in this case, 2000 x gravity.

Similarly, if the desired relative centrifugal force is known, the necessary speed for a given rotating radius may be determined by connecting the two known points and reading the intersection of the ruler with the Speed Scale.

WHO 83/279

Fig. 7.2 Nomogram for computing relative centrifugal force and rotational speed
Table 7.2 Centrifugation parameters for preparing platelet-rich plasma and platelet concentrate

<table>
<thead>
<tr>
<th>Type of product</th>
<th>Angle head</th>
<th>Swing-out head</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light spin, platelet-rich plasma</td>
<td>4170g</td>
<td>1740g</td>
</tr>
<tr>
<td></td>
<td>4500 r/min</td>
<td>2500 r/min</td>
</tr>
<tr>
<td></td>
<td>2 min</td>
<td>3 min</td>
</tr>
<tr>
<td>Heavy spin, platelet concentrate</td>
<td>5140g</td>
<td>5000g</td>
</tr>
<tr>
<td></td>
<td>5000 r/min</td>
<td>4000 r/min</td>
</tr>
<tr>
<td></td>
<td>5 min</td>
<td>5 min</td>
</tr>
</tbody>
</table>

For saline-active antibodies:
Serum from group A person (anti-B), diluted with 6% albumin to give 1+ macroscopic agglutination (3 ml 22% bovine albumin + 8 ml normal saline = 6% bovine albumin).

Positive control: Group B red blood cells in a 2–5% saline suspension.

Negative control: Group A red blood cells in a 2–5% saline suspension.

The equation for calculating relative centrifugal force (rcf) is:

\[
\text{rcf} = 0.000 \ 011 \ 18 \times r \times N^2
\]

\[
r = \text{rotating radius (centimetres)}
\]

\[
N = \text{rotating speed (revolutions per minute)}
\]

Times given include acceleration but not deceleration, and are only approximations. Each individual centrifuge must be evaluated for the various components.

For albumin-active antibodies:
1 part anti-D diluted with 25–30 parts Rh diluent control to give 1+ macroscopic agglutination.

Positive control: D-positive red blood cells, in a 2–5% saline suspension.

Negative control: D-negative red blood cells, in a 2–5% saline suspension.
For *antiglobulin serum*:
Antiglobulin serum, unmodified.

Positive control: A 2–5% saline suspension of D-positive cells is incubated for 15 minutes at 37°C with anti-D diluted to give 1+ macroscopic agglutination after addition of antiglobulin serum, and then washed 3 times with saline (except for the last step in the procedure).

Negative control: A 2–5% saline suspension of the same D-positive red blood cells used to prepare the positive control is incubated for 15 minutes at 37°C with 6% albumin and then washed 3 times with saline (except for the last step in the procedure).

For each medium (saline, albumin, antiglobulin), prepare five tubes (10 × 75 mm or 12 × 75 mm) for positive reactions and a duplicate set of tubes for negative reactions. Add the serum and test cells to each tube just before centrifugation.

In pairs, one positive and one negative, centrifuge the tubes for different times (e.g. 10, 15, 20, 30 seconds). Observe each tube for agglutination and record observations. For an example see Table 7.3.

The optimum time of centrifugation is the least time required to fulfill the following criteria:

- Agglutination is as strong as that determined in preparing reagents.
- The red cell button is clearly delineated and the periphery is sharply defined, not fuzzy.
- The supernatant fluid is clear.
- The red cell button is easily resuspended.

**Table 7.3 Centrifuge calibration for anti-human globulin tests**

<table>
<thead>
<tr>
<th>Centrifugation criteria</th>
<th>Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Supernatant fluid clear</td>
<td>No</td>
</tr>
<tr>
<td>Cell button clearly delineated</td>
<td>No</td>
</tr>
<tr>
<td>Cells easily resuspended</td>
<td>Yes</td>
</tr>
<tr>
<td>Agglutination</td>
<td>±</td>
</tr>
</tbody>
</table>
Since, in the example shown in Table 7.3, both the 30-second and 45-second spins fulfill these criteria, the optimum time for this centrifuge is 30 seconds.

For the washing procedure, fill all tubes for the antiglobulin test with saline. In pairs, one positive and one negative, centrifuge tubes for different times (e.g. 30, 45, 60, 90, 120 seconds). All red blood cells should be in a clearly delineated button with no cells remaining up the side of the tube. The shortest time required to accomplish this is the optimum washing time for this centrifuge.

DIFFERENT APPROACHES FOR STANDARDIZING EQUIPMENT

Automation

There are several instruments that wash, decant, mix and rewash cells automatically. Some systems go a step further, adding to each tube the antiglobulin serum for the antiglobulin test.

Instrument evaluation

Instruments may undergo evaluation at three levels. First, the manufacturer has to evaluate them in order to produce data on which to base performance claims. Second, evaluation is undertaken on behalf of potential users by laboratories acting for government departments and organizations. Third, the potential user can evaluate a particular instrument for reliability and for the special requirements of his or her own laboratory.

ICSH provides general guidance for manufacturers and has provided protocols for evaluation of special instruments. The principles outlined are common to the evaluation of a wide range of instruments, should be generally applicable to reagents and kits as well, and should enable the evaluator to adapt a protocol specifically for his or her own requirements.

Evaluation at the second and third levels may be divided into a preliminary planning stage and a technical stage. Planning should take account of the length of time available to carry out the evaluation (especially important in the case of instruments that are borrowed or leased) and requirements for staff, reagents,
reference materials and samples. Depending on the circumstances of the evaluation, a decision will have to be made on whether to test only those claims made by the manufacturer or to investigate areas for which claims are not made.

Sufficient samples of test material should be available in high, low and intermediate levels of concentration or activity to permit replicate testing. Division into aliquots and storage in a refrigerator or in the lyophilized state should be carried out where necessary.

The reagents used should be as specified by the manufacturer (or proven equivalents). Care must be taken to ensure that their storage and shelf-life will not expire during the period of evaluation, and that there will be sufficient quantities to allow complete testing from single supply batches.

*Note:* Some manufacturers may not wish to be responsible for the performance of an instrument unless their recommended reagents and/or consumables are used. At a later stage various batches of reagents should be assessed to determine whether or not batch variation exists and whether some reagents can be prepared in the user's laboratories.

Sufficient volumes of control and calibration material must be obtained and should be stored appropriately throughout evaluation. Where calibration materials are supplied or recommended by the manufacturer, the validity of assigned values must be considered.

Arrangements should be made for participating in an external assessment scheme. The results will allow performance of the test instrument to be compared with that of other instruments.

Records should be kept throughout the technical stage of the evaluation, and should include down-times (with causes), routine maintenance, significant events such as change of operator, batches processed (to assess throughput), and quantities of reagents used. It is also useful to record the response time of service technicians.

Capital costs and the costs of reagents, consumables, maintenance and staff should be monitored. Where appropriate, comparison may be made between the cost per test by the established method and the cost per test for the instrument under evaluation.

In addition to the assessment of safety (electrical, mechanical, microbiological, chemical, radiation), full evaluation requires:
• scientific assessment (accuracy, or comparability with other results, linearity, precision within and between batches, carry-over);
• assessment of efficiency (throughput, usefulness, reliability and costings).

Quality assessment using a haematology analyser as an example
The method of calibration will have to be determined for each instrument in accordance with its operational manual.

Materials
Samples will usually be of fresh blood obtained from volunteer donors and patients as follows:
• healthy donor
• healthy donor with lipaemia (post-prandial)
• polycythaemia (haemoglobin 180–200 g/litre)
• microcytic anaemia (mean cell volume 75 fl, haemoglobin 100–110 g/litre)
• leukocytosis (leukocytes 20–40 × 10⁹/litre)
• leukopenia (leukocytes 0.5–2.0 × 10⁹/litre)
• thrombocytosis (platelets 500–800 × 10⁹/litre)
• thrombocytopenia (platelets 50–80 × 10⁹/litre)
• macrocytic anaemia (mean cell volume 100 fl, haemoglobin 100–110 g/litre)
• jaundice (serum bilirubin 30 mol/litre)
• multiple myeloma (monoclonal immunoglobulins detected by immunoelectrophoresis).

The volume of blood to be collected depends on the requirements of the instrument being tested.
Reference materials used should be appropriate to the methodology under evaluation, e.g.
• ICSH-related haemoglobincyand (HiCN) reference preparation: 10 ml
• red cell, white cell and platelet reference material (if available): 10 ml.

Arrangements for external quality assessment samples should be made with the organizer of an external quality assessment
scheme and, if appropriate, with a regional quality assessment scheme, for the supply of material during the trial period.

Assessment of performance

- *A linearity test* should be performed to give results of 10 concentrations, evenly spaced within the limitations of the specific instrument, for the following:
  - Haemoglobin and red cell count using a sample obtained from a patient who has polycythaemia, diluted in the patient’s own plasma. The linearity of mean cell volume, mean cell haemoglobin and mean cell haemoglobin concentration can be determined from this experiment.
  - Leukocyte count using a sample from a patient who has leukocytosis, diluted in the patient’s own plasma.
  - Platelet count using a sample from a patient who has thrombocytosis, diluted in the patient’s own plasma.
- *Precision*. Replicate testing of whole blood samples within 2 hours of collection; 4–6 hours later, with the instrument having been switched off after completion of the experiment and then recalibrated; 24 hours after collection and storage at 4°C.
- *Accuracy and comparability*:
  - **Haemoglobin.** Test samples from high, intermediate and low range, the haemoglobin concentrations of which have been determined by the ICHS reference method\(^1\) (calibrated by haemiglobincyanide).
  - **Packed red cell volume.** Test samples for high, intermediate and low range, whose packed cell volumes have been determined by the ICHS reference method.\(^2\)
  - **Cell counting.** Compare test instrument results obtained on 10 samples from each of the conditions listed above with those obtained by the reference method on the same samples. Where the instrument has a separate channel for sampling prediluted specimens (i.e. capillary blood) a comparison should be made with results from whole blood from the same subject.

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• **Throughput.** Determine the maximum possible number of samples tested or measurements done per hour.

• **Practical usefulness.** With reference to the results of technical evaluation and determination of throughput, the value of the instrument in a routine haematological or blood transfusion department should be assessed, i.e. its suitability for clinical diagnosis and monitoring of therapy, as well as for screening of donors and for epidemiological surveys of the population.

• **Acceptability in practice:** Comments should be made on staff reaction to the instrument and maintenance problems encountered. Number and duration of down-times and reasons for these should be documented.
Chapter 8
Transportation

W. Wagstaff,1 Nandrani S. de Zoysa2 and Masri Rustam3

INTRODUCTION

Organizing the transportation service of a blood transfusion centre is a complex undertaking because it must be coordinated with all other activities of the centre and because it includes transport both of people and of a wide variety of materials. A choice must be made between contracting the service to outside agencies and creating a transport department within the centre. Local topography, the availability and cost of fuel and supporting services, and the availability of appropriately skilled personnel must be taken into account. The possibility of using public transport systems must also be considered.

CHOICE OF VEHICLE TYPE

Multipurpose collection vehicle

Where a good road system exists, a multipurpose collection vehicle may prove to be the most economical way of transporting

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mobile teams to and from distant donor sessions. Road and communication systems must be adequate to allow for a changeover of vehicles in the event of breakdown between the transfusion centre and a distant donor site, to avoid the possibility of a team being stranded for a long time. In deciding on such a multipurpose vehicle, which would carry personnel, refrigerated blood and the equipment for setting up a mobile donor session, it is wise to choose a basic chassis similar to that of coaches or trucks in common use in the region concerned.

**Poor roads and communications**

For each mobile session in areas where roads and/or communications are poor, it may be necessary to use two vehicles, preferably of the four-wheel drive type, to provide mutual back-up. One of these could be a minibus, used for carrying personnel, and the other would carry mobile equipment and refrigerated blood.

**Availability and cost of spares**

The local availability and cost of spares, and the presence of an agency capable of carrying out repairs, must be carefully considered when the vehicle is being chosen.

**Ease and cost of maintenance**

Another important consideration is the ease and cost of vehicle maintenance. In deciding between in-house servicing and contracting-out routine maintenance to a local agency, a careful cost analysis must be undertaken, bearing in mind the need for 24-hour cover for repairs to vehicles carrying refrigerated blood.

**Availability and cost of fuel**

The local availability and cost of fuel may also be decisive factors. Diesel engines are generally cheaper to run and more reliable, but diesel fuel may not be universally available. The effects of climatic extremes must also be taken into account, such as petrol
evaporation in very hot climates and freezing of diesel fuel in very cold conditions.

SPECIAL ADAPTATION OF VEHICLES

Refrigeration

Vehicles used to transport blood over other than very short distances should have built-in refrigeration that operates from either mains electricity or a built-in emergency generator. When fresh blood is refrigerated and cooled to 4°C, the refrigerator insulation should be able to keep the blood below 10°C for 24 hours without further running of the refrigerator motor.

Adaptation of vehicles

Where vehicles are adapted to carry donor teams, they should provide maximum possible comfort, bearing in mind the long working day of such teams and the probability of long-distance travel. At the very least, the standards set by commercial passenger-carrying vehicles should be met.

Publicity vehicles

In predominantly rural areas with poor communications and possibly low levels of literacy, it is useful to have a publicity vehicle with a public address system and equipped to show films. Ideally this function can be combined with another, for instance the transport of mobile teams or donors. If possible, such a vehicle should carry a generator powerful enough to support these functions without recourse to mains electricity.

Specially designed vehicles

The cost of construction or purchase of specially designed vehicles containing fixed couches for the bleeding of donors should be carefully calculated in advance. It should be borne in mind that, apart from the high initial capital cost, specially designed vehicles will be more difficult to maintain, and such maintenance may be
expensive or even impossible, depending on local circumstances. Where total reliance is placed on a completely integrated mobile donation unit, a simple mechanical breakdown will result in the loss of blood donor sessions, and most transfusion services would be unable to bear the cost of purchasing and maintaining a reserve unit. It is usually much more economical to use portable equipment to set up a session at a local venue.

**Mobile laboratory or apheresis unit**

The cost of a mobile laboratory or apheresis unit should be compared with the cost of transporting blood or donors to the transfusion centre. Such units usually represent an unnecessary level of sophistication, no matter what the degree of development of the transfusion service.

**TRANSPORT OF BLOOD AND BLOOD PRODUCTS**

**Multiple self-sufficient district centres**

Every possible effort should be made to bring blood from a donor session back to the transfusion centre for testing. The distances from the regional centre and the extent and condition of the road network will be critical in deciding whether to set up multiple self-sufficient district centres.

**Essential transport**

Maximum use can be made of essential transport (such as the vehicles used for donor sessions) by adapting them appropriately. For instance, built-in refrigeration would allow such vehicles to be used for the local distribution of tested blood, by taking the blood to a donor session venue and arranging for local hospitals to collect it from there.

**Routine and emergency deliveries to hospitals**

Routine and emergency deliveries to hospitals of blood and products best kept at 4°C may be made either in a vehicle with
built-in refrigeration or by using an insulated container in an ordinary vehicle. Where a portable container is used, it should be capable of maintaining the temperature of the blood between 4°C and 10°C for at least 24 hours; this can usually be achieved by precooling the open container to 4°C before putting in the cooled blood, and then adding a cold source such as ice. Such a cold source must not, of course, come into contact with the blood container itself. The insulated container should be strong enough to survive transportation; a strong cardboard box lined with polystyrene will often perform admirably. This type of box will also serve for the transport of platelets at room temperature, while frozen products may be transported using a suitable cold source (e.g. solid carbon dioxide).

Bearing in mind the urgency of the delivery, an insulated box should be carried by the cheapest and most logical means, e.g. by pedestrian or cyclist, or in a motor vehicle, train or aeroplane.

Where transport of blood and blood products is not under the direct control of the transfusion centre, great care must be taken to ensure that the carrier understands the nature of the material and the urgency of the task. It is not unknown, for instance, for a taxi driver carrying blood to divert significantly from his or her itinerary to accommodate a fare-paying passenger. The receiving hospital must always be informed of the means of transport being used and of the estimated time of delivery.

**Use of public transport**

If significant use is made of public transport on a payment-for-service basis, every effort must be made to negotiate favourable terms with the agency concerned. This may be especially beneficial if the arrangement is under direct or indirect governmental control and the transfusion service itself is state-supported.

**Transport of plasma**

Plasma that is frozen shortly after donation and intended for fractionation into labile products must be transported to the fractionation centre at as low a temperature as possible. In practice, if the fractionation unit is no more than 3–4 hours’ journey from the blood transfusion centre, and if the plasma has
previously been maintained at $-40^\circ\text{C}$, good insulation around tightly packed units of frozen plasma will suffice for transportation. However, the plasma must be transferred immediately on arrival to storage at $-40^\circ\text{C}$ or below. Where the journey time will be longer, extra means of temperature control must be employed, such as packing frozen plasma in solid carbon dioxide within an insulated container or transporting it in a custom-built mobile freezing unit (although the complexity and cost of such a unit and of its maintenance may make its purchase and use impossible in other than a highly developed country).

It is worth considering a mobile freezer unit based at the fractionation centre, which will visit regional or district transfusion centres to collect frozen plasma and deliver fractionation products. If a transfusion centre experiences any difficulty in sending plasma for fractionation without significant loss of therapeutic activity, careful thought should be given to the advisability of the practice. In these circumstances, other means of making the best therapeutic use of locally collected plasma must be explored, with prime consideration being given to the production of simple components such as cryoprecipitate.

MAINTENANCE AND BREAKDOWN SERVICE

Maintenance

Regular maintenance schedules should be enforced for all vehicles, even if temporary unavailability of a vehicle may cause the service some difficulty. Provision must also be made for the maintenance and repair of special features on vehicles, particularly refrigeration, which may be outside the scope of a normal vehicle workshop.

Breakdown service

A 24-hour breakdown service is essential, and should be capable of everything from minor roadside repairs to the provision of a back-up vehicle to which blood and/or personnel and equipment may be transferred. The possibility of breakdown, the distances between the various centres in the transfusion service, and the extent and condition of the road network must all be considered
when a decision is made about the size of the transport vehicle fleet.

**Costing in-house maintenance**

Careful costing of in-house maintenance should be carried out and compared with tenders for the same work submitted by workshops outside the transfusion service. It may be beneficial to combine maintenance of transfusion service vehicles with that of vehicles operated by other health service organizations such as hospitals and the ambulance service. The possibility of exploiting any local workshop operated by the armed services should also be considered. The need for a separate contract to maintain mobile refrigeration should not be forgotten. Alternatively, special training must be arranged for in-house vehicle fitters.

**TRANSPORT DEPARTMENT STAFF**

**Transport manager**

In a large and busy centre it is essential that a separate post of transport manager be established, although in a smaller centre the duties may be assumed by a senior member of the administrative staff. The duties of the post should include coordination of all transport functions to ensure maximum utilization of vehicles and staff, responsibility for transport staff, duty rosters for vehicle maintenance, and the security of stores of fuel and spare parts held at the centre. The transport manager should take a full part in planning mobile sessions, deciding the type of vehicle to be used, the time to be allocated for the journey and the accessibility of possible venues.

**Drivers**

Drivers should be qualified to drive all types of vehicle in the transfusion service fleet, and their duties arranged to maintain this all-round proficiency. Simple maintenance tasks such as checking of fluid levels and tyre pressures will form part of their duties. Drivers should take a full and active part in the setting up and dismantling of mobile blood donor sessions.
When more than one driver is required for a mobile donor session, tasks should be identified which can be carried out by the drivers, in order to make maximum use of their presence. In undeveloped country districts, for example, a driver may even be used to show publicity films.

**Vehicle fitters**

Depending on the maintenance policy adopted, the transfusion service staff may or may not include vehicle fitters. If employed, fitters must be familiar with all types of vehicle used and be qualified to drive them on public roads. Simple training may be given in the care of built-in refrigeration. Their job description should also allow for their employment on other tasks around the centre. Proficiency with oxyacetylene cutting and welding equipment, for example, may be valuable in more than one department.
Chapter 9
Inventory control, storage and disposal

E. Brodheim¹ and R. W. Beal²

LOGISTICS OF BLOOD SUPPLY

Definition and principles

In the context of blood supply, the term ‘logistics’ refers to the acquisition, management and transport of blood products to ensure their availability when and where required, their storage under satisfactory conditions, and their efficient use without wastage. It includes control of recruitment of donors into the system, assessment of the medical suitability of potential donors, and decisions regarding the derivation of blood components from individual donations.

The term also includes policy decisions relating to the holding of blood and blood components—setting of inventory levels for storage locations and for production, methods of distribution of the products, and assignment of responsibilities within the blood transfusion service.

Many factors influence the logistics of blood supply. Some are matters of policy decided as the result of objective scientific study or mathematical analysis or, occasionally, as an expedient response to need. Policies should be flexible enough to respond to both foreseeable and unpredictable changes such as the following:

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Variations in donor numbers, for example because of the weather, changing economic conditions, and the impact of donor acceptability criteria such as haemoglobin concentration, body weight or the interval between donations.

- Conditions of storage (see below).
- Seasonal and other variations in demand for blood and blood products. Demand can often be accurately predicted for a six- or twelve-month period, but not always for the shorter term.
- Not all blood collected can be processed into all possible components. When a transfusion service supplies a large number of small hospitals, rather than being based within a major hospital that is the sole or principal user of the blood and blood products, the demand for blood of less common groups may be difficult to predict accurately. There is then an increased risk of outdated of this blood, and a consequent reduction in cost-effectiveness of the service.

There is a measurable statistical relationship between shortfall and outsourcing for any blood component. This relationship depends on the distribution philosophy followed. For products in short supply with a long shelf-life, outsourcing should be very low. For components with a short shelf-life, however, some outsourcing may have to be accepted if all clinical needs are to be met.

**Control**

Any management system requires detailed supervision. For blood supplies, this may range from benign oversight of relatively unrestricted ordering to strict control requiring justification of requests at physician-to-physician level. The style appropriate to a particular transfusion service is the product of many factors, including the size of the service, the extent to which staff of the service and of the hospital are trained in transfusion medicine, various financial considerations, and even the personalities of the transfusion service staff and the requesting physicians.

Whatever management style is used, good communication between clinical users and the suppliers of transfusion products is important. Forewarning of possible requirements is not only clinical courtesy but, in some instances, a logistic necessity. Smoother management is possible when potential shortfalls are anticipated and planned for (predictive), than when shortfalls result in a series of minor crises (reactive). It is important that a predictive plan be used wherever possible.
INVENTORY CONTROL CONCEPTS

Inventory control is both internal and external: a blood collection centre should always maintain accurate inventories of the resources available on its own premises (internal) and in user institutions (external). Management of the external resource is particularly important with regard to the more labile components, most of which are stored in user institutions rather than in collection centres.

The primary objective of inventory control is to maintain adequate supplies of blood and components at each of the hospitals in the region, with minimal outdated and movement of units between institutions. Each region has special characteristics and may therefore require different strategies, but this goal can be achieved by effective planning and timely exchange of the information necessary to monitor and control the system. For example, the delivery of blood from a transfusion centre to the hospitals may be in reaction to emergency demands or to information that supplies are low, or may be planned in advance on the basis of predicted need.

In controlling the inventory of whole blood, packed cells, reconstituted cells and, to some extent, platelet concentrates, it is important to know whether such units are assigned (cross-matched) or unassigned ('free'). Careful supervision of the selection of blood for the assigned inventory and the management of the inventory are essential to ensure that the oldest blood is transfused first. Assigned but unused blood should be released for other use as soon as practicable and not held for a patient who no longer requires it. Hospitals should have a 24- or 48-hour rule under which blood not asked for within the specified time is released for other purposes. The consistent implementation of this rule is important for both the hospital and the transfusion centre to ensure the most efficient use of blood.

