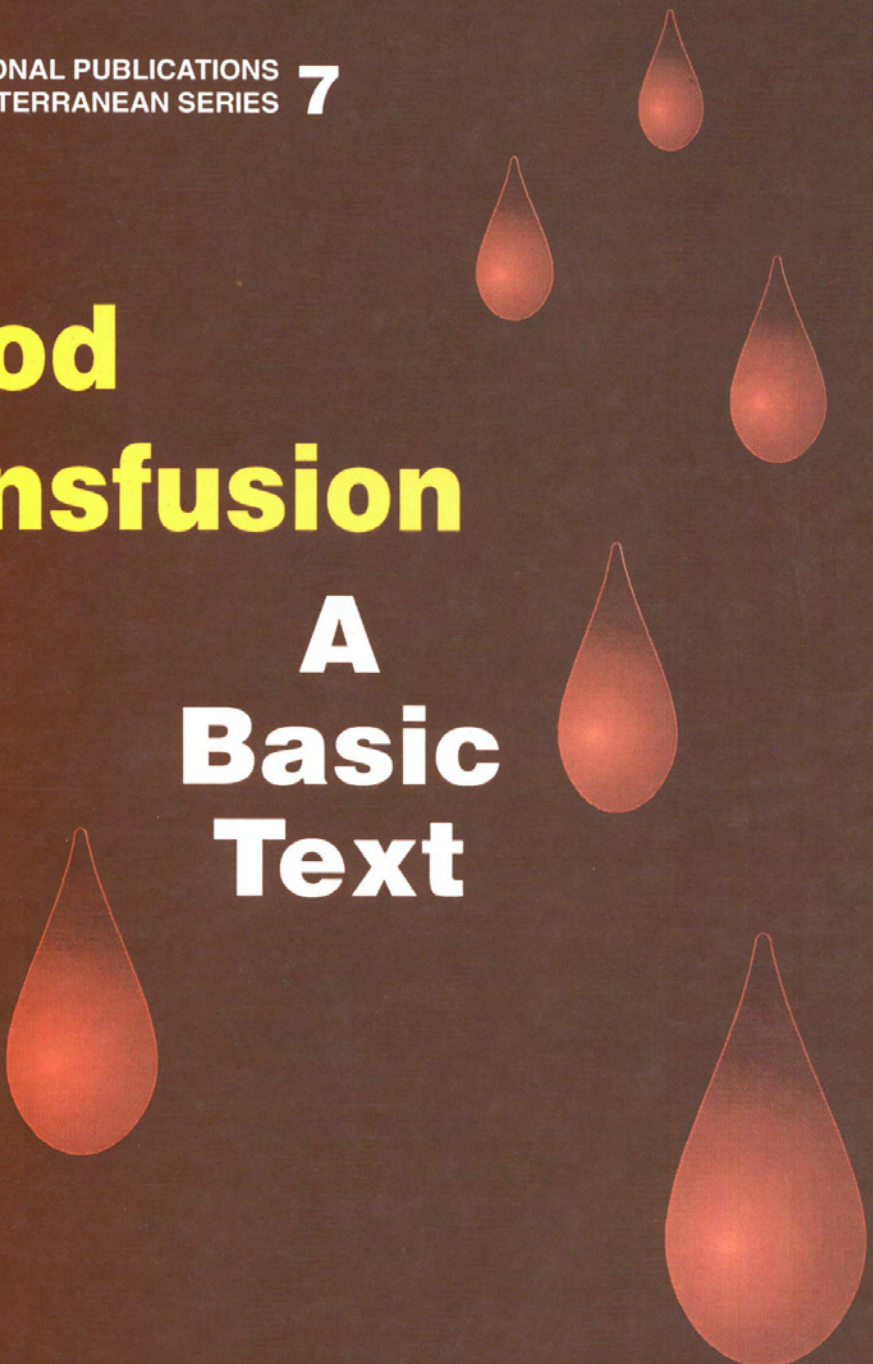
WHO REGIONAL PUBLICATIONS
EASTERN MEDITERRANEAN SERIES 7

Blood Transfusion

A Basic Text



WORLD HEALTH ORGANIZATION
Regional Office for the Eastern Mediterranean

WHO REGIONAL PUBLICATIONS, EASTERN MEDITERRANEAN SERIES 7

Blood Transfusion A Basic Text

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1994

WHO Library Cataloguing in Publication Data

Blood Transfusion: A Basic text. /
editors, Britten, Anthony F. H., Fereydoun, A. and El-Nageh, Mohamed M.

p. 184 (WHO Regional Publications, Eastern Mediterranean Series ; No. 7)
1. Blood transfusion 2. Textbooks I. Britten, Anthony F.H.,
II. WHO Eastern Mediterranean Regional Office

ISBN 92-9021-181-4 (NLM Classification: WB 356)
ISSN 1020-041X

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FOREWORD

One of the main goals of the International Society of Blood Transfusion (ISBT) is to ensure a strong and continuing educational element within the speciality of transfusion medicine. The ISBT provides educational programmes in biannual International and Annual Regional Congresses. The series of intercountry workshops organized by the Eastern Mediterranean Office of the World Health Organization, including intercountry workshops supported by the Arab Gulf Funds for the United Nations Development (AGFUND) and conducted in Amman, Jordan, emphasizes and perpetuates this commitment by providing ideal forums for this purpose.

The core of the topics dealt with at these workshops (contributed by WHO staff and international experts) is placed into this user - friendly manual. The text gives essential practical details whilst recognizing the variations in importance of procedures in different countries, in the available facilities and resources, and in the levels of education and training of staff.

There is much valuable information for those developing their blood transfusion service, or reviewing their own blood bank practices, which would contribute directly to upgrading technical expertise among blood bank colleagues.

The manual covers the fields of motivation of blood donors, blood collection quality assurance in blood transfusion, organization and management of a blood transfusion service, and case studies with suggested solutions. This pulication should prove most useful as an educational tool and for reference work.

S. Leong
President
International Society
of Blood Transfusion

PREFACE

Recent situation analyses of blood transfusion services in countries of the Region have shown that there is a need to develop and improve blood transfusion service. A meeting held in Riyadh, Saudi Arabia in April 1984, brought together the Directors of National Blood Transfusion Services from the Eastern Mediterranean Region and served to bring into focus the development needs for blood transfusion as well as inspiring the creation of a fund for the development of blood transfusion in the Region. Resources for this fund were provided by the World Health Organization and the Arab Gulf Programme for UN Development Organizations (AGFUND).This has been the source of support for a series of workshops and other activities aimed at the development of blood transfusion services.

In May 1987 a planning meeting was held at the World Health Organization's Regional Office for the Eastern Mediterranean (EMRO) in Alexandria, Egypt, involving representatives from the World Health Organization, the League of Red Cross and Red Crescent Societies, representatives of countries from the Region and international consultants with deep-rooted interests in the Region. These discussions provided the foundation for a series of workshops held in Amman, Jordan from 1989 onwards, the proceedings of which have been published by EMRO [1,2,3].

The financial support of AGFUND is gratefully acknowledged. Without this generous backing there would have been little progress with this project. The continuous support and encouragement of Dr H. Gezairy, Regional Director WHO/EMRO, and of Dr M. Khayat, Director, Programme Management WHO/EMRO, was essential for the initiation and maintenance of this effort.

The generosity and warm hospitality of the Jordanian Government and the support of staff of the Jordanian National Blood Transfusion Service contributed to the success of the workshops. The active participation of, and the warm welcome extended to participants by Dr Janiet Yousef Mirza is gratefully acknowledged. The contributions of a number of international faculty members provided the foundation for this text. Without the breadth and vision of this outstanding group, this text would have been incomplete, at best.

INTRODUCTION

This book is the result of an initiative on the part of the Eastern Mediterranean Regional Office (EMRO) of the World Health Organization (WHO), which is concerned with the need to develop blood transfusion services in the Region, and with the need of existing blood transfusion services to keep pace with the rapid technical development of health care services. The content reflects material presented by international experts and WHO staff during a series of workshops, conducted by WHO/EMRO and supported by AGFUND in Jordan.

The intention has been to build upon the substance of the presentations during the workshops and to turn this material into a unified readable text. The reader should have at least an elementary knowledge of blood transfusion technology. The content is derived from needs which are specific to the Eastern Mediterranean Region, but it is hoped that it will be of sufficiently general interest to adapt it easily to other regions of the world.

The choice of the main topics for the workshops required careful consideration. There is already an extensive body of scientific literature in the field [4,5] and covering the full range of technical subspecialities would have been repetitive and time-consuming. It was thought important to identify those topics which would focus on essential areas in which difficulties are commonly encountered. After much discussion, three broad areas were identified. These were the subjects for the first three workshops and constitute the core of the book: organization and management, blood donor motivation and blood collection, and quality assurance. It was felt that these three broad areas accounted for the principal weaknesses in national blood transfusion services in the Region and that any blood transfusion organization which had resolved its problems in these three areas would be able to operate effectively. The workshop format was not thought to be suitable for laboratory technology subjects. It was felt that these essential skills could best be learned on the job or, in selected cases, by well planned intercountry training programmes.

Annex 1 contains a glossary of useful terms and abbreviations encountered in the text. Annex 2 reproduces the recommendations of the three workshops held in Jordan and Annex 3 reproduces World Health Assembly Resolution WHA 28.72 pertaining to blood and blood products. Annex 4 summarizes the role of WHO and some international organizations in the field of blood transfusion. Annex 5 provides suggested solutions to questions posed in a series of case studies presented throughout the text, which it is hoped, will be of use to the reader. Annex 6 contains the original Arabic text of Dr. Sartaway's presentation.

1. Blood transfusion

1.1 A brief history

The association of the shedding of blood with death is deeply rooted in the earliest writings; fear of bleeding is a natural reaction which comes instinctively to all. Inversely, the concept of treatment with blood and its value has been more difficult to assimilate, as it has become confused by the many intellectual and technical hurdles which have had to be overcome. The widespread practice of therapeutic bleeding has not contributed positively to the idea of transfusing blood into a patient.

The earliest known therapeutic attempt at blood treatment was an effort to save the life of the dying Pope Innocent VIII in 1492 by having him drink the blood of three healthy boys. The three donors died, as did the Pope. In 1615 Libavius proposed a technique for artery-to-artery administration of blood for the treatment of a patient "exhausted in strength, weak, enervated, scarcely breathing". This was before Harvey's description of circulation, published in 1628. The first transfusion into an animal was performed by Lower in 1665; in 1667 Jean-Baptiste Denis performed the first transfusion into a human patient, using the blood of a lamb. In a subsequent experiment a patient received blood from a calf and later received a second transfusion from the same source. An unpleasant reaction ensued, with "a plentiful sweat ... and ... great pain in his kidneys" [6]. This important description of the world's first haemolytic transfusion reaction set the stage for the struggle, still with us today, to find the right balance between life-saving transfusion and life-threatening complications of transfusions gone wrong. After the death of one of Denis' patients, transfusion was discouraged in France; it was 150 years before Blundell made the first successful blood transfusion from one human to another [7]. Attempts to emulate his life-saving procedure led to some successes and many unexplained failures. It was not until Landsteiner's discovery in 1900 of what we now know as the ABO groups [8], that there was a rational explanation for incompatibility and haemolysis following transfusion.

The discovery of sodium citrate as a safe and effective anticoagulant [9] opened the way to the storage of blood after collection from the donor, the essential precursor to the concept of blood banking, first put into practice in 1917 [10]. The first organized blood donor service followed in 1921 [6] and by the 1930s a number of blood banks had opened although most transfusions continued to be of the 'direct' variety, with the donor lying next to the patient. A well-known complication of these early blood transfusions was the transmission of syphilis, a factor which led to the routine serological screening of blood donors for syphilis.

Discovery of the rhesus groups by Landsteiner in 1940 [11] provided an explanation for previously mysterious haemolytic reactions in occasional blood recipients, and opened

the way to prevention and treatment of haemolytic disease of the newborn. The resulting techniques for red cell antibody detection quickly led to recognition of many new blood group antigen systems and introduced the possibility of reliable cross-matching of patient and donor blood.

The Second World War provided the impetus for the first large scale blood transfusion service. Furthermore, the parallel development of plasma fractionation techniques [12] permitted the preparation of safe and stable albumin solutions for large-scale military use. The success of battlefield resuscitation and surgery was one of the great medical advances of the Second World War. This lesson was well learned and new blood transfusion services sprang up throughout the industrialized world in the late 1940s, the first large-scale blood collection organizations for civilian use. The occurrence of occasional outbreaks of hepatitis among the troops was not widely recognized at that time as a manifestation of a serious potential threat to the safety of blood transfusion in civilian life.

Since that time the principal impact upon blood transfusion services (BTSs) has been one of scientific refinement as knowledge has increased, coupled with substantial growth in the size, cost and complexity of the major blood collection organizations. Important advances included the recognition that 'fresh' plasma was useful in the treatment of haemophilic bleeding, that exchange transfusion could prevent kernicterus in newborns afflicted with haemolytic disease and that several hundred different red cell antigens could be implicated in transfusion incompatibility, but none so important as ABO and Rh. Other advances included the discovery that plastic blood collection containers reduced bacterial contamination to acceptable levels and facilitated the centrifugation of blood for separation of plasma and other components; that plastic containers permitted the simple removal of plasma from donor blood and reinfusion of the red cells (plasmapheresis [13]) and that plasmapheresis made it possible to collect large volumes of plasma for fractionation; that it was possible to prepare four basic components from donations of whole blood (red cells, plasma, platelets and cryoprecipitate) and that the systematic use of this technology (component therapy) would become the cornerstone of modern blood banking; that the postpartum treatment of Rh(D)-negative mothers could prevent sensitization to the D antigen and go far towards elimination of the problem of haemolytic disease of the newborn.

The discovery of the 'Australia antigen, now known to be associated with hepatitis B, heralded a new era in blood transfusion; specific tests were introduced in the early 1970s to detect donors carrying the hepatitis B surface antigen (this was to be the second of a growing number of screening tests for transmissible infections). After a slow start, and the gradual realization that hepatitis B was not the only transfusion transmissible hepatitis virus, the late 1980s saw the introduction of several new tests intended to detect donor infections capable of being transmitted to the recipient(s) of their blood [human immunodeficiency virus (HIV), human T-cell lymphotrophic virus type I/II (HTLV-I/II), hepatitis C]. The impact of AIDS was an important stimulus to these advances. Furthermore, the insensitivity of existing tests for non-A/non-B hepatitis has led to the use

of surrogate tests such as tests for liver enzymes and the antibody to the hepatitis B core antigen. Thus, in the last few years the number of routine screening tests has increased from two to seven, sharply increasing the complexity and cost of operating a BTS. There is every reason to believe that this trend will continue.

Technological refinements have now been made in several areas. Improved storage solutions for red cells have extended the shelf-life of red blood cells from 21 days (ACD), to 28 days (CPD), to 35 days (CPD-A1), to 42 days (additive solutions, mixed with red cells after the removal of plasma). Various techniques (most notably filtration) are being explored for removal of leukocytes from red cells and from platelet products. HLA-typing is increasingly used for selection of platelet donor. These histocompatibility methods are leading BTSs inexorably into deeper involvement with bone-marrow transplantation. BTSs are using the techniques they have learned for plasmapheresis and cytapheresis to undertake therapeutic apheresis and intraoperative blood salvage [14].

In spite of the vast experience available from many countries, there is little agreement on how best to organize a blood transfusion service. The major programmes, arising out of the wave of enthusiasm in the 1940s, have changed little in their basic organization. It appears that local needs and social structures play an important role in such complex organizations and that there is no single 'right way' to do it. This topic is discussed in more detail in 2.2.

1.2 Present situation

Blood transfusion currently faces interesting challenges. In the industrialized countries, the advent of a number of high technology approaches to old problems is leading to unprecedented re-examination of how blood services should be organized. In addition, the advent of AIDS has provoked a greatly heightened emphasis on safety, with the inescapable implications of complexity and cost. The huge and growing burden of record-keeping has led to the introduction of electronic data processing, and has brought with it a new generation of problems. Rapidly growing costs are forcing a re-examination of priorities and in some countries the search for economies of scale has led to the merger of previously independent blood centres.