INVENTORY CONTROL METHODS FOR BLOOD PRODUCTS

Identification of blood products

All blood donations should preferably be identified by means of a number, comprising five or more digits and, in some instances, alphabetic characters. Some countries have regulations requiring
that this identifier remain unique for a specified time. In locations where the number may not be unique (that is, it may be repeated after one or more years), it should become unique to the transfusion centre concerned when the dates of collection and/or expiry are taken into account.

All components made from a single donation, such as red cell and platelet concentrates and fresh frozen plasma, should take the same identifying number as the original donation. When the same product from more than one donation is pooled a new number will be allocated. The numbers of the individual donations that go into the ‘new’ pooled product should be documented permanently in the transfusion service records.

A uniform system for identifying and labelling blood products has been described by the ISBT Working Party on Automation and Data Processing.¹ A set of codes for identifying blood components and blood types was confirmed by the same Working Party. Adoption of a uniform system of codes and labelling will facilitate logistics in a given region.

**Inventory levels and inventory control**

Each transfusion service should establish desired inventory levels, by product and blood type, for all commonly used products as outlined above. This can be done by mathematical analysis or by consultation.

**Documentation and information interchange**

The means used for documenting an inventory of blood and its components may be manual or automated, and may involve one or more of the following:

- eye-readable characters (figures and letters);
- machine-readable/eye-readable characters (for example OCR—optical character recognition);

Management of blood transfusion services

- bar-coded numbers;
- a combination of the above.

Blood products are either stable (e.g. albumin, immunoglobulin) or labile (e.g. cryoprecipitate, platelets) and this influences the choice of documentation method.

Scope of records
The information maintained should provide the following data and capabilities:

- records of products available;
- separate records of special items such as frozen rare blood, phenotyped units, autotransfusion units;
- error-checking procedures to ensure that outdated units, hepatitis-B-antigen-positive or syphilis-positive units are not released;
- administrative procedures that prevent delays in distribution;
- statistical summaries and management reports;
- long-term planning capabilities.

Consignment to a user institution
When blood products are consigned to a user institution, a record should be made of their unit or batch numbers. This will be done with light-pens or lasers in the case of centres using machine-readable labels and manually in those using only eye-readable characters.

Data returns
The user institution must account to the transfusion centre daily for each unit issued, in one of three categories, by ABO and Rh group:

- used;
- assigned (reserved or cross-matched for future use);
- unassigned (free).

Where mechanical or automated means of information transfer are not available, the data returns will usually be the unassigned inventory by group.
Issue to patients

Where blood and blood components are issued and used, a record of the issue should be held by the hospital and should include the unit or batch numbers. A record of the number and nature of the products used is inserted into the patient’s medical record. These entries may be made manually or mechanically.

Stock figures

Stock figures for both transfusion centres and hospitals should be readily available at appropriate intervals for monitoring and management of stock, i.e. turnover.

Blood products in short supply

In some hospitals, blood components that are in short supply are issued by physicians, who are responsible for management of the stock-holding and therefore need up-to-date information on product availability and the clinical appropriateness of particular requests. Products in this category vary in different countries, and even in different centres, but include frozen red cells, hepatitis B immunoglobulin, single donor platelets and white cell transfusions. Physicians with these responsibilities could also monitor urgent and unusual requests for commonly used components.

INVENTORY CONTROL METHODS FOR REAGENTS AND MATERIALS

Disposable items

Disposable items include the following, although not all are relevant for all transfusion services:

- test cells (e.g. for screening, antibody identification panels);
- antisera;
- intravenous solutions;
- packs, bottles and other collecting materials;
- general store items (e.g. needles, syringes).
Inventories may be managed by computer programs, or by a manual system if automation is not available. The requirements for effective and efficient inventory control include:

- definition of item by generic name, trade name, volume, and product code if allocated;
- date of manufacture or expiry date;
- supplier and name of contact;
- lead time for supply;
- desirable stock figure;
- reorder point and normal reorder quantity;
- where relevant, cost.

For internal supervision and audit purposes the record system should also document the consignee of all such items.

**Nondisposable Items**

Inventory control of machinery, laboratory equipment and nondisposable items is an important and sometimes neglected area of effective management. The principles of control are the same, whether a manual or an automated method of documentation is used. For example, information on a refrigerated centrifuge should include the following:

- date of purchase;
- supplier;
- price;
- maintenance arrangements (e.g. ad hoc, routine visit) and provider (including name of contact);
- details, including dates, of regular maintenance visits;
- agreed rate or time of depreciation;
- estimated date of replacement.

**REFRIGERATION AND STORAGE**

Among the most important determinants of the safety and efficacy of blood and blood components are the conditions under which they are stored. The refrigeration and storage facilities of
the transfusion service are therefore some of its most important assets.

**Refrigeration**

*Specifications*

A wide range of refrigerators is available to blood transfusion centres. Not all of them, however, are necessarily appropriate for the service concerned or for the particular task for which refrigeration is required. Although a manufacturer may claim that a particular machine meets the requirements laid down by various authorities, the transfusion centre should attempt to validate this claim for itself or should have this done by competent professionals.

Concise standards for blood storage refrigerators are included in the American Association of Blood Banks' *Standards for blood banks and transfusion services* and in the Canadian Red Cross Blood Transfusion Service's *Serological and immunological methods*.\(^1\) Each transfusion centre and hospital should have its own set of specifications for its refrigerators and freezers, based on accepted standards. It should also develop, in discussion with refrigeration engineers, a test protocol that can be applied when new refrigerators are considered.

Ideally, the following constraints should apply to a refrigerator used in a transfusion centre:

- The refrigerator should be purpose-designed and should not, in normal circumstances, be a modified domestic refrigerator.
- In no circumstances should the refrigerator contain a freezing compartment.
- The refrigerator should be dedicated for storage of blood and blood products; in no circumstances should other pathology materials, pharmaceutical supplies, or food be stored in it.
- The refrigerator should have an alarm system, preferably both visual and audible. If this is not feasible, the use within the refrigerator of a maximum-minimum thermometer should be regarded as the absolute minimum requirement.

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Location

In a transfusion service, the prime factor influencing the location of refrigeration is convenience of access. In a hospital, particularly one in which the transfusion unit is not staffed on a round-the-clock basis, the location of the blood storage refrigerator assumes particular importance. It is essential that refrigerated blood be accessible to surgical and anaesthetic staff at relatively short notice and, equally, that unauthorized and/or inappropriate access be prevented.

Charts and alarms

The importance of a safe and effective alarm system cannot be overemphasized. Not only is the stock placed in jeopardy in the event of an alarm failure, but there is also a potential risk to recipients if inappropriately stored blood is subsequently transfused.

Automatic charts (preferably 24-hour charts) should be inspected regularly and changed as indicated. The alarm system should be tested at least once daily and these tests documented. The alarm should be located in a part of the hospital that is always staffed by personnel trained in responding to it. Where reliance has to be placed on a less sophisticated system of which a maximum-minimum thermometer is an integral part, the thermometer should be checked at least twice daily.

Maintenance

Regular preventive maintenance of refrigerators is essential to a safe and efficient blood service. There is good evidence to show that regular preventive maintenance is less expensive in the long run and certainly safer than crisis management in the event of equipment failure.

Storage

The blood transfusion centre is responsible for appropriate storage of blood and blood components within its own premises, during transport between the centre and the user institution, and at the user institution. This last responsibility involves not only the transfusion unit of the hospital, but also subsidiary storage
areas in operating theatre suites and wards. Storage catastrophes caused by ignorance are more likely to occur in the wards of a hospital than in its transfusion unit, and appropriate measures must be taken to minimize this risk.

Storage temperatures

Appropriate storage temperatures should be indicated on the product label. Typical storage temperature ranges for commonly used products are:

- 22 °C — platelet concentrates
- 2–10 °C — fractionated products, including plasma volume expanders and immunoglobulins
- 4–6 °C — whole blood, packed cells, reconstituted red cells
- −30 °C — frozen plasma, cryoprecipitate
- −80 °C — frozen red cells and platelets

DISPATCH

The methods for supply of blood and blood products include the following:

- *Dispatch without specific request.* This approach may appear to be valid for a blood product available in adequate supply but cannot be justified in most services because of the general scarcity of blood and its components.
- *Telephone order.* Ideally, telephoned orders should be documented by the transfusion centre and by the hospitals, using manual or computer methods.
- *Automatic replacement.* Some developed centres have programmes that initiate stock replacement procedures at predetermined intervals and/or when prescribed stock levels have been reached. Due allowance should be made for the lack of personal involvement in such schemes.
- *Proforma return.* A manual variant of automatic replacement is the reissue of products on receipt of proformas indicating usage. This method depends on the completion and return of usage data by the institution concerned and, in particular, the physician responsible for the administration of the product. It can be made to work, but sometimes with difficulty.
When blood and blood products are ordered from the transfusion service by a user institution, the response required includes:

- ensuring that stock is on hand to meet the request;
- assessment of transport availability;
- assessment of storage requirements during transit;
- preparation and dispatch of accounts for the products concerned, where relevant.

When blood components are dispatched, careful attention must be paid to the temperature required. Products already stored at 4°C and at −20°C or lower can be maintained at those temperatures in polystyrene containers provided that wet ice and dry ice respectively are used in the containers.

Effective dispatch can be achieved by manual or automated means. An efficient manual system is likely to be of more value than an inefficient automated programme. Any computer-based programme should be capable of taking into account all the variables involved in an effective manual system.
Chapter 10
Quality control in blood transfusion centres
G. Medgyesi¹ and J. Kádár²

GENERAL CONSIDERATIONS

Quality control is a delicate and essential task of all transfusion centres, designed to ensure maximum biological potency and safety of blood and blood products. At all stages of production each individual is responsible for quality assurance at the level of his or her particular job. Where possible, in a large transfusion centre, a separate quality control department should be established, but every centre should have a quality control officer with sufficient authority to take appropriate action on any unsatisfactory procedure.

Quality control begins with the proper construction of the premises and covers the continuous monitoring of equipment and of the competence of personnel, and the testing of a defined number of units of each product for the appropriate parameters. When unfavourable results are obtained, the procedures must be reviewed and corrective measures taken. This ensures that each product is manufactured under the correct conditions and by the correct procedure. When every step of every procedure is carried out correctly, the final product will be of satisfactory quality.

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PREMISES OF BLOOD TRANSFUSION CENTRES

The first requirement for adequate quality of blood products is the provision of adequate facilities. Standards set for transfusion centre premises usually involve inspection and approval of the plans and/or the completed premises by the competent authorities. All rooms and work areas where products are manufactured or stored must be orderly, clean, and free of vermin and any objects that are not required in the manufacturing process. Clogging and backsiphoning of drainage systems must be avoided. Precautions must be taken to exclude infectious agents from all manufacturing areas. Workrooms should be well lit and ventilated, and the ventilation system should be constructed so as to prevent the possible dissemination of microorganisms from one manufacturing area to another. Filling rooms, and other rooms with open, sterile operations, must meet standards compatible with the good manufacturing practices of WHO\(^1\), and such rooms should be constructed and equipped to permit thorough cleaning and to keep airborne contaminants to a minimum. The establishment should:

- Provide adequate space for those of the following activities that are applicable:
  - medical examination of donors in privacy;
  - withdrawal of blood without risk of contamination, in a room where there are no activities unrelated to blood collection;
  - proper storage of blood or blood components awaiting the completion of tests;
  - quarantine storage of blood or blood components in a designated location pending repetition of any serological tests that initially give questionable results;
  - storage of finished products before distribution;
  - quarantine storage, handling and disposal of products and reagents that are unsuitable for use;
  - the orderly processing, compatibility testing, storage and distribution of blood and blood components in such a way as to prevent contamination;
  - plasmapheresis, plateletpheresis and leukapheresis;
  - packaging and labelling operations.

• Provide adequate lighting, ventilation, and screening of open windows and doors.
• Provide adequate, clean and convenient handwashing and toilet facilities for both donors and personnel.
• Provide for safe and sanitary disposal of waste, and items used during collection, tests or processing, as well as of blood and blood components unsuitable for use or distribution.

QUALITY ASSURANCE OF EQUIPMENT

Quality assurance of the growing variety and complexity of equipment is imperative: accuracy and reproducibility of procedures can be expected only when the functioning of all equipment is carefully monitored. The nature of quality assurance activities depends on the procedures performed in each centre, and no universally applicable directions can be given. However, basic principles can be applied to any type of equipment (see Table 10.1).

Instruction manual

A manual clearly outlining operating instructions, safety precautions, potential hazards and a preventive maintenance schedule should be available to all appropriate personnel. It should detail procedures to be followed when calibrating new and newly repaired equipment, plus information on the frequency and extent of recalibration.

Installation and calibration

Calibration should always be performed when an instrument is installed and before it is put into use. Manufacturers usually provide assistance in the case of the more complex instruments, but it is the responsibility of the department personnel to assess the performance of any instrument. It is therefore essential that they have the name of the equipment and of the manufacturer; the model, serial and inventory numbers of the equipment; the date and limitations of the warranty; the name, address and telephone number of the repair service; the manufacturer’s installation and operating instructions; and details of special safety precautions.
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Type of test</th>
<th>Testing interval</th>
<th>Limits of variation</th>
<th>Symptoms of malfunction</th>
<th>Frequent causes of variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoclave</td>
<td>1. Check and record pressure, temperature and time</td>
<td>Each use</td>
<td>Autoclave should maintain: 1 atmosphere 121 °C, for 20 minutes</td>
<td>Failure to gain or hold pressure</td>
<td>Worn door seal</td>
</tr>
<tr>
<td></td>
<td>2. Check effectiveness with biological or temperature indicators and record</td>
<td>Each use</td>
<td>Biological or temperature indicator results unsatisfactory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated centrifuge, for blood component preparation</td>
<td>1. Quality control of components prepared</td>
<td>Representative number each month</td>
<td>As established for each component</td>
<td>Usually detected by component quality control</td>
<td>Improper utilization Faulty timer Worn brushes</td>
</tr>
<tr>
<td></td>
<td>2. Speed appropriate to the component being prepared</td>
<td>Variable: depends upon amount of use. Suggested monthly if used daily, otherwise quarterly</td>
<td>Limits not clearly defined, suggested ± 100 r/min</td>
<td>Deviation from limits</td>
<td>Worn brushes</td>
</tr>
<tr>
<td></td>
<td>3. Timer</td>
<td>Variable as above</td>
<td>Suggested ± 10 seconds</td>
<td>Deviation from limits</td>
<td>Timer loose or fails to stop at zero</td>
</tr>
<tr>
<td></td>
<td>Day of use</td>
<td>Deviation from limits</td>
<td>Faulty thermostat</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>1.</td>
<td>1°C to 6°C</td>
<td>Alarm signal audible</td>
<td>Door left open.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>and visual.</td>
<td>Mechanical failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deviation from limits</td>
<td>Incorrect chart used</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1°C</td>
<td>Failure to wind</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>chart clock</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Ink pen plugged</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>No fluid in probe</td>
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<td></td>
<td></td>
<td></td>
<td>bottle</td>
<td></td>
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<tr>
<td>2.</td>
<td>± 1°C</td>
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<tr>
<td></td>
<td></td>
<td>Failure to activate</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>1°C outside limits</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3.</td>
<td>Quarterly</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1°C to 6°C</td>
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<td></td>
</tr>
<tr>
<td>4.</td>
<td>Day of use</td>
<td>20°C to 24°C for</td>
<td>Faulty thermostat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td></td>
<td>platelets; 1°C to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6°C for other</td>
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<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>components</td>
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</tr>
</tbody>
</table>

Performance evaluation

Performance limits must be established for each piece of equipment used at the blood transfusion centre, based on the expected quality of the final test results or blood components. When any instrument is newly installed or repaired these predetermined limits should be checked and recorded. Maintenance of accuracy and calibration of equipment for a particular procedure can also be checked by monitoring the quality of any components involved. If there are problems with blood component quality, the equipment and/or the procedure should be rechecked immediately, regardless of when either was last checked.

Each department should establish its own limits of variation by monitoring the performance of the equipment over an acceptable period of time. Table 10.1 shows the recommended limits of tolerable variation and the test frequency for some instruments by way of example.

Even if mechanical parameters are within required limits, it is very important that the components that are prepared, and the final results of tests, should be monitored periodically to ensure acceptable performance.

Equipment that is used infrequently should be subjected to mechanical checks before each use, to ensure satisfactory functioning. The necessary frequency of mechanical checks on equipment that is frequently used should be determined by monitoring the quality of the end product. A review of the results should enable each department to adjust the frequency of mechanical checks to satisfy its needs.

Corrective action

Whenever the test results and/or the specifications for components fall outside predetermined limits, the operators should try to identify the problems and modify conditions to ensure that equipment functions properly. A plan of corrective action should be prepared and approved by the director of the transfusion centre.

Documentation

There should be clear documentation of scheduled preventive maintenance, safety checks, calibration of equipment,
recalibration of repaired equipment, and corrective action taken in case of variance from predefined performance limits, and of the personnel responsible for these activities.

QUALITY CONTROL OF REAGENTS

The primary objective of a reagent quality control programme is to ensure that reagents function as expected. The main principles of this activity are outlined below.

The manufacturer is responsible for the quality of the reagents issued, and the reagent user for the tests performed. The potency or specificity of reagents may be compromised in certain circumstances, such as contamination of open vials, erroneous labelling, or unfavourable environmental conditions during shipment and/or storage. It is therefore a good policy to check the specifications of all reagents at the user laboratory, including those that have been officially licensed. In all cases, use of reagents should conform with the methods specified in the manufacturers’ package inserts.

Instruction manual

An instruction manual describing the tests performed with reagents should be available. It should be reviewed regularly by a suitably qualified person, and any changes in procedure should be recorded in the manual. Transfusion centre personnel should be familiar with the manual and should adhere to its instructions.

Manufacturers’ instructions

Users should keep a file of manufacturers’ circulars for quick reference. The reagent lot number and the date on the filed circular should be noted, for the instructions may be subject to change(s).

Receipt and storage of reagents

Technical staff should be advised on what to look for upon receipt of new reagents and how to handle them. After the consignment
Management of blood transfusion services

has been checked against the shipping form, seals and labels should be checked, cells inspected for haemolysis and serum for visible evidence of contamination. The following principles apply to storage of reagents:

- the oldest reagents should be used first;
- there should be a system for indicating when supplies run low;
- reagents must be stored under proper conditions.

**Reagent evaluation**

Quality control tests on new lots of reagents should precede routine tests in donors or patients. Testing and documentation are part of the daily work, and in larger transfusion centres it may be necessary to assign more than one technician to quality control testing. The tests should be performed, interpreted, and evaluated by a person who is also a reagent user, and should be carried out on the same vial of reagent and the same equipment as will be used in routine tests. All results should be recorded and dated, and the records should be signed by a responsible person.

**Corrective action**

When a reagent produces results outside the limits set by the manufacturer, corrective action is necessary. Any deficiency should be immediately reported to the manufacturer and also to the national supervisory authority, since other users may not discover the defect until harm has been caused. A deficient reagent should never be used.

The following procedure is suggested for confirming a suspected reagent deficiency:

- Confirm that established methods are being followed, which do not conflict with the manufacturer's instructions. Personnel should be aware of the specific function of each reagent and of its limitations.
- Repeat the testing.
- Test other bottles of the same lot, as well as different lots of the reagent. If the same type of reagent supplied by another manufacturer is available, test this also and compare the results.
Documentation and record forms

Forms for quality control testing of reagents should contain the following information:

- the name of each reagent;
- lot number, expiry date and manufacturer of each reagent;
- identification of the individual(s) performing, recording, and interpreting the tests;
- grade and strength of reactions;
- an indication of periodic review by supervisory and technical personnel to interpret and evaluate all quality control testing.

QUALITY CONTROL OF SYSTEMS AND PROCEDURES

Activities in a blood transfusion centre should be organized to ensure the uniformity, safety and effectiveness of products and services. Procedures must be introduced that describe and define the integrated use of equipment and reagents, and the tasks and responsibilities of individuals and/or groups.

Procedure manual

Transfusion centres should maintain written manuals that include detailed descriptions of, and instructions for, all administrative, educational and medical-technical systems and procedures used within the centres. A description should include a statement of the principle or purpose of the procedure and should define parameters that permit periodic review of safety and effectiveness of the system or procedure. Manuals should be regularly reviewed and updated whenever necessary.

In establishing systems and procedures, due consideration must be given to the safety of the donor, the patient and the staff.

Implementation of systems

The time and effort spent in preparing written manuals is wasted unless the outlined systems and procedures are followed in the daily operation of the transfusion centre. Personnel must
therefore be familiar with the systems and procedures and follow them precisely. The overall plan should:

- provide ready access to system and procedure manuals for all personnel;
- require new personnel to read and initial all parts of the manuals that apply to their positions;
- provide for notification of all personnel, preferably in writing, of new or revised systems or procedures;
- define the immediate supervisor’s responsibility to ensure that personnel are following the established systems and procedures.

**Corrective action**

Procedures or systems that are found to be unsafe, ineffective or inappropriate should be investigated to determine the reason for their failure. There may be flaws in the procedures or systems themselves or in the understanding of staff, or there may be inherent variability in reagents and other consumables. Necessary revisions should be accomplished as rapidly as possible.

**Documentation**

Written records should be kept of quality control results for all systems and procedures, of review and revision of manuals, and of completion of formal or in-service training programmes by personnel. Records should be initialled by the medical director and/or appropriate supervisory personnel.

**Examples of systems and procedures**

*Donor suitability*

To determine the suitability of a donor, the staff should have clear instructions for review of medical history, for performing physical examination, and for equipment and reagents needed to perform qualifying tests. Minimum and maximum acceptable values for each test procedure should be given, together with directions on conditions that should be referred to the transfusion centre.
physician. There should be a system for recording donor rejections, including the reason for rejection.

To assess the effectiveness of donor suitability criteria, rejection records should be reviewed periodically, and any deviation from normal rejection rates should be investigated. The addresses of rejected donors should be recorded for possible subsequent recruitment and for follow-up investigations.

Identification of donor blood

The same identification number(s) should always be affixed to the donor record, the blood container and the pilot samples taken at the time the blood is drawn. For repeat donors, the ABO group and Rh type of the donor should be matched with previous records to avoid discrepancies.

Component preparation

A procedure for component preparation should always include:

- instructions for taking blood or plasma;
- storage conditions for blood drawn for component preparation;
- time restrictions for specific steps in processing;
- instructions for use of equipment;
- instructions for labelling components.

The procedure should also include periodic calibration of centrifuges and other equipment. Records should be kept of recipients’ responses to component preparations. If these deviate from expected responses, the preparation method must be reinvestigated.

Donor blood testing

The collecting centre must rigorously test all donor blood before it is released for transfusion. The procedures manual should identify the following:

- tests performed on donor blood drawn in-house;
- tests performed on donor blood received from other sources;
- the method for performing each test, including controls to be used;
• instructions for the use of equipment and reagents;
• a system for recording test results and the final interpretation;
• a system for comparing test results and the final interpretation;
• a system for checking for technical errors or discrepancies;
• a system for detecting clerical errors;
• the method for resolving discrepancies;
• a system for retaining donor samples, including duration and conditions of storage.

Reagents, supplies, and equipment used in performing these tests should be monitored to ensure satisfactory functioning.

Donor blood labelling
All containers for blood and blood components should have identifying labels affixed before leaving the collecting facility. Labelling procedures should include:

• a description of labels that must be affixed to the unit;
• a system for identifying the ABO group and Rh type of the unit;
• a system for identifying units to be quarantined;
• a system for checking labelled units to detect errors.

All equipment employed in processing donor blood must be calibrated and serviced regularly.

Storage of donor blood and components
The quality of blood products and ancillary services depends a great deal on the storage conditions in the transfusion centre. A description of storage conditions, a statement of acceptable storage temperatures, and methods for controlling the temperature of all blood, components and reagents should include:

• the type and contents of containers holding sensors for thermometers and alarms;
• the action to be taken in case of power failure or alarm activation (plus tests to assess the responsiveness of staff in these circumstances);
• directions for determining temperatures of alarm activation, and a schedule of testing;
• directions for good housekeeping practice, mainly cleaning and
defrosting of refrigerators and freezers;
• directions for keeping quarantined, cross-matched, and
noncross-matched components separate;
• definitions of the extent of permissible loading of containers;
• instructions for inspection of blood before issue, for outdating,
clots, haemolysis, abnormal colour, air or gas bubbles,
condition of the label, evidence of leakage, and lack of pilot
tube or segments.

Mock drills can be held to test procedures for coping with
power failure. Periodic unannounced inspections will also help
determine whether conditions of good housekeeping, separation
of products, and proper loading of blood storage refrigerators
and freezers prevail.

If applicable, expiry dates should be marked on or assigned to
all blood, components, reagents, and supplies.

Unprocessed blood and blood components should be stored
separately from processed units. The procedure for quarantine of
blood and components should include:

• storage of unprocessed units in a specified and labelled area of
the refrigerator;
• specifications for the storage of isolated units (e.g. those that
are hepatitis B surface antigen-positive), preferably in a
separate refrigerator;
• instructions for the disposal of blood and components not
suitable for transfusion;
• a system for recording discarded units.

Shipping and handling of donor blood (see also Chapters 8 and 9)

To ensure appropriate handling of blood and blood components
in transit, an audit trail should be maintained to monitor their
movements and conditions of transport up to the time of
transfusion, including confirmation of identity and specificity
(ABO group and Rh type). Procedures for shipping blood to, or
receiving blood from, other centres should be established.
Instructions should include the following details:

• the type of shipping containers, inserts and closures to be used;
• the amount of wet ice (for whole blood) or dry ice (for frozen
components), which should be adequate for the duration of
transit, allowance being made for variations in the shipping conditions;

- proper packaging to maintain the temperature within the range acceptable for the product being shipped, and to avoid breakage of containers;
- appropriate transportation to be used in routine and emergency situations;
- all notification procedures for arrival at destination, and upon receipt of improperly shipped products;
- examination of contents for correct temperature, for evidence of leakage, and to ensure agreement with the delivery invoice;
- method and frequency of testing to monitor shipping temperatures;
- quarantine of units until any discrepancies have been resolved;
- all pertinent records.

**MONITORING BLOOD COMPONENT QUALITY**

The quality of components should be evaluated to verify that each unit contains the specified amount of component and/or attains the specified level of activity. It is not possible to test each individual blood component unit, but a representative sample of the units processed must always be evaluated. If results comply with designated values, it can be assumed that similarly processed units are of equal quality and are suitable for transfusion. The choice and frequency of test will depend on the components and their intended function, as well as on the quantity of each type processed. For transfusion centres that prepare certain components only infrequently, a larger percentage of units may need to be tested to verify satisfactory preparation.

**Component evaluation**

Selected *in vitro* measurements and subsequent calculations may provide useful information on the survival and function of blood and blood components, though evaluation of clinical effectiveness by *in vivo* testing is often desirable. The ultimate quality of the blood or component unit is reflected in the patient's response. If an adverse response is observed after any transfusion, the transfusion centre should be notified at once and an investigation
mounted to determine the cause. Continued emphasis should be placed on recipient follow-up to detect post-transfusion hepatitis, so that carriers of viral hepatitis B may be removed from the panel of donors.

**Corrective action**

When test results are unacceptable, corrective action must be undertaken and recorded. As a first step, a check should be made on whether the established component preparation procedures, including phlebotomy procedures, have been followed. Proper functioning of the component preparation centrifuge and the acceptability of its own quality control results must be ascertained. Storage temperatures should be checked. The quality control tests should then be repeated, on the same test sample and on another sample from the same batch, since an anomalous result may stem either from an error in testing or from the choice of a non-representative sample. If the result is again unacceptable, further investigation must be undertaken and the necessary corrective measures applied.

If *in vivo* results are unacceptable, following satisfactory performance in the *in vitro* quality control tests, the procedures laid down for blood and component administration should be checked. For example, continued bleeding or lack of platelet increment in patients with thrombocytopenia may be indicative of improper preparation or storage, or of the use of microaggregate filters for platelet transfusions. Frequently, the corrective action may be only a matter of conferring with, or instructing, nurses and/or physicians.

**Documentation and forms**

Details of quality control testing and of corrective actions must be documented; this can be done on the worksheets on which laboratory measurements (e.g. net weight, erythrocyte volume fraction, white blood cell and platelet counts) and necessary calculations are already recorded. A review of results and description of any corrective action can also be recorded on the same form.
Sterility testing of blood components

As an ultimate test of the aseptic techniques used, samples of blood components can be checked for sterility, for example by following the recommendations of the WHO Expert Committee on Biological Standardization. Where sterility testing is undertaken, a typical programme might be the following:

• whole blood
  – 2% of daily production
• red blood cell concentrate, washed red blood cell concentrate, frozen-deglycerolized red cell concentrate, washed-filtered red cell concentrate
  – 2% of daily production or at least a sample of each series of daily preparations
• platelet concentrate, leukocyte concentrate
  – sample of each preparation
• cryoprecipitate
  – if prepared in bottles, 10% of the daily production
  – if prepared in plastic bags, a sample of each product
• fresh frozen plasma
  – 10% of each series if prepared in bottles.

Note: Where the standards of good manufacturing practice are scrupulously observed, and especially where systems of plastic bags are used, many experts believe that sample sterility testing is irrelevant.

Testing for viruses

Each donor should be screened for antibody to human immunodeficiency virus (HIV) by an appropriate method (see Chapter 11) and tested for HBsAg (hepatitis B surface antigen) by a method that is at least as sensitive as reversed passive haemagglutination. Units of blood or components obtained from donors whose blood is HIV-antibody-positive, and/or for whom HBsAg results are positive, must be removed and discarded upon
receipt of the test results. Tests for other viruses may be introduced wherever and whenever they appear necessary.

**Quality control by *in vivo* measurements**

Measurement of *in vivo* survival and function is a most important aspect of quality control of blood and its components. The extent of a recipient patient's benefit is assessed by obtaining pre- and post-transfusion laboratory data, and comparing these results with the patient's clinical response to the transfusion.

The safety of transfusion practice is based on correct identification of the donor’s blood and the intended recipient, correct handling of the blood and/or component, and observation of the recipient during and after transfusion.

**In *vivo* survival of whole blood and red cells**

The *in vivo* effectiveness of red blood cell transfusions can be evaluated by measuring the increment in erythrocyte volume fraction following transfusion: there should be a 3% increase per unit transfused to a 'stable' patient weighing 70 kg, i.e. a patient who is not bleeding and who does not have haemolytic disease. The survival of transfused red cells may be decreased in patients with active bleeding, haemolytic anaemia, or chronic renal or hepatic failure. These disorders may increase the transfusion requirement, even if blood preparations are of optimal quality.

When all donor units are incompatible in a patient whose antibodies cannot be characterized and for whom transfusion is urgently needed, the clinical effectiveness of the red blood cell transfusion may be determined by assessing the 30-minute survival of labelled donor cells.

The *in vivo* effectiveness of washed, leukocyte-poor and frozen-thawed red cells may be estimated as described for red blood cell concentrates. During and after the transfusion of leukocyte-poor red blood cells, the patient should also be checked for evidence of a febrile transfusion reaction. Since the occurrence of such reactions depends on the type of units received, recurrent febrile reactions may indicate the need for a component containing fewer leukocytes, such as frozen-thawed deglycerolized red blood cells. Leukocyte-poor red cells prepared by filtration may be found to be equally effective.
Effectiveness of granulocyte concentrates

Until quite recently there was no consensus on indications for granulocyte transfusion; evaluation of its effectiveness remains difficult. However, attempts have been made to assess the outcome of such transfusions by determination of the serum complement level and the measurement of serum chemotactic activity.

Granulocyte recovery can be best estimated from the following formula:

\[
\text{granulocyte recovery} = \frac{(\text{granulocyte increment/ml}) \times \text{blood volume (ml)} \times 100}{\text{number of granulocytes transfused}}
\]

Post-transfusion cell counting, the traditional method of assessing the efficacy of blood transfusion, is generally unreliable for granulocyte transfusions because these cells leave the vascular compartment very rapidly. Appraisal of effectiveness must therefore be based on clinical improvement in terms of normalization of body temperature, favourable changes in chest X-rays, and/or general stabilization following a period of deterioration.

In vivo tests for platelet effectiveness

Platelet recovery and function after transfusion are the ultimate measure of the quality of platelet concentrates. In selected patients, platelet recovery may be determined by measuring the increment in platelet count at 1 hour and 24 hours after transfusion. Expected recovery at the end of the first hour is usually about \(7 \times 10^9\) platelets/litre per square metre of body surface per unit of platelet concentrate. Causes of poor in vivo recovery include poor quality of the transfused units, and acute bleeding, fever, sepsis, splenomegaly or antiplatelet antibodies in the transfused patient. In vivo recovery can be calculated in terms of platelet increment (per unit transfused per square metre of body surface) as follows:

\[
\text{platelet increment} = \frac{\text{platelet count (post-transfusion} - \text{pretransfusion})}{\text{number of units transfused} \times \text{body surface area}}
\]

Platelet function can be evaluated by clinically assessing the effectiveness of the transfusion in arresting haemorrhage or by
determining the improvement in the bleeding time, 1 hour after transfusion.

Platelet survival can be determined by radioisotopic techniques, for which indium-111 offers several advantages over chromium 51. However, these techniques are not widely available outside specialized units.

**Clinical activity of single-donor cryoprecipitates**

Failure to arrest haemorrhage, or an increase in the number of units required to achieve haemostasis, may indicate a reduction in cryoprecipitate activity. The *in vivo* recovery may be calculated as follows, by measuring the increment in factor VIII activity 1 hour after transfusion in a stable haemophilia A patient without inhibitor to factor VIII:

\[
\text{factor VIII recovery} = \frac{\text{activity}_{po} - \text{activity}_{pr}}{\text{number of units transfused}} \times \text{plasma volume}
\]

where

- \(\text{activity}_{po}\) is post-transfusion factor VIII activity in units/ml,
- \(\text{activity}_{pr}\) is pretransfusion factor VIII activity in units/ml,
- and plasma volume is expressed in ml.

The *in vivo* recovery may be slightly less than the theoretically expected value based on the dosage calculation; this is because of extravascular diffusion of factor VIII after transfusion. It has been claimed that the recovery of factor VIII is not significantly related to the clinical state of either a bleeding or a non-bleeding patient. In patients with von Willebrand's disease, the apparent *in vivo* recovery does not correlate with the amount of cryoprecipitate transfused.

**In vivo effectiveness of fresh frozen plasma**

To maintain labile coagulation factor activity, i.e. to maximize haemostatic effectiveness, fresh frozen plasma should be separated from whole blood and frozen within 6 hours of withdrawal. *In vivo* effectiveness will normally be measured by clinical response. Where effectiveness is in doubt, pre- and post-transfusion assay of the appropriate factor may be carried out on samples taken from the patient, in a manner similar to that described for cryoprecipitate.
QUALITY CONTROL OF BLOOD TRANSFUSION PRACTICE

Identifying recipients and donors

The final steps in safe transfusion routine occur at the bedside. The nurse or physician who actually administers the blood or component is the last person who can detect errors in identification before the patient receives the transfusion, and is therefore one of the most important links in quality control. The person concerned must ascertain that:

- The name and identification number of the patient are identical with those on the transfusion form and on the compatibility label affixed to the unit for transfusion.
- The ABO group and Rh type of the patient as well as of the donor are recorded on the transfusion form and are compatible. In special cases where ABO groups and/or Rh types are not identical, the details should be marked on the transfusion form and direct confirmation of suitability requested from the transfusion centre.
- The type of blood product given is consistent with the physician’s written order.
- The physical properties of the product are checked before administration (e.g. colour, weight and temperature of the product; intact bag, no sign of coagulation).

Handling the blood or component

If it is not possible to begin the transfusion within 30 minutes of removing the blood from refrigeration, the blood should be returned to the transfusion centre. Many transfusion centres set a time limit on the use of issued blood; this limit is usually 30 minutes, since a unit of red cells refrigerated at 4°C commonly reaches 6°C after 30 minutes at ambient temperature in a temperate zone. The time limit may be adjusted according to the local climatic conditions.

Starting the transfusion

The person administering the transfusion must observe and record the patient’s vital signs before starting the procedure.
Knowledge of pretransfusion temperature, pulse, blood pressure
and respiration is essential—a change in these parameters may be
the first sign of adverse reaction to the transfusion.

Filters

Blood and blood components must be administered through
a filter. Opinions differ as to whether the use of a microaggregate
filter, as opposed to the usual 120-μm filter incorporated in
a standard giving set, is of any clinical benefit to the patient. It is
recommended, however, that a microaggregate filter, with pore
size of less than 40 μm, be used for the transfusion of fresh frozen
plasma, to remove cell debris.

Care during transfusion

The transfusion should be started at a slow rate (except in extreme
urgency) and the nurse or physician must remain with the patient
for the first 5–15 minutes of the procedure; if no problems occur
within this time, the risk of immediate life-threatening
complications declines sharply. If there is no evidence of adverse
reaction, the rate of transfusion may be increased to the desired
level.

After the first 15 minutes the vital signs should be regularly
checked and recorded, at a maximum interval of 30 minutes.

After each unit has been transfused, the responsible personnel
should record the time, the volume, and the type and identity of
component administered. Some transfusion services require that
a copy of the completed transfusion form be returned to the
transfusion centre. The patient should be kept under observation
for at least 1 hour after the end of transfusion. In addition, care
must be taken to observe and register any delayed transfusion
reactions or post-transfusion hepatitis.
Appendix to Chapter 10

Some international standards and international reference preparations used in the control of blood products and related substances

The international standards and reference preparations listed here are intended primarily for the control of the corresponding national reference preparations.

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Distributing laboratory</th>
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<tbody>
<tr>
<td>Anti-A blood-typing serum, human</td>
<td>Amsterdam</td>
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<tr>
<td>Anti-B blood-typing serum, human</td>
<td>Amsterdam</td>
</tr>
<tr>
<td>Anti-A,B blood-typing serum, human</td>
<td>Amsterdam</td>
</tr>
<tr>
<td>Anti-Rh(_o) (anti-D) incomplete blood-typing serum, human</td>
<td>Amsterdam</td>
</tr>
<tr>
<td>Anti-C complete blood-typing serum, human</td>
<td>Amsterdam</td>
</tr>
<tr>
<td>Anti-E complete blood-typing serum, human</td>
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<tr>
<td>Anti-C incomplete blood-typing serum, human</td>
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</tr>
<tr>
<td>Human serum immunoglobulins G, A and M (IgG, IgA, IgM)</td>
<td>Potters Bar</td>
</tr>
<tr>
<td>Human serum complement components C1q, C4, C5, factor B and whole function complement CH50</td>
<td>Amsterdam</td>
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<tr>
<td>Blood coagulation factor VIII:C, concentrate, human</td>
<td>Potters Bar</td>
</tr>
<tr>
<td>Blood coagulation factor VIII-related activities in plasma</td>
<td>Potters Bar</td>
</tr>
<tr>
<td>Blood coagulation factor IX, human</td>
<td>Potters Bar</td>
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<tr>
<td>Preparation</td>
<td>Distributing laboratory</td>
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<tr>
<td>Haemiglobincyanide reference preparation</td>
<td>Bithoven(^3)</td>
</tr>
<tr>
<td>Thrombin, human</td>
<td>Potters Bar</td>
</tr>
<tr>
<td>Antithrombin III, plasma</td>
<td>Potters Bar</td>
</tr>
<tr>
<td>Heparin, porcine</td>
<td>Potters Bar</td>
</tr>
</tbody>
</table>

\(^1\) International Laboratory for Biological Standards, Central Laboratory of the Netherlands Red Cross Blood Transfusion Service, Amsterdam, Netherlands.

\(^2\) International Laboratory for Biological Standards, National Institute for Biological Standards and Control, Potters Bar, England.

\(^3\) National Institute for Public Health, Bithoven, Netherlands.
Chapter 11

Transfusion and viral infections: prevention of transfusion-transmitted AIDS and hepatitis

G. Medgyesi

Transfusion provides an ideal vehicle for any infectious organism that may be present in the blood. Indeed, infection is the most frequent serious complication of transfusion therapy. Efforts are made in all transfusion services to reduce the risk of this type of adverse transfusion reaction, and in every area endemic infectious agents—parasites, bacteria and viruses—have to be identified to determine the screening that is necessary. The strategies adopted to prevent the transmission of human immunodeficiency virus and viruses that cause hepatitis are discussed in this chapter.

TRANSFUSION AND VIRAL HEPATITIS

Prevention of post-transfusion viral hepatitis B

Routine screening of blood donations for the surface antigen of hepatitis B virus (HBsAg) has been established for many years in most blood transfusion services. The introduction of sensitive, third-generation tests has greatly decreased the prevalence of post-transfusion viral hepatitis B but the risk has not been completely eliminated. The minimum detectable amount of

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HBsAg is estimated to represent 100 minimum infective doses of hepatitis B virus. According to a carefully controlled large-scale study in the United States, about 1% of some 1500 transfusion recipients were infected by hepatitis B virus despite routine screening of blood for HBsAg.

**Non-A, non-B hepatitis**

The prevention of post-transfusion non-A non-B hepatitis is a more difficult problem. One safety measure that can and must be taken is follow-up of recipients and identification of donors involved in post-transfusion hepatitis cases. In certain countries the policy of the blood transfusion service is to exclude from further donation any donors involved in two post-transfusion hepatitis cases. Other services calculate a 'degree of involvement'. For instance, if a patient given four units of red cell concentrate and cryoprecipitate from a total of six donors had developed post-transfusion hepatitis, all the respective donors would be given a 'degree of involvement' of 0.1. Different transfusion services set their exclusion limit by this index at 0.3 to 0.4. More advanced methods for calculating the probable risk associated with a given donor have also been proposed.

Another approach is the use of laboratory tests which, although not specific for the infection, may indicate non-A non-B hepatitis infectivity. In the large-scale study in the United States mentioned above, about 10% of the recipients were found to be infected by non-A non-B hepatitis. Clinically detectable acute hepatitis developed in a smaller proportion of these cases, and a number of the patients who had asymptomatic infections developed chronic hepatitis or became chronic carriers. The authors of the study concluded that 40% of the cases of post-transfusion non-A non-B hepatitis could have been prevented for the loss of 3% of the blood collected. This conclusion was based on testing the donations for serum alanine aminotransferase activity, which is increased in patients with liver damage. Other authors have reported much less favourably on the efficiency of this type of screening. Some transfusion centres screen donations for antibodies to the core antigen of hepatitis B virus (anti-HBc), since the incidence of non-A non-B infectivity was found to be higher in anti-HBc-positive individuals than in those lacking this antibody.
Each blood transfusion service has to formulate its own policy to resolve the problems of post-transfusion non-A non-B hepatitis. The need for effective measures is obvious: in some large developed countries more than 90% of post-transfusion hepatitis cases are of this type and an appreciable proportion of infected patients die from liver failure within 10 years. On the other hand, available test procedures eliminate only a portion of infected donations at the expense of discarding some that are not infected. Thorough cost-benefit analyses are necessary. However, the approach to this problem has been changed by the recent identification of hepatitis C virus as the major causative agent for non-A non-B hepatitis and the development of an assay. This assay has already been introduced in some transfusion services, and is being considered for introduction in others. When it has been established, the need for continuing surrogate testing will have to be reassessed in those countries in which it is used.

TRANSFUSION AND ACQUIRED IMMUNODEFICIENCY SYNDROME

Between 1979 and 1981, observations of patients with very unusual infectious diseases and/or tumours led to the description of a previously unknown disease syndrome, called acquired immunodeficiency syndrome (AIDS). The mechanism underlying the opportunistic infections and Kaposi's sarcoma proved to be a defect in cellular immunity involving T lymphocytes.

In 1983 a virus called lymphaadenopathy-associated virus (LAV) or human T-lymphotropic virus III (HTLV-III) was isolated from the lymph nodes and lymphocytes of patients with AIDS. A year later, convincing evidence had accumulated that this virus is the causative agent of AIDS. The virus, now called human immunodeficiency virus (HIV), is a slow retrovirus (lentivirus). Recently a second, similar but distinct virus, HIV-2, has also been shown to cause AIDS.

HIV was shown to replicate in a subset of T lymphocytes, functionally characterized by the helper-initiator effect in the immune mechanism and bearing the CD4 surface marker. It does not induce a malignant transformation in these cells, but it is highly cytopathic, causing either lysis or less severe damage followed by reticuloendothelial clearance. Current evidence suggests that the CD4 antigen itself is an essential part of the virus
receptor. All the evidence from patients confirms that CD4 cells are reduced in number and in function in AIDS. It is known, however, that some macrophages and related cells also bear the CD4 antigen, which explains some of the intrinsic defects seen in these cells. AIDS may be associated with an encephalopathy, and the brain cells infected by HIV are probably the CD4-positive microglia.

The infection can be transmitted by the percutaneous route or by sexual contact, either homosexual or heterosexual. At present there is no evidence that the virus can be transmitted through casual contact with an infected individual, such as contacts in a family setting, schools or other groups living or working together, food or water, blood-sucking insects, airborne or faecal/oral routes. In 1982 the first case of transfusion-associated AIDS was described in an infant given transfusions for erythroblastosis fetalis. More cases were reported soon afterwards. It is now established that the infection can be transmitted by infected blood and blood components, including plasma and factor concentrates. The risk increases particularly in products prepared from donor pools.

**Prevention of HIV transmission: donor selection and screening**

When an individual becomes infected with HIV virus, antibodies to viral proteins are produced but, unlike the case in most other infections, they appear to have little or no ability to neutralize the virus. While not apparently benefiting the patient, however, those antibodies are very useful as a marker of infection. Screening tests for HIV-antibody became commercially available in early 1985; since then there have been several improvements in the test systems.

Guidelines formulated at an International Society of Blood Transfusion workshop in October 1985 require that ‘only blood and blood products found non-reactive for anti-HTLV III/LAV should be used for transfusion’. In many countries national legislation also requires blood donations to be tested and found HIV-antibody-negative before being issued. It should not be forgotten, however, that several months may elapse between HIV infection and the appearance of circulating antibody (seroconversion). Blood donations collected in this latency period may thus be infectious despite a negative antibody test.
The desirable safety of the blood supply can be achieved only when laboratory screening of donations is combined with efforts to exclude all individuals with recognized risk factors. Donor selection can be passive, when effective education leads prospective donors voluntarily to self-exclusion, or active, by attention to medical history and physical examination. Reliance on self-exclusion is most effective when epidemiological studies have identified risk factors for AIDS; continual education of donors is essential and is likely to be most effective in the case of unpaid donors. Although the composition of risk groups is not the same in all geographic areas, the most common are male homosexuals, intravenous drug abusers, haemophiliacs, individuals who have received blood or blood derivatives within the past five years, individuals who have spent some time in highly endemic areas (especially when they have had sexual contact(s) there), and sexual partners of all the above categories.

The public should be discouraged from using the blood transfusion services for the sole purpose of HIV-antibody screening, and persuaded to use alternative facilities, which may include physicians’ offices, public health clinics or other community-based health facilities. It is also essential to assure the public that neither AIDS nor any other disease can be contracted from giving blood. Healthy people who do not have recognized risk factors should be encouraged to become donors.