While advances have been dramatic in most industrialized countries, blood transfusion in the developing countries has tended to stagnate at post-Second World War level, with chronic shortages, lack of component therapy and unsolved safety problems. In many instances these problems are perpetuated by financial limitations, political instability, endemic infections which can be transmitted by transfusion and cultural taboos which inhibit blood donation. The net effect is that blood transfusion takes place in dangerous conditions, its lifesaving purpose subverted by lack of effective control. This situation has become more urgent with the emergence of AIDS and the growing understanding of the complexity of hepatitis and its threat to transfusion recipients.

With each country at a different level of development, and with national health priorities also uniquely different, there is no single solution to these problems. It seems inescapable that there will be different levels of response to these needs. However, the fact that blood is needed for its life-saving properties cannot justify its provision without basic safety precautions. The need for adequate supplies of safe blood exists everywhere that hospital services are found.

1.3 The 1990s and beyond

Technical advances are taking place in many areas that will affect blood collection organizations and the practice of transfusion medicine. These include computerization, recombinant DNA technology, improvements in cell separation and leukocyte removal from blood products, development of new therapeutic plasma fractions, a growing number of tests for transfusion- transmissible infections, changing patterns of blood usage with red cell use falling and platelet use continuing to increase rapidly, the growing use of plasmapheresis to obtain sufficient plasma for fractionation, the growing use of cytapheresis for the production of platelets, increased emphasis on autologous donation and intraoperative blood salvage, the continuing search for blood substitutes, growing attention to the field of transfusion medicine and the specialized training of physicians and transfusionists. This is without doubt a time of adaptation to rapid change.

A significant question to all who are associated with BTS is: what is the future of blood donation? This question is provoked in part by the continuing fascination with the idea of artificial blood. This discussion is difficult for those responsible for operating blood transfusion services because each optimistic public announcement of some new development has the effect of confusing the general public and blood donors are inclined to ask why they should give blood if artificial blood is available. This is an understandable reaction, and an effective answer to it is needed.

The term 'artificial blood' is used only for substances intended as a substitute for the oxygen-carrying function of red cells. There are two principal approaches to this endeavour, haemoglobins [15] and perfluorocarbons [16]. The former has not been demonstrated to be safe. The latter has many unsolved problems of toxicity and instability. Both can have, at best, a brief clinical effect because survival in the circulation is less than 24 hours. It must be concluded then that there is as yet no blood substitute in sight which could take the place of red cells. There is also no early prospect of a substitute for platelets. Factor VIII is the only blood product which has an imminent prospect of replacement; two recombinant DNA products have been used in patients with haemophilia, with promising results. However it remains unclear whether production on an industrial scale will succeed, whether these products can be produced at a cost which can compete with plasma-derived factor VIII and, indeed, whether recombinant products have any real advantage.

All indications are that human blood will continue to be needed for the foreseeable future and that volunteer blood donors will continue to be the essential source. However, it is likely that emphasis may shift towards apheresis donations for plasma, platelets and bone-marrow stem cells, while whole blood donation will continue to be necessary to meet the need for red cells.

1.4 Islamic principles and blood transfusion

At the second Amman workshop on blood donor motivation and blood collection, Dr M. Sartaway* presented a paper entitled 'Islamic Rulings on Blood Transfusion' which presented several important conclusions concerning blood donation and the principles of Islam.

- While spilled blood is considered impure, donated blood is not spilled and the status of impurity does not apply to it.
- Blood transfusion between a man and his wife will not invalidate their marriage.
- It is forbidden to sell blood. However, if a person who is fit to donate blood refuses to do so without payment, it is permissible to pay on the part of the payer, but the payee commits an offence by mixing a bad deed with a good one.
- Giving blood does not invalidate fasting; giving blood by transfusion to a fasting person does not invalidate the latter's fast.

Dr Sartaway argues logically for the need for blood from a human being to save the life of another. Moreover, he argues that if giving blood to a patient is necessary for survival or for relief, then, according to Islam it is mandatory to do so. This follows the basic Islamic principle which makes it imperative to preserve life, and the underlying Islamic rules "Harm must be eliminated"[1] and "Necessity overrules constraints".[2] Blood donation is in agreement with the principles of Islamic social justice.

Since Dr Sartaway's text has such significance for blood transfusion in the Islamic world, the Arabic text is reproduced in full. (See Annex 6)

Islamic rulings on blood transfusion (Dr M. Sartaway)

Remarkable advances have been achieved in medicine, in pursuance of human welfare. These have given rise to a number of new issues which had never been tackled or judged by early Muslim scholars, since they did not exist at their time. However, since Islamic law is meant to regulate acceptable human behaviour, it is imperative to arrive at rulings with regard to incipient medical issues such as: organ transplant *in vitro*. fertilization (test-tube babies), surrogate motherhood, sterilization, blood transfusion, etc.

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1. The Koran
2. The Koran

Muslim scholars have attempted to derive clear Islamic rulings on these and other issues, in the light of the principles of Islamic Faith and the general rules of Islamic law.

Islam enjoins preserving human life and protecting it against all potential harm, affliction and hardship, and it insists on ensuring peace and security for human beings. This article is an attempt to identify the Islamic view of one of these incipient medical issues, namely, blood transfusion.

In most cases, blood transfusion is considered necessary and indispensable, since, from the medical point of view, it may be impossible for a particular patient to survive without it.

It is well known that blood cannot be produced artificially, as it consists of living cells which scientific research remains unable to synthesize. Nor can any use be made of animal's blood in this respect, because of its natural difference from human blood. Therefore, only the blood of a human being can be used to save the life of another.

Islamic law urges every Muslim to be in constant support of his brother, and even makes such support a legal requirement in many cases. According to a Hadith (saying) by the Prophet Mohammed, (peace be upon him) "He who relieves a believer of one form of distress in this life shall be relieved by God of a greater distress on the Day of Resurrection"; and "God will help any servant of His, as long as he continues to help his brother".

The Prophet (peace be upon him) enjoined Muslims not to abandon their fellow community members when they are faced with death or destruction: "A Muslim is a brother to every Muslim: he neither lets him down, nor does him injustice, nor gives him away", i.e. he does not let his brother fall victim to the enemy, or to a killer disease if he can prevent it.

Endeavouring to save the lives of Muslims and non-Muslims, by protecting them from fatal dangers, and keeping them away from what is harmful, is one of the greatest obligations to he Almighty. God says "Whoso quickeneth a human being, it shall be as if he had quickened all mankind". Quickening a human being is achieved by saving his/her life from destruction, a case which is typically applicable to blood transfusion to a patient from a healthy person.

Therefore, if giving blood to a patient is necessary for his survival, or to relieve his complaint, then, according to Islam, it becomes mandatory, as a case of implementing a basic Islamic principle which makes it imperative to preserve human life. Two important main Islamic rules are also applicable here, namely: "Harm must be eliminated," and "Necessity overrules constraints". Furthermore, it is in agreement with the principles of social justice as implied in countless evidence.

Yet, if the use of blood in medical treatment is necessary, then having an adequate stock of blood and storing it are also necessary. It is an Islamic rule that when something is indispensable for meeting an obligation, then this very thing or action becomes obligatory. A great number of accidents take place every day, most of which require

emergency treatment which cannot be completed without blood transfusion. Therefore, quantities of blood must be made available in hospitals. Hence, blood banks have been established.

This is the argument for blood donation. On the other hand, a patient may not refuse to take the necessary amount of blood since, by so doing, he puts his life at risk, something which is totally forbidden by God: "Do not kill yourselves; God has been to you Most Merciful" (IV: 29. "Do not cast yourself to ruin by your own hands" (II: 195)

It is also worth mentioning here that in the Hadith, there is an earnest call for phlebotomy and cupping in patient treatment, because of their proven benefits to man. This indicates that blood donation is not only harmless to the donor, but it is also useful to him, as it activates the process of replenishing blood cells.

The Prophet (peace be upon him) says : "Cupping is a most useful type of medical treatment". He also says: " If any of your methods of treating the ill is effective, an incision by a phlebotomy scalpel is certainly one".

Drawing blood by a syringe is similar to drawing it through phlebotomy; yet the blood taken by a syringe from one person can be beneficially used by transfusion into the veins of another person, while phlebotomy remains short of this.

To sum up, blood donation is a collective duty, i.e. if it is done by a few people, and the blood donated is sufficient to meet the existing and expected needs of the community, then the rest of the community have nothing to account for. But if the blood donated falls short of meeting these needs, all members of the community are guilty of an offence, since they will be considered as having abandoned to their fate those who are ill or battle- and accident-stricken.

In certain cases blood donation becomes an individual duty. This applies, for example, in a situation where there is a patient whose blood group is matched by that of one single person within easy reach. Blood donation becomes this person's individual obligation. If he fails to fulfil it, he shall be considered as having committed a sin.

A great number of Muslim scholars have ruled blood donation permissible.

No reliable opinion has been pronounced to the contrary.

Nevertheless, it should be mentioned here that putting this Islamic view into practice is subject to certain medical conditions known to professional people, such as: (a) donation must not be harmful to the donor, as in the case when the donor is young or anaemic, or when the amount of blood taken from him is likely to cause him adverse effects; (b) no blood should be given to a patient unless it is sure to benefit him. This can be guaranteed by carrying out the tests necessary to prove that the blood given is free of any pathological factors.

Legal consequences of blood donation

Questions that must be asked are:

1. Is the blood drawn out of the body by a syringe impure? If so, is it permissible to use it for medical purposes?
   There is consensus among scholars that blood becomes impure once it is out of the body. This is in accordance with the Quranic verse listing items prohibited to Muslims: " ... or blood poured forth" meaning : spilled blood. Blood drawn out by a syringe, however, is not spilled and consequently the status of impurity does not apply to it. Texts quoted from the Hadith enjoining the purifying of clothes and the body of blood drops or stains, consider such blood as "poured forth" or spilled. But, even if blood drawn by a syringe is considered impure, Muslim scholars tolerate medication with impurities in cases of need.
2. Does blood transfusion entail prohibition of marriage between donors and recipients?
   Some of the Hadith make it clear that certain marriages are invalidated as a result of a child having been breast-fed by a woman other than his mother. This ruling has been explained, in detail, in books of Fiqh (Islamic jurisprudence). The reason for such prohibition is the fact that breast-feeding helps bones and muscles to grow; such growth takes place while the infant is nourished with milk, before it depends solely on ordinary food.
   A Hadith of the Prophet states that "the marriage-prohibiting breast-feeding is only that which helps bone and muscle growth." Blood transfusion does not bring about such growth, because the function of the blood is to carry nutritive substances to the cells of the body, and not to directly contribute to nourishing and sustaining the body. Therefore, if blood transfusion takes place between a man and his wife, it will not invalidate their marriage.
3. Is selling blood permissible ?
   God has given man a position of honour: " We have honoured the sons of Adam" (XVII: 70). For this reason, the selling of the human body, its organs, or blood is forbidden. However, if a person, who is fit to give blood, refuses to donate his blood unless he/she is financially compensated, it is permissible in this case to pay for the blood. Giving such a payment does not constitute an offence on the part of the payer, while the payee commits an offence and puts himself in the position of one who mixed a good deed with a bad one.
4. Does drawing blood with a syringe break the fast (of a Muslim)?
   Donating blood does not invalidate fasting, nor does giving blood by transfusion to a fasting person invalidate the latter's fast.

2. Organization and management*

Chapter 1 briefly mentioned the wide range of functions and services which comprise a blood transfusion service. An organization of such sophistication cannot function without strong leadership and competent management. Successful blood transfusion services have one feature in common: the existence of one or more committed leaders who have provided inspiration and direction over a period of time. Chapter 2 will cover some of the most important organizational and management functions, with the key point of leadership further discussed in section 2.2.4.

2.1 Role of blood transfusion services in the health care system

Blood transfusion does not exist in isolation. It is an integral and indispensable part of the health care system. Without blood transfusion, effective management of severe trauma, major elective surgery and serious obstetric complications is not possible. Furthermore, there is a key role for transfusion in the management of serious medical and paediatric conditions such as gastrointestinal bleeding, cancer, leukaemia, haemophilia, congenital haemolytic anaemias and life-threatening malaria. To plan a national health service without planning the transfusion service is to overlook an essential part of the infrastructure. To create a hospital without a blood bank, and plans for where the blood is to come from, is to invite severe difficulties in the daily operation of that institution. The reality is that no hospital can function effectively without a blood supply. If such a supply does not exist, the physicians and the patients' families will find ways, often uncontrolled and dangerous, to make blood available. Such is the life-giving capability of blood, and so emotionally searing the lack of blood when needed, that blood has be found. The unavailability of blood is not acceptable.

National blood transfusion policies should, therefore, include a reasonable plan to ensure the availability of essential blood and blood components [17]. This plan should consider also the need for plasma fractions, a more flexible matter since there are suitable though less satisfactory substitutes for these costly products. An important side issue in this regard is the consideration of where the plasma for fractionation is to come from. If blood is collected, there is always the potential for producing plasma. The national plan should therefore consider whether to attempt the collection of plasma for fractionation and how this fractionation should be accomplished; the possible options involved have been described elsewhere [17]. Failure to plan this dimension of the programme will guarantee

*Readers may wish to refer to other relevant WHO publications [17,18].

that it will not function and that potential recipients of plasma products (e.g. haemophiliacs) will not be treated.

2.2 Organization of blood transfusion services

2.2.1 Global overview

Worldwide statistics for blood collection do not exist. However, it is possible, from national statistics, projection of partial information and from reasonable estimates to develop an overview of blood transfusion worldwide (Tables 2.1 and 2.2). In general, industrialized countries need to collect 50 blood donations per year for every 1000 inhabitants. This quantity is barely sufficient to meet the need for plasma products, and over-collection of whole blood (Switzerland has more than 100 blood donations per 1000 per year) or large-scale plasmapheresis (USA) may be necessary to avoid shortages of plasma derivatives. The blood collection needs of developing countries are less, reflecting less developed economies and correspondingly less complex health care systems. In some cases the need may be less than one blood donation per 1000 population.

Similarly, the diversity of transfusion services tends to be proportional to economic strength and is reflected in the simple statistic of red cells prepared from whole blood (Table 2.2). Even wider differences are apparent from a review of the production of plasma products. Very few countries are self-sufficient in this regard (Belgium, Finland, Scotland and Switzerland, for example) while the USA provides nearly half of the world's supplies from commercial sources. Clearly there is a wide spectrum of levels of blood transfusion services. It is not possible to define one level to which all countries should aspire.

2.2.2 Consequences of lack of organization

It is helpful to review what happens if there is no organized blood transfusion service and no coordinated plan for a blood transfusion service. As noted, the unavailability of blood in a life-threatening situation is obviously impossible for relatives of a patient to accept. The absence of such a service therefore forces the physician(s) involved and the patient's family and friends to take what action they can. Inevitably, such action takes place at hospital level, with facilities established for the collection of blood. Since donors are not readily available, and the organization of a volunteer donor programme requires sophisticated long-term arrangements **(see 3.5.4)**, the problem is approached in the only possible way, by making the patient, family and friends responsible for providing donors.

This 'family donor' system is found in many countries and hospital transfusion services may depend totally upon this method of finding blood. There are, however, several reasons why this system is unsatisfactory and dangerous. It may not be possible for the patient's family to find suitable donors, family donors may feel obliged to donate even if they know that they have some health condition which prohibits donation of blood for transfusion and blood donated by family members may not be of the correct blood group.

Moreover, since this blood morally belongs to the patient it is not easily made available to other patients who may have a greater need. It is not possible, therefore, to utilize family donations effectively for creating a blood bank, a stored blood supply available to whoever may need it, nor is it possible to utilize such blood for the effective production of platelets and other blood components. Finally, since this blood is dedicated to a particular patient, it may often be transfused to that patient even if not ultimately needed.

The most serious danger of the family donor system is that the difficulties described above may create entrepreneurial opportunities for the organization of professional donors, paid by clubs or syndicates to serve as family surrogates. Such systems have the ability to make the donors dependent upon this activity for their livelihoods. The resulting deep corruption may be difficult to eradicate yet dangerous to both donor and patient. The donor is tempted to give blood too frequently; stories are common of professional donors admitted to hospital in shock after several donations in one day. Moreover, it is not possible to rely upon health history information provided by the donor. Because donors of this kind often come from economically and socially deprived sections of society, there is a greater likelihood that the donor will be anaemic and in a poor general state of health and less likely, out of financial need, to reveal any medical condition. Intravenous drug abusers, in particular, may be carriers of infections transmissible by blood, thereby further endangering the patient's life.

In addition, the professional donor system has the potential to corrupt personnel working in the blood bank. Since these are the people who have first access to the family, there is great temptation to accept payoffs for referring the family to the donor syndicate. Corruption of this kind thus introduces further dangers for the patient by subverting the professional integrity of the transfusion service staff.

Already, systems of this kind are undesirable and should not be allowed to develop. The secret is to create a viable, ethical, professional programme which succeeds in providing the required services. Paid donor programmes cannot succeed if something better is already in place.

Finally, it must be decided where the transfusion service is to be located and how it is to be organized. For example, should it be within a hospital or hospitals in one or more self-standing blood centres? To some degree the answer to these questions will depend upon which organization has been assigned the responsibility for providing the service. Nevertheless, it is important that blood distribution centre(s) be located where there is convenient transportation to the major hospital(s), while the principal blood collection centre(s) should be located where there is convenient public access. The blood transfusion service should be located where it is possible for the responsible organization to maintain control of the service.

The required services should be defined, qualitatively and quantitatively, and the resources should be available for making an effective service possible. Buildings and utilities should be suitable; financial resources should be adequate; equipment should be

appropriate and effectively maintained; dynamic leadership, appropriate management and sufficient trained staff are essential as is a realistic plan for the collection of sufficient blood.

2.2.3 Creating a new organization

There are, at present approximately 130 countries which do not have effectively coordinated blood transfusion services. Since this situation is not satisfactory and is potentially dangerous, many countries are taking steps to rectify this organizational void. That only a minority of countries have succeeded in this regard testifies to the fact that solutions are elusive. It may be helpful, therefore, to consider the hurdles which must be overcome (Box 2.1).

BOX 2.1 Reasons for difficulties in creating a blood transfusion service

- **Financial**: unavoidably high cost may be beyond the resources available.
- **Human resources**: skilled personnel and leadership needed.
- **Strategic**: blood needs difficult to achieve, e.g. volunteer donors generally within middle-class populations; insufficient resources dedicated to blood donor recruitment.
- **Political**: e.g. responsibility divided between different ministries; reluctance to delegate sufficient authority to responsible management of blood transfusion service; other political priorities take precedence over health issues.
- **Organizational**: e.g. blood transfusion services placed within the structure of laboratory services and non-laboratory aspects neglected; resources restricted by competition with other laboratories; training and assignment of personnel compromised by conflicting priorities.

The first steps in creating a new blood transfusion service organization are to demonstrate the need and to assess the feasibility of successfully creating a new organization. Box 2.2. lists the questions to consider when assessing the current need; Box 2.3 lists the criteria which must be met in order to establish the feasibility of creating a stronger coordinated BTS.

BOX 2.2 Assessing the need to create a blood transfusion service

- Does a coordinated BTS exist?
- Are there significant problems with the BTS?
- Is the blood supply adequate?
- Is the blood supply safe? Is the blood supply adequate and safe throughout the country?

BOX 2.3 Assessing the feasibility of strengthening the blood transfusion service

- Are the operating costs of a BTS affordable?
- Is the government committed to the project?
- Does the leadership exist to guide the BTS?

2.2.4 Planning a blood transfusion service

The essential elements of a national blood transfusion service are summarized in Box 2.4. The basic organizational structure of the blood transfusion service must be defined (see 2.2.5) as well as who will be responsible, where it will be located, how it will operate, how it will be financed and what its aims and operating philosophies will be. The plan and needs to take into account certain essential functions which will not be effective without central coordination. These include the coordination and control of product availability, the regulation of operations to ensure quality and a specialized facility for laboratory problem solving.

Optional functions, desirable everywhere but essential in countries with sophisticated blood transfusion services, are listed in Box 2.5. These functions all relate to the experience and skills which characterize major blood transfusion services. Box 2.5 outlines the reasons why blood transfusion services require central coordination.

BOX 2.4 Essential elements of a national blood transfusion service

- Organizational structure
  - organizational responsibility and accountability
  - leadership
  - location
  - financing
  - aims and philosophies
- Coordination of availability of essential blood components
- Coordination of availability of plasma fractions or essential substitutes
- Policy concerning provision of plasma for fractionation
- Centralized problem-solving laboratory
- Regulatory standards and oversight system designed to assure quality

BOX 2.5 **Desirable optional functions of a national blood transfusion service**

- Provision of plasma fractions
  - albumin
  - immune globulins (polyvalent and hyperimmune)
  - factor VIII
  - factor IX
  - others
- Special services
  - plasmapheresis and cytapheresis
  - autologous blood collection
  - freezing of red cells and platelets
  - histocompatibility laboratory (HLA, transplantation immunology)
  - disputed parentage resolution
  - tissue and organ procurement for transplantation
  - unrelated bone-marrow donor programme
  - collection of bone-marrow and stem cells for transplantation
  - blood coagulation laboratory
  - haemotherapy services for haemophilia, thalassaemia, etc.
  - plasma fractionation
- Educational services
  - physicians
  - medical students
  - nurses
  - technologists
  - general public
- Reagent production
  - red cell antisera, cell panels, anti-human globulin, etc.
  - HLA antisera, trays, cell panels, etc.
- Research and development
- International linkage with other blood transfusion services

BOX 2.6 Coordination is necessary

- to develop and maintain a national blood policy
- to provide a forum for discussions with outside organizations
- to ensure coherent planning, financing and management
- to assure quality (see Section 4)
- to coordinate operations
  - inventory control and balancing
  - problem solving
  - special services
  - plasma fractionation
- to manage training of personnel
- to manage research and development
- to assure international coordination
  - international relations
  - importing and exporting policies

It has been pointed out that different ways of organizing blood transfusion services have succeeded in different places. It is therefore reasonable to conclude that there is no single correct way to design the organization. The blood transfusion service, of course, must be compatible with the health care system, political structures, perceived needs for blood, availability of suitable blood donors and realistic financing, and it must be constructed in such a way that it will ensure adequate blood, skilled personnel and financial resources. These requirements are not simple, as demonstrated by the considerable difficulties experienced within the last decade in countries such as Australia, Canada, France, the Netherlands, Sweden, the United Kingdom and United States of America.

2.2.5 Organizational models

It is emphasized again that many different models have proven successful and that no single model is right or wrong. It should also be emphasized, however, that whichever model is selected, it must be planned and supported to the extent that it can succeed. Failure to do so will lead relentlessly to the types of problems described in 2.2.

Approximately 70 countries have organized national blood transfusion services. There are four broad types of organization which have been tried successfully: centralized, regionalized, coordinated hospital services and a coordinated mixed system. The essential common feature is that each system is coordinated as to overall policy and direction,

regulatory control, quality standards, logistic coordination and specific centralized facilities (e.g. reference laboratory, coordination of plasma resources and products). The differences relate to where the control lies. The advantage of strong centralized control is that coherent management is relatively simple and standard practices and logistic coordination can be established. The difficulties include the danger of insensitivity to needs at the periphery and the bureaucratic nature of strong central management in large countries. Centralized systems have been successful in small or sparsely populated countries such as Finland, Jamaica, Kuwait and Singapore. Regionalized systems are a useful compromise, permitting control from decentralized locations, with looser central coordination of specific functions. This approach is particularly relevant in large or densely populated countries, such as Australia, Canada, France, the Netherlands and the United Kingdom. The advantages are those of centralization, with the added benefit of local (regional) management which must remain responsive to local needs. Coordinated hospital services involve decentralization at the hospital level, with each hospital controlling its own blood supply. The advantage is that each institution can control its own affairs and develop programmes specific to its own needs. Successful programmes of this kind can be found in Malaysia and Scandinavia. The disadvantages are that coordination of such a loosely decentralized system is difficult and often achieves only limited success. Coordinated mixed systems include aspects of all of the above. These are found only in countries of great size and diversity, such as India and USA. The obvious problems are that coordination is difficult and conflicts can obstruct the best laid plans.

BOX 2.7 Responsibility for blood transfusion service

Overall	**Operational**
National government	National, provincial or local government • Red Cross/Red Crescent • Military • Private - non-profit - commercial • Hospitals • Other

Having selected one of the four basic models, the next decision is to determine which organization(s) will have the responsibility and authority for operating the blood transfusion service(s). The principal options are summarized in Box 2.7. While the ultimate responsibility for this decision, and for the success of the programme, lies with

the national government, responsibility and authority for operating the programme can be delegated to other organizations. Who is responsible is not as important as the recognition that this responsibility must be clearly defined and supported with adequate resources and sufficient authority to operate.

If the programme is to be operated by the government, the option remains to delegate the local functions to local government or hospital administrations. There are a few countries where coordinated transfusion services are operated totally at hospital level. The programmme may be delegated to the Red Cross/Red Crescent. This is most likely to succeed if centralized or regionalized systems are planned. Since the strengths of the Red Cross lie in community outreach functions, such as donor organization and blood collection, one important option is for the Red Cross/Red Crescent to collect the blood with government laboratories taking over from there. In a few countries, Namibia and Zimbabwe for example, there has been success with vesting the responsibility in private non-profit organizations. This approach has arisen from private initiative and is unlikely to succeed in countries lacking a strong tradition of private voluntary service. Commercial private operations are still found in some countries but there is widespread recognition that the profit motive and blood safety are not compatible; commercial blood banks cannot succeed when there are successful non-profit programmes in place.

Government programmes may not necessarily be easy to coordinate. Several different branches of government may be involved, perhaps in competition rather than in partnership. For example, strong military blood programmes may compete successfully with civilian services for resources and blood donors. Furthermore, the ministry of health may have overall responsibility for blood transfusion services, while the most important hospitals, those affiliated with medical schools, may fall within the purview of the ministry of education. Thus, with the ministries of defence, health and education all seeking resources for their programmes, competition for the attention of the minister of finance may determine outcomes which do not reflect the policies of the ministry of health. One answer to dilemmas of this kind may be to utilize the services of a neutral organization, such as the Red Cross/Red Crescent to manage the entire national blood transfusion service. This approach has been successful in some 20 countries, including Australia, Canada, Ethiopia, Papua New Guinea, Suriname and Switzerland.

There are successful programmes operated by the Red Cross/Red Crescent Societies; there are successful governmental organizations; there are a few examples of non-profit private organizations operating successful services; there are a few countries where coordinated transfusion services are operated totally at the hospital level. It is as important to establish who is responsible as it is to recognize that this responsibility must be clearly defined and and supported with adequate resources and sufficient authority to operate.

2.2.6 Case Studies*

Case 1

The country has a population of 500 000. It is a tropical island chain, with six inhabited islands. The annual mean per capita income is US$1750. There are three hospitals, one on each of three different islands; each hospital collects blood. One hospital receives help from the Red Cross in recruiting volunteer donors. The other hospitals depend upon patients' families to find donors. It is said that these families, unable to find donors and desperate to ensure that there be blood available, pay professional blood donors to serve as family donors. Nationwide, 6000 units of blood are collected each year. Only whole blood is transfused. There are no training facilities for blood bank personnel in the country. There are no doctors trained in blood transfusion. There is no legislation concerning blood transfusion and no regulations exist; there is no policy concerning donor eligibility or technical standards; 13% of all donors are positive for HBsAg; 4% test positive for HIV. Malaria is not found.

1. Should an attempt be made to centralize this country's BTSs at the national level?
2. How can the 'professional donor' problem be alleviated?
3. How might component usage be developed?
4. How can BTS personnel be effectively trained?
5. Is there a need for blood transfusion legislation and regulation and, if so, how might it be accomplished?
6. Does this country need rules concerning blood donor eligibility and laboratory technical standards and, if so, how might these be accomplished?
7. How can this country assure the safety of blood transfusions?

Case 2

The country has a population of 30 million, two million in the capital. There are 11 provinces; each has a regional (provincial) hospital in the provincial capital. There are 97 district hospitals. Health services are a provincial responsibility. Roads are poor and often impassable in the rainy season. It may take four days to drive from the capital to the most distant province. There are no national laws, regulations or policies pertaining to blood transfusion. The annual mean per capita income is US$450 per year. Total annual blood collection, nationwide, is thought to be about 80 000 units but no centralized statistics exist. Cryoprecipitate and platelets are available only in the national capital. Testing for HBsAg is only occasionally attempted because of the high cost of test kits; 7% of donors are positive. With the help of international aid, testing for HIV antibodies has been established at the national medical centre in the capital; ELISA equipment has been installed in each of the provincial hospitals, but testing is sporadic and without quality

*See Annex 5 for suggested solutions.

control. Of the donor population, 2-20% are positive for HIV. Malaria is endemic throughout the country; life-threatening malaria is common in children, especially in the rainy season. There is no central authority for blood transfusion. There is a shortage of plastic collection bags and standardized reagents. There is an excellent training centre for technologists in the capital and trained personnel are found in most of the provincial blood banks. There is, however, a serious problem of emigration of trained personnel because of poor salaries and lack of career opportunities.

1. Should the operation of this country's BTSs be nationally centralized?
2. Is there a need for legislation and regulation of blood transfusion?
3. How can infectious disease testing of donor blood be strengthened?
4. How can the problem of shortages of blood collection bags and reagents be alleviated?
5. Suggest a reasonable policy for malaria control and the prevention of transfusion transmission of malaria.
6. How can the drain of trained personnel be reversed?

Case 3

This country of 5 million people has a rapidly growing economy due to large-scale exportation of petroleum products. The health care system has been newly created, and has sophisticated facilities and many expatriate personnel in responsible positions. There is no national blood transfusion service. The blood supply was previously dependent upon the importation of blood but this practice has been banned by legislation. Each hospital now collects the blood it needs. There are no official statistics concerning blood collection or usage. The university hospital in the capital city (700 beds) collects 6000 units per year, from paid donors. Cryoprecipitate and platelets are prepared in this hospital; single-donor platelet products are produced by apheresis. It is known, from a combination of commercial sources and from official government trade figures, that there is heavy importation of plasma derivatives (albumin 2000 kg per year; factor VIII 2 million IU per year; IVIG 70 kg per year). No plasma is produced for fractionation. There are plans to build a plasma fractionation plant so as to avoid the necessity of importing plasma derivatives.

1. How can this country reduce its dependence upon expertise from other countries?
2. Should a national blood transfusion service be established and should the operation of the BTSs centralized?
3. How can the dependence upon paid blood donors be eliminated?
4. How much plasma is required to produce sufficient plasma derivatives to meet the demand?
5. Will the establishment of a plasma fractionation plant help the country to become self-sufficient in plasma derivatives?

2.3 Self-sufficiency and the blood resource

The World Health Organization's basic policy with regard to the supply and utilization of human blood and blood products is set out in Resolution WHA 28.72 (see Annex 3), item 3 (2) which forms the basis for countries for the goal of self-sufficiency. In the context of blood resource, self-sufficiency means that a country provides all the blood it needs from its own resources and can be considered as the goal for planning purposes. However this does not exclude collaboration (interdependence) with other organizations/countries whose scientific and ethical standards are compatible; on the contrary, collaboration and cooperation are desirable. The concept of self-sufficiency is based on the following assumptions:

- that all blood donors give voluntarily and without receiving payment;
- that blood come from the local population rather than being imported from other sources;
- that self-sufficiency applies to the source of blood, but does not necessarily apply to the source of essential supplies (plastic collection containers, laboratory reagents, etc.), equipment, technology, plasma fractionation, etc.

a) Voluntary donation

The principle of voluntary donation has both an ethical element and a safety element. The ethical aspect relates to the undesirability of trading in human parts (see also 1.4).This has been challenged by those who seek to profit from the commercialization of plasma collection by plasmapheresis, but is generally accepted by those involved in blood collection for transfusion purposes. The ethical principle is entrenched in WHO policy (see Annex 3).