Screening methods

A serum sample taken at each donation is tested for HIV-antibody. Most of the available techniques are immuno-enzymatic procedures, based either on enzyme-linked immunosorbent assay (ELISA) or on the competitive immunoassay principle.

In ELISAs, an HIV-antigen preparation is fixed to the solid phase (e.g. microtiteration plate wells, or beads). Antibodies in an antibody-positive serum will be fixed to the immobilized antigen. Anti-human immunoglobulin antibodies conjugated to an appropriate enzyme are then added, and the reaction is revealed by the enzyme reacting with a chromogenic substrate.

In competitive immunoassay, if anti-HIV-antibody is present in the test sample, less of the enzyme-conjugated HIV-antibody will be fixed to the immobilized antigen.
Since the test systems available are changing rapidly, selection should be based on the most up-to-date information. Large-scale comparative trials are reported from time to time in scientific journals, and diagnostics that prove to be satisfactory may be licensed by national health authorities. The chosen method should be sensitive enough to detect low-dose antibody carriers, and its specificity should be broad enough to pick up possible antigenic variants of HIV. Ideally, the test should detect anti-HIV-2 (LAV-2) antibodies in addition to anti-HIV-1. Although high sensitivity is the most important requirement for a screening test, an excessively high number of false-positives may pose too heavy a burden on a blood transfusion centre.

Establishing a system of quality control on the test methods being used in the screening laboratory is very important. When a result is positive the test must be repeated on the same sample. If the repeat is also positive a donor is excluded from further blood donation, and his or her blood is discarded after autoclaving. Many countries have adopted the policy of sending the reactive sample to a reference laboratory where additional tests are carried out to determine whether the observed reactivity revealed true HIV-antibodies. It is advisable to take a second sample from the donor, and submit both to the reference laboratory to avoid errors as far as possible.

Donors should be notified before donation about the testing of their blood, and should be assured that all test results will be kept strictly confidential. In the case of a verified positive test, the donor should be tactfully notified by an appropriate person. Health professionals should be informed about the significance of the tests and about guidelines for counselling of individuals whose tests are positive.

**Efforts to produce more and safer plasma derivatives**

Since recipients of clotting factors prepared from large plasma pools are at high risk of HIV, non-A non-B hepatitis and possibly other virus infections, manufacturers have incorporated treatment with heat, chemicals, radiation or combinations of these in their production processes for factor VIII and factor IX concentrates. Such viral inactivation methods are currently widely used and others are under investigation. The risk of transmitting HIV in factor VIII and factor IX concentrates treated by proven methods of virus inactivation can therefore be markedly reduced.
Additional strategies for reducing risk may include the use of single donor and/or small-pool preparations. Albumin preparations from human plasma, prepared to meet WHO requirements, have been shown not to transmit HIV. Such preparations can also be considered safe with respect to the possibility of transmission of hepatitis A, B and non-A non-B viruses. Use of ethanol precipitation in the fractionation scheme reduces the risk of HIV transmission by the product. Immunoglobulin preparations manufactured by procedures based on the conventional Cohn-Oncley method are not considered to present a risk of HIV transmission.

CONCLUSIONS

The problem of transfusion-transmitted virus infections imposes a considerable strain on blood transfusion services. Testing donations for infective agents adds to the cost of producing blood and blood products and decreases both the number of acceptable donors and the amount of blood and plasma that can be safely processed for transfusion purposes. A realistic balance must therefore be maintained between the operational implications of each quality control operation and the public health implications of disregarding or weakening the quality control element in question.

Efforts to ensure an adequate and safe blood supply should include striving for optimal use of blood products and of blood derivatives. The most important principles are the following:

- Strategies that reduce the demand for blood by health care services, e.g. improved antenatal care, should be encouraged.
- When appropriate and safer components and derivatives are available they are preferable to whole blood or plasma.
- Whole blood or plasma should be transfused only when their administration is absolutely essential to the care of the patient.
Chapter 12
Planning the workforce

Susan R. Hollán¹ and F. Haskó²

INTRODUCTION

A workforce plan should include a coherent set of practical proposals for the training, motivation and utilization of personnel. Planning of staff numbers needs to be flexible and dynamic. Goals, objectives, and even basic assumptions and concepts underlying the plan will change as new information is gleaned from monitoring and evaluating implementation of the plan, or when the experience of other blood transfusion services is taken into account. There has been great interest recently in the development of techniques based on projections for forecasting long-term personnel requirements, rather than relying solely on knowledge of the current situation or on past experience.

In developed countries there is concern over the growing cost of health service personnel and their utilization, especially in relation to commensurate improvements in the health status of the population. It is estimated that between 60% and 80% of health budgets is spent on personnel. Staff costs are lower in developing countries, where the main concern is the lack of trained staff, especially in the blood transfusion service, which is a relatively unpopular field for medical specialization. Special attention should therefore be paid to the selection and training of personnel for transfusion centres.

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² Deputy Director for Production, National Institute of Haematology and Blood Transfusion, Budapest, Hungary.
This chapter examines workforce planning and sets out a detailed method for assessing the personnel needed for the various activities in the blood transfusion centre.

RECRUITMENT AND SELECTION OF STAFF

The quality of staff in a blood transfusion service is of the utmost importance, and maintaining this quality depends upon:

- availability of suitable candidates;
- the right decision in the selection of the staff;
- the level of the basic training of the staff;
- opportunities for continuing education;
- possibilities for promotion of the best qualified personnel.

The aim of recruitment and selection of staff is to appoint enough employees of the required quality for the tasks of the centre. To attract suitably qualified applicants and to decide which candidates should be selected, accurate job descriptions should be prepared, which should include the overall purpose of the job, the main tasks to be carried out, the responsibilities of both employer and employee, and the qualities required in potential employees. It is most important that the status and salary of the posts in the transfusion service, particularly those for medical staff, should be at least as attractive as similar posts in other branches of the health service.

Every activity of blood transfusion centres has medical implications, since each may affect the health of the donor or the recipient. Medical staff are essential in the selection of donors; blood donations, plasma and cell apheresis procedures, as well as deliberate immunization of voluntary donors, must be carried out under the direct supervision of a licensed physician. Transfusion centres have also to provide consultation services to hospitals on transfusion and transfusion-related problems.

The medical director and the medical staff should participate actively in the development of national blood policy, formulate the local policy of the centre, and advise hospital staff on blood transfusion matters. They formulate the principles of use and abuse of blood, as well as the criteria for an optimal cross-match/transfusion ratio, acceptable age limit of red cells and admissible percentage of outdated. Their involvement in donor
propaganda and in the development and subsequent maintenance of an adequate panel of voluntary unpaid donors is essential.

Physicians can provide certain specialized laboratory and clinical services (e.g. haematological, immunological and haemostasis assays, haemophilia and antenatal care, outpatient transfusion service for congenital anaemias). Medical staff participate in the continuous training of other staff members and in the postgraduate teaching of physicians and surgeons from the local hospital or elsewhere in the region.

It is generally held that the director of a transfusion centre should be a medical doctor. Even in countries where there is a lack of medical doctors, transfusion centres cannot operate without at least one physician responsible for the medical aspects of their activities. The physician may be full-time or part-time, depending upon the size and scope of the particular centre. It is unlikely, however, that physicians will have had sufficient training and experience in blood-group serology, immunology and genetics, as well as in the chemistry, physics and biotechnology that are an integral part of the up-to-date processing of blood components and, especially, the production of plasma derivatives. In this area, science graduates play a major role in production, research and development in transfusion centres, and may serve as excellent directors for plasma fractionation plants.

The effectiveness of transfusion centres also depends largely on good management. Senior medical, scientific and technical staff play an important role in management but must have the support of competent and qualified administrators.

**STAFF TRAINING**

**Basic training of medical staff**

In most developed countries, physicians in charge of blood transfusion centres usually have a background in clinical pathology or internal medicine, often with special training in haematology, which is generally a recognized speciality in countries with well-developed transfusion services.

As a laboratory discipline with clinical applications, blood transfusion is widely practised by physicians, surgeons and obstetricians. The director of a transfusion centre cannot have training in all these fields, but must keep abreast of clinical advances, especially in haematology. Knowledge of both
laboratory aspects and clinical application of these disciplines is essential for the director and senior medical staff of a transfusion centre.

Serious consideration must be given to making optimal use of the limited number of medical doctors and skilled technical staff available in any country, but especially in developing countries where a lack of experts may be the most significant limiting factor in the development of a national blood-transfusion service. Assistance to developing countries in the form of combined training schemes in haematology, immunology and blood transfusion would produce specialists who, in addition to their work in blood transfusion, would be experts in diagnostics and therapy, specialities that are essential to the development of high-level medical care.

**Basic training of non-medical staff**

Science graduates, especially those qualified in biology, chemistry, immunology or pharmacy, are highly suitable candidates to head teams concerned with the preparation of anticoagulants and other solutions, and preparation of equipment for blood collection and processing of blood components. They may also head laboratories for blood-group serology, microbiology and quality control. They can provide consultation services to hospitals on serological and other transfusion-related laboratory problems. Science graduates can make a major contribution to the introduction of new technologies and laboratory assays in different fields of research and development.

*The donor organizer*

One of the main tasks of blood transfusion centres is to plan and schedule the collection of blood from sufficient numbers of volunteer donors to meet patients' needs for blood and blood components. In a small centre this may be the responsibility of the director, but in larger services there should be a donor organizer to arrange publicity, recruit and call donors and maintain donor records. The task requires clerical assistance, and volunteers to undertake public relations activities, which are of the greatest importance since donor recruitment is the cornerstone on which all other functions of the blood centre depend.
It is advantageous for the blood donor organizer to have some training in health education, but a layman trained in administrative work and with a natural flair for public relations can fulfil this task.

**Technical staff**

The key role of the chief technician in a transfusion centre lies in supervising the work of technicians and other laboratory staff, and in responsibility for the adherence of those staff to procedural regulations. There may be two or more chief technicians in large transfusion centres.

A chief technician may also function as deputy to the medical director. In some circumstances, highly qualified chief technicians act as directors of transfusion centres but still need to collaborate with the physician in charge of the medical aspects of the work.

The other technical staff of a transfusion centre comprise qualified medical technologists and/or technicians. The centre must provide advanced and continuous training to these members of staff to ensure that safety and quality are maintained in the collection, processing, storage, distribution and transport of blood and products, and that laboratory assays and quality control tests are reliably and efficiently performed. Cleaning, washing and sterilizing are essential to the safety and good quality of a transfusion centre, and where these procedures are carried out by unskilled personnel there must be continuous supervision by technically qualified staff members.

**Nurses**

Collection of blood and apheresis techniques can be performed by nurses or by trained phlebotomists under the supervision of a physician. The work of these staff is supported by professional or voluntary donor attendants who care for the donors and may carry out any administrative work needed during blood collection. It is of the greatest importance that all staff members in charge of donor selection, and collection, testing, processing, and distribution of blood should be responsible trained people who will not depart from approved procedures even under the pressure of emergencies. They must be meticulous in clerical and technical work, to avoid errors or omissions in identifying donors, blood specimens or recipients.
Management of blood transfusion services

Qualified laboratory technicians and nurses—at least in smaller centres—should be able to substitute for each other during night duties. Most transfusion centres have on-call programmes and round-the-clock coverage by their medical and technical staff to deal with emergency demands.

Ancillary personnel

Full-time laboratory aides (for cleaning and sterilizing materials), cleaners, a storekeeper and a kitchen aide (for preparing refreshments for blood donors) are all needed in larger transfusion centres. There should also be a night-watchman, with other duties apart from the care of the building. It is his responsibility to call for emergency help in the event of electricity failure or any other unforeseen problem that could interfere with the safe operation of equipment (refrigerators, cold rooms, automatic laboratory and processing equipment).

Management staff

In a small transfusion centre the director will assume the additional role of manager, and one secretary can undertake the call-up of donors, their registration and general administrative tasks. An administrative officer, possibly part-time, is needed in even the smallest centres. Administrative duties include maintenance of staff records, ordering of equipment and reagents, payment of accounts and salaries, billing, supervision of the cleaning, and responsibility for maintenance of the premises and the equipment.

For the development and efficient operation of large transfusion centres, collecting up to several thousand donations each week, producing large quantities of different blood components, and with a number of other functions (e.g. laboratory diagnostic work, care of different patient groups, education, research), highly qualified and effective managerial staff are essential. The managerial staff must be able to provide the director with financial statements (including money spent, as well as money authorized but not spent) and inventory data at any time. Cost accounting techniques allow the cost of any department in the centre to be estimated, as well as the costs of different activities and the real unit costs of blood, blood components or derivatives (see Chapter 16). Managerial staff have to prepare cost-benefit ratios for any investment or for the
planned introduction of new technologies. They also have to prepare the annual budget, and the managerial elements of development plans or other applications for funds, for presentation to governmental or other funding bodies.

*Maintenance and other staff*

Staff are needed for maintenance of the premises, utilities, equipment and vehicles of the transfusion centre.

In large centres drivers are needed to transport staff members and equipment to mobile donor sessions, groups of donors to the centre and blood from the centre to hospitals.

An animal attendant or attendants must be employed if the centre keeps rabbits and/or other animals needed for pyrogenicity and toxicity tests, and for the preparation of antiglobulin serum or other immune sera of animal origin.
Appendix to Chapter 12
Examples of staff categories in the donor department of a blood transfusion centre

<table>
<thead>
<tr>
<th>Tasks to be performed</th>
<th>Personnel required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical examination of donors.</td>
<td>Licensed physician</td>
</tr>
<tr>
<td>Supervision of collection of blood, plasma and components</td>
<td></td>
</tr>
<tr>
<td>Laboratory examination of donors</td>
<td>Qualified laboratory technician</td>
</tr>
<tr>
<td>Collection of blood</td>
<td>Trained nurse, donor attendants</td>
</tr>
<tr>
<td>Organization of donors</td>
<td>Organizer with some health education. Voluntary coworkers</td>
</tr>
<tr>
<td>Donor administration</td>
<td>Manual: semiskilled office worker. Machine: skilled or semiskilled typist and/or terminal operator</td>
</tr>
<tr>
<td>Donation administration</td>
<td>Semiskilled office worker</td>
</tr>
<tr>
<td>Statistics</td>
<td>Skilled or semiskilled administrator; statistician if possible.</td>
</tr>
<tr>
<td>Distribution of blood</td>
<td>Qualified health worker, assistants</td>
</tr>
<tr>
<td>Plasmapheresis</td>
<td>Trained nurse</td>
</tr>
<tr>
<td>Cleaning, washing up</td>
<td>Unskilled workers</td>
</tr>
<tr>
<td>Internal transport of various loads</td>
<td>Unskilled workers</td>
</tr>
<tr>
<td>Transport</td>
<td>Driver</td>
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</table>
Chapter 13
Continuing education in the blood transfusion service

Susan R. Hollán

GENERAL CONSIDERATIONS

Training of the staff of blood transfusion centres and postgraduate teaching of clinicians are crucial elements of an efficient national blood transfusion service. The teaching programme should be adapted to the basic function of the service, and give staff the necessary theoretical knowledge and technical skill to ensure that the centre provides the region with blood components of guaranteed biological activity. It should emphasize the importance of close contact between transfusion centres and clinical units.

In developing countries the establishment and expansion of national blood transfusion services may be hampered by a lack of relevant expertise, and it would be valuable to train physicians in blood transfusion, haematology and immunology in a combined specialist’s training scheme.

TRAINING PROGRAMMES

Faced with significant increases in knowledge of the structure and function of blood cells and plasma constituents, the newly developed methods of plasma fractionation and processing of

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blood components, advances in immunology, blood-group serology, coagulation and cryobiology, and the ever-changing aspects of the clinical application of blood transfusion, transfusion centres have need of regular education programmes. Surprisingly, however, even countries with highly developed health services often lack adequate systematic training in the theory and practice of blood transfusion. Outdated concepts of transfusion may still prevail among some senior hospital staff. Regular postgraduate education of medical residents and senior staff of all medical institutions is needed to achieve a cost-effective use of blood which is also safe, rational and scientifically based.

The best way of keeping abreast of current trends in haemotherapy and advances in both technology and clinical practice is to teach. The staff of a transfusion centre should therefore actively participate in disseminating information in this increasingly important and rapidly advancing field of medicine.

**TRAINING OF TRANSFUSION CENTRE STAFF**

The first and most basic task of a blood transfusion service is to produce adequate quantities of safe and effective blood and blood products. A regional centre has to provide whole blood, blood components and, where applicable, plasma fractions of guaranteed biological activity. The staff must be aware that the quality of the final product depends upon the quality of their performance in donor selection, collection of blood or plasma, and the handling of the source material throughout processing. The productive, diagnostic and safety aspects of a transfusion centre are thus not separate, but integrated elements.

The training programme for staff should include sample calculations of the quantity of blood and components needed in a national blood programme, and the required size of a panel of donors with rare blood groups and of a panel of donors with high levels of specific antibodies.

In planning the size of the plasmapheresis and cell apheresis panels, the need for plasma and its derivatives must be calculated. Large quantities of platelets are needed for patients on aggressive chemotherapy and after bone marrow transplantation, and may be required for patients on prolonged extracorporeal oxygenation or artificial liver support.

When new operative procedures (such as coronary bypass surgery) or diagnostic techniques are being initiated in a region,
immediate and projected blood requirements must be considered. The transfusion centre will be able to meet the quantitatively and qualitatively increasing demands only if the senior staff fully understand the basic principles of the new procedures and the hazards involved. For this reason postgraduate training is indispensable.

There are three ways of increasing the supply of blood products:

- recruiting more donors;
- making wider use of plasmapheresis and cell apheresis;
- optimizing the use of fresh blood.

Increasing the number of voluntary, unpaid blood donations necessitates a great deal of work, including propaganda, organization and recruitment. A training programme must therefore include principles and practice of donor propaganda and recruitment. The best approach to this subject will vary according to local circumstances, but attracting new donors, especially unpaid voluntary donors, to undergo plasma and/or cell apheresis always requires broad educational efforts. It must be stressed to potential donors that blood derivatives are as important to those who need haemotherapy as the water supply is to the community.

A training programme for transfusion centre staff should also include methods for improving the organization of donor sessions, the preparation and use of mobile equipment, and the application of new techniques to improve staff efficiency at donor sessions. Detailed instructions should be given on the hazards and contraindications of blood donation and on potential accidents. Much emphasis should be laid on the risks of transmitting diseases by blood and derivatives. The epidemiology and prevention of these diseases should be taught, and the epidemiology of relevant non-infectious diseases prevalent in the area to be supplied with blood and blood products may also be covered.

Practical training should be given in new techniques of collecting specific components as well as in the techniques of giving blood transfusions. Participants in these postgraduate training courses should learn the theory and practice of new techniques of blood and plasma donation, cell separation and preservation, and plasma fractionation. Basic biological and
biophysical considerations and methods of preserving blood cells in the liquid and frozen states should be dealt with in detail.

Where applicable, staff should be trained not only to use the most advanced methods of plasmapheresis and cell apheresis for obtaining large quantities of plasma or cell concentrates from donors, but also in the therapeutic use of intensive plasmapheresis and cell apheresis. In particular, the pathogenesis, diagnosis and treatment of auto-immune diseases should be covered, with special emphasis on haemotherapy and plasmapheresis.

The preparation of equipment and instruments used for collection, processing and storage of blood should be covered. Detailed instruction is needed on minimum requirements for equipment, reagents, anticoagulants, sterilization procedures, and for the control tests on quality, biological activity and viability of the final products. Quality control should be a core subject of any training course and should include guidance on the evaluation of laboratory tests, including automated techniques. It is essential to stress that there should be no compromise between quality and quantity. The effectiveness of the course can be assessed by frequent monitoring of the preparations produced by the trainees and by tests of their laboratory proficiency.

Since the structure, function and viability of blood cells define their optimum storage conditions, any new information in this field should be covered in the course. Staff should be familiar with estimation of cell survival, and with the structure, function and fractionation of plasma proteins, even though they may not themselves practise fractionation.

The most important area of training is in blood-group serology. The ABO, Lewis, I, and Rh systems and other erythrocytic antigenic determinants should be learnt, as well as allo- and auto-antibodies and red cell incompatibility in vitro and in vivo. Platelet, lymphocyte, granulocyte, endothelial cell, macrophage and serum protein antigens and their respective antibodies should be studied, together with the complement system and the preparation of test sera, Coombs sera and cell panels for blood-group serology. The application of blood groups to questions of parentage and identity may be covered where appropriate.

Lectures on recent concepts of haemostasis, and practical training in the diagnosis and treatment of haemorrhagic diseases and thrombosis may be included in the training programme, with guidance on methods of production and use of plasma fractions with haemostatic activity. Detailed lectures should also be given on indications for blood transfusion, paying special attention to
component therapy, and the use and misuse of blood. Theoretical and practical aspects of treating hypovolaemic shock, and the hazards of massive transfusion may be covered, together with the quantity and quality of blood components needed for extracorporeal circulation and haemodialysis. To encourage the optimum use of blood, detailed information should be given on the use of plasma expanders and electrolyte solutions, and different plasma proteins, with an overview on artificial oxygen-carrying systems.

A training programme should include the special aspects of haemotherapy in infancy and childhood: the pathophysiology, diagnosis, treatment and prevention of haemolytic diseases of the newborn, the technique of exchange transfusion and treatment of haemorrhagic diseases of the newborn, and substitution therapy in immune deficiency.

It is also important that the course covers aspects of management, financing, cost-benefit ratios and developmental work in the national blood transfusion service.

TRAINING OF HOSPITAL STAFF

Postgraduate teaching programmes for residents and senior hospital staff need not include technical details of the processing of blood components and plasma fractions, or other basic functions of blood transfusion centres, but should be largely devoted to clinical uses and misuses of blood transfusion, and the safety of the procedure, in the context of modern clinical medicine. It should be stressed throughout the programme that each patient is an individual case and that consequently no universal prescriptions can be given—only scientifically based recommendations. Ultimately, the trainee must apply the available information to the solution of patient care problems.

National education programmes should be regularly revised to take account of the most recent advances in blood transfusion practice. The continued sharing of information and technology, and the elaboration of international standards and recommendations for products and methods are of the utmost importance.
Chapter 14
Personnel management

W. Wagstaff

INTRODUCTION

In planning and managing the personnel of a blood transfusion centre, it must be remembered that such an institution has a heavy service function, as well as the usual scientific laboratory functions of investigation and research. In addition, a blood centre is unique in having a vital interface with the healthy public as opposed to patients. All staff should be aware of these aspects, especially the public relations functions, and should be selected with this in mind. Job descriptions for every post within a centre should be drawn up with care and candidates chosen for their suitability for particular posts.

It is equally essential that the unique position of the blood transfusion service be taken into account in planning career prospects for staff, in deciding pay and allowances and in determining the gradings allocated within sections, so that a harmonious relationship may develop between staff of the transfusion service and their counterparts in areas of the health services more directly associated with clinical care. Too often, blood transfusion staff come to be regarded as the ‘poor relations’ of the health care system.

As with any functional unit, a satisfactory working environment should be fostered by the establishment of a formal system

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1 Permission from the Trent Regional Health Authority to use its document on disciplinary and grievance procedures in the preparation of this chapter is gratefully acknowledged.

2 Director, Regional Transfusion Centre, Sheffield, England.
of management/staff relationships, agreed by both. Grievance and disciplinary procedures should be drawn up with full consultation and staff consultative committees established within blood centres to discuss and resolve problems not directly connected with terms and conditions of service (e.g. canteen facilities).

It should be stressed that the following detailed account of personnel management represents an ideal situation in a well-organized blood transfusion service with an equally strong supporting health structure. In every situation the blood transfusion service should be seen to be in line with other services in the local health system, so that those elements of this chapter that would be of direct application in a given situation should be abstracted by the managers concerned.