The safety element relates to the importance of the donors' health status and of being able to elicit a reliable health history from every prospective blood donor. Donors who are motivated by financial gain, or who are coerced into donating, cannot be trusted to give reliable information. That paid and replacement donors are less safe than volunteer donors has been well proved [19,20,21,22]. Donors who give blood for payment invariably come from disadvantaged sections of society, and are thus likely to conceal medical conditions of concern, while intravenous drug abusers and prostitutes are more likely to carry infections which are transmissible by blood.

b) Reliance on the local population

Many authorities have emphasized the need for national self-sufficiency. In large countries one may encounter a policy of regional self-sufficiency. Within the European Community, for example, there is lively consideration of European self-sufficiency, recognizing that some of the 12 Community members are not self-sufficient in blood and that others have the capacity to overproduce. Implicit in this discussion is the necessity to define the area which is to be self-sufficient and to have clear policies concerning whether or not importation of some blood products is permissible. In general, this discussion begins at the country level but, as indicated above, it may be refined for consideration of part of a country or group of countries.

c) Blood products covered by self-sufficiency

Clearly the concept of self-sufficiency applies to whole blood and its components prepared for transfusion purposes. The question of plasma and plasma fractions is more difficult. It is recommended that self-sufficiency be sought in plasma for fractionation but that the technology for fractionation be shared between countries, because the technical difficulties of fractionation and the economies of scale are such that only large-scale fractionators can succeed.

One further area should be discussed. Box 2.8 gives definitions for supply, usage, need and demand and consideration of these definitions is helpful. For instance, usage cannot exceed supply and is, in fact, always less than supply because of inevitable losses and inefficiencies in management. Demand may exceed supply, but generally increases if supply is adequate. There is therefore the potential for demand to grow beyond true need. Defining need is discussed in depth in chapter 3.4. Here it is sufficient to stress that those responsible for achieving self-sufficiency should also be involved in defining need and monitoring usage. The goal is a negotiated target for supply which will meet all needs for rational usage. This goal does not include the expansion of supply to meet irrational demands, since this will result in excessive use which is unsafe as well as costly. Box 2.9 summarizes the principles of self-sufficiency.

BOX 2.8 Supply, usage, need and demand

- Supply: products available for transfusion
- Usage: products actually used for transfusion
- Need: products that are needed for transfusion (an objective fact, but not necessarily easy to agree upon)
- Demand: products that are wanted (ordered); demand is subjective

BOX 2.9 Principles of self-sufficiency

1. The self-sufficiency concept applies to:
   - whole blood
   - components prepared from whole blood (red cells, plasma,platelets, cryoprecipitate)
   - Plasma for fractionation
2. The self-sufficiency concept is generally applied at the country level, but can be applied to groups of countries or to part of a country
3. Need should be negotiated and agreed; the goal is to achieve a supply adequate to meet the need
4. Donors are volunteers and not remunerated

2.4 Organizing a blood centre

2.4.1 Organizational elements

Once the basic policy requirements of the BTS (definition of needs, desired functions, legislation, regulation, policy setting, definition of responsible organization and its authority) have been fulfilled, blood centres may be planned. The operational elements of organization of a blood centre are listed in Box 2.10. The first element is obviously to decide what functions a particular centre is to fulfil. For example, is it to be a blood collection centre or a specialist centre for the production of blood and plasma products or is it to have a combination of functions? If it is a blood collection centre, it must be decided how much blood will be collected annually (see 3.4).

BOX 2.10 Elements of organization of a blood centre

- Definition of the work to be done
  - what functions is the centre to carry out?
  - how much blood is to be collected?
- Staffing
  - what skills are needed?
  - how many people are needed?
  - how will the staff be trained?
  - how will the staff be managed?
  - table of organization (organogram)
- Facilities
  - building
  - equipment
  - utilities (communications, water,power, heating/cooling)
  - transportation
- Maintenance of equipment
- Consumable supplies
  - blood collection containers
  - laboratory reagents, tubes or microplates, etc.
  - office supplies
- Budgeting

The staffing of a blood centre depends on the functions to be undertaken and the volume of work to be done. The critical questions to resolve are: what products are to be produced? How much blood is to be collected, and how many products are to come from this blood? What additional services, if any, are to be provided? The answers to these questions will determine what skills are needed and how many people will be required.

Effective staffing also depends upon effective training of the staff, and a system for retention of well trained staff. The budget needs therefore to take into account the extra people required for training functions and the time required for training. Salaries and benefits should realistically be sufficient to attract new staff and to encourage existing staff to remain with the organization. Economizing by paying low salaries can lead to the loss of key personnel.

Staff should include all those listed in Box 2.11. A useful rule of thumb is that a blood centre needs one staff member for every 500 units of blood collected annually.

The building(s) should be attractive and clean, with stable temperatures maintained at levels suitable for donor comfort, and for working with blood (20-22°C). The heavy equipment required in blood centres (refrigerators, freezers, centrifuges, etc.) all generate heat during operation so ventilation systems should be planned to remove this hot air. Ideally, buildings in dusty climates should have special air filtration systems to keep dust out of the working areas, where it can do irreparable damage to equipment.

BOX 2.11 Staff needed in a blood centre

- Donor organizers (3.5.4, 3.5.5)
- Technologists (phlebotomy, laboratory, distribution)
- Public relations/information
- Support personnel (drivers, secretaries, telephonists, caretakers)
- Administration
- Medical director
- Management (may be combined with the position of medical director)

If blood is to be collected in the centre the location obviously must be easily accessible to the general public. A common mistake is to build a blood centre that it is too small. A successful programme tends to grow in volume and complexity. It is wise to plan for excess space at the start of a new programme.

Equipment selection is one of the areas where the greatest difficulties are encountered. As a general rule, durability is preferable to the latest technology. Maintenance is critical to the successful operation of equipment, so it is essential either to have a maintenance contract with the vendor or to have local trained maintenance staff who are familiar with the equipment and quickly available in emergencies. Key equipment, needed in every blood centre, includes refrigerators, freezers, centrifuges, controlled temperature platelet agitation chambers, an emergency generator, voltage regulators (if power is irregular or prone to cuts) and communications equipment (telephones, fax, etc.). Vehicles should be suitable for blood delivery, blood collection and arrangement of meetings, throughout the territory served by the programme.

2.4.1 Case studies*

Case 4

The country has a population of 4.5 million. Blood is collected by each of the 17 hospitals (annual total 31 000 units, including 12 000 units at the 900-bed university

*See Annex 5 for suggested solutions.

hospital) and by the well-equipped army (18 000 units). Only whole blood is collected with no component production. The university hospital makes about 500 platelet concentrates each year, and a few cryoprecipitates, but most blood is transfused as whole blood because it belongs to the family who donated it. All hospitals draw blood from family donors. Army donations are made by soldiers when ordered to do so. From time to time the army offers blood to civilian hospitals. In addition, a newly created government blood centre, the National Blood Transfusion Centre (NBTC), draws about 3000 units annually from volunteer donors, prepares platelets and cryoprecipitates, and operates a reference laboratory for resolving crossmatch problems. There are few complaints of unavailability of blood for emergencies. The medical director of the NBTC, who is responsible for donor recruitment, admits that it is very difficult to get donors. The university hospital is always short of special blood components (platelets and cryoprecipitate) and blames the NBTC for being 'useless' and 'never having what is needed'.

1. Why is the university hospital short of blood components?
2. Why does the medical director of the NBTC have difficulty recruiting donors?
3. What can be done to improve the blood transfusion system in this country?

Case 5

The country has a population of 80 million. There is no national blood transfusion service. The country is divided into seven states, each of which is responsible for its own health care services. One of the states has a state blood transfusion service which collects about 700 units of blood each year. The other states do not have blood transfusion services. The Red Crescent collects 6500 units of blood each year, in six blood centres; this blood is made available to blood donors or to other persons considered by the medical director to be deserving. Each of the 193 hospitals collects blood as needed for emergencies. All transfusions are in the form of whole blood. Collections are from family donors, or from the large number of professional blood donors, paid by the family. Before the blood can be collected, the family must buy a blood collection bag, generally available from street vendors for US$15. No statistics are available concerning blood usage. No testing for transmissible diseases is done on donor blood. No information is available concerning the prevalence of hepatitis and AIDS in this country. There is general agreement that blood is always in short supply but blood transfusion is not thought to be risky. Blood substitutes, saline or dextran solutions, are not used 'because they are too expensive and blood doesn't cost anything'.

1. What should be done to ensure that this country has an adequate and safe blood supply?
2. What misconceptions need correction?
3. Suggest an organizational model upon which a successful blood transfusion service could be built in this country.

2.5 Organization of Blood Collection

2.5.1 Principles of organization

The principles upon which specific plans and blood collection operations can be built are considered here. The practical details are covered in Section 3.

Active effort and precision are required for the organization of the collection of adequate amounts of blood. It is NOT sufficient to create facilities and then wait for volunteer donors to come and donate. A passive approach will not produce adequate amounts and will not meet needs.

The active approach requires definition of needs, establishment of blood collection goals (see 3.4) and formulation of specific plans which will enable the goals to be achieved. It is therefore necessary to consider the principal options available for collecting blood. The basic approach to the collection of blood is to assemble volunteer donors in sufficient numbers to meet collection goals. This can be achieved in two ways, through fixed blood collection centres and through mobile blood collection units (Box 2.12).

It is worth considering the different types of facility available when establishing fixed blood collection centres. Many blood transfusion services utilize all the options. Generally, if a specific blood centre exists it will include a blood collection centre, though this is not necessarily required. Blood is commonly collected in hospital facilities; this is logical because this is where blood is needed for transfusion and hospitals are well situated for the collection of blood from the patient's family. However, hospitals are not necessarily suitable for blood collection, for three reasons:

- family donors are not the preferred source of blood;
- a hospital is not the ideal places for reaching the general public for blood donation;
- blood collected in one hospital may not be made available to another, thus restricting flexibility.

Other locations may be more suitable for the collection of blood, particularly if public accessibility is good. The underlying principle for all fixed blood collection sites is that this facility is specifically established for blood collection. The facility will justify its existence if it proves able to attract sufficient people to come to the centre to donate blood.

Mobile blood collection systems are quite different. The principle is that the blood collection team will travel with its equipment to where the donors are. Mobile blood collections are events, arranged at specific dates and times, and involving the temporary use of a location for blood collection. This requires the collaboration of donor groups, or partner organizations (sponsors), where there are people who might not find it convenient to come to a fixed collection site. The arrangement of a mutually convenient time and place for blood collection is essential for the organization of mobile blood collections. Mobile blood collections may be conducted on the premises of the sponsoring organization, in a nearby location if one exists that is suitable for blood collection, or in a

vehicle owned by the blood transfusion service and designed for blood collection; self-contained blood collection vehicles are expensive.

BOX 2.12 Options for blood collection locations

- Fixed collection centres
  - blood collection centres
  - hospitals
  - others, e.g., shopping centres, major office complexes, railway stations
- Mobile blood collections
  - suitable building facilities, e.g., sponsoring partner in blood collection, nearby facility of another organization
  - self-contained blood collection vehicles

Blood transfusion services with modest needs can generally manage with hospital facilities only. Large blood transfusion services utilize fixed collection sites as well as mobile blood collections. Emphasis on one or the other will depend upon local conditions and the need for blood. Reliance upon 80% mobile and 20% fixed collection is found in many blood transfusion services. The essential differences between the two approaches, and the specific advantages of each, are summarized in Box 2.13.

BOX 2.13 **Characteristics of blood collection systems**

- Fixed collection centres
  - equipment and personnel stay in one place
  - blood donors come to the collection centre
  - convenient for the blood transfusion service
  - controlled working conditions
  - needs include: convenient location, suitable building
  - transportation for donors
  - useful for donor retention (frequent donation of regular donors)
  - suitable for individual donors, or small groups of donors
  - not suitable for large groups of donors
- Mobile blood collections
  - personnel and equipment travel to donors
  - convenient for the donors
  - donor groups may be very large (and must be large enough to justify the cost)
  - working conditions may be difficult to control
  - needs include: transportation for personnel and equipment, cooperation of sponsoring organization
  - sufficient number of donors for accurate planning (date, time, place, number of donors, etc.)
  - useful for finding new blood donors, particularly young people
  - useful for collecting blood from large donor groups
  - facilitates the collection of blood throughout a large territory (far away from the blood centre)
  - not always suitable for frequent donation (depending upon convenience of sponsoring organization)

2.5.2 Case studies*

Case 6

The country has a population of 600 000. There are three population centres, each with one hospital. Total annual blood usage in the country is 2300 units. The largest hospital, in the capital, does all the laboratory work required by the government. Road transportation is difficult; there are rough mountainous roads and bandits are active in some areas.

1. How should blood collection be organized in this country?
2. How can this function be coordinated at a national level?

Case 7

The country has a population of 2.5 million. The capital, the largest city, has 600 000 people. There are 19 hospitals. The most distant hospital is 170 km from the capital. Roads are good. Total annual blood usage is 28 000 units.

1. How should blood collection be organized in this country?
2. How can this function be coordinated at a national level?

Case 8

The country has a population of 20 million. There are four cities with a population of more than one million each, of which the capital is the second largest. There are six provinces. Roads are good in five provinces but are often impassable in the one mountainous province (population 800 000; six hospitals) in which the provincial capital (population 200 000; two hospitals) is the largest city. Total annual blood usage in the country is approximately 250 000 units.

1. How should blood collection be organized in this country?
2. How can this function be coordinated at a national level?

2.6 Management Principles

2.6.1 Role of the manager

No organization can function without strong leadership and competent management. Successfull blood transfusion services have one feature in common: the existence of one or more committed leaders who have provided inspiration and direction over a period of time.

The manager is the person responsible for implementing the work of the organization. Depending upon the type of organization, this person may be called commander-in-chief, chief executive officer (CEO), director-general, secretary general, chief, president, chairman, etc. The essence is that the manager is in charge of implementing programmes

*See Annex 5 for suggested solutions

and functions. The manager relates to the three key elements of supporting staff (implementation team), Board of Directors (policy making body) and the external environment. Nobody else is in a position to coordinate these. The staff and Board can work together to gather information about the external environment and to respond to external opportunities and threats. The chief executive can represent Board policies and direction to the staff and can represent staff capabilities, ideas and needs to the Board.

A manager must respect the difference between the policy-making role of the Board and implementation by the staff. This distinction is important in all well functioning organizations. It can be seen, for example, in government, in the difference between the legislative branch (Congress, Parliament, House of Deputies, etc.) and the executive branch (civil service) and also in private companies, charitable organizations, the armed forces, universities, health care institutions and the United Nations. Determining policy is a separate function from programme implementation. This separation is emphasized because most organizations have to contend with confusion between these two roles. Members of the Board may easily be tempted to become involved in operational activities; this interferes with normal working relationships among the staff and undermines the role of the manager. A good manager will anticipate this problem and will intercept interference if it occurs. Conversely, the staff, whose careers and responsibilities are affected by the policies of the organization, are always tempted to seek ways to influence policy decisions. This is normal, and can be creatively developed by open internal discussion, but it must not be permitted to shift from a healthy concern for the success of the organization to the disruption of policy decisions. Here again, the manager has a key role to play. The manager can facilitate the two-way flow of information between Board and staff and can also facilitate decision-making by the Board by arranging the necessary staff support (information gathering, preparation of reports, drafting of working documents, etc.). It is the manager's role to ensure that the policy-making role of the Board functions smoothly and without staff interference, and that the policies of the Board are respected and supported by the staff. An effective manager has the integrity and openness to maintain the trust of both Board and staff. A manager who is concerned only with staff needs will not survive because the Board will quickly appoint a replacement. A manager who is concerned only with satisfying the Board will quickly lose the trust of the staff and will not be an effective leader.

Many organizations fail to distinguish clearly between policy and management functions (Box 2.14). The predictable results are confusion, conflict and a dysfunctional organization.

BOX 2.14 Policy and management functions

Policyfunctions	Management functions
• Strategic planning	• Management and operational planning
• Location of facilities	• Setting targets
• Resources	• Budget development and control
- financial development	• Human resources
- budget approval	• Facilities utilization
- policies	• Materials management
- programme development	• Financial management
- marketing	• Ensuring appropriate capacity
- operations	• Production and product management
• Appointment of top management	• Sales and distribution
• Management structure	• Advertising and promotion
	• Systems and controls
	• Monitoring and reporting

External factors, policy and the implementation of policy, are of critical importance to BTSs. Any successful BTS will have taken account of external factors beyond its direct control, will have a concerned and well informed policy setting body and will have a well managed staff sufficient to implement the programmes and policies of the organization. A blood centre that is failing in its mission will be found to have problems in one or more of these three areas. The best staff in the world cannot succeed without reasonable policies and effective adaptation to external influences. The manager is responsible for ensuring suitable response and adaptation to those factors as necessary to ensure the success of the BTS.

The remaining discussion deals with the manager's implementing (internal) role and its application to the effective management of a BTS.

2.6.2 Effective management

Delegation and motivation

A useful definition of management is: the art of getting things done through people.

Nobody, however able, can do all the work alone. The art of management is to get the most from other people. Most people are not performing to the extent of their capabilities.

In fact, most have not even dreamed of what their real potential might be. It is always possible to develop people to greater levels of creativity and responsibility. The successful manager is good with people, knows the strengths and weaknesses of key staff, develops the strengths and ensures that the weaknesses are protected.

Team building is at the root of all successful staff. The right people are selected and are given the opportunity to show what they can do. Two processes are fundamental to bringing out the best in one's staff: delegation and motivation.

Delegation begins with an analysis of the manager's own job. What are my responsibilities and tasks? Must I do them all myself? Can they be done by someone else and, if so, who would be best for this task? Can it be done by one person or should it be delegated to more than one? What training will be needed? What resources should be assigned to make it possible to succeed? Managers can delegate everything that need not be done personally, especially tasks which they are good at and are used to doing since it is likely that they will also be able to teach others how to do these well.

Whatever work is delegated, the ultimate responsibility still lies with the manager. Failure should not be blamed on the delegate without good reason, because failure means that delegation was not appropriate or well targeted by the manager. But delegated work well done provides an opportunity for genuine praise to encourage the employee to further effort and greater achievement.

Delegation provides not only an opportunity for employees to gain experience and stature but it relieves the manager of work and opens up more time for projects which might otherwise not be attempted.

Motivation is a powerful force which can generate effort beyond the normal call of duty. Motivation is internal; an employee may or may not be strongly motivated. Motivation is not something which can be provided to other people. However, good leadership can inspire employees and bring out their latent motivation. Managers should:

- do the utmost to ensure that the work is interesting, challenging and demanding;
- let people know what is expected of them;
- let people know when they are meeting required standards;
- ensure that rewards are clearly linked to efforts and results.

Pay and advancement are not the primary motivators for employees but, if pay and career opportunities are not satisfactory, the manager should seek to improve them. Failure to do this will result in discouragement and loss of good, trained staff. Conversely, the act of interceding on their behalf will motivate the staff and strengthen their commitment. Ways to build motivation are listed in Box 2.15.

BOX 2.15 Motivating employees

- Know key staff individually
- Know what interests and motivates them
- Provide increasingly more challenging opportunities
- Know when people have reached the limit of their capabilities
- Know their strengths and weaknesses
- Encourage formal training or higher qualification, as appropriate
- Recognize good performance immediately
- Speak openly about how well the team is doing
- Take risks with early and generous rewards (pay, promotion, etc.)
- Delegate interesting and exciting work
- Involve the staff in decisions; seek their views
- Seek their ideas on job improvement; they know their jobs best
- Share information, promptly and honestly
- Involve staff in budget development and control
- Help staff when they have a problem
- Make sure that staff approach their work with a positive attitude

Maslow's hierarchy of human needs (Box 2.16) provides the theoretical underpinning for the foregoing management principles. The 'primary needs' are universal and do not need discussion. This means that employees will expect reasonable salary, benefits, free time and job security. These primary needs are taken for granted and are not a major motivating factor. The 'secondary needs' are unique to each individual and it is these that a good manager, by knowing the staff well, can utilize in the development of each person's motivation.

BOX 2.16 Maslow's hierarchy of human needs

Primary needs

- Physiological needs
  - food
  - air
  - rest
- Safety needs
  - security
  - freedom from threat
  - freedom from pain

Secondary needs

- Social needs
  - affection
  - love
  - affiliation
- Esteem (ego) needs
  - recognition
  - status
  - achievement
  - competence
- Self-actualization needs
  - personal growth
  - realization of potential
  - self-fulfillment

Key functions

There are six key functions essential for any successful manager: planning, initiating, controlling, supporting, informing and educating (Box 2.17). The emphasis at any one time will reflect the needs of the moment but a balance must be maintained over time, without neglecting any of the six functions. Too much emphasis on controlling will produce an unhappy workforce. Neglect of evaluation will negate effective control. Concentration on support functions may be necessary with a stressed workforce but, if other functions are ignored, will gradually reduce the group's sense of purpose. Failure to provide information will undermine group participation. Coherent work is impossible without a workable plan. The manager is in a position to integrate all these functions and to ensure that they are wisely balanced.

BOX 2.17 **Key functions of management**

1. Planning
   - seeking information
   - defining purpose, objectives and tasks
   - making a workable plan
2. Initiating
   - briefing the group on the plan and its purpose
   - explaining why the plan is necessary
   - assigning tasks to group members
   - setting group standards
3. Controlling
   - selection and management of people
   - management of income and expenditure
   - management of information systems
   - maintaining group standards
   - influencing tempo
   - monitoring progress towards objectives
   - stimulating the group to actions and decisions
4. Supporting
   - recognizing persons and their contributions
   - encouraging the group and its individual members
   - disciplining the group or individuals
   - developing team spirit and motivation
   - resolving disagreements
5. Informing
   - clarifying tasks and plans
   - providing up-to-date information
   - receiving information from the group
   - summarizing suggestions and ideas
6. Evaluating
   - checking the feasibility of an idea
   - testing the consequences of a proposed solution
   - evaluating group performance and helping the group to evaluate itself

The three essential skills of management are: leadership, communication, and thinking.

Leadership is a subtle skill, quite different from management but essential for all successful managers. Leadership requires a clear vision of where the organization is going and perseverance in pursuing its objectives. It requires a strong sense of teamwork and the integrity to earn lasting trust. Gentle humour, tact and compassion, with individuals and the group, are valuable qualities. Most leaders are in position of leadership because they have been put there by somebody else and given responsibility and accountability for the group's actions. The ability to earn the respect of the group is essential for effective leadership. Many groups include emergent leaders, persons without formal authority, whose leadership skills influence the group and may even challenge the position of the official leader. Recognizing, encouraging and promoting such people is a skill one expects from the appointed leader.

Communication may be achieved through speaking, writing or visual means. The good manager, with a message to convey, will plan the communication for maximum effectiveness. There are four distinct steps in this process:

1. identify the purpose and the audience;
2. decide the content;
3. decide the means, timing and location to be used;
4. judge the response.

Good communication depends upon good management information. Information must be comprehensive, relevant, easily understood, timely and accurate. Information has value only if it is used. It is effective only if clearly presented. Too much information is as bad as no information.

Thinking skills are essential for all managers because decision-making, problem-solving and creative thinking are required every day. The individuality of personality and management style is nowhere more prominent than in this area of management. Does the manager make decisions alone (autocratic)? Are problems solved through open discussion and group action (democratic)? Does the manager seek input and advice before making the decision (consultative)? Does the manager make the decision and then try to lead the group into making the same decision (manipulative)? Are decisions left to the group to make (laissez-faire)? In the real world there are times for democratic decision-making and times for consultation; sometimes decisions must be made alone; the skilled manager will select the correct style for each situation. Whichever style is preferred, there are six steps which should be followed in problem-solving:

1. recognize the problem;
2. define the problem;
3. generate solutions;
4. examine the options;
5. make a decision;
6. implement the decision.

The successful manager has learned how to balance the different elements of the job. Most new managers are focused primarily upon the work to be done (the task) and, as they become more mature in their management role, pay increasing attention to those with whom they work (the people). Many managers, instinctively or through a powerful ego need, project themselves positively at all opportunities (the self). All organizations have their own unique principles, culture, image, traditions and style. Employees, including management, have to buy into this organizational culture (the organization). An organization does not function in isolation and cannot survive without commitment to those whom it serves (the clients).

These are the five essential commitments of management: task, people, self. organization and clients. An equal balance of the five is rare in managers but any significant imbalance has to be addressed if trouble is to be avoided. Insensitivity to one's people will lead to unhappiness and poor communication; this can lead to unrest, poor productivity and disruption of work. Ignoring the task will damage productivity and quality, with disastrous consequences. Ignoring one's own image may hurt the organization by weakening the perception of quality leadership. Insensitivity or opposition to the traditions of one's organization can make enemies (particularly with older, influential employees and Board members) and can thereby undermine the manager's effectiveness. Ignoring, or failing to identify, the client(s) is a common weakness which can reduce the relevance of the organization.

Management in context

All organizations have to have an organizational structure (often represented diagrammatically in a table of organization or an organogram). The structure represents the manager's concept of who is responsible for which functions and who reports to whom. There is no right or wrong structure, but it is helpful for structures to be clear and simple. In principle, responsibilities should be divided in such a way that nobody reports to more than one person. A useful guideline is that one person should not directly supervise more than seven persons. It is tempting, but usually a mistake, to design the structure to fit the talents and needs of existing key personnel. Generally it is best to design the structure to fit the needs of the organization and then to find the right people to fit into each position. Designing the management structure is the responsibility of the manager, often with input and final approval of the Board. The existence of a unique organizational culture has already been referred to. Top management, and the Board, can influence this culture subtly in many ways and may seek to change it through radical policy changes. This is always difficult and meets resistance at many levels, so it should not be attempted lightly. In general, management of an established organization takes place in an environment in which the organization's culture determines style, tone and priority to a remarkable degree.

The organization is part of the outside environment. Changes of government, economic ups and downs, societal needs, changing demographics, technological advances

and legislative change will affect the organization. These factors are beyond the direct control of the manager but have to be taken into account in strategic planning and everyday management.

The foregoing discussions have considered management at levels which include attention to the basic tasks of the organization, creative management of people, conceptual thinking and the external political environment. All of these elements fall within the scope of management but their importance varies with the level of management. As the manager advances within the organizational hierarchy, the technical role becomes secondary to the political and leadership roles.

2.6.3 Case study*

Case 9

Design a table of organization for your BTS, showing clearly who is in charge, who reports to whom and how the major responsibilities are assigned.

2.6.4 Essential resources

The successful management of any organization, including BTSs, requires the availability of sufficient resources to make the work possible. The key resources required for a BTS are money (financial resources), people (human resources) and blood. The blood resource is discussed separately in 3.5.

Human resources are the key to any strong organization; this topic has also been discussed in 2.6.2. Finding the right people, seeing to their training and orientation, ensuring fair compensation, benefits and free time, providing a stimulating work environment and establishing creative career development opportunities require the presence of specialized human resources staff in an organisation of more than 100 employees.

Financial resources have to be adequate if the organization is to succeed. Lack of adequate financing is the commonest cause of failure of a newly established BTS. The basic requirement for sound financing is accurate budgeting (see 2.6.5) and a realistic plan for ensuring that there will be sufficient operating funds for the BTS to pay its staff on time, to purchase essential supplies, to maintain equipment, buildings and vehicles, and to pay vendors. This sounds simple and obvious, yet financial breakdown is so common that it is worth analyzing common errors and considering solutions. Well known and common mistakes are summarized, with their solutions, in Box 2.18.

*See Annex 5 for suggested solutions.

BOX 2.18 Causes of inadequate financing

Cause of inadequacy	Solution
• Inaccurate expense budget	Realistic budget
• No budget	Independent budget for BTS (see text)
• Reliance upon international aid	Local funding must be found for recurrent (operating) expenses
• Income budget not realistic	Realistic income budget (see text)
• Expense budget without funds for working capital, contingencies, equipment replacement or maintenance of capital items	Realistic expense budget (see section 2.6.3)
• Reliance upon charitable funding sources	Find a realistic source of funding
• Cost-recovery considered inappropriate for voluntary programme	See discussion in text

It is common for new BTSs to be proposed in developing countries where there may be one or more international sponsors willing to provide assistance. Help of this kind can be valuable in planning, training key people, establishing basic facilities (buildings, major equipment, vehicles, etc.) and sometimes in providing sufficient start-up funds (working capital) to launch the programme. International funds should not generally be relied upon for operating (recurrent) expenses [17]. An essential part of planning the creation of a new BTS is therefore having a realistic plan for developing the income necessary for effective continuing operation of the programme. The principal sources to be considered in seeking to ensure funding for a BTS are listed in Box 2.19.

BOX 2.19 **Income sources for a blood centre**

Income source	Mechanism	Comments
• Suitable		
Government	BTS prepares budget; government adopts budget and provides funds	Satisfactory if government commitment is reliable; tends to restrict growth
Cost recovery	Hospitals pay BTS for services received	Satisfactory if hospitals can pay; tends to cause conflict between hospitals and BTS; encourages healthy BTS growth
	Insurance pays BTS for services to hospitals or patients	Satisfactory if system is reliable; may favour the BTS if cost controls are weak
	Patients pay BTS for services received	Always difficult, because many people are not able to pay, but may be the only possible source of funds
	Government pays BTS for services provided	Satisfactory if system is reliable; may lead to tension between BTS, government and hospitals
• Unsuitable		
Donations	International aid	Donor fatigue will collapse the programme if local sources are not found to pay for operating expenses
	Charitable donations	Cost of operating a BTS is too great; reliance on charity will lead to financial starvation

Unrelated business income	Income-generating services (e.g. clinical laboratory, retail business)	Laboratory services may be a useful adjunct to BTS by reducing the unit cost of testing donated blood; total reliance on unrelated income to support a BTS will distort priorities and prevent normal growth of the BTS

A common problem for BTSs in developing countries is that they may be managed as part of the government laboratory services. The director of the BTS may then have no control of the BTS budget, with disastrous consequences. Purchase of blood collection containers may be neglected; essential laboratory reagents may not be regularly available; training of key personnel may be impossible; excellent trained staff may be reassigned away from the BTS. It is essential for a BTS to have an independent budget, under the control of the BTS director. Preferably it should be completely separated from the laboratory services.

Voluntary blood donation is commonly perceived by independent, non-profit-making BTSs (e.g. Red Cross and Red Crescent) as a barrier to charging for services on the basis that if donors give their blood freely, it is not right to charge a fee to the hospital or patient. When this opinion prevails, it is predictable that the BTS will be unable to obtain sufficient operating funds, will be seen to be inadequate and will fail. In reality, it is quite reasonable to charge a fee to recover the costs of operating the BTS. Many excellent and highly ethical BTSs operate in this fashion. This is not profiteering by the BTS. It is simply recovering the costs of the daily work so as to make it possible to continue operating a successful programme. It is quite ethical to charge a fee which is sufficient to recover all operating expenses and generate enough additional funds to support growth which is considered necessary. This is not exploiting the donor's generosity. In fact, it is providing the financial resources necessary to make it possible to manage the donor's gift in a responsible fashion. It is important to explain this principle to donors and thus avoid misunderstandings. Moreover, it is preferable for the burden of cost recovery not to fall on patients many of whom cannot afford to pay and who may be deterred from seeking proper treatment.

2.6.5 Budgeting and planning

Budgeting and planning are considered together because they are closely linked. The budget is a financial plan which determines how much it will cost to operate a centre for a fixed period of time (most organizations budget for one year at a time) and how the funds will be obtained to pay for these costs. The budget is no more nor less than a detailed plan of work and its financial support. It is part of the overall planning process and must be consistent with it.

All organizations need a strategic plan, defining the aim(s), long-term goals, short-term objectives (result-oriented programmes) and specific actions to be undertaken. If the planned actions are to be effectively accomplished, they will need to be integrated into the annual work plan with funds budgeted for this purpose. The policy aspects of strategic plans are ultimately determined by the Board.

Management planning must take into account practical matters such as staffing levels, resource requirements, customer relations, budgeting, production, inventory levels and operational support requirements. Within this management framework, operational planning can be delegated to middle management. This will take care of matters such as scheduling, operational staffing, daily financial arrangements, inventory management, safety, security and quality control.