**JOB DESCRIPTIONS**

**Description of tasks**

The following points should be included in describing the tasks associated with each post:

- The title and grade of post.
- The department concerned.
- A short summary of the job.
- A detailed description of principal responsibilities.
- Lines of personal responsibility. It is essential that each person knows who is his or her direct superior, and the staff for whom he or she is in turn responsible.

Flexibility must be built into any job description to allow for future development in the work concerned and for the possible need to cover the absence of colleagues. Provision should be made for full consultation with the person concerned before new tasks are introduced.

**Detailed job analysis**

A job analysis, detailing the qualities required in any candidate for the post, will be the basis for the job description of the
appointment. (An example of a personal specification and of a typical job description are given in the appendices 1 and 2 to this chapter.) The job analysis should seek answers to the following questions:

**Personal requirements**

- What educational qualifications are necessary for the proper performance of the work?
- What additional knowledge and qualifications are desirable?
- What is the minimum age at which the average candidate is likely to be able to perform this job satisfactorily?
- What is the most desirable age for appointment to this position?
- What minimum working experience is essential before appointment to this position?
- What additional experience would be desirable?
- What aspects of the work call for dexterity, physical skill or effort?
- Is the work routine or varied? In what way?
- To what details must special attention be paid?
- Does the work involve the solution of problems? If so, how complex are the problems?
- What particular qualities of temperament are required to perform the work satisfactorily?

**Responsibilities**

- What are the main areas of responsibility?
- With which features of the work is the job-holder most likely to have difficulty?
- For what material, equipment or valuables is the holder of the position responsible?
- What discretion may the job-holder exercise without reference to a higher authority?
- How frequently do recommendations and decisions need to be made?
- With which employees does the job-holder have contacts and for what purpose?
- What degree of patient or donor contact is involved in the post? For what purposes?
What confidential information does the job-holder keep and to what does he or she have access?
What would be the consequence of a leakage of information.

Other aspects

What are the hours to be worked (including nightshift and weekend duties)?
What, if any, features of the working environment make the job unpleasant or dangerous?
What are the possible consequences of errors?
How is work checked? How often?
How long might an error remain undetected?
How closely is the work supervised?
Which features of the work make it particularly satisfying, pleasant or enjoyable?

PAY AND ALLOWANCES

In almost all circumstances staff salaries are linked to job grades. It is essential to ensure that each grade carries a high enough salary to persuade staff to remain in the transfusion service after completing their training. It is equally essential that there are adequate facilities for making the actual salary payments, especially for staff paid weekly, whose salaries may be comparatively low and thus allow little flexibility in domestic budgeting.

A fair and equitable system of allowances should be established and constantly up-dated, to cover any extra costs incurred by staff in the performance of their duties.

Where local voluntary organizations contribute to the running of donor sessions, some form of recompense or reward to the organization may be appropriate to signify the gratitude of the transfusion service. This item should not be overlooked in budgeting for the payment of allowances.

The facility should be provided for staff to have their questions on pay and allowances answered by people who are expert in this field. There should be no delays in answering such questions.
Salaries in governmental health services may not always compare favourably with those paid in commercial concerns, and appropriate pension schemes should therefore be established. If such pensions are linked to inflation rates, there is more
likelihood of suitable staff remaining in the health service as a permanent career.

MOTIVATION AND CAREER PROSPECTS

To a great extent job motivation stems from dedicated leadership. It is essential that pride in the job, and in the health service generally, be encouraged, even though this may be difficult when blood transfusion personnel have only minimal clinical contact with patients. The importance of modern transfusion practice, and the continuing need to extend this branch of medicine by research and development, should be stressed to the staff. A good research and development department within a transfusion centre will help to generate enthusiasm and further motivation of the staff. Moreover, feedback of clinical results from the hospitals served by the transfusion centre should be encouraged, to sustain the interest of staff engaged in relatively routine tasks.

Rotation of junior staff within the transfusion centre allows them to identify their own areas of maximum interest and expertise. Middle-grade staff members should be able to choose the particular speciality to which they can bring most enthusiasm and ability.

Participation in national and international scientific meetings and workshops is worth promoting at appropriate staff levels. As part of a continuing education programme regular internal seminars are also a valuable means of maintaining and promoting staff interest.

Career prospects in any post in a transfusion centre should be made clear to an applicant during interview to avoid later disappointment and resentment. This is particularly true in the case of medical and scientific staff, since the later possibility of entry into a more routine hospital service after training in a highly specialized field is often reduced. This relative lack of mobility should be taken into account when defining the responsibilities that determine grades.

Medical career prospects and job satisfaction within the transfusion service depend very much on the formulation of a proper training scheme leading to higher qualifications or recognized specialization on which career grades at least equal to those of clinical colleagues can be based. The importance of offering good career prospects to first-class medical, scientific and technical staff cannot be overstressed, and it is becoming easier to
implement this with the growing acceptance of the permanent place of a properly organized blood transfusion service in modern medical practice.

Where staff members believe themselves justified in applying for up-grading, applications should be investigated thoroughly and without delay. If necessary, a new job evaluation for the post in question may be carried out, particularly if the person applying for up-grading has been in the post for some time.

DISCIPLINARY PROCEDURE

A. The main steps

The procedure outlined in this section is a practical example, given in great detail mainly because the subject is often neglected and misunderstood in many branches of medicine. Although some parts of the procedure may not be universally applicable, relevant portions may give a valuable guide. Local legislation and common law must, of course, be taken into account.

A typical disciplinary procedure has up to four main stages as illustrated in Fig. 14.1. Most employees progress through these for minor offences, but if an offence is considered serious or gross the employee may enter the procedure at stage 2, 3 or 4.

B. Who is involved?

The person making arrangements for disciplinary proceedings should involve:

- The employee concerned.
- Those people who are authorized to take disciplinary action.
- Appropriate full-time personnel officers (by informing them of the problem, discussing it with them and inviting them to investigative and disciplinary interviews) wherever there is the possibility of a final written warning, dismissal, transfer or down-grading.
- When available, a full-time union official where allegations are made against union members and are likely to lead to a written warning or worse. Unless circumstances are exceptional, this contact with full-time officials will be established only after

153
consultation between the manager concerned and the appropriate personnel officers.

- The appropriate training officer (by informing him or her of the problem, discussing it, and inviting the training officer to investigative and disciplinary interviews) where the allegations are against trainees below the age of majority.
- A parent or guardian (by informing them of the problem and discussing it with them) where allegations are made against trainees below the age of majority.
- Any witnesses and sometimes those involved in collecting evidence, e.g. auditors (by discussing the problem as part of
investigations and possibly inviting them to disciplinary hearings).

It is up to the employee to make arrangements for his or her representative to attend hearings. Management should reserve the right to involve the full-time union officer directly where appropriate.

C. Getting the facts

Ascertaining the facts of any case is the crucial basis of any disciplinary procedure. With certain rare exceptions, mere suspicion of an offence is not enough. However, there does not have to be absolute or conclusive proof of an offence, except for contravention of a statutory duty like a driving ban. Instead, the normal rule is that management has to show that:

- they genuinely believed that the employee was guilty;
- their belief is based on reasonable grounds, after as much investigation as was reasonable in the circumstances.

Effective feedback on actual or likely problems is essential, and must be comprehensive enough to allow a decision on whether or not a prima facie case exists; that is, does it really look as if there is a case to answer?

Anyone undertaking disciplinary proceedings must keep his or her immediate superior informed.

Speedy action is important, particularly in the case of gross offences.

Proof of an offence may take one of the following forms:

- A confession/admission. A signed statement should be obtained.
- Witnesses, e.g. workmates, supervisor, members of the public.
  Signed statements should be obtained if possible and notes made.
- Testimonials of third parties, e.g. doctor’s certificate, reports, appraisals, formal complaints.
- Statements by the police concerning criminal investigations into offences at work.
• Direct evidence, e.g. records (of absenteeism, performance at work, vehicle journeys, expense sheets), damaged or stolen property or equipment.
• Circumstantial evidence, e.g. unusual discrepancies in cash or goods recorded and received. Notes must be taken. This type of evidence can be taken into account but is naturally given less credence.

Where a criminal offence has allegedly been committed at work, or outside work but relevant to work, management can take action independent of any criminal charges by the police or court proceedings. There may also be a management observer in court. This means that:

• The employee should not be penalized just because a charge is pending or he or she has been arrested.
• The outcome of any criminal proceedings need not be awaited before independent action is taken. Exceptionally, however, it may be necessary to await the trial, reserving the right to take action in the light of any evidence revealed at the trial.

New facts that come to light after a disciplinary decision and up to the date that the action (e.g. dismissal) is effective, or up to the date of any appeal, should be taken into account as they may affect the action or the results of appeal.

D. The disciplinary hearing

No formal disciplinary action should be taken without a disciplinary interview or hearing, which must be held as soon as possible after the alleged offence is discovered. The difference between the disciplinary hearing and any interview held solely to investigate the allegations must be made clear to all concerned, although an interview will often serve both purposes. In this case, the proper procedure must be followed.

The hearing should be arranged in writing at the earliest mutually convenient date. (A suggested form of letter is given in Appendix 3 to this chapter.)

The letter sent to the employee should:

• confirm the date, time and venue, making clear that the interview is of a disciplinary nature;
• state briefly the allegation and the possible consequences if the allegation is substantiated;
• enclose a statement of management findings and all available documentation necessary for the employee to make sense of the alleged facts;
• advise the employee of the right of representation.

The people who will normally be present at the hearing have already been identified above. The interview will include:

• the history and circumstances of the alleged offence(s) and the proof gathered to date, including the calling of any witnesses;
• an explanation to the employee of the disciplinary action contemplated should the allegations be substantiated;
• a chance for the employee (or representative) to question witnesses, present any new facts, call witnesses (whom management may question), offer an explanation and identify any mitigating circumstances;
• adjournments when requested;
• an announcement of the decision, the reasons for it and any consequences of repeating the offence;
• advice to the employee of a right of appeal.

Except for recorded oral warnings, a follow-up letter will confirm these last two points. (An example of such a letter is given in Appendix 4 to this chapter.) Proper records must be kept of all proceedings.

E. Appropriate disciplinary action

<table>
<thead>
<tr>
<th>Level of offence</th>
<th>Examples</th>
<th>Times disciplined for similar offence</th>
<th>Appropriate action</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Minor</td>
<td>Unauthorized lateness or absenteeism; abuse of uncertified sickness facility; disharmony among employees.</td>
<td>None</td>
<td>Informal counselling or recorded oral warning.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One</td>
<td>Recorded oral warning or written warning.</td>
</tr>
<tr>
<td>Level of offence</td>
<td>Examples</td>
<td>Times disciplined for similar offence</td>
<td>Appropriate action</td>
</tr>
<tr>
<td>------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Two</td>
<td>Written warning or final written warning (or transfer of incompatible employees).</td>
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<td></td>
</tr>
<tr>
<td>Three</td>
<td>Final written warning or dismissal with notice or downgrading (or transfer of incompatible employees).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four</td>
<td>Dismissal with notice.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**II Medium/serious**

<table>
<thead>
<tr>
<th>Violation</th>
<th>Times</th>
<th>Appropriate action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overstaying leave; refusal to arrange holidays to suit operational require-</td>
<td>None</td>
<td>Written warning or final written warning.</td>
</tr>
<tr>
<td>ments; refusal to comply with reasonable reorganization; less serious</td>
<td>One</td>
<td>Final written warning or dismissal with notice or transfer or downgrading.</td>
</tr>
<tr>
<td>neglect of duty; use of language or behaviour offensive to other employees,</td>
<td>Two</td>
<td>Dismissal with notice.</td>
</tr>
<tr>
<td>patients or members of the public; not observing established standards of</td>
<td></td>
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<tr>
<td>appearance; in jobs not involving direct patient contact, failure to report</td>
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<td></td>
</tr>
</tbody>
</table>

158
<table>
<thead>
<tr>
<th>Level of offence</th>
<th>Examples</th>
<th>Times disciplined for similar offence</th>
<th>Appropriate action</th>
</tr>
</thead>
<tbody>
<tr>
<td>contracting or being in contact with a prescribed disease; irremediable breakdown in working relationships; minor criminal offence committed outside work and relevant to work; unauthorized use of, or carriage of goods or passengers in, service vehicle; private use of service equipment or facilities.</td>
<td></td>
<td></td>
<td>(a) Follow steps in A on page 153.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>(b) Appropriate action is normally instant dismissal (or dismissal with notice).</td>
</tr>
<tr>
<td>III Gross</td>
<td>Gross incompetence (especially where a health or safety risk results); gross negligence; gross neglect of duty; unsafe working practices; gross defiance of proper instructions or standing orders; gross insubordination; gross abuse (e.g. of colleagues, public); violence or fighting; illtreatment or mishandling of patients; sexual misconduct</td>
<td>Nil</td>
<td>(c) Mitigating circumstances (see F on page 162) may reduce the penalty to a final written warning or transfer to a more suitable or 'safer' job or down-grading.</td>
</tr>
</tbody>
</table>

159
<table>
<thead>
<tr>
<th>Level of offence</th>
<th>Examples</th>
<th>Times disciplined for similar offence</th>
<th>Appropriate action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>at work; unfitness for duty through alcohol or drugs; in a job involving</td>
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<tr>
<td></td>
<td>direct patient/donor contact, failure to report contracting or being in</td>
<td></td>
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<tr>
<td></td>
<td>contact with a prescribed disease; vandalism of property; timekeeping</td>
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<tr>
<td></td>
<td>fraud; providing false information or withholding relevant information</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>when applying for jobs; theft; expenses fraud; corruption; breach of</td>
<td></td>
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<td></td>
<td>security or confidentiality; failure to disclose a financial interest in</td>
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<td></td>
<td>contracts; other fraud or dishonesty; unauthorized private trading on</td>
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<tr>
<td></td>
<td>service premises; participating in other employment or occupation that</td>
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<tr>
<td></td>
<td>prejudices or adversely affects employment with the service; criminal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>offence committed at work, or outside</td>
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</tbody>
</table>
### Special case: progressive incompetence (other than gross incompetence)

Progressive incompetence may be defined as the situation in which management has increasing doubts about an employee’s competence, ability, adequacy or performance in terms of skill, knowledge, aptitude and adaptability. Over a period of time, a number of relatively small incidents may add up to sufficient reason for taking action. An incompetent employee cannot help what is happening, but is often also guilty of deliberate misconduct, such as neglect of duty, or idleness. Where the problem is mainly one of misconduct, disciplinary action should be taken as recommended in the preceding sections. Otherwise, the recommended procedure is as follows:

- The employee’s performance should be carefully appraised against established standards.
- The employee should be interviewed informally, attention being drawn to deficiencies in his or her performance and to the criticisms made. Agreement should be reached with the employee on the extent of the deficiencies. Remedial measures should be discussed and, where appropriate, suitable training, advice and supervision should be initiated.
- If these measures do not produce a satisfactory improvement in performance, a formal disciplinary interview should be held. If appropriate, a written caution may also be sent to the employee, warning of further disciplinary action unless his or her
performance reaches a satisfactory level within a specified period. (A reasonable period for improvement should be allowed, which will depend largely on the employee’s seniority, length of service, and job complexity.)

- The employee’s performance during this period should be monitored.
- A further disciplinary interview should then be arranged, unless it is obvious that this will be of no benefit. If performance has reached satisfactory levels no further action is necessary, but the previous warning should remain on record for a specified period. If performance remains unsatisfactory, a final written warning of dismissal in the event of there being no improvement by a specified date should be issued. The employee’s performance should again be monitored.
- If performance remains unsatisfactory, a third disciplinary interview should be held, at which the possibility of transferring the employee to another post is considered. If no suitable vacancy exists, or if the employee declines an alternative post, notice of dismissal should be given.

F. Circumstances affecting disciplinary decision

The following circumstances should be taken into account when deciding whether the disciplinary action indicated in the previous section should be mitigated or reinforced.

<table>
<thead>
<tr>
<th>Mitigating circumstances</th>
<th>Reinforcing circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Offence not covered by employee’s contract terms, written rules or instructions, or union agreements</td>
<td>Offence against express terms of contract, rules or instructions, or union agreements</td>
</tr>
<tr>
<td>(2) Inconsistency: similar offences by this or other employees in similar circumstances not penalized</td>
<td>Consistency: similar offences by this or other employees penalized in the past</td>
</tr>
<tr>
<td>(3) Offence committed ‘in the heat of the moment’</td>
<td>Offence premeditated over a period</td>
</tr>
<tr>
<td>(4) Provocation by other(s)</td>
<td></td>
</tr>
</tbody>
</table>

162
<table>
<thead>
<tr>
<th>Mitigating circumstances</th>
<th>Reinforcing circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5) Employee genuinely unaware of doing anything wrong</td>
<td>Employee fully aware of doing wrong</td>
</tr>
<tr>
<td>(6)</td>
<td>Dishonesty in confessing</td>
</tr>
<tr>
<td>(7) Regret or apology expressed</td>
<td>No regret or apology expressed</td>
</tr>
<tr>
<td>(8) Work, domestic or financial problems or stress at time of offence</td>
<td></td>
</tr>
<tr>
<td>(9) Physical or mental health problems</td>
<td>Poor work and behaviour record (includes all previous offences)</td>
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<td>(10) Older employee</td>
<td></td>
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<tr>
<td>(11) Long service</td>
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<tr>
<td>(12) Good work and behaviour record generally</td>
<td></td>
</tr>
<tr>
<td>(13)</td>
<td>Employee in position of seniority</td>
</tr>
<tr>
<td>(14) Employee in position of trust and responsibility (e.g. for money, resources, people)</td>
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<tr>
<td>(15) Colleagues unhappy about continuing to work with offender</td>
<td></td>
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<tr>
<td>(16) Risk caused to donors or patients</td>
<td></td>
</tr>
<tr>
<td>(17) Effect on credibility, reputation and integrity with public of both employee and service, especially if case attracts media publicity</td>
<td></td>
</tr>
<tr>
<td>(18) Management delay in dealing with offence</td>
<td></td>
</tr>
<tr>
<td>(19) Unreasonable or erroneous procedure followed by management</td>
<td></td>
</tr>
<tr>
<td>(20) Failure by management to try to minimize risks by seeking another 'safer' job for employee</td>
<td>Unreasonable refusal by employee of suitable alternative employment offered</td>
</tr>
<tr>
<td>Mitigating circumstances</td>
<td>Reinforcing circumstances</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>(21) In dismissal cases, where employment would have ended soon anyway</td>
<td>Non-use of grievance procedure by employee to try to resolve problem (if relevant)</td>
</tr>
<tr>
<td>(22)</td>
<td>For absences: key job needing quick replacement, e.g. employee’s absence causes operational problems, safety risks, risk of negligence claims</td>
</tr>
<tr>
<td>(23)</td>
<td>For incompetence, neglect of duty, negligence or unsafe working, if caused by lack of:</td>
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<tr>
<td></td>
<td>- proper selection</td>
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<tr>
<td></td>
<td>- adequate guidance or training</td>
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<td></td>
<td>- clear terms of reference</td>
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<td>- adequate supervision</td>
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<td></td>
<td>- adequate support staff</td>
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<td></td>
<td>- adequate past standards upheld by service</td>
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<td></td>
<td>- offer of available suitable alternative work.</td>
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<tr>
<td>(24) For defiance of proper orders:</td>
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<tr>
<td></td>
<td>- if employee genuinely believed that safety problems would result</td>
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<td></td>
<td>- if any history of poor relationships exists</td>
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<td></td>
<td>- where competence of supervisor is questionable</td>
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</tbody>
</table>

(26) For theft: repeated thefts over a period

(27) For criminal offences outside work:

164
Mitigating circumstances | Reinforcing circumstances
---|---
- if offence is serious
- if offence is relevant to own job (e.g. theft by a cashier)
- job unsuitability also as per (13), (14), (15) and (16) above

N.B. Where employee is or will be imprisoned for an offence not directly relevant to the job, he or she may be dismissed on grounds of intolerable absence from work if:

- it is certain, after inquiries, that the absence will be lengthy; and
- the service cannot wait for the employee’s return because of the factors in (14) and (23) above; and
- the factors in (9)–(13), (15), (17), (20) and (21) have been taken into account

**Appeals**

- Employees may appeal in accordance with established procedure.
- The question of legal representation at an appeal hearing should form part of the agreed disciplinary procedure.
- Appeals should be processed by independent personnel officers.
- The authority of an appeals committee to make final decisions must be fixed and agreed in advance.
- Time limits should be fixed within which an appeal against disciplinary action must be lodged.
GRIEVANCE PROCEDURE

Scope of a grievance procedure

- The grievance procedure should deal only with the formal situation and not, for example, with day-to-day problems, queries or welfare counselling.
- The procedure should cover the application or interpretation of conditions of service, working conditions, welfare and alleged discrimination on grounds of race or sex. It should not apply to:
  - pay, or any other matter more appropriate for negotiation with a trade union or staff organization;
  - staff grading: there must be a separate procedure for applications for change of grade;
  - discipline, for which there should be a separate procedure;
  - anything that would be contrary to established policy or the law.

Why have a grievance procedure?

- So that individual grievances or complaints can be resolved fairly and consistently and can be seen to be resolved.
- To help resolve problems and potential disputes so that the provision of health care services is not disrupted.
- To encourage good management-employee relations.
- So that employees and management know their rights and responsibilities and how to proceed in the event of a grievance.

The aims and principles of a grievance procedure

- The grievance procedure should aim to settle the grievance fairly and as near as possible to the point of origin.
- It should be simple and rapid in operation.
- The procedure should be written down and should provide for:
  - the grievance to be discussed first between the employee and his or her immediate superior;
  - the employee to be accompanied at the next stage of the discussion with management by the staff representative if he or she so wishes;
  - the right of appeal.
• The scope of the grievance procedure should be clearly defined.
• The procedure may provide for a grievance notification form. This:
  – helps weed out trivial or flippant cases;
  – shows how to register a grievance;
  – gives the employee a proper acknowledgement of receipt of grievance;
  – provides the basic information needed to process the grievance;
  – provides a proper record in case the grievance procedure must involve a higher level of management.
• The procedure may also provide for a progress record, which helps ensure that the grievance is being processed properly.
• It may provide time limits that guarantee action but that are realistic and do not aggravate the situation.
• In specifying those empowered to resolve grievances, time limits for the procedure, and circumstances in which the disputes procedure should be evoked, the grievance procedure must be flexible in order to be workable.

Why have separate grievance and disputes procedures?

• Separate procedures are likely to be simpler to administer.
• To class a grievance under the same heading as a dispute can make the grievance seem more serious than it need be.
• The grievance procedure may be regarded as an extension of management’s welfare responsibilities, whereas the disputes procedure is generally part of the collective bargaining system.
• Certain procedural conditions are appropriate to grievances but not to disputes and vice versa, for example:
  – It is acceptable to say that grievances should be resolved quickly but to apply a sense of urgency to all disputes may serve to aggravate the situation.
  – The first stage of a disputes procedure may be dealt with at a higher level of management than is the case for grievances, because of the potentially more serious consequences of a dispute.
  – A disputes procedure needs greater flexibility than a grievance procedure.
  – Other aspects of a disputes procedure, such as joint meetings, inter-union disputes, time off work, industrial action, are not appropriate to grievances.
In procedures designed to deal with both grievances and disputes, there may be a blurring of the distinction between the two.

**A grievance interview**

- Before the interview it is essential to collect as much background information as possible, such as:
  - job description
  - personal file
  - grievance notification form and grievance progress record
  - details of previous, similar grievances, including action taken
  - the opinions and views of others.
  The limits of responsibility of the staff member conducting the interview should also be determined.
- Relevant personnel should be invited to attend the interview, in addition to the complainant, including where relevant:
  - the employee’s representative
  - representatives of the management levels involved
  - departmental personnel officer, or equivalent.
- It is essential to listen carefully to the complainant, allowing his or her grievance a full airing.
- All the facts of the case must be gathered and verified, and full notes should be made on the nature of the grievance and its history.
- The various solutions to the problem should be jointly identified with the complainant.
- The full implications of the problem must be carefully considered. This may necessitate adjourning the interview and discussing the situation with management or seeking further advice before any final decisions are reached.
- Any proposed action should then be agreed with the complainant.

**Appeal**

A channel of appeal should be established for complainants, to be invoked in those cases where the grievance procedure cannot resolve the difficulty at a local level.
RELATIONSHIP WITH HOSPITALS AND THE GENERAL PUBLIC

Rotation of medical and scientific staff between blood transfusion centres and hospitals should be encouraged, and courses of instruction in transfusion techniques arranged at the centres for members of hospital staff. It is important for this interchange to be in both directions, to allow hospital-based staff to appreciate the problems of running a complex transfusion service and the extent of what can be achieved by a well-developed service, and to allow transfusion service staff some insight into the problems involved in clinical and laboratory support of hospital practice, particularly in the handling of emergencies. Equality of status of senior personnel in transfusion services and hospitals is essential.

In dealing with the general public, the prime aim of any transfusion service is to establish an adequate panel of volunteer donors. This can be done by encouraging the image of a successful and well-integrated service. Public relations is an art in itself. It should not be supposed that all good administrators automatically make good donor organizers, and it is essential to take personality into account when appointing donor panel staff. Previous experience in the field of public relations is often most valuable.

It is essential that all complaints and suggestions from donors are given instant attention and that all justified claims by donors against the service are settled without delay. An example of this would be the settlement of bills for the cleaning of clothing stained by blood at, or immediately after, donation.

There must be willing collaboration with local donor organizations, and all requests for talks to groups of the public should be granted without delay. The staff giving these talks should be well versed in all general aspects of transfusion practice and in any problems peculiar to the group of people being addressed.

Sympathetic consideration should be given to using members of voluntary organizations at local donor sessions. These people will undoubtedly know the donors far better than the provincial donor organizers based at the transfusion centre, and their presence at sessions may encourage a ‘family’ atmosphere, which is always beneficial.
Appendix 1 to Chapter 14
Example of personal specification for a job (Assistant Area Personnel Officer)

General characteristics

Age 28 to 35 years. Male or female. Good general health: no recurrent illnesses, and able to climb stairs. Strong, confident personality without aggressiveness.

Qualifications

Education: qualification equivalent to university entrance level. Training: appropriate professional qualifications. Experience: at least two years' experience in a national health service personnel department. Preferably two years' line management service in an organization with an active personnel management department.

Aptitudes and social skills

Ability to communicate effectively and convincingly, without antagonism, with people at all levels.

- Ready comprehension of others' points of view, plus ability to respond rapidly when necessary.
- Capacity for independence of action, combined with sound judgement in deciding what matters to refer to immediate or higher-level superior.
- Ability to take a broad view of all issues, and to consider the future implications of all decisions.
An eye for detail, with a reasoned approach to problem-solving. Ability to achieve progress in the face of possible difficulty or hostility.

**Personality**

Desirable personality traits:
— extrovert, outgoing and interested in people
— ability to remain calm and clear-thinking, even when provoked
— flexibility of approach in all situations
— good sense of humour
— ambition to achieve promotion.

**Circumstances**

Freedom—and willingness—to work overtime and weekends when necessary and to attend courses, meetings, etc. outside normal working hours.

Ideally, possession of an appropriate means of transport, e.g. bicycle, motorcycle or car (with valid driving licence).
Appendix 2 to Chapter 14
Example of job description
(Senior Technician)

Job title
Senior Technician

Grade
Senior Technician

Job summary
Maintenance of day-to-day operations and routine testing of blood donor laboratory, plus day-to-day running of computer services of blood transfusion centre.
   Hours of work 37 hours per week basic, plus participation in an on-call rota.

Principal responsibilities
Operation of automatic blood-grouping equipment, including reagent production; care and maintenance of equipment; ensuring that accurate testing is performed; liaison with manufacturers for servicing and repair.
   Organization and control of the manual blood-grouping of new blood donors.
   Organization and control of all clerical procedures.
   Maintenance of a file of blood donors with unusual serological
test results; further investigation of blood samples from such donors.

Maintenance and extension of the file of rare red cell types for inclusion in national and international panels.

Organization and control of further training of junior technicians on rotation; participation in introductory training and in the basic, advanced and medical officers’ courses held at the transfusion centre.

Maintenance of a 24-hour-a-day computer service for the blood transfusion centre.

Liaison with the regional computer team for up-dating any computer operation in line with developments in the testing and/or processing of blood donations.

Liaison with computer manufacturer for the maintenance, servicing and repair of minicomputer and peripheral units.

Ensuring the integrity of computerized blood donor records and the correct transfer of information to microfiche.

Awareness of developments in the collection, storage and testing of blood donations, and in computer record-keeping.

Implementation of changes in methodology on instruction from medical and senior laboratory staff.

Responsibility for maintenance of all laboratory equipment in the blood donor laboratory, including cleanliness, accuracy and safety.

Advice on and selection of new or replacement equipment as and when required.

Responsibility for the interests and training of junior staff with respect to their professional examinations.

Other duties and responsibilities within the same grade or job level may arise from time to time; these changes will be discussed with the officer concerned before implementation.

**Responsible for:**

Nine technicians and two laboratory clerks.

**Accountable to:**

Senior Scientific Officer for day-to-day running of blood donor laboratory and Senior Chief Technician for computer services in the blood transfusion centre.
Appendix 3 to Chapter 14
Sample letter confirming disciplinary hearing

*Note:* Blanks should be completed as appropriate.

Dear ............

**Disciplinary Interview**

Further to our recent conversation, I am writing to confirm that your attendance is required at a hearing, which I am convening under the Service’s Disciplinary Procedures, on . . . [date] at . . . [time] in . . . [place].

The purpose of the interview is to discuss with you allegations that . . . I must point out that, should these allegations be found to have substance, they would normally result in . . .

In accordance with the Procedure, I enclose a statement of management findings to date and the available documents necessary to familiarize yourself with the allegations.

If you wish, you may be accompanied at the interview by a representative of your trade union, professional organization or staff association or by a colleague not acting in a professional capacity. You should make the necessary arrangements for him or her to attend.

Yours faithfully,

.................
Appendix 4 to Chapter 14
Sample letter confirming disciplinary action

Notes: 1. A copy of this letter will serve as a record for the file; a separate record will be needed of oral warnings.
2. Blanks should be completed, or phrases deleted, as appropriate.

Dear ............

Disciplinary Interview—Written Warning/Final Written Warning/Transfer/Down-grading/Dismissal

I refer to the disciplinary interview held on . . . by . . . in the presence of . . . [other non-participating management, any witnesses] and your representative(s) . . . . (If employee was not represented, insert: “It is noted that you declined to be represented”.)

The purpose of the interview was to discuss with you allegations that . . . . [Summarize allegations/complaints.]

In the light of . . . . [summarize proof, e.g. witnesses, admission, medical reports, other evidence], management believed that you did/were in fact . . . . [summarize the offence].

Because of this [and any previous extant and relevant disciplinary action taken against employee] management had no alternative but to . . . . [State disciplinary action taken and any special conditions or circumstances connected with the action, e.g. monitoring at regular intervals, job transfer, down-grading, period for which action is valid, date paid up to.]

You were also warned that repetition of a similar offence within . . . . [time period] will result in . . . . [next step of}
Management of blood transfusion services

disciplinary action]. (This paragraph does not apply to
dismissals.)

You have the right to appeal to . . . against this decision, which
may be exercised by writing to . . . within . . . days/weeks of
receipt of this letter.

Yours faithfully,

(Appropriate officer)

Copies: Appropriate departmental management
Department’s administrative/personnel section
Chief personnel officer (except for written warnings)
Chapter 15
Legal responsibilities to blood donors and recipients
A. André

INTRODUCTION

Because blood for transfusion is of human origin, it cannot be classified as a medicament. Transfusion is a medical undertaking involving two human beings, the donor and the recipient, which may have serious immediate or delayed consequences. Donation must therefore be made as safe as possible for the donor, and transfusion for the recipient.

The human origin of blood and blood products is the basis of a number of ethical rules that must govern transfusion practice. Compliance with these rules must be compulsory so that penalties may be imposed for any abuses in the organization of transfusion, including the promotion of blood donation, the taking of blood, and the preparation, storage and distribution of blood and blood products.

The importance attached to these ethical rules, and the ease with which they may be converted into legislation, will vary with the legal system existing in each country. Relatively strict rules will be embodied in the legislation of some countries, and noncompliance will automatically entail sanctions—either peculiar to transfusion or dealt with under the heading of unintentional assault and battery occasioning harm to donor or recipient. In some countries, however, there will be no legislation, but whichever body has undertaken to organize the blood

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transfusion service will have drawn up rules based on the same ethical principles.

In most countries of the world there are no legislative measures or even generally accepted guidelines on blood transfusion. This may lead to unacceptable blood donation and transfusion practices; in resolution WHA28.72 the World Health Assembly therefore urged Member States to enact effective legislation governing the operation of blood services, and to take any other necessary action to protect and promote the health of blood donors and recipients.

**ETHICAL ASPECTS**

The ethical code formulated by the International Society of Blood Transfusion and adopted by the International Red Cross is provided as an appendix to this chapter. Its most fundamental principles are that blood donation must be voluntary and unpaid, and that the health of donor and recipient must be protected.

**LEGAL ASPECTS**

Legislation governing blood transfusion must define the relevant clinical, technical, administrative and socioeconomic criteria and conditions to be applied to the practice.

**Clinical criteria**

Clinical criteria for the donor will consist of clinical examination and laboratory tests, including immunological tests. The number and extent of these tests will be dictated by the existing state of scientific knowledge of any disability that the donor might suffer as a result of giving blood, and of the repercussions that might be suffered by a recipient of blood from a donor who was not in good health.

Immunological criteria for the recipient must minimize the incidence of transfusion accidents or any subsequent immunization resulting in possible accidents. Conditions of surveillance during and after transfusion should also be defined.
Technical conditions

Technical conditions for the organization, equipment and premises must also be clearly defined in relation to therapeutic requirements and clinical needs, not only for whole blood, but also for its labile and stable products.

Socioeconomic criteria

Legislation must preclude any commercial transactions with regard to the blood donor and also on the part of anyone who takes, prepares and distributes the blood. A service charge may be levied for the supply of blood or its components, but this should be calculated on a non-profit basis.

The definition of legal criteria must be sufficiently general as not to interfere with the proper functioning of the transfusion service and to enable the most up-to-date techniques to be rapidly applied.

Age of consent for blood donation

The organization of a blood transfusion programme will set upper and lower age limits for donation. Legally, it is more convenient if the lower limit selected coincides with the age at which majority is reached. This varies throughout the world, but is commonly set at 18 years. It is necessary to obtain the consent of the legal guardian before a prospective donor can be accepted below the age of majority.

The upper age limit for donation will vary: anyone who has ceased to be capable of understanding the nature of the act involved can no longer be regarded as capable of giving blood, regardless of his or her age.

INFORMED CONSENT

The nature of the donation procedure, of whatever type, must be explained to the potential donor, together with the risks. This is especially important with new donors, since repeat attendance may in itself be accepted as informed consent to the procedure.
The donor will be asked to sign an attendance register, usually to indicate that he or she has read and understood the list of conditions that would preclude him or her from donation. This signature may also be taken as a record of consent to the procedure. Apheresis techniques and the attendant risks should be explained with care, and consent forms, after being signed by the donor, should be witnessed by a competent member of staff.

INSURANCE

A human being who donates blood for transfusion as a volunteer and without payment performs an act of altruism. All possible steps should therefore be taken to ensure that the donor does not suffer any harm or loss, whether it be a pathological condition occurring during, or as a consequence of, the donation, or an accident occurring in the place where the donation is taken.

If, despite all precautions, the donor does suffer harm or loss during, or as a result of, the donation, there should be sufficient insurance cover to provide compensation. The mechanism selected for compensation will obviously vary from country to country.

Ordinarily, the donor should not be held responsible for any adverse consequences of the transfusion to a recipient. However, if the withholding or falsification of information by the donor proves to be the cause of adverse reactions in the recipient, the situation will be viewed differently.

The recipient must not suffer harm as a result of transfusion, and must obviously be compensated if a mistake is made. Any doctor should be sufficiently well insured as to be able to compensate any patient who suffers harm as a result of error by the doctor.

LIABILITY

Public health authorities have a general responsibility to provide adequate treatment for the whole population, including treatment based on human blood and blood products. This responsibility involves the establishment of a body competent to carry out the essential functions of promoting blood donation, taking the blood, and preparing, storing and distributing blood and blood products in conformity with established rules. The responsible
medical officer of a blood transfusion centre may be held to be personally liable if, through negligence, he or she fails to make proper use of the resources at his or her disposal.

In considering a doctor’s personal liability, a distinction must be drawn between two categories of doctors, those responsible for blood donation and those responsible for blood transfusion.

**Doctors responsible for blood donation**

Where it can be proved that a doctor responsible for blood donation has not ensured the safety of donors by complying with all criteria covered by relevant legislation or guidelines, there is a clear liability towards the donors. A doctor may also be liable if it can be shown that failure to respect these criteria caused harm to recipients, without necessarily causing harm to donors; however, this is more difficult to prove.

**Doctors responsible for blood transfusion**

The liability of the doctor responsible for transfusion has been the subject of much legal discussion. There is a large body of opinion that the doctor giving a transfusion should be totally liable for harm of any kind to the recipient resulting from transfusion. This liability might require the doctor to make final detailed checks at the patient’s bedside. However, the most such final checks can prevent is a transfusion accident caused by an ABO grouping incompatibility. Furthermore, these checks may be difficult to carry out in cases of extreme urgency or when multiple successive transfusions must be performed, for example, in the operating theatre. Moreover, the recipient may suffer harm as a result of other factors that cannot be checked by the doctor giving the transfusion. An inquiry may therefore be necessary to assign liability for adverse reactions suffered by a transfusion recipient.

The problem of medical responsibility for transfusion is complicated. The situation may arise, for instance, in which a mistake is treated as an accident, or where, in case of great urgency, telephone requests are wrongly written down. Between the time when a blood sample is taken from the patient for immunological compatibility tests and the time when the blood transfusion is given to the recipient, there are many areas in which
Management of blood transfusion services

mistakes may be made; in the event of an accident, each of these areas must be examined as a possible cause.

**Confidentiality of records**

The confidentiality of patients' medical records is the subject of legislation worldwide. Blood donor records should be afforded the same degree of confidentiality, and proper arrangements must be made within a transfusion centre for the security and eventual disposal of these documents. This confidentiality is of particular importance in the case of a donor for whom a positive result is obtained in any of the screening tests for diseases.
Appendix to Chapter 15
A code of ethics for blood donation and transfusion

The object of this code (as drawn up by the International Society of Blood Transfusion, 1980) is to define the principles and rules to be observed in the field of blood transfusion; these should form the basis of national legislation or regulations.

I. The donor

1. Blood donation shall, in all circumstances, be voluntary; no pressure of any kind must be brought to bear upon the donor.
2. The donor should be advised of the risks connected with the procedure; the donor’s health and safety must be a constant concern.
3. Financial profit must never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donors should always be encouraged.
4. Anonymity between donor and recipient must be respected except in special cases.
5. Blood donation must not entail discrimination of any kind, either of race, nationality or religion.
6. Blood must be collected under the responsibility of a physician.
7. The frequency of donations and the total volume of the blood collected according to the sex and weight of the individual, as well as the upper and lower age limits for blood donation, should be defined by regulations.
8. Suitable testing of each donor and blood donation must be performed in an attempt to detect any abnormalities:
(a) that would make the donation dangerous for the donor,  
(b) that would be likely to be harmful to the recipient.

9. Donation by plasmapheresis should be the subject of special  
regulations that would specify:  
(a) the nature of additional tests to be carried out on the  
donor,  
(b) the maximum volume of plasma to be taken during one  
session,  
(c) the minimum time interval between two consecutive  
sessions,  
(d) the maximum volume of plasma to be taken in one year.

10. Donations of leukocytes or platelets by cytapheresis should be  
the subject of special regulations that specify:  
(a) the information to be given to the donor about any drugs  
injected and about the risks connected with the procedure,  
(b) the nature of any additional tests to be carried out on the  
donor,  
(c) the number of sessions within a given time frame.

11. Deliberate immunization of donors by any foreign antigen  
with the aim of obtaining products with a specific diagnostic  
or therapeutic activity should be the subject of special  
regulations that would specify:  
(a) the information to be given to the donor about the  
substance injected and the risks involved,  
(b) the nature of any additional tests which have to be carried  
out on the donor.

N.B. The purpose of the special regulations in items 9, 10 and  
11 above is to safeguard the donor. After being told about the  
nature of the operation and the risks involved, a statement of  
informed consent must be signed by the donor. For donors  
immunized against red cell antigens, a special card should  
indicate the antibodies and specific details as to the  
appropriate blood to be used in case the donors need to be  
transfused.

12. The donor must be protected by adequate insurance against  
the risks inherent in the donation of blood, plasma or cells, as  
well as the risks of immunization.

II. The recipient

13. The object of transfusion is to ensure for the recipient the  
most efficient therapy compatible with maximum safety.
14. Before any transfusion of blood or blood products, a written request, signed by a physician or issued under his responsibility, must be made, which specifies the identity of the recipient and the nature and quantity of the substances to be administered.

15. Except for the emergency use of type O blood or red blood cells, every red cell transfusion necessitates preliminary blood grouping tests on the recipient, and compatibility tests between the donor and the recipient.

16. Before administration, one must verify that blood and blood products are correctly identified and that the expiry date has not been passed. The recipient’s identity must be verified.

17. The actual transfusion must be given under the responsibility of a physician.

18. In case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.

19. Blood and blood products must not be given unless there is a genuine therapeutic need. There must be no financial motivation on the part of either the prescriber or the establishment where the patient is treated.

20. Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products, subject only to their availability.

21. As far as possible the patient should receive only that particular component (cells, plasma, or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires only part of it may deprive other patients of necessary components, and may carry some additional risks to the recipient.

22. Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interests of both recipient and donor by avoiding abuse or waste.

23. The optimal use of blood and blood products requires regular contact between the physicians who prescribe and those who work in blood transfusion centres.

III. Controls

24. Appropriate controls should be required by the Health Authorities to verify that blood transfusion practices meet
internationally accepted standards and that the guidelines or regulations issued in accordance with this code are effectively respected.

25. The following should be regularly checked:
(a) the proficiency of the staff,
(b) the adequacy of the equipment and premises,
(c) the quality of methods and reagents, source material and finished products.
Chapter 16
Basic financial considerations for planning a national blood transfusion programme
C. R. Duncan

Financial techniques may be used to convert raw data into information that provides a valuable basis for management decisions. Blood transfusion services can make use of such techniques in order to plan and control their expenditure on equipment, personnel, facilities, supplies, and other resources, thus making maximum use of available funds.

This chapter deals with two important areas of finance, namely capital budgeting and cost accounting, each of which comprises techniques designed to answer a specific type of financial question.

CAPITAL BUDGETING

Capital budgeting techniques may be used in forecasting the future outcome of financial decisions made today. For instance, major investments in medical equipment are sometimes made solely on the basis that improved health care can be offered as a result. Capital budgeting, however, may reveal that many such purchases will cause severe financial difficulties for the health facility—in this case, the blood transfusion service. It allows the consideration of other factors, such as the potential of the

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equipment to generate income during its lifetime, to enter into the decision to purchase.

The capital budgeting technique presented in this chapter has been adapted to the particular needs of health services, so that it may be applied to decisions that do not necessarily involve a question of ‘profit’. The word ‘capital’ refers to money spent on large, once-only purchases of expensive equipment. It does not concern itself with small purchases or with recurring day-to-day expenses.

Careful budgeting of capital expenditure is important for the following reasons:

- Large sums of money are generally involved.
- There is always the risk of making the wrong decision, which might have serious repercussions in the future.
- Decisions on capital expenditure are generally irrevocable.
- Capital in most countries is scarce and must be rationed to the most worthwhile projects.

Many proposals for purchase fail for political reasons or because of inappropriate policies or lack of money. In its need for capital—essential for the purchase of equipment that will allow efficient production of blood and blood components—the transfusion service is in competition with all other parts of the health service. Capital budgeting then becomes additionally valuable, since a proposal that is supported by a thorough financial evaluation, showing the purchase to be a wise investment, is more likely to receive favourable consideration.

Some of the more sophisticated capital budgeting techniques require knowledge that may not be available to the management of individual transfusion centres. This chapter therefore deals with only one technique—the ‘payback period’—specially adapted to the needs of the transfusion service.

**The capital budgeting process**

Seven major steps are involved in capital budgeting:

- A need for change is discovered or identified.
- An objective, or solution to the problem, is defined.
- Alternative solutions are identified.
- Evaluations are performed.
• The best alternative is selected.
• A proposal is made to higher management.
• The proposal receives approval.

For instance, the blood transfusion service may decide that it needs to install an automated process of producing blood components, to replace an existing manual process. This may be because the new process is ultimately cheaper or because the transfusion centre has become too crowded to accommodate the staff needed for the manual process. The three manufacturers who produce suitable automated equipment each charge a different price, both for the main equipment and for the necessary consumables. Moreover, the degree of automation of the equipment differs, so that different numbers of personnel would be required to operate each type. However, none of the equipment would require existing facilities to be expanded, since each process would occupy less space than the existing manual process.

This is an example of the type of problem to which the capital budgeting technique can be valuably applied. Although other problems will require minor modifications to the technique, most will contain sufficiently similar elements to allow the application of capital budgeting.

Once the need has been identified, the objective can be formulated in terms of the desired outcome of purchasing the equipment. The objective will consist of criteria or requirements that establish minimum standards, financial and non-financial, for acceptability of the equipment. Financial standards will be concerned with the time necessary for the equipment to repay the initial costs (through savings compared with the manual process) and with the cost and availability of maintenance services and spare parts. Non-financial concerns will include the minimum quality of blood components produced by the process, and the minimum production rate.

A statement of objectives should always be set down in writing, to provide continuing guidance throughout the process of capital budgeting and as a starting point for the written proposal that must be submitted later.

Once the objective has been formulated, alternative solutions to the problem can be considered. For the example above, there are four possible alternatives (assuming that none of the manufacturers makes provision for leasing the equipment):

• Continue with the existing manual process but build or lease additional working space and hire additional workers.
• Purchase the automated equipment from manufacturer no. 1.
• Purchase the automated equipment from manufacturer no. 2.
• Purchase the automated equipment from manufacturer no. 3.

The next step is to perform a series of evaluations of each alternative, the first of which is almost always concerned with patient care. Each alternative should be compared with predetermined standards that relate to the service offered to patients, for instance the quality of blood components produced by the process. This will normally involve collecting information from equipment manufacturers and/or vendors, from other facilities in the transfusion service that have experience of the equipment and, ideally, from pre-purchase testing of the equipment in the transfusion centre.

Any alternative that does not meet the predetermined standards should be eliminated; no further evaluation will then be necessary.

The next stage in evaluation is political. The success of any proposal to purchase will depend not only upon the availability of capital but also upon current regulations and administrative policies within the transfusion service. Knowledge of the prevailing political climate may forewarn that the timing of a proposal is not ideal or that more preparatory work should be done before the proposal is submitted if it is to have any chance of being approved.