The budget for a BTS can be standardized to a considerable degree because the basic functions of blood collection, processing, testing, storage, distribution and transfusion are inescapable. The principal expense categories to be considered are shown in Box 2.20.

BOX 2.20 Major expense items in a BTS budget

- Personnel (number of people, salaries, benefits, training, insurance, etc.)
- Supplies (blood collection containers, laboratory reagents and test-kits, secretarial and computer supplies,petrol, etc.)
- Equipment (maintenance and repairs)
- Capital items (e.g., building expansion, heavy equipment acquisitions, vehicles, depreciation, cash reserves for contingencies, etc.)
- Communications (telephone, fax, mail)
- Utilities (electricity, gas, oil, water, etc.)
- Miscellaneous

It is not necessary here to go into great detail about the budgeting process. Specialist literature exists in abundance and experts are available to do this type of work. The essential point to stress is that the success of a BTS will depend in large part upon the soundness of its financial management and that this will require attention and control by

the director of the BTS. This will be possible only if the BTS has control of its own budget and financial management.

Three major strategies are possible in the preparation of the budget: a) preparation can be done by top management and handed down for implementation (top-down planning); first-line, supervisory and middle-management staff are not involved and may feel left out and become indifferent; b) budget preparation can take place at the operational level (bottom-up planning), with full staff involvement but without management guidance; operational concerns may dominate, to the detriment of the overall strategy; c) these two approaches can be integrated with top management defining strategies and objectives while middle management and supervisors draw up the action plans; this is preferable as it creates a sense of participation and commitment among the staff which gives the plan a greater chance of success. In all cases, coordination of the budget elements and leading the budget approval process is a management responsibility.

The actual cost of operations will vary from one BTS to another, depending upon the local economy, the sophistication of the BTS and its range of services. The greatest costs are personnel and supplies, particularly collection containers and test kits. Fully developed programmes will cost approximately US$100 per blood donation; the simplest programmes may cost as little as US$30 per donation; any budget based upon lower costs than this will certainly be unrealistic. The following case studies will provide some opportunity for those not experienced in budgeting to practise the basics of budgeting for a BTS.

Regular financial reporting should be tied into the budget plan. Generally, monthly reports will suffice for monitoring the financial status against the budget, so that serious variances can be quickly spotted and corrective action taken as appropriate. Reports should be designed for clear understanding, with significant variances highlighted. Data should be accurate and timely; it is no use receiving April's report in September, when changes should have been implemented in May; monthly reports should be ready within 14 days of the end of the month. Financial reports should be in summary form for top management and more detailed for lower levels. Regular meetings are needed to permit discussion of finances and budget variances.

2.6.6 Case Studies*

Case 10

It is time to prepare the annual budget for the ABC BTS for the calendar year 1994. In 1992, 53 000 units of blood were collected; of these, 4% were technically unsuitable for use and a further 8% were discarded because of positive tests for transmissible infections; 40% of the remainder were used as whole blood and 60% were separated into red cells and plasma; from the latter, 6500 platelet concentrates were made and 4700 cryoprecipitates;

*See Annex 5 for suggested budgets.

there were many shortages of red cells and platelets during the year. In 1993 the budget plan was based upon collecting 58 000 units and production to date has been close to this target. Regrettably, red cells and platelets have continued to be in short supply. Blood usage is estimated to increase by 8% each year.

Prepare a realistic expense budget for 1994, bearing in mind all reasonable expenses and likely growth needs. Estimate the number of personnel that will be needed and reasonable salary and benefits for each. Estimate the number of collection containers that will be needed, based upon US$2.50 for each primary container and US$2 for each satellite container. Test kits for each required laboratory screening test for infectious diseases will cost US$1.50.

Case 11

Prepare two alternative 1992 income budgets for the ABC BTS:

1. assuming that the government will pay all the budgeted expenses of the BTS, in monthly installments at the end of each working month and that, on the first day of the year, the BTS will have operating cash on hand equivalent to 60 days' operating expenses.
2. assuming that fees for services will, for the first time, be paid by hospitals, that hospitals pay, on average, 45 days after receiving service and, that on the first day of the year, the BTS will have operating cash on hand equivalent to 15 days' operating expenses.

3. VOLUNTEER BLOOD DONORS: MOTIVATION, RECRUITMENT AND RETENTION

3.1 Basic principles

Blood donors should give their blood voluntarily and without expectation of payment. The reasons for this are discussed in 2.2.2. Family donors, or replacement donor systems have been shown not to meet the criteria of a volunteer system and are therefore undesirable and to be discouraged. This section discusses the creation and strengthening of volunteer programmes and considers in some detail how to convert existing family or paid donor programmes into volunteer programmes.

International organizations involved with the collection of blood for transfusion are clear in their endorsement of the principle that blood donors should not be remunerated and should give their blood voluntarily and without coercion. The important policy statements, outlined in Annex 3 underline the principle that blood transfusion services should not pay blood donors and should ensure that the donors are volunteers. This may appear to be a clear requirement. However, experts who agree totally on the underlying principles do not uniformly agree on definitions of 'payment' and 'volunteer'. Simple definitions of these key words are offered here, together with examples, to assist the reader in understanding the complexity of this matter.

Payment (remuneration) of a blood donor is the rewarding of the donor with money, or merchandise or services which can readily be converted into money. Volunteer donors give blood of their own free will and without coercion of any kind.

Specific examples, clarifying these definitions, are cited in Box 3.1 All the possible situations cannot be listed here but the underlying principles are sufficiently clear for rational decisions to be made. There are grey areas, dubious practices, generally involving small inducements which may strongly motivate certain people, which are best not introduced and which should be eliminated if already in use. They constitute an unnecessary expense, are a source of controversy and complicate decision making.

Donor programmes which rely entirely on volunteers are difficult to create from nothing. Three general truths underlie the organizational approach to this task:

- People do not give blood unless they are asked to do so.
- People are not naturally motivated to donate their blood.
- There are more than enough potential blood donors.

As a general rule, it is necessary to ask people to give blood before they will do so. Exceptions occur after major disasters or when friends or family members need blood, and occasional dedicated donors will volunteer their blood without being asked, but these exceptions constitute only a small proportion of the blood donors that are needed. The organization of a successful blood donor programme involves the creation of a network of supportive people (volunteers) who will collaborate to ask people to donate blood. This requires a large and complex organization. A BTS may require many tens of thousands of blood donors each year.

BOX 3.1 **Volunteers and non-remuneration**

Volunteer

- The following are considered to be volunteer blood donors:
  - a donor who volunteers to give blood when requested by the BTS
  - a donor who volunteers to give blood when requested by a colleague, friend or family member
  - a donor who gives blood on his own initiative
  - a soldier who volunteers to give blood when requested to do so.
- The following are NOT considered to be volunteer blood donors:
  - a soldier who is ordered to give blood.
  - a member of a patient's family who gives blood because he is told, for example 'your father will not get the blood he needs unless you donate', or 'your father will have to pay for the blood unless you donate', or 'your father will not be discharged from hospital until you donate'
  - a group of students who are told 'your friend was in a terrible accident and he will die unless you donate blood'
  - prisoners
  - persons who cannot fully understand what they are agreeing to do
  - persons who are too young to make legally binding decisions

Payment

- The following are considered as payment for blood donations:
  - the BTS gives money to the donor
  - the donor receives money from patient or family
  - the donor is paid by an organizer who has been paid by the family

- the donor receives a voucher or merchandise which has monetary value
- the patient is excused hospital bills because of a donation in his name
- tickets in raffles or lotteries in which the prize is valuable
- paid time off from work, if sufficient to motivate the donor

• The following do NOT constitute payment of blood donors:

- payment of bus fare, to and from the blood collection centre
- sufficient time off from work given to make blood donation possible
- small gifts or prizes given in recognition of 1st, 20th, etc. blood donation (pins, badges, certificates, etc.)
- social events to which blood donors are invited to receive recognition of their contribution.

Such inducements and rewards do not motivate people to become blood donors but serve to reinforce the spirit of mutual collaboration between BTS and blood donor.

The BTS must create a public attitude which favours blood donation. This is not a simple process; it requires continual and active effort. The general public will not take the initiative to come spontaneously to give their blood. Finding blood donors requires finding groups of people who will donate blood. There are two principles here: a) too many blood donors are needed for it to be possible for the BTS to recruit each individual donor; b) it is necessary to recruit groups, outside organizations, which can reach, motivate and organize their own people. Such organizations may include religious groups, major employers, hospitals, unions, universities and high schools, the military, government employees, community organizations, etc. In general, the leaders of such organizations are in a strong position to influence their own members. The role of the BTS is therefore to work with the leaders of these groups, encouraging the recruitment of donors from within the membership. This is more effective than attempts by the BTS to recruit donors directly. In other words, the role of the BTS is to recruit and motivate a variety of organizations in the community, the role of which is to recruit blood donors from within their own membership.

Blood donors must be healthy and mature. In most countries, adults comprise half to one third of the population; 50 - 90% of these are in good health. Depending upon local regulations, blood may be donated two to six times annually. A simple calculation will demonstrate that the number of potential donations far exceeds the need for blood for transfusion. The challenge for the BTS is not a shortage of potential donors; the challenge is to motivate and organize these donors so that the right amount of blood will be collected at the right time at the right place.

3.2 Motivation

The motivation to donate blood involves several distinct processes. It requires, first, an awareness of the need for blood. This requires education. Education can come from the public media and in schools, for example. It can come more intimately from doctors and nurses caring for patients and from experienced blood donors talking to family or friends. Public education requires constant repetition and reinforcement. Awareness of the need is an essential part of donor motivation but awareness alone is not sufficient to cause people actually to give blood.

Motivation requires interest in the idea of blood donation: 'This is something I could do myself'. Interest is an outgrowth of awareness but does not come simply from impersonal public messages. It develops over time, within the family or among friends, in school or in the workplace, through discussion and reconsideration. It is a small group function, not a function of the public media. Interest alone does not lead people to donate blood. It is, however, an essential step in the process of motivation towards commitment to donate blood.

Motivation implies that the person has a desire to give blood. This desire is found only in people who have already been made aware and interested. Desire may come in an organized fashion, through the process of being asked, by a friend or colleague, to give blood. It seldom comes from public appeals which are generally too impersonal to motivate an individual to take action. The role of the BTS is to harness the strength of the networks of donor groups for organized individual recruitment. The desire to give blood may also come in a disorganized fashion, through family crisis or public disaster. This is a normal human reaction and can also be constructively exploited by the BTS. However, it is not sufficient to rely upon such crises to provide the blood that is needed.

Even the desire to donate blood will not lead to blood donation without the necessary organization. Desire must be channelled into action. This has nothing to do with motivation of the donor; it has to do with organizing the BTS to take advantage of the donor's latent generosity. It must be possible for the donor to come to the BTS or for the BTS to go to the donor (see 2.5). The donor cannot give blood unaided.

The four essential steps in donor motivation are summarized in Box 3.2. The essential point is that motivation is a continuing process, requiring public education, group organization, discussion and good planning. It will not happen without continual effort.

BOX 3.2 Four stages of blood donor motivation

Stage	Process
1. Awareness	Public education; school curricula; media; meetings of community leaders
2. Interest	Group discussion; lectures
3. Desire	Personal crisis (private or public)
4. Action	Convenient organization and scheduling by BTS

Motivation of the whole population is necessary if the BTS is to succeed in collecting sufficient blood. This challenging task requires in-depth knowledge of the population, existing groups, their leaders, their attitudes, etc. Before a public education programme can be planned, knowledge must be available of the current understanding, attitudes and taboos within the community, of who can lead and influence the people, and of the opinions and feelings of these leaders regarding blood donation. Planning the work of the BTS around the needs and feelings of its customers, those people upon whom it depends for blood donation, blood donors and donor groups, is referred to as 'marketing'.

3.3 Marketing

Marketing implies that organizational planning will be oriented to the customer. This concept requires careful consideration of who the customers may be. A BTS may take the view that the customer is the hospital receiving the service. This is true, but only part of the truth. Certainly the customers include the blood donor population, without whom no BTS can function. The customers also include those volunteers who help to operate the programme; the people who work within the organization, and those outside institutions whose collaboration is needed. They also include the patients who receive blood and the physicians who care for the patients. It is essential for a BTS to know who its customers are if it is to to succeed in satisfying their needs. A BTS must know its market.

The basic function of the relationship of the BTS with its customers is to define a voluntary exchange. In business this may involve the exchange of money for food. A blood donor exchanges a pint of blood for a very special sense of satisfaction. The principle is the same, whether in business or in a charitable organization. The BTS must be able to deliver the sense of value, the feeling of having done something worthwhile, so that the customer, the blood donor, is pleased with the transaction.

A 'market' is not the same as a 'public'. A market is a group of people with whom one seeks to have a voluntary exchange. A public is a group which may affect the organization but with which there may be no exchange involved (e.g., government, the medical society). Thus marketing, which is customer-oriented planning, is not the same

as public relations. Market orientation, the concern for the customers' needs, is an important attitude for a BTS. It requires the commitment of management and the entire organization to the philosophy that the 'customer comes first'.

'Marketing' is often frowned upon in the idealistic volunteer world of blood donation. It may be thought of as selling or advertising; someone who practises marketing is thought of as high-pressure, a salesman, perhaps as someone not to be trusted. These prejudicial views bear reconsideration because the principles of marketing apply to the successful organization of blood donation as to any business. A salesman seeks to encourage clients to want to make a purchase; a donor recruiter seeks to encourage individuals or groups to want to make a blood donation. The skills required are similar; much can be learned from marketing specialists. A BTS should have a positive view of 'marketing'. It is the best way of understanding the people with whom it must work if it is to succeed. Marketing provides a basis for planning and ensures that the efforts of the BTS not only serve the needs of patients, doctors and hospitals, but also serve the needs of blood donors.

Marketing consists of a process which can be divided into six steps (see Box 3). The first two steps comprise examination of the present situation, within and beyond the organization. What are its strengths and weaknesses? What are the opportunities for it and the threats to it in the environment? This is known as a SWOT analysis (strengths, weaknesses, opportunities and threats). An organization can exploit its strengths, improve its weaknesses, take advantage of opportunities, and protect itself against external threats. There is nothing it can do to change the environment, but it can adapt to the environment. It is dangerous to ignore environmental factors.

The third step, segmentation of the market, is concerned with identification and analysis of the different segments in society with which the organization will be working. Each segment will have its own characteristics and the organization will adapt itself accordingly. Examples of segments of society with which it may work in the organization of blood donors include major employers, educational institutions, students, labour unions, religious groups and their leaders, men, women, tribal and ethnic groups, rural and city dwellers, near and distant communities, the wealthy, the poor, regular donors and new donors. The relevant segments will be different in different places, but the need to work segment by segment with the community applies to all BTSs.

BOX 3.3 Steps in the marketing process

1. Analysis of strengths and weaknesses of one's own organization
2. Analysis of the opportunities and threats posed by the outside environment.
3. Segmentation of the market
   - geographic
   - demographic
   - lifestyle
   - usage level
4. Market research
   - primary research: surveys, focus groups, observation and analysis
   - secondary research: published studies, census data
5. Marketing plan
6. Evaluation

Market research is the formalized process of learning everything possible about current and potential customers. Which segments offer the greatest opportunities for effective partnership? What are the unique characteristics of each segment which will affect the nature of this partnership? What can this segment contribute and what are its needs and desires? The marketing plan takes all this information and applies it to the development of a plan which fits the mission and goals of the organization. What is it going to do? When is it going to do it, and with whom? What will the product be? How can it be improved? How can it be changed for maximal customer satisfaction?

Evaluation is an essential part of any plan. Is it working? Is it costing too much? If it isn't working, what was done wrong? What can be done to improve? Evaluation is a continuing process.

What has all this to do with a blood transfusion service? This description of the marketing process has been written in marketing language to emphasize the principles and the process itself, but every part of this process applies to a BTS. It applies in the recruitment and retention of blood donors. It applies to planning the resources of the BTS, human and financial. It applies to the service functions of the BTS. Who is the customer? What does the customer want?

Marketing is a planning process which can be turned to the advantage of a BTS. It is a process which will lead to change, continuing change, so it will not be easy or comfortable. But it will provide a valuable tool for remaining well adapted to the changes in the environment. Change is inevitable. It is an antidote to organizational inflexibility,

the refusal to consider change, an unwillingness to ask questions, the desire to do what is convenient for the organization rather than what may be needed by those it serves.

3.4 Defining needs and establishing recruitment goals

3.4.1 Approaches

One of the most important, and most difficult steps in effective donor recruitment is to establish clear goals and a clear definition of what the BTS is trying to achieve. For a mature programme, with a long history of successes and failures, with knowledge of current patterns of blood usage and changes from year to year, it is a straightforward matter to project needs into the future, to plan blood collections accordingly and to make minor adjustments as needed from time to time.

This process is much more difficult for a new programme, which has no historical data to enable estimation of trends. It is quite usual for first efforts at donor recruitment to produce insufficient blood. How can this problem be overcome? There are three principal reasons for failure of this kind:

- immature organization;
- lack of clear goals;
- underestimation of need.

The first reason is readily understandable in a new organization. Good management, sufficient resources and the normal process of learning from experience should take care of this difficulty. Failure to establish clear goals is a common mistake and can ruin the best intentions. The tendency to underestimate need is more complicated and is worth some analysis. There are three approaches to the estimation of how much blood is needed:

- in relation to total population;
- in relation to hospital beds;
- in relation to past, present and future blood usage.

Estimation of blood needs, in relation to the total population, must be done with great care. Table 3.1 indicates the enormous variation between different countries in the amount collected in a year. It may be reasonable to use such data to get a rough estimate of blood needs, or for rough confirmation of estimates derived in other ways, however if the two estimates are far apart the situation will have to be reanalysed to find the cause of the discrepancy.

Usage of blood may also be related to the total number of hospital beds, particularly acute hospital beds [17,23]. This too is a useful way to get a rough estimate. Blood usage usually is between 3 and 15 donations per acute hospital bed per year. However, an estimate which may err by 200-300% is not precise enough for the purpose of planning blood collections.

It is necessary therefore to get detailed information about actual blood usage. This is difficult, so the methods and the problems involved are described in detail.

TABLE 3.1 **Blood collections per 1000 population (Western Pacific Region)**

>40		20-40		10-20		5-10		2-5	
Japan	68	Hong Kong	29	Brunei	17	Tonga	9.9	Laos	3.4
Australia	58	Singapore	24	W.Samoa	17	Fiji	9.7	Viet Nam	2.6
New Zealand	56	Amer.Samoa	23	Kiribati	12	Papua N.G.	9.0		
		Macao	23	Malaysia	10	Vanuatu	9.0		
		Rep.Korea	22			Philippines	7.3		
						Solomon Is.	6.5		
						China	5.7		

The first step is to obtain a complete list of hospitals in the BTS area with the number of beds and the type of service provided by the hospital. These data are usually available centrally through health authorities. The next step, obtaining information about blood transfusion in each hospital, is more difficult. If previous surveys have been conducted by government or non-governmental agencies these data should be acquired for inclusion in the analysis. However, regardless of the availability of previous data from independent sources, up-to-date information should be sought from every hospital. This is usually difficult; there may be no statistics available and there may be no adequate records from which such data can be compiled; even if such information is available, the hospital administration may not be willing to provide the data. The secret is not to ask for too much information and to ask only for simple facts which are essential. There are many more data that are interesting and desirable, but the information in Box 3.4 will be sufficient at the start. Nevertheless, there are several problems to be anticipated with even these simple data (see Box 3.5). Bearing in mind the points in Box 3.5, there are steps that can be taken to ensure that the data are usable and comparable as follows:

- All data should be expressed on an annual basis (i.e., if available information covers only four months, it should be multiplied by three).
- If data are not up-to-date, they should be adapted to allow for changes in the intervening period.
- It should be ascertained that the information received is, in fact, complete.
- Inconsistencies between blood collections and blood usage should be resolved before interpretation is possible.
- The method employed for counting blood donations should be standardized (it is recommended that the 'number of successful blood donations' be used in the analysis of need).

- The volume of blood donations should be standardized also, but this may not be possible immediately (therefore, for the initial statistical analysis, it is sufficient to count the number of donations and disregard differences in volume).

BOX 3.4 Essential hospital data for assessing blood transfusion activity

- How many blood collections are made by the hospital?
  - where are the donations made?
  - is this blood used by other hospitals also?
  - how are the donors recruited?
- Is blood obtained from other sources?
  - where?
  - how much?
- What is the volume of each blood donation?
- What type of container is used for blood collection?
- How many blood transfusions are carried out by the hospital?
  - whole blood
  - red cell concentrates
  - platelets
  - plasma
  - cryoprecipitate
- Is the blood supply sufficient?

The standard blood donation in most industrialized countries is 450ml + 45ml. In Italy it is 350ml; in Japan 200ml or 400ml, depending upon donor size and donor choice; in Romania 225ml. Many countries have regulations which may unnecessarily restrict the volume of blood donated, thereby placing unreasonable obstacles before the BTS.

BOX 3.5 Problems encountered in interpreting blood collection data

- Time period covered by the data may be unclear, or less than one year.
- Data may be obsolete.
- Records may be scattered, and data therefore incomplete.
- Blood collected/available for use will normally be somewhat (up to 15%) more than is actually transfused; if this is not the case, re-analysis is necessary.
- Blood donations may be counted differently from place to place, e.g.
  - number of donors presenting
  - number of donors accepted
  - number of donors in the donor file
  - number of successful blood donations
  - number of acceptable blood donations
  - total volume of blood collected (in litres or millilitres)
- The volume of each blood donation may not be the same in every hospital and may not be the same for every blood donation.

Using this approach, it is typical for useful data to be obtained from some hospitals while little or no information is available from others. It therefore becomes necessary to take the available information and extrapolate it in order to come up with a reasonable estimate for total blood collections and/or blood usage for the area in question (see 3.4.2).

It generally happens that estimates of blood needs prove to be too low. The reasons for this are set out in Box 3.6. An approach to avoiding this problem is provided in the case studies (in 3.4.2).

BOX 3.6 Reasons for underestimating blood needs

- Data may be incomplete
- Data may be for a previous year, while usage is increasing annually
- Data may not make allowances for unavoidable losses
  - loss of donors who are unsuitable
  - loss of blood due to technically unsatisfactory blood collection
  - loss of blood which tests positive for transmissible infections
  - loss of blood due to breakage or contamination
  - loss of blood due to expiration
- Actual blood usage may be less than actual need.

It should be clear from this discussion that the planning of recruitment goals requires setting the target substantially higher than the apparent need for blood. The case studies in 3. illustrate this in more detail.

3.4.2 Case Studies*

Case 12

A blood centre is being planned starting 1 January 1994, to manage the total blood supply for a country of two million people. The annual mean per capita income is US$6500. There are 15 hospitals, with a total of 7500 beds. There is no other blood centre in the country. Table 3.2 lists the available hospital data. What would be reasonable estimates for blood collections and blood usage in this country?

Case 13

This country had estimated blood collections in 1992 totalling 46 480 units. In the same year blood usage was estimated to be 38 099 units. Most hospitals indicate that there is usually enough blood for their needs, but that sometimes patients have to wait for the blood they need. Up to the end of 1993 all blood was collected by individual hospitals; in 1994 it is planned to consolidate this activity through a single blood centre serving all of the hospitals. What is the need for blood? What should be the recruitment goal to ensure a sufficient supply to meet this need?

*See Annex 5 for suggested solutions.

TABLE 3.2 **Hospital data 1992**

Hospital	Services	No.of beds	Blood collection	Blood transfusions WB	RBC	Plasma	Platelets	Cryoprecipitate
A	general, acute	430	1 420	1 285	-	-	-	-
B	rehabilitation, chronic	240	-	10	-	-	-	-
C	general university	2 200	28 500	16 500	6 300	200	900	2500
D	general, acute	1 170	3 700	3 300	NA	NA	NA	NA
	obstetric	70	200	+400	-	-	-	-
F	general, acute	360	900	700	-	-	-	-
G	general, acute	760	2 500*	2 200	NA	NA	NA	NA
H	infectious diseases, chronic	220	-	24	NA	-	-	-
I	general acute	490	1 600	1 400	NA	NA	NA	NA
J	general, acute	380	1 460	1 225	85	13	-	-
K	general, acute	510	1 600	1 400	NA	NA	NA	NA
L	military, general	230	2 100	920	-	-	-	-
M	private	160	900	850	NA	NA	NA	NA
N	private	190	1 100	1 050	NA	-	-	-
O	private	90	500	450	NA	NA	NA	NA
	Total	7 500	46 480	31 714	6 385			
	Grand total			38 099				

*The only information from hospital G is that 585 blood collections were made in March, April and May 1988. The annual estimate of 2500 is based upon these three months, multiplied by four (2340), with a slight increase to allow for growth in the intervening years.

NA= Not available

3.5 Donor recruitment

3.5.1 General principles

Donor recruitment is the process that includes public motivation, identification and recruitment of donor groups, education and motivation of volunteer recruiters, donor groups and individual donors, organization and scheduling of blood collection sessions, maintenance of records of donor groups and individual donors, development and maintenance of a comprehensive programme for retention of known donors, maintenance and analysis of statistics, and recognition of the contribution of donor groups and individual donors. This time-consuming and difficult task requires well trained and competent staff, dedicated to the task of donor recruitment. It is generally considered necessary to have one full time donor recruitment staff member for every 5-10 thousand blood donations annually [17].

The following general principles (summarized in Box 3.7) underlie the whole process of donor recruitment.

Donors are volunteers and are not paid

This principle has been discussed (2.3, 3.1) and is taken as the basis upon which the donor recruitment programme is built.

BOX 3.7 **Principles of donor recruitment**

- Donor shall be volunteers and shall not be paid
- Motivation and education of donors are continuing processes
- It is easier to introduce young people to blood donation than their parents
- Group leadership is the best way to recruit new donors
- Retention of known donors is crucial
- People will not donate blood until they have been specifically asked
- Public appeals for donors can weaken the programme
- Donor recruitment must be a steady year-round activity
- Inducements do not motivate voluntary donors
- Publicity can be helpful but does not recruit donors by itself
- Donation by public leaders can set a valuable example

Motivation and education of donors are continuing processes

The techniques for carrying out the processes of motivation and education of donors depend on local conditions. A public which generally knows about the need for blood

from community donors is ready for recruitment. A public which lacks this knowledge, and which continues to have fears and taboos concerning blood donation, will need careful education and leadership. A public which believes that there are religious grounds for avoiding blood donation will need reeducation with the help of its religious leaders.

It is easier to introduce young people to blood donation than their parents

Active education programmes, starting at the junior school level, can ensure that high school students will be aware of blood donation by the time they become old enough to give blood. Active donor recruitment in high schools, colleges and universities creates an excellent source of healthy donors, ready to become blood donors for life.

Group leadership is the best way to recruit new (first-time) donors

All groups in the community which have the potential to assemble sufficient numbers of people to justify organizing blood collections should be identified and brought into the programme. It is often helpful to bring leaders of such groups into the organization of the BTS, through participation in committee activities.

Retention of known donors is crucial

The previous work of the donor recruiters is lost if a donor gives blood once and then does not return for future donations. An active programme of donor retention is necessary. The phlebotomy staff must ensure that the donation process is a pleasant experience for the donor, and can assist the recruiters by establishing when the donor(s) will be able to give again. Involvement of donors in the recruitment process can help to cement their interest and sense of involvement in the programme. Special attention needs to be given to the retention of two categories of donors, first-time donors (and those who have not given so frequently that they can be counted as regular donors) and donors who have been temporarily deferred for health reasons. Donors of less than four or five donations may need special encouragement before and during the donation, and careful persuasion to return for the next. Donors who are temporarily deferred may often feel a sense of rejection ('I'm not good enough for them"; 'My health is not good enough for me to be a blood donor'). It is important for the staff who are explaining the deferral to anticipate these problems and to ensure that the donor leaves with a good understanding of why the deferral was necessary, how long it will apply and a good feeling about coming back to donate when the reason for the deferral has come to an end.

Donor retention is emphasized not only because it significantly eases the work of donor recruiters. Even more important is the fact that regular donors are safer than new donors. Regular donors become personally known to the BTS and have in the past been repeatedly tested negative for transmissible infections. First-time donors have been shown to have a higher prevalence of transmissible infections. This is not a reason for ignoring first-time donors, who are essential for maintaining the supply of donors but it is emphasized because the retention of safe donors, and the development of a cadre of regular donors, are necessary but frequently neglected in the planning of a donor recruitment programme.

People will not donate blood until they have been specifically asked

The process of recruitment must include a mechanism for specifically asking each donor to give blood, at a particular time and place. The donor's willingness to do so should be established, and a commitment obtained from the donor.

Public appeals for donors can weaken the programme

Public announcements of blood shortages must be used sparingly. Frequent announcements give the impression that the BTS is failing in its mission and does not know what it is doing. If, in special circumstances an appeal is necessary, it is helpful to explain to the public why this appeal must be made. It should be noted, however, that appeals of this kind have uncontrollable results and often are not particularly productive. The public appeal is not a good recruitment tool.

Donor recruitment must be a steady year-round activity

The purpose of blood collection is to maintain at all times a supply of blood which will be able to take care of immediate needs. This implies the storage of blood for a period of time before it is used. The expiration date is typically 3 to 6 weeks after collection, depending upon the preservative solution added to the blood. Most units of blood are transfused well before the expiration date; the average length of time a unit of blood is kept before use is about 10 days. Thus it is not possible to collect blood at one time of year and to stop collecting at another. Blood must be collected every week, in closely similar amounts. In practice, this means collecting blood every day, or at least every weekday. It is best if these daily collections are planned for approximately equal amounts each day. Blood usage does not vary greatly with the seasons, so needs are roughly equal around the year.

There are certain practical problems with the requirement for steady collections. In many countries the summer is a time for festivals and holidays which are disruptive of routine operations; special planning may be needed to overcome such difficulties. Public holidays may disrupt normal schedules for several days. Planning must allow for greater collection before and after such holidays. Certain occasions are traditional for blood donation and staff and facilities may be swamped by crowds wanting to donate blood; this should be anticipated and the necessary adaptations made to facilitate smooth operations. In Islamic countries the month of Ramadan is a difficult period for donor recruitment. Generally it is possible, by collecting more blood immediately before and after Ramadan, to alleviate the shortage which would otherwise occur.

Inducements do not motivate voluntary donors

It is tempting to try to reinforce the recruitment of voluntary blood donors with small gifts and other inducements (T-shirts, raffle tickets, ballpoint pens, etc.). Gimmickry of this kind does not add to the effectiveness of the programme; in fact, it merely adds unnecessary costs and logistic complications. If inducements are truly motivating people to give blood, they have the same potential danger as payment of donors. If inducements are not motivational, they serve no useful purpose (see also 3.2).

Publicity can be helpful but does not recruit blood donors by itself

Most donor recruitment programmes overemphasize audiovisual publicity (posters, radio and newspaper announcements, etc.). Without a thorough organizational process to reach the donors individually, these publicity techniques will not recruit blood donors. However, they can have a reinforcing effect, reminding people of the date of a blood collection event and generally raising the image (profile) of the BTS.

Poster competitions can be very valuable in heightening public interest, particularly among young people. Unexpected and outstanding talent can come from such competitions and the entrants may become lifelong supporters of the BTS.

Blood donation by public leaders can set a valuable example

Blood donation by prominent people (politicians, royal family, religious leaders, etc.) can, with associated publicity, have a valuable leadership influence within the community. The positive example encourages others to do the same. Those who may be tempted to offer lame excuses for not giving blood may find it more difficult to do so when some public figure has demonstrated the feasibility.

2.5.2 Donor demographics

The demographics of the potential donor population should be ascertained. How many people are there? What percentage are under 18, over 65? What is the level of education/literacy? What is the economic spectrum? Is this a homogeneous population or is it multi-ethnic? Is one language dominant and known to the whole population or is it a multilingual community? What is the general state of health of the population, and are there endemic diseases which are transmissible by blood transfusion?