A number of minor problems may affect the purchase of any major item of equipment, and consideration of these should form part of the evaluation process. Among the points that should be considered are the following:

• How is the equipment to be moved from the delivery truck to its final location? (Freight shipment may specify ‘tailgate delivery’, meaning that it is the responsibility of the transfusion centre to remove the equipment from the truck, carry it into the building and install it.)
• Will the equipment fit through doors, corridors and stairwells, and into elevators where necessary?
• Does the equipment require:
  – a waste or drainage pipe?
  – non-standard electricity supply?
  – venting, vacuum, gas, or other services?
• Will the operator(s) need special training?
• Who will pay for freight or shipment of the equipment?
Financial considerations

- Is the equipment insured against loss or damage during transport? If so, by whom?
- Does the quoted price include sales tax or other taxes?
- Will the equipment impose unacceptable loads on the floor or on the ventilation or electrical systems? Will it generate heat that will cause discomfort to workers? Will it produce radioactive or other hazardous waste products that will present disposal problems?
- Who will undertake routine preventive maintenance? Is a service or maintenance contract available?
- Who will carry out repairs in the event of breakdown? Will repair be carried out speedily and at reasonable cost?
- Can the equipment make use of materials and supplies from another manufacturer?
- Are essential materials and supplies readily available at reasonable cost?
- Does the equipment require auxiliary furniture, such as a table on which it should be placed or a chair for the operator?
- Are the necessary utilities and sufficient space for the equipment available at its intended location?
- Will there be sufficient storage space near the equipment for supplies needed daily and in a storeroom for bulk supplies?
- Will the equipment withstand voltage fluctuations in the electrical power supply to the transfusion centre?

The final stage in the evaluation process involves the financial considerations. The payback period method provides valuable information about the potential financial results of purchasing any of the alternatives. This method will be described in detail after the remainder of the overall capital budgeting process has been discussed (see p. 193).

On completion of the evaluations, a choice is made and a proposal to purchase is prepared for presentation to higher levels of management if their approval is necessary. The proposal should include statements of the objective, the criteria for selection, and the final choice; details of the evaluation should generally be included as an appendix to the document.

Once approval of the proposal is received, the purchase may proceed with considerable confidence that the chances of error have been minimized. Should the proposal be rejected, investigation of the reasons for rejection would be useful when subsequent submission of a fresh proposal is contemplated.
Management of blood transfusion services

**Terminology**

Some explanation of the terms used in applying the payback period technique is essential before the technique is described in detail.

**Initial investment**

The capital invested in the purchase of equipment, i.e. the monies paid to the vendor in the initial purchase, is referred to as the 'initial investment'.

**Cash flow**

Capital budgeting in this case is concerned with the flow of cash, both into and out of the blood transfusion service. Cash flowing in is referred to as 'cash inflow' and that flowing out is called 'cash outflow'. The initial investment is thus a cash outflow, because it reduces the amount of cash in the transfusion service.

After initial investment, monies flow into the transfusion service as 'revenue' or 'savings'. Revenue is the result of fees charged for services or products delivered by the equipment purchased, and savings are the result of the chosen equipment being cheaper to operate than the existing system or than any of the other alternatives. Such revenue and savings represent cash inflow since they increase the supply of cash in the transfusion service.

The routine running costs of the equipment, including salaries, supplies, materials and maintenance, represent cash outflow. Capital budgeting considers the entire initial investment, and includes all the costs that are a direct result of the decision to purchase (or not to purchase). On occasion, the purchase of new equipment may result in a need for extra supervisory staff time or for additional supervisory personnel. Only in such a case, that is, when the supervisory costs will increase as a direct result of the investment, can this expense be legitimately included as an 'operating cost'. Capital budgeting does not take account of the depreciation of the equipment over its expected lifetime, nor is it concerned with overhead expenses, which are generally dealt with by cost accounting procedures.

**Net cash benefit**

The difference between cash inflow and cash outflow each year is called the annual net cash benefit and represents the amount of
cash remaining in the transfusion service 'pocket' at the end of a year as a result of the purchase of the new equipment. It is used to pay back the initial investment and to provide a return to the transfusion service that relates to the risk taken in making the investment.

Payback period

The payback period is the amount of time required for the equipment to pay back the initial cost of its purchase. Repayment can be in the form of either the difference between revenue (income) and operating costs, or savings in operating costs compared with those of the existing equipment or process.

The payback period technique

Consideration of alternative purchases in terms of the payback period presents three possible situations, which are discussed below as Cases 1, 2 and 3.

Case 1

Case 1 represents a situation in which the blood transfusion service is considering the purchase of equipment that will provide a new product or service. Any fees that are charged for this product or service will generate revenue that is directly attributable to the investment.

All possible alternative purchases must be evaluated, but the transfusion service has the further option of choosing none of them, i.e. of making no purchase and of continuing to provide only the services and products that are currently available.

In performing a financial evaluation, total operating costs are estimated as the sum of personnel costs, costs of supplies, and a proportion of the maintenance costs. (Other costs should be added in only if they can be identified as being a direct result of the investment.)

Personnel costs are calculated as the number of minutes of personnel time per unit of product multiplied by the expected annual number of units produced, the result being multiplied by the cost of salary (and additional benefits) per employee per minute.
The cost of supplies per unit of product is estimated and multiplied by the expected annual number of units produced. As noted earlier, overhead and other indirect expenses, such as the cost of supervision, are not normally included as operating costs.

It is also important, though often difficult, to estimate the expected life of the equipment. If an initial investment cannot be repaid within the expected lifetime it is a poor risk and should normally be rejected. Estimations of expected life may be based on experience of similar equipment, or on experience with the same equipment in other transfusion centres. However, differences in equipment replacement policy in other centres may result in differences in expected life; some centres may be more prepared to spend money on maintenance and repair, while others are anxious to obtain the latest equipment regardless of true need. Each transfusion centre must ultimately arrive at its own estimate, but it would be wise to be somewhat pessimistic to allow for unforeseen problems.

A Case 1 example is illustrated in Fig. 16.1. Of various alternatives that have been evaluated for non-financial considerations, only two have been found to be technically acceptable. These must now be financially evaluated to determine which will repay its initial cost sooner.

The initial investment required for Alternative 1 is 5,000 francs and that for Alternative 2 is 10,000 francs. (‘Franc’ is used here as a generic term for a unit of money rather than to represent a specific national currency.) These monies, which include charges for freight, delivery, installation, testing, staff training, etc. are paid at the start of the project.

The annual revenue from the two alternatives is the same, which is true in most cases. Annual operating costs, however, are

---

**Fig. 16.1 Case 1**

Revenue will be generated as a direct result of investment. The option remains to choose none of the alternatives.

<table>
<thead>
<tr>
<th></th>
<th>Alternative 1</th>
<th>Alternative 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial investment</td>
<td>5,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Annual revenue</td>
<td>12,000</td>
<td>12,000</td>
</tr>
<tr>
<td>Annual operating costs</td>
<td>9,500</td>
<td>4,000</td>
</tr>
<tr>
<td>Annual net cash benefit</td>
<td>2,500</td>
<td>8,000</td>
</tr>
<tr>
<td>Payback period (years)</td>
<td>2</td>
<td>1.25</td>
</tr>
</tbody>
</table>

194
different, and thus the figures for annual net cash benefit (revenue minus operating costs) also differ.

The final step in the evaluation process is to determine the payback period, by dividing the initial investment by the annual net cash benefit. The results are 2 years for Alternative 1 and 1.25 years for Alternative 2, so that, if its expected life is significantly longer than 1.25 years, Alternative 2 is the better choice. Only if its expected life were 1.25 years or less would Alternative 2 fail to repay its initial cost.

Case 2

The situation in Case 2 is also one in which income will be generated as a direct result of the investment. In this case, however, the option to do nothing does not exist: the transfusion service must select one of the alternatives. In Case 1 an entirely new product or service was being contemplated; in Case 2, replacement equipment for an existing product or service is considered. A typical example would be the purchase of equipment to automate a process that is at present carried out manually.

In this situation it is usual to identify the ‘default’ alternative; that is, the alternative that will be selected if none of the others is found to be superior from a financial standpoint. The differences between the default alternative and each of the other alternatives in turn are then evaluated.

An example is illustrated in Fig. 16.2, where Alternative 1 is the default alternative and the ‘Incremental difference’ column is used to record the differences between Alternatives 1 and 2. (If more alternatives are to be considered, further incremental difference columns should be established.)

![Fig. 16.2 Case 2](image)

Revenue will be generated as a direct result of investment. One alternative must be selected.

<table>
<thead>
<tr>
<th></th>
<th>Alternative 1</th>
<th>Alternative 2</th>
<th>Incremental difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial investment</td>
<td>5 000</td>
<td>10 000</td>
<td>5 000</td>
</tr>
<tr>
<td>Annual revenue</td>
<td>12 000</td>
<td>12 000</td>
<td>—</td>
</tr>
<tr>
<td>Annual operating costs</td>
<td>9 500</td>
<td>4 000</td>
<td>—</td>
</tr>
<tr>
<td>Annual net cash benefit</td>
<td>2 500</td>
<td>8 000</td>
<td>5 500</td>
</tr>
<tr>
<td>Payback period (years)</td>
<td>—</td>
<td>—</td>
<td>0.91</td>
</tr>
</tbody>
</table>

195
The first difference of interest is that in the initial investment—in this case 5000 francs. Revenue generated by the two alternatives is the same but, because of differences in operating costs, there is a difference of 5500 francs in the annual net cash benefit.

The payback period is determined from the data in the incremental difference column, by dividing the initial investment by the annual net cash benefit. In this case it is 0.91 year.

Interpretation of the payback period from incremental difference is more difficult than the interpretation in Case 1. Here, it means that Alternative 2 will require 0.91 year to pay back the difference in cost between the two alternatives. (It is assumed that, if Alternative 2 is rejected, Alternative 1 must be chosen; the payback period for Alternative 1 is therefore unimportant.)

Case 3

In Case 3, no revenue is received as a result of the investment, either because no fee is charged for the service provided or because revenue from fees cannot be attributed directly to the purchase. As in Case 2, however, one alternative must be selected. A typical example of this situation would be the purchase of new glassware-washing equipment, the presence of which would have no direct or readily identifiable influence on revenue received by the transfusion centre. This type of situation is quite common in the health service.

In the example shown in Fig. 16.3, two alternative machines are under consideration. Once again, incremental differences are of interest because Alternative 1 must be selected if Alternative 2 is rejected. The difference in initial investment is 5000 francs. Annual net cash benefits, in this case, constitute only the savings in operating costs, because there is no direct revenue. The

![Fig. 16.3 Case 3](image-url)

No revenue is generated as a result of the investment.
One alternative must be selected.

<table>
<thead>
<tr>
<th>Alternative 1</th>
<th>Alternative 2</th>
<th>Incremental difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial investment</td>
<td>5000</td>
<td>10000</td>
</tr>
<tr>
<td>Annual operating costs</td>
<td>9500</td>
<td>4000</td>
</tr>
<tr>
<td>Payback period (years)</td>
<td>9.51</td>
<td>4</td>
</tr>
</tbody>
</table>
incremental difference is given in parentheses to indicate a negative value, i.e. an annual saving of 5500 francs if Alternative 2 is selected. Dividing the incremental difference in initial investment by that in operating costs gives a payback period of 0.91 year for Alternative 2.

Advantages and disadvantages of the payback period method

The principal advantage of the payback period method is that little or no sophisticated information is necessary; all of the required data are relatively easy to collect. There are, however, two main disadvantages to the method:

- It does not consider benefits beyond the payback period.
- It does not consider the time-value of money.

More complex techniques, such as net present value and internal rate of return, may be used to overcome these drawbacks, but require data such as the cost of capital or the required rate of return, which may not be available.

Writing the proposal

Generally, there is no particular required format for a written proposal. It is normal, however, to begin with a statement outlining the need for the proposed investment, followed by an explanation of the objective and the criteria applied to the selection of alternatives. The chosen alternative is usually described next, with an indication of how it fulfils the criteria. (Rejected alternatives, with reasons for their rejection, may then be listed.) The final item is generally a request for approval of the purchase, possibly accompanied by a purchase order or request for purchase form, so that negotiations may be concluded with signature of the form.

Preparing the purchase order

Most organizations have a prescribed format for the purchase order form, which can be discussed only in general terms here.
The purchase order form will almost invariably require the following details to be supplied:

- the name of the requester;
- the name and signature of the approving officer;
- the vendor’s name and address (sometimes more than one vendor may be listed);
- a description of the equipment to be purchased.

Describing the equipment may prove difficult since purchasing departments generally want as much flexibility as possible in order to obtain the best price and delivery terms. They prefer not to be limited to particular manufacturers, vendors or even equipment features. Flexibility is often a requirement of an organization’s regulations, as a measure of protection against fraud, favouritism, or wasteful purchasing practices. The requester, however, prefers to have exactly the item of equipment that has been evaluated and selected, and this difference may lead to conflict. Careful specification of equipment in terms of performance, rather than simply by identification of a particular make or model, may satisfy all parties and avoid these difficulties.

For example, if a printer is required for connection to a microprocessor that forms part of an automated process or computer system, the specification might read as follows:

<table>
<thead>
<tr>
<th>Item:</th>
<th>Printer for microprocessor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested brand:</td>
<td>JMW Computers, Model 15</td>
</tr>
<tr>
<td>Quantity required:</td>
<td>One</td>
</tr>
<tr>
<td>Colour:</td>
<td>Any</td>
</tr>
<tr>
<td>Specifications:</td>
<td>The printer should produce type in English characters in a $7 \times 9$ matrix on plain bond paper. A serial interface with RS-232C connections and voltage faces should be included. A 1-metre long cable with male type ‘D’ connector at each end and straight-through pin connections should be included. The printer should print at a speed of 120 characters per second from ASCII text, should have bidirectional logic-seeking, and should include tractor drive. It should be capable of printing 132 characters per line and should accept paper up to 0.5 metre wide. It should be capable of the following variations in typeface: normal, bold,</td>
</tr>
</tbody>
</table>
underlined, superscript and subscript. Software codes must be used to change from one typeface to another.

The operating a.c. voltage (primary power) of the printer should be 220 volts, 50 hertz.

**COST ACCOUNTING**

Whereas capital budgeting is concerned with the future outcome of a decision made today, cost accounting uses past and present data to estimate and control current costs. It is concerned with operating funds rather than with capital expenditure, that is, monies spent on recurring expenses such as salaries, personnel benefits, supplies and materials, maintenance, telephones and electricity. It is designed to ensure that such expenses are kept within planned limits and that budgets are not exceeded. Additionally, as applied to the blood transfusion service, cost accounting allows the costs of units of whole blood and of blood products to be estimated.

It is sometimes claimed that the ‘true cost’ of a product (e.g. a unit of platelets) or service (e.g. a cross-match) has been calculated but such calculations are often based on a number of spurious assumptions. The cost can only be a theoretical figure, since expenses such as salaries and electricity charges must be shared by all products and services and cannot be assigned to any individual product or service. Establishing the cost of each product or service is therefore a matter of estimation, assigning to each department, product and service a fair share of the costs for which exact assignment is impossible. This type of estimation is one of the purposes of cost accounting.

Some cost accounting systems are extremely thorough and detailed, but are likely to be beyond the needs or capabilities of the smaller blood transfusion centres, which are better served by less sophisticated systems. This chapter therefore describes the principles around which a cost accounting system appropriate to the organizational complexity of the particular transfusion centre may be designed.

**Cost centres**

Fig. 16.4 illustrates a flow-chart of a transfusion centre, with outputs—for consumption by the end-user—designated as
Fig. 16.4 Blood transfusion centre flow-chart

‘products’, ‘services’ and ‘other’. The rectangular boxes represent functional elements within the transfusion centre, each of which may be regarded as a ‘cost centre’, i.e. as the smallest part of the organization for which costs are to be separately identified and controlled. Examples of cost centres are shown in Fig. 16.5; in this case there are 12 of them, but the complexity of this arrangement may be lessened by combining certain groups of centres. For instance, the five boxes at the top could be grouped as one cost centre called ‘Administration’ (this combination and title have been assumed in the remainder of this chapter). ‘Donor recruitment’ and ‘Blood collection’ could be grouped together as ‘Donor recruitment and collection’ or simply ‘Donor’.

Fig. 16.5 actually includes two distinct types of cost centre. Those that can be combined under the title ‘Administration’
provide services only within the transfusion centre itself; no fee can be charged for these services, and Administration is therefore a ‘non-revenue’ centre. All the other centres, providing services for which income-generating fees may be charged, are called ‘revenue’ centres. This distinction is made regardless of whether the transfusion centre actually makes a charge for its products and services or not; it is made solely on the basis of potential to generate revenue.

**Time units**

Revenue centres are the primary focus of the cost accounting function, and activities within the revenue centres are listed in Fig. 16.6. Each of these activities involves a certain average amount of time to produce the average output; an ABO test in the ‘Typing and testing’ centre, for example, might require an average of 5 minutes to perform. Each cost centre undertakes activities for which average personnel times can be estimated. Personnel times and costs are important in cost accounting because they represent a significant proportion of the total cost of a service or product and are used in the estimation of that cost.

A transfusion centre should therefore determine personnel times for all the activities listed in Fig. 16.6. The results should
then be grouped and totalled by output. For example, in the
‘Donor recruitment and collection’ cost centre, the time required
to produce a unit of whole blood is the sum of the average times
required to recruit a donor and to draw a unit of blood from him
or her. Fig. 16.7 provides an illustration of this, showing that an
average of 10 minutes—or 10 time units—is required by the
‘Donor recruitment and collection’ cost centre to produce each
unit of whole blood. Thus, if 100 units of blood are produced in
the period under consideration, a total of 1000 time units are
expended in the process. The actual period of time over which this
takes place should normally be recorded but is not shown here,
since it could be a single day in a large transfusion centre or
a month or more in a small centre.

Similar forms for recording production volume and times in the
‘Typing and testing’ and ‘Component preparation’ cost centres
are shown in Figs 16.8 and 16.9 respectively. (These are intended
only as suggested formats, which could be modified to include
more information where necessary.)
### Fig. 16.7 Calculation of total time units: Donor recruitment and collection

<table>
<thead>
<tr>
<th>Month:</th>
<th>Year:</th>
<th>Recorded by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost centre: Donor recruitment and collection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product or service</th>
<th>Units produced</th>
<th>Time units</th>
<th>Total time units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>100</td>
<td>10</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

100

1000

### Fig. 16.8 Calculation of total time units: Typing and testing

<table>
<thead>
<tr>
<th>Month:</th>
<th>Year:</th>
<th>Recorded by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost centre: Typing and testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product or service</th>
<th>Units produced</th>
<th>Time units</th>
<th>Total time units</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO</td>
<td>100</td>
<td>5</td>
<td>500</td>
</tr>
<tr>
<td>Rh</td>
<td>100</td>
<td>3</td>
<td>300</td>
</tr>
<tr>
<td>Antibody</td>
<td>10</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

220

1000

A modified form for the ‘Storage and distribution’ cost centre is illustrated in Fig. 16.10; the additional data recorded here allow monitoring of the quantity of each blood product in storage. The number of units in storage at the start of the recording period is noted in the ‘Opening balance’ column. Units added subsequently
Fig. 16.9 Calculation of total time units: Component preparation

<table>
<thead>
<tr>
<th>Product or service</th>
<th>Units produced</th>
<th>Time units</th>
<th>Total time units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red blood cells</td>
<td>80</td>
<td>12</td>
<td>960</td>
</tr>
<tr>
<td>Plasma</td>
<td>40</td>
<td>12</td>
<td>480</td>
</tr>
<tr>
<td>Cryoprecipitates</td>
<td>1</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Platelets</td>
<td>2</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>0</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Frozen blood</td>
<td>0</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>123</td>
<td></td>
<td>1500</td>
</tr>
</tbody>
</table>

are recorded under ‘Units added to storage’, and the time involved in handling and recording data on these units is recorded under ‘Time units storage’. Every time blood or blood components are removed from storage and distributed or discarded, data are recorded under ‘Units distributed or removed’; the time units involved in the process are also recorded. The remaining columns are for ‘Total time units’ and ‘Balance’ (i.e. the number of units remaining in storage at the end of the recording period).

Data on time expended in various processes are essential to assessing the productivity of a transfusion centre. Since one time unit is defined as one minute of productive time, a staff member working for 1 hour at 100% productivity is capable of 60 time units’ worth of output. Productivity over a given period of time is measured by dividing the output, in terms of time units, by the time worked during that period. For example, if personnel in the ‘Component preparation’ cost centre worked 500 hours in a particular month and produced 15000 time units’ worth of output during that time, their productivity was 30 time units per man-hour.

There are no hard and fast standards of productivity: each transfusion centre should establish its own standard, taking full account of staff absences for sickness and holidays. If the man-hours used in calculations are paid hours (as opposed to hours actually spent working), productivity in most organizations is unlikely to exceed 45 time units per man-hour and will generally
### Fig. 16.10 Calculation of total time units: Storage and distribution

<table>
<thead>
<tr>
<th>Product</th>
<th>Opening balance</th>
<th>Units added to storage</th>
<th>Time units storage</th>
<th>Units distrib. or removed</th>
<th>Time units distrib.</th>
<th>Total time units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryoprecip.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukocytes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frozen blood</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
be less. Moreover, it is important to remember that time units do not reflect all the work done and are therefore only a partial measure of productivity; some allowance must be made for the unmeasured work. A suitable initial productivity standard might be 35 time units per paid man-hour.

It should be remembered that setting a productivity standard that is too high can be as bad as setting one that is too low. Too high a standard may lead to errors in working practices and hence lowered quality, as well as staff dissatisfaction; too low a standard can be costly and may result in staff becoming bored.

Data about time units can also be used in estimating the number of workers needed to accomplish a particular volume of work. For instance, if 700,000 time units' worth of work must be produced in the coming year by a certain department, which works 44 hours per week, in a transfusion centre that has set 35 time units per man-hour as a reasonable productivity standard, it is possible to calculate how many staff the department will need:

- The number of required time units is divided by the standard productivity:
  \[
  \frac{700,000}{35} = 20,000 \text{ man-hours}
  \]

- The number of man-hours is divided by the annual number of hours worked by one staff member:
  \[
  \frac{20,000}{2,288} = 8.74
  \]

Thus, the department will require either eight full-time workers and one part-time or, rounding up, nine full-time workers. The latter is probably the better estimate since it would provide coverage for times of peak or emergency demand.

**Measuring the cost of cost centres**

Since labour expenses are an important element in the overall running costs of a transfusion centre, time data are important in estimating the cost of cost centres.

Revenue centres produce services and products, while non-revenue centres provide support for these activities. However, the total cost of a product or service includes not only the costs
incurred in the revenue centres but also a proportion of the costs of the supporting non-revenue centres. These are important considerations in developing budgets and controlling costs.

Three procedures are involved in determining the cost of cost centres:

- accumulation;
- allocation;
- reapportionment.

Accumulation

Accumulation is the process of identifying, as far as possible, all costs that are directly associated with a given cost centre. Identification of labour costs provides an example. Some staff members may work in more than one cost centre, in which case their salaries can be divided between cost centres on the basis of the estimated percentage of their time spent in each.

Accumulation is also concerned with the cost of direct supplies, i.e. supplies and materials that are used only for specific purposes, such as particular reagents used only in the ‘Typing and testing’ cost centre.

Allocation

Many costs cannot be accumulated. Electricity costs are an example; it is impossible to identify the proportion of the transfusion centre’s total electricity consumption that has been used by each cost centre.

However, a quantifiable basis must be found for allocating fair shares of the cost, and this should generally have some causal relationship to the nature of the expense. In the case of electricity, charges are usually related to the floor area occupied by each cost centre; thus a cost centre that occupies 10% of the transfusion centre’s total floor area will normally be allocated 10% of the total electricity costs. There will inevitably be inequities in this system; a small but highly sophisticated laboratory, for instance, may consume a disproportionate amount of electricity.

The cost of indirect supplies is similarly allocated. Such items as soap, towels, and pencils may be considered as indirect supplies. To accumulate the cost of these items (and thus to treat them as direct supplies) would involve maintaining an extensive—and expensive—supply inventory system. A suitable basis for
allocating costs to the various cost centres is therefore the percentage of time units produced by each cost centre.

The form illustrated in Fig. 16.11 may be used for both accumulation and allocation of costs by cost centre. It would be useful to add a footnote to the form, explaining the basis for any allocation of costs.

Note: The cost of containers for whole blood and blood products should not be included in the accumulation of supplies and materials. It is added as a final step in the determination of costs.

Reapportionment

There are two parts to the process of reapportionment. First, the cost of the non-revenue centres is assigned to revenue centres on a 'fair shares' basis similar to allocation. Thus the cost of each revenue centre is composed of its own expenses plus a share of the cost of support by the non-revenue centres. This process removes

**Fig. 16.11 Accumulation and allocation**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benefits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional services</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Direct supplies</td>
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<td></td>
</tr>
<tr>
<td>Indirect supplies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buildings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport &amp; postage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telegraph &amp; telex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Financial considerations

all costs from the ‘Administration’ (non-revenue) centre by distributing them among the various revenue centres.

The second part of the reapportionment process takes account of the work (and associated costs) ‘flowing’ through the transfusion centre, from the drawing of blood from donors to the distribution of whole blood and blood products. As the products ‘flow’ through the transfusion centre, the costs associated with them must also move, so that the cost of the end products includes all the costs of processing. The steps involved in this procedure are inherently fairly simple but must be described at some length for the sake of clarity.

A suggested form for the reapportionment process is shown in Fig. 16.12. The left-hand column (column 1) lists the various cost centres, and column 2 shows the total costs of each cost centre after accumulation and allocation (derived from the bottom line of Fig. 16.11).

Columns 3, 4 and 5 are employed in dividing the costs of the non-revenue ‘Administration’ cost centre among the revenue centres. Column 3 records the percentage of service provided by the ‘Administration’ centre to each revenue centre. This is calculated on a basis similar to that of allocation and is generally related to the nature of the administrative service provided—in this case generally one of supervision of staff and activities. Reapportionment of costs may therefore logically be based on the percentage of staff working in each revenue centre.

Note: In calculating staff percentages, staff actually employed within the Administration cost centre should be excluded from the total.

The next step is to multiply the first entry in column 2 (labelled ‘A’ in Fig. 16.12), which represents the total costs of the ‘Administration’ centre, by each of the percentages recorded in column 3. The results, which are the administrative costs reapportioned to each revenue centre, are recorded in column 4.

The final step in reapportioning administrative costs is to add the figures in column 2 to those in column 4. Results are recorded in column 5 and represent the cost of each revenue centre plus the cost of its administrative support.

Because a transfusion centre produces not only services but products as well, there is a further stage to the process of reapportionment. Whole blood drawn from recruited donors is passed to the ‘Typing and testing’ cost centre, from which it emerges as ‘resource blood’. Since all other blood products are
### Fig. 16.12 Reapportionment

<table>
<thead>
<tr>
<th>Cost centre</th>
<th>Accumulation &amp; allocation costs</th>
<th>%</th>
<th>Administrative reapportionment</th>
<th>Resource blood reapportionment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td>Administrative</td>
<td>A</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Donor</td>
<td>-----</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Typing and testing</td>
<td>-----</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>SUBTOTAL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>Component preparation</td>
<td>-----</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>Storage</td>
<td>-----</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>TOTAL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>
derived from this resource blood, it may be regarded as the raw material for the products of the transfusion centre. The value of resource blood is represented by the costs incurred in processing it through the cost centres. Thus the value accumulated in the ‘Donor recruitment and collection’ and the ‘Typing and testing’ cost centres must be re-apportioned to the ‘Component preparation’ and ‘Storage and distribution’ cost centres. This allows costs to ‘follow’ the product through its processing. Columns 6, 7 and 8 of Fig. 16.12 are concerned with this procedure.

The first step is to determine the average percentage of resource blood that remains as whole blood. This figure is recorded in column 6 against the entry ‘Storage’, meaning that this percentage of resource blood is stored, and later distributed, as whole blood, incurring no further processing costs. The remaining percentage of resource blood is also recorded in column 6, against the entry ‘Components’, signifying that it is subjected to further processing before being stored and distributed as blood components. The two percentages, which must obviously add up to 100%, may be estimated or determined from the transfusion centre’s records.

**Calculating the cost of blood and blood products**

Once the cost of the cost centres has been established by the procedures described above, it becomes possible to estimate the total cost of the blood and blood products produced by the transfusion centre. However, calculations are complicated by the fact that 100 units of whole blood will yield more than 100 units of blood products. Fig. 16.13 illustrates this. Average production figures should be used in completing a figure of this type, and it should be noted that the percentages for all components must add up to 100%.

The component percentages, referred to in the remainder of this chapter as ‘component proportions’, are used to allocate costs to the components. Fig. 16.14, which lists the calculations and data required to determine the time taken for each of the activities in the cost centres, is used in conjunction with Fig. 16.13 in estimating the total costs of blood and blood products.

*Step A* in Fig. 16.14 involves the calculation of the total time taken in the Donor recruitment and collection cost centre to produce a unit of whole blood. The necessary data must be taken from records made over a specified period of time, e.g. the
Management of blood transfusion services

Fig. 16.13 Component proportions

100 units of whole blood will yield the following:

<table>
<thead>
<tr>
<th>Component</th>
<th>Units</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red blood cells</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Cryoprecipitates</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Leukocytes</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>100</td>
</tr>
</tbody>
</table>

**OR**

<table>
<thead>
<tr>
<th>Product</th>
<th>Units</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**OR**

<table>
<thead>
<tr>
<th>Product</th>
<th>Units</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen blood</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Fig. 16.14 Total time units required for whole blood and blood products

<table>
<thead>
<tr>
<th>Step</th>
<th>Cost centre</th>
<th>Product</th>
<th>Calculation</th>
<th>Time units</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Donor recruitment and collection</td>
<td>Whole blood</td>
<td>Total man-hours (units prod.) × 60</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Typing and testing</td>
<td>Tested blood</td>
<td>ABO minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rh minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antibody minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other, minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total minutes</td>
<td>=</td>
</tr>
<tr>
<td>C</td>
<td>Component preparation</td>
<td>Red blood cells</td>
<td>RBC minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Plasma minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cryoprecipitates</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Platelets</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Leukocytes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Frozen blood</td>
<td>=</td>
</tr>
<tr>
<td>D</td>
<td>Storage and distribution</td>
<td>1. Storage</td>
<td>Storage minutes</td>
<td>=</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Distribution</td>
<td>Distribution minutes</td>
<td>=</td>
</tr>
</tbody>
</table>

previous year. The number of man-hours expended in the cost centre is then divided by the total number of units of whole blood produced over the same period, and the result is divided by 60 to provide a production time in time units of 1 minute.
Step B is a similar calculation for the ‘Typing and testing’ cost centre and yields production time units for one unit of typed and tested blood. In this case, however, not all blood is subjected to all tests, and the calculation must be ‘weighted’ to allow for this. For example, if a particular test requires 5 minutes, but only 50% of blood units are subjected to that test, the weighted production time is 2.5 time units (i.e. 50% of 5 minutes). The times taken for all tests on one unit of blood must then be totalled to yield the time units for the ‘Typing and testing’ cost centre.

In step C, time units are separately calculated for each component produced in the ‘Component preparation’ cost centre.

Step D, calculation of time units for the ‘Storage and distribution’ cost centre, involves two elements that can be referred to as D1 and D2. Step D1 involves calculating the time taken by a worker to receive the blood or blood product, record its receipt, and place it in storage; D2 yields the time taken to remove the blood or blood product from store, record its removal and implement its distribution.

After completion of steps A to D, it is possible to calculate the total labour time for producing a unit of whole blood or a unit of blood component as follows:

- For whole blood:
  total time units = A + B + D1 + D2

- For a blood component:
  total time units = (component proportion) \times (A + B + C + D1 + D2)
  where the component proportion is derived from Fig. 16.13.

Knowledge of the total labour time then allows the cost per unit of whole blood to be estimated by the following procedure:

1. The cost of the ‘Storage and distribution’ cost centre (from Fig. 16.12) is divided by the total time units for storage and distribution (from Fig. 6.10).
2. The result of step 1 is multiplied by the time units for storage (from step D1 above).
3. The result of step 1 is also multiplied by the time units for distribution (from step D2 above).
4. Total cost of the unit of whole blood is then the sum of: step 2 + step 3 + cost of container.

Estimation of the cost of a unit of blood component follows a similar procedure:
(1) The cost of the ‘Component preparation’ cost centre (from Fig. 16.12) is divided by the total time units for component preparation (from Fig. 16.9).
(2) The result of step 1 is multiplied by the total time units for preparation of the component in question (from step C above).
(3) The cost of the ‘Storage and distribution’ cost centre (from Fig. 16.12) is divided by the total time units for storage and distribution (from Fig. 16.10).
(4) The result of step 3 is multiplied by the total time units for storage (from step D1 above).
(5) The result of step 3 is also multiplied by the total time units for distribution (from step D2 above).
(6) Total cost of a unit of blood component is then the sum of: step 2 + step 4 + step 5 + cost of container.

The process of estimating the cost of the blood and blood components produced by the transfusion centre is then complete.
Chapter 17
Use of computers in the blood transfusion service

F. Olti

GENERAL CONSIDERATIONS

The growing demand for improving the efficiency, accuracy and effectiveness of blood transfusion services and the generally decreasing price of computer hardware make the introduction of computers into blood transfusion centres almost inevitable. It should be stressed, however, that the price of software is increasing proportionally, and may form the major part of the cost involved. Each transfusion service must make its own selection of organizational philosophy and appropriate hardware. This chapter discusses some proposals for defining the tasks and choosing the computer, based on the recommendations of the International Society of Blood Transfusion (ISBT) Working Party on Automation and Data Processing.

The main areas in which the computer can help the management of a transfusion centre are:

- donor administration;
- blood collection;
- blood processing;
- inventory management;
- blood distribution.

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1 Head of Computing Services, National Institute of Haematology and Blood Transfusion, Budapest, Hungary.
Management of blood transfusion services

The computer can be used effectively where fast and accurate storage and retrieval of information are needed, especially in connection with the following activities:

- all aspects of donor administration;
- grouping and testing of blood, and recording of test results;
- processing the tested blood and recording details of processing;
- labelling blood product bags with processing details;
- checking blood products into and out of inventory and maintaining records of status and movements;
- distributing blood products to users, and recording relevant details for billing purposes.

Use of a computer demands suitably trained staff to work at the terminal stations, to read the simple questions from the screen and enter the answers on the keyboard, or to enter questions on the keyboard and read and record the computer’s answer. This type of work requires only literacy and a disciplined approach. However, optimal use of a computerized system also requires a number of highly qualified professionals who are fully conversant with blood banking and management, computer hardware and software, business procedures and other activities of a transfusion centre. Thus, the introduction of a computer into an existing blood transfusion service can simplify a number of tasks but necessitates the creation of one or more additional senior posts, and this may cause conflict among personnel.

To introduce a computer into a blood transfusion centre it is necessary to:

- define the tasks, the main features required of the application software, the predicted amount of data, and the location of inputs and outputs;
- characterize and purchase the hardware and basic software;
- modify or elaborate the application software.

Management may not always be free to follow this course, and may frequently have to reach decisions on hardware before choosing software. In this case, a better solution might be to purchase a complete management system (software and hardware), designed for a transfusion centre and available as a commercial package.
GUIDELINES FOR ACTION

If a transfusion centre has the financial resources available to buy hardware, and the infrastructure will support the efficient operation and maintenance of a computer system, the definition of tasks is the most important step in the planning of computer application.

One approach to defining the tasks and main essential features of the application software is to establish a working group, headed by someone with appropriate experience in computer systems and comprising representatives of the concerned departments of the transfusion centre. This working group should determine the type of information needed by each department and the information it can supply. This will clarify the contents of the various data bases and the need for connections with the other data bases and the departments.

If financial resources are severely limited, the task of the working group becomes very difficult. It may need to decide first on the type and capacity of the affordable hardware, and then on the tasks that it is capable of undertaking; ideally these tasks should still include donor administration, recording of blood grouping and test results, and labelling.

Characterization of hardware and basic software

Computer hardware consists of three main elements:

- the central processor unit (CPU);
- the backing stores, mainly discs; and
- terminal workstations.

The capacity of a central computer system depends on the type of machine, on the basic software to be used, and on the organization of the work. For a blood transfusion centre it is important to consider the amount of data to be stored for each donor, and the volume of possible future workloads. The number and location of terminals depend on the structure and needs of the organization.

The price of a central computer system will vary with quality, capacity and manufacturer. A significant factor in the choice of system will be local availability of reliable and immediate servicing.
Basic software usually consists of:

- the operating system;
- high-level programming language;
- different algorithm libraries;
- data base management and other systems.

The more flexibility the basic software has, the easier elaboration of the application software becomes; this is an important factor in the choice of computer type. During elaboration of the application software, a critical review of the tasks to be computerized is often valuable. Flexibility in approach can dramatically facilitate software assembly.

Where installation of a central computer system proves impossible, it may still be feasible to use microcomputers, the costs of which are relatively low, to solve particular problems. The microcomputer (or personal computer) consists of a central processor, a keyboard, a screen, and usually a built-in disc-drive; various options exist for peripheral connections. The capacity of the central processor unit and of the disc varies widely. Using microcomputers has the disadvantages that the data files of different installations are not linked, so that transfer of data between departments remains manual, and the management of the transfusion centre cannot make quick surveys of the inventory and operations. However, microcomputers are able to:

- control laboratory instruments, and analyse, store, and print out the results;
- store and retrieve special donor data;
- help with inventory control;
- store and retrieve blood-grouping and test results.

Nevertheless, they are no substitute for a central computer system, although they can ultimately be connected to such a system and thus act as terminals.

Elaboration of application software

While the formulation of tasks and information channels is the duty of the working group of transfusion specialists, elaboration of the application software, i.e. the writing of different programmes, needs programming experience and specialized
knowledge of the hardware and software. It is difficult, if not impossible, to ‘translate’ the demands of the transfusion centre into the language of a pure software expert. There are two ways of tackling this problem: either a member of a transfusion centre staff learns enough about computers and programming to be able to write the programmes, or a software expert learns about blood transfusion activities.

The first solution is preferable but difficult to accomplish. It is generally easier to find an open-minded software group prepared to learn the principles and procedures of the blood transfusion service. It then becomes important to build up good personal relationships between the staff of the transfusion centre and the program writers, and to have one member of the centre’s staff whose defined responsibility is liaison between his or her colleagues and the programmers.
Chapter 18

The role of international organizations in blood transfusion

F. Lothe

The international organizations dealing directly with the promotion of blood transfusion services and the problems involved are the International Society of Blood Transfusion (ISBT), the League of Red Cross and Red Crescent Societies (LORCS) and the World Health Organization (WHO). The International Federation of Blood Donor Organizations (IFBDO), International Society of Haematology (ISH), International Society for Thrombosis and Haemostasis (ISTH) and the World Federation of Haemophilia (WFH) deal with special aspects of blood transfusion, while the International Committee for Standardization in Haematology (ICSH) and the International Organization for Standardization (ISO) are concerned with aspects of standardization within blood transfusion practice. The Council of Europe also deals with blood transfusion problems, but has a restricted geographical representation. International organizations that may be a source of funding for special projects include the United Nations Development Programme (UNDP), the United Nations Children’s Fund (UNICEF), the United Nations Industrial Development Organization (UNIDO), and the World Bank.

Generally speaking, most of the resources for development of blood transfusion services must be generated within the countries themselves. While the word ‘resources’ may be taken to mean

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initial and recurrent expenses, it also means technical expertise, information and reference services. The latter group of resources may be made available fairly easily, but the provision of major funding requires fulfilment of the conditions specified by the funding agencies. Thus, sound, well-formulated proposals are usually required which are later embodied in detailed project documents.

Such projects should be a logical part of national health plans, and it should be within the resources of any country concerned to continue the service or activity after external cooperation has ceased.

Note: Further information on contacting the organizations discussed in this chapter can be obtained from Health Laboratory Technology and Blood Safety, World Health Organization, 1211 Geneva 27, Switzerland, or from the Head of the Blood Programme, League of Red Cross and Red Crescent Societies, P. O. Box 372, 1211 Geneva 19, Switzerland.

INTERNATIONAL SOCIETY OF BLOOD TRANSFUSION

ISBT is a scientific society consisting of individual members, national societies and regional divisions. Its objectives are as follows:

- to maintain and promote high technical and ethical standards;
- to contribute to the extension of knowledge in the field of blood transfusion and related disciplines;
- to provide opportunities for the presentation and discussion of research and development in these fields;
- to facilitate exchange of information between members.

To achieve these ends, international meetings are organized, notably the International Congress, and usually include some training opportunities as well as scientific sessions. Other promotions include the publication of the journal *Vox sanguinis*, a newsletter, educational guides on a variety of subjects, the establishment of a code of ethics, studies on socioeconomic aspects of blood transfusion, automation and data processing, and the formulation of recommendations for an international nomenclature of blood groups.
Close collaboration is maintained with LORCS and WHO in the field of training; joint training courses are held and joint documents prepared. Collaboration with other international organizations, such as ISH and ICSH, is increasing.

**LEAGUE OF RED CROSS AND RED CRESCENT SOCIETIES**

The LORCS has a blood programme department, and the Secretariat in Geneva is supported and guided by an International Group of Red Cross Blood Transfusion Experts. The League generally works through, and in collaboration with, the national Red Cross and Red Crescent Societies.

In more than 20 countries these societies have a national blood programme that covers most or all of the needs for blood and blood products. An additional 35 national societies have one or more blood centres, and participate in the collection, processing, storage and distribution of blood. Most of the 136 member societies of the LORCS are actively engaged in recruitment of voluntary unpaid donors.

The main purpose of the blood programme of LORCS is to promote voluntary, nonremunerated blood donation throughout the world, taking note of the principles expressed in the “Code of ethics for blood donation and transfusion” formulated by the International Society of Blood Transfusion (see Appendix to Chapter 15).

The services of the LORCS include:

- giving assistance to national societies in the establishment and development of blood transfusion services;
- encouraging regional cooperation in the field of blood transfusion;
- maintaining liaison with different international organizations, notably WHO and ISBT;
- arranging training, seminars, conferences, and other educational activities for the staff of blood transfusion services;
- providing information to National Societies and other voluntary blood transfusion services and to the public.

News of Red Cross activities, as well as information on events and progress in the field of blood transfusion, are provided in the newsletter *Transfusion international.*
The role of international organizations

WORLD HEALTH ORGANIZATION

The basic principles of WHO's role in the field of blood transfusion are expressed in resolution WHA28.72, in which Member States are urged:

- to promote the development of national blood services based on voluntary nonremunerated donation of blood;
- to enact effective legislation governing the operation of blood services and to take other action necessary to protect and promote the health of blood donors and of recipients of blood and blood products;

and in which the Director-General of WHO is requested:

- to increase assistance to Member States in the development of national blood services based on voluntary donations, when appropriate in collaboration with the LORCS;
- to assist in establishing cooperation between countries to secure adequate supplies of blood and blood products based on voluntary donations;
- 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.

Furthermore, current WHO policy in general gives priority to the promotion of peripheral services, rural development and self-sufficiency in support of primary health care in the context of the overall goal of Health for All by the Year 2000. Accordingly, the provision of an adequate supply of whole blood on a countrywide basis is a priority in the development of blood services. The principle of self-sufficiency is observed whenever practicable. Training has high priority and tends to be organized in collaboration with LORCS and ISBT.

A booklet on the collection, fractionation, quality control, and uses of blood and blood products has been published, and international reference preparations and reagents are established and available upon request.

Requests for established WHO international reference preparations or reagents, free of charge for the control of national reference preparations, may be made through WHO or the appropriate collaborating laboratory (see Appendix to Chapter 10).
INTERNATIONAL FEDERATION OF BLOOD DONOR ORGANIZATIONS

The Federation is concerned with the promotion of voluntary, nonremunerated donation of blood, international exchange of information and provision of news in the field of blood transfusion through their three-monthly publication.

The Federation is most active in such European countries as Belgium, France, Italy and Spain and in the countries of South America.

INTERNATIONAL SOCIETY OF HAEMATOLOGY

The ISH is organized on a geographical basis and thus has American, Asian-Pacific and European-African Divisions, which also take turns in being responsible for the overall administration of the Society. A particularly important function is to promote, and give guidance in, the training of haematologists. Other activities comprise facilitating international exchange of information through a newsletter, scientific publications, the organization of international meetings, and the promotion of research, standardization (including nomenclature) and evaluation of methods. Standardization is carried out through the International Committee for Standardization in Haematology.

INTERNATIONAL SOCIETY OF THROMBOSIS AND HAEMOSTASIS

As its title suggests, ISTH is concerned with all aspects of thrombosis and haemostasis. Its activities comprise facilitating international exchange of information through a newsletter, scientific publications and the organization of international meetings, the promotion of training, and the coordination of research and standardization.

The technical aspects of the Society’s work are assured by the International Committee on Thrombosis and Haemostasis, which deals particularly with questions such as standardization (including nomenclature) and evaluation of methods. In this function, close relations are maintained with the International Committee for Standardization in Haematology.
WORLD FEDERATION OF HAEMOPHILIA

This Federation has as its objectives to assist haemophiliacs and persons with related disorders in every possible way, and to contribute by all means to the solution of scientific, technical, social and ethical problems related to such disorders. WFH promotes the establishment of national haemophilia societies and provides some training in this field, including the preparation of cryoprecipitate at national level for the treatment of haemophilia. Information regarding activities in this field is provided through a twice-yearly bulletin.

INTERNATIONAL COMMITTEE FOR STANDARDIZATION IN HAEMATOLOGY

The ICSH is responsible for standardization in the field of blood transfusion as well as in haematology. Its functions are to promote and encourage improvements in methods and standards, to maintain a forum for communication among international organizations, and to promote improvements of laboratory functions in haematology and blood transfusion. The term 'standards' relates to specifications for biological and chemical reagents or reference preparations, to reference methods or reference procedures, to systems of nomenclature and classification, to operating methods, controls and calibrators for equipment and test procedures, and other relevant matters.

Much of the work is conducted through expert panels, task forces and standing committees in various special fields, which make recommendations for procedures and standards. These are subsequently published in international journals.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

This organization is concerned with the development of definitions and specifications for quality and performance of equipment and materials. The work is carried out through a series of international committees dealing with special fields. Committee ISO/TC76 deals with transfusion, infusion and injection equipment for medical use and thus with bottles and plastic bags with fixtures and connections for blood transfusion.
Management of blood transfusion services

and infusions. Committee ISO/TC84 is concerned with syringes for medical use and needles for injections.

COUNCIL OF EUROPE

The Council of Europe has a Committee of Experts on Blood Transfusion and Immunohaematology, which deals with a wide variety of questions in these fields through a series of subcommittees. The activities include the establishment of:

- rules for international exchange of blood and blood products;
- European Bank of Frozen Blood of Rare Groups, in Amsterdam;
- recommendations on quality control, histocompatibility, training, use of blood and blood products, and prevention of transmission of disease through transfusion;
- standards for therapeutic blood products and reagents;
- coordination of research, and organization of training courses and symposia.
- preparation of documents based on experiences in various European countries on various subjects in the field of blood transfusion;
- organization of training courses on various subjects in the field of blood transfusion.

Participation in these activities is limited to Europe, but the rules, standards and recommendations have much wider application.
Selected reading


DUNCAN, C. Correspondence course on budgeting. I. Budgeting manpower. Atlanta, Centers for Disease Control, 1978.