Those responsible for donor recruitment should know the answers to all these questions. The total population will affect the blood collection goal. A population with a high proportion of young people, as is true in most developing countries, will require a disproportionate level of organizational effort among young people (schools, colleges and universities, youth groups and organizations). A population with many people over the age of 65 years (common in the industrialized countries) will need more blood because more is consumed by the elderly; the existence of many healthy elderly people who have been regular blood donors creates the possibility of raising the upper age limit for blood donation (blood donation may be considered even after the age of 80 years).

A high literacy rate permits the use of written materials for donor education; this approach will not be effective in multilingual communities with low literacy rates. A stable economic situation is favourable for recruitment of volunteer blood donors; the typical volunteer donor has above average education and above average income; voluntary blood donation is characteristically a function of middle class people. An unstable or weak economy will not favour donor recruitment: when people are living under stress they have less time for others; when the most urgent priority is finding the next meal, people are less likely to be motivated to volunteer their blood.

Public health realities must be taken into account. In a country with local endemic areas for malaria, clearly the focus for recruitments should be on the non-endemic areas. If hepatitis B or AIDS is prevalent, those segments of society least at risk must be ascertained and targeted for blood donation.

3.5.3 The role of young people

The young donor is the donor of the future; a high percentage of donations may come from high school, college and university students. A special programme for the organization and recruitment of young people should form part of the programme of any BTS (see 3.5.6).

Education about blood and blood transfusion should be aimed at the whole population, but it is most effective with young people and this is where the greatest organizational effort is needed. There is much value in the development, in conjunction with the education authorities, of a formal curriculum concerning blood. This can often be integrated into biology courses, with information becoming more advanced each year. Such a stepwise curriculum can be started in the earliest years of school, with basic knowledge about blood well secured before the teens. The idea of blood transfusion can be introduced at this stage, with gradual expansion of the materials taught, until by the age of 16 every student will have a good idea of blood, the principles, uses and dangers of blood for transfusion, the feasibility of serving as a blood donor and the continuing need for healthy people to do so.

The age at which young people may begin to give blood is not universally agreed. There is no magic moment when a boy or girl suddenly becomes suitable for blood donation. As a result, arbitrary rules are made, setting the minimum age for blood donation. For good reasons, rules of this kind should be determined with local conditions in mind. Factors to be taken into consideration include age of seniority, voting age, age of induction into the armed forces and minimum age for driving, with local cultural traditions strongly influencing opinions on this point. Worldwide the minimum age for blood donation varies from 16 up to 21. The most usual is 18, but the tendency is to set more liberal guidelines. Australia and Hong Kong have had good results from setting the minimum age at 16.

Some jurisdictions require parental permission for blood donation by minors (generally those less than 21 years of age). This is a legal matter but it can complicate the operation of a BTS if laws are too restrictive. Every BTS must therefore take a serious interest in laws which affect its operation and may consider trying to influence laws which seem inappropriate.

Young people are not only the most enthusiastic segment of society but are generally more ready than their elders to seek ways to resolve society's ills. Blood donation is an excellent outlet for this fountain of constructive energy. This is true not only of blood donation itself but also of the organizational work which makes blood donation possible.

Students can play a leadership role in the organization of blood collection at their schools and universities. This certainly involves the organization of other students, and may even extend to organizing parents or the general community to take part in blood donation events organized at the school. This sort of community volunteer work is not only valuable for the BTS, it enhances the image of the school in the community and provides an opportunity for young people to be directly involved in community services.

A BTS with a strong youth programme will have effective donor recruitment in other areas. A BTS which is having difficulty with donor recruitment is urged to make special efforts to develop a strong youth programme.

Two technical problems arise out of a successful blood donation programme among young people and these should be taken into consideration. The first relates to the hiatus caused by school holidays. Students may be out of school or university for several weeks during the summer. A special programme is needed to retain student donors during this period, otherwise an important part of the regular donor base is lost during an already difficult period. The second problem is also one of donor retention: how does one retain regular student donors after they have graduated and gone out into the world? The answer to this question depends upon local circumstances. If this issue is not carefully addressed there is a danger that committed blood donors will be lost unnecessarily.

3.5.4 Planning and organizing a donor recruitment programme

It is clear that there are many dimensions to a successful donor recruitment programme. It is not sufficient to stick a poster on the wall and wait for the donors to arrive. Passive recruitment will not produce donors. An active, well rounded programme is needed. The essential elements (summarized in Box 3.8) have already been described but the following need further consideration.

BOX 3.8 **Essential elements of a donor recruitment programme**

- Set annual collection goals; calculate annual recruitment goals
- Develop budget (realistic expenses; sufficient resources)
- Select and train donor recruitment manager/director/coordinator
- Establish management structure
  - relationship to BTS management
  - structure of donor recruitment department
  - relationship to other BTS departments
- Prepare job descriptions
- Select and train staff
- Establish public information (public relations) programme
- Develop standard operating procedures (SOPs)
- Know the community (marketing)
  - demographics
  - segments (government, industry, schools, ethnic, youth, etc.)
- Identify and involve community leaders
  - identify potential donor groups
  - form a leadership committee
  - work with blood donor associations
- Select and train trainers of volunteer recruiters
- Identify suitable site(s) for fixed blood collection centres
- Develop a production plan
- Make specific collection plans (12-month schedule, with monthly updating)
  - mobile collections (donor groups)
  - fixed sites (individual donors, small groups and general public)
- Train donor groups
  - group leaders
  - donors
- Establish donor retention programme
- Establish donor records system
- Define performance indicators
- Establish system to monitor and evaluate performance

a) Selection of staff

The size and nature of the donor recruitment staff will depend upon the size of the programme and the types of work that are planned. A useful rule of thumb is that one full-time paid staff person will be needed for every 5000-10 000 blood donations per year. A BTS, responsible for collecting 120 000 units of blood per year, will therefore need 6 to 12 full time paid staff for donor recruitment functions. These include the responsible director (manager), trainers, field personnel, telephone recruiters (if needed for fixed sites) and the necessary secretarial support staff. In very large programmes it may be useful to include specialists to handle key segments (youth, significant ethnic minorities, government, etc.).

The staff will have important roles with people in the community and must be suitable for such work. A good public presence, speaking ability, teaching skills, outgoing personality and good appearance are valuable characteristics. The donor recruitment staff should also include people with analytical and planning skills. In a large BTS the donor recruitment director has major management responsibilities. Selection of this person should take into account the ability to relate effectively to community leaders, coordinate a complicated operation, and to achieve the required goals by effective management of the donor recruitment staff. This is a senior management position; people who are not 'managerial' will not succeed in the role.

b) Training donor recruitment staff

This is a responsibility of the recruitment director. The first step is therefore the training of the director. In a large BTS, lacking director-level experience in donor recruitment, it may be necessary to send the director elsewhere for training in essential skills. Training should achieve broad understanding of blood and blood transfusion, the philosophy underlying the recruitment of volunteer donors, community organization and echniques and principles of management, planning and donor recruitment. The recruitment director will be responsible for selecting and ensuring the training of subordinate staff.

c) Training of volunteers

The extent of volunteer involvement in donor recruitment will vary from programme to programme and will be influenced by existing traditions of voluntary work. However, it is a universal truth that volunteer donors are more responsive to other volunteers. The volunteer is 'one of us' while paid staff may be seen as self-serving. A donor recruitment programme can therefore be greatly strengthened by including a strong cadre of volunteer recruiters. The training of volunteers is best carried out by other volunteers. The role of paid staff in this regard is to see to the training of a group of volunteer trainers, thus ensuring that the volunteer training process becomes largely self-sustaining. The training of group leaders can thus become a volunteer function.

d) Donor retention programme

The importance of this function is referred to in 3.5.1. Donor retention comes from principled leadership at the top of the organization with top management setting the tone: this is an organization with which everyone is proud to be associated. The effectiveness of donor retention efforts is significantly affected by the work and attitude of the phlebotomy staff. A pleasant and enjoyable donation experience will encourage donors to repeat the experience. A pleasant reception, quick, efficient processing, a smooth phlebotomy, a friendly phlebotomist and a grateful good-bye all help to ensure that the donor will return regularly.

Many donor retention functions belong within the donor recruitment department but donor retention cannot succeed without the collaboration of the entire organization. Technical functions for which the donor recruitment is responsible include a variety of means of communicating with donor groups and donors. 'Can you host mobile blood collections more frequently'? 'How many times per year are you willing to give blood'? 'Please let us know if you change your address/ work/ university/name'. It may be possible to set up a routine where every donor, after donation but before departure from the donation site, is asked 'May we make an appointment with you for your next donation?' A reminder, a few days before the date, by telephone or postcard, can reinforce the earlier commitment. A postcard can be designed which includes the donor's signature from the time the appointment was made. The appropriate follow-up technique will depend upon local circumstances. Good telephone and postal systems are important. A volunteer network is very useful.

The specific situations concerning the retention of student donors are discussed in 3.5.3. These underline the reality that no BTS can afford to lose track of its regular donors. Reliable records are essential.

e) Donor records

An essential part of operating a donor recruitment programme is keeping good records. Three types of records should be kept:

- operational statistics, permitting analysis of performance, trend plotting, segment analysis, reporting and planning;
- records of donations by individual donors, permitting recognition of milestone accomplishments, analysis of frequency of donation over time, spotting donors who have become inactive and, increasingly important, linking each donor to identification numbers for each donation and thus allowing retrospective study in donors subsequently associated with problems such as hepatitis or HIV;
- records of the activity of donor groups, facilitating appropriate recognition of achievement and spotting trends towards greater or lesser productivity.

Records should be detailed, accurate and up-to-date. Constant maintenance is essential. Information can be maintained manually (card file systems) but in large

programmes it may be appropriate to consider computerization. Whichever system is selected, confidentiality and security must be maintained and access to these records must be limited and controlled. The records must be safe from fire, flood and theft. In computerized systems, it is essential that back-up files are constantly updated and maintained in a secure and separate location.

Security is emphasized for three reasons:

- the information is essential for everyday operations;
- the files contain sensitive and confidential information about certain donors;
- donor records can be used competitively if they fall into the wrong hands (there are cases on record of donor recruitment staff, dissatisfied with their working conditions, leaving the BTS after stealing the donor information, and then setting up a donor programme in competition with the BTS). Box 3.9 lists the essential records to be kept for each donor.

BOX 3.9 Essential records for each blood donor

- Name(s)
- Address
- Telephone
  - home
  - work
- Employer
- Date of birth
- Unique identification no.
- Record of each donation, with running total
  - date
  - blood no.
  - total donations
- Deferral (with effective dates) or disqualification
- Sex
- Blood Group (ABO, Rh)
- Date eligible for next donation

3.5.5 - Examples of successful donor recruitment programmes

Donor recruitment in the Islamic Republic of Iran[1]

Until 1974, all the blood required by hospitals was provided by paid donors. After the establishment of the Iranian National Blood Transfusion Service, conversion to an entirely voluntary blood donor base was complete in Teheran by 1976 and regional centres were being established in other cities. This rapid evolution was supported by two basic educational approaches:

- Constant diffusion of straightforward educational material regarding the uses of blood, the growing need for blood and the ease and safety of blood donation. The dangers of using blood from professional donors were stressed. This educational programme was reinforced by the assistance of religious leaders, lending legitimacy to blood donation by providing appropriate Koranic quotations, by giving blood themselves and permitting this act, and the organization of blood collection sessions in sacred places, to be filmed. This influence was able to change the widely-held misconception that blood is 'unclean' and to establish the principle that giving blood during Ramadan does not break the fast. Young people were included in this educational process by visits to many schools and universities, as well as student field trips to blood centres.
- Intense short-term campaigns, focused upon specific groups which had been targeted for blood donation (e.g. a factory, a ministry, one sector of a city). It was helpful to go first to the most senior officials, persuading them to set an example by giving blood themselves. Blood collection took place in many different locations, of which there were four general categories: mobile teams, fixed centres, hospital centres, and mobile trailers.

Important ingredients in the success of this programme were an enthusiastic professional staff, precise planning, a reputation for integrity and scientific expertise and the image of a caring well organized institution. Public support for the donor recruitment programme was thus assured.

Donor recruitment in West Bengal[2]

The first blood bank in Calcutta was formed in 1942. There was no programme for the recruitment of voluntary blood donors and the service was totally dependent upon professional donors. Commercial blood banks, owned by physicians, began to flourish. In 1967 the State Government introduced a voluntary blood donation scheme parallel to the paid system. In the absence of any systematic donor recruitment system, voluntary donations were sporadic and made a negligible contribution to the State's blood resources.

1. Based upon the presentation by Dr F.A. Ala.
2. Based upon the presentation by Mr Debabrata Ray.

In 1980, a group of 89 volunteer blood donors formed the 'Association of Voluntary Blood Donors, West Bengal' (AVBD), with the goal of motivating people to donate blood voluntarily to the government blood banks. This group of volunteers, with no material resources of any kind, with no paid staff, and with office hours in the evenings only, determined to run its recruitment drives with professional efficiency.

Motivational programmes were planned, based on approaches to individuals and groups and with support from the media. Outdoor blood collection 'camps' were organized, with the help of government blood banks. National conferences on blood donor motivation were organized to attract national attention to this social movement. A quarterly bulletin is published, with national and international distribution. AVBD is working with the Indian Ministry of Health on the production of various documents. By 1990 AVBD was recruiting 80 000 new blood donors annually, more than half of the estimated needs for West Bengal (150 000 donations).

Donor recruitment in the Chinese population of Hong Kong[1]

Blood transfusion first became established in Hong Kong in the 1950s. Hospitals would ask the relatives of patients to find blood donors; these relatives would often resort to radio appeals in their search for donors. This system created many problems. In an effort to ease the situation Chinese doctors trained in the industrialized countries and expatriate nurses working in colonial hospitals, made personal appeals to their friends.

Chinese traditions and culture are averse to the giving of blood. The strong opposition was assumed to be based on the superstition that the body is inviolate and must remain so. The truth is probably more due to fear of the unknown, and partly to the cultural mores of the Chinese community in Hong Kong.

In 1955 there were only 2600 donors, of whom 125 were local Chinese volunteers. The community was largely ignorant of blood donation and was opposed to giving blood. In the 1960s the continuing shortage led to a growing tendency to trade in blood. In the 1970s the Hong Kong Government decided that a central body should be created to operate the entire blood programme in Hong Kong. This responsibility was given to the Red Cross Society and became effective in 1980.

By 1989, annual blood collections were 156 000, of which 96% were from local Chinese; 86% of these donors were males and females under the age of 30 years. This change in the attitude to voluntary blood donation was the result of long-term education of the general public, with special emphasis on the early education of young people. The cooperation of community leaders and educationalists was sought and it was found necessary to circumvent the traditional leadership of parents. The results show that traditional prejudices are gradually being overcome.

1. Based upon the presentation by Dr Susan Leong.

3.5.6 Donor recruitment in the overall organization of the blood transfusion service

The key role of the manager of the donor recruitment department has already been emphasized, together with the fact that this is a senior management position. This person must be able to meet with community leaders and to command their respect. The ability to manage a diverse department, with many distinct functions, is essential. This person must, therefore, be selected by the overall director of the BTS and must be part of the management team. Support of the BTS director is essential. This is an important job, requiring recognition as such and salary to match the assigned responsibility. It is essential to be able to employ someone of sufficient stature and to retain the services of a competent director.

Donor recruitment should be integrated with the other operational departments of the BTS. The phlebotomy staff should be part of the production planning process and appropriate staffing should be made available for blood collection operations. The phlebotomy staff should also be an intimate part of the donor retention process: they can achieve two-way communication with each individual donor; they can facilitate the arrangement of appointments for subsequent donations; above all, they can ensure that the donation is a technically and socially pleasant experience for the donor. Close collaboration between the donor recruitment and phlebotomy departments can provide the foundation for a potent donor retention programme. In fact, some BTSs have created a Donor Services Department with a single director responsible for both donor recruitment and blood collection. Failure to secure a good working relationship between recruiters and phlebotomists can lead to serious problems (they may have conflicting goals, as a result of which recruiters may blame phlebotomists for insensitivity and annoying the donors, and phlebotomists may blame recruiters for shortage, excess or erratic scheduling of donors).

The laboratory staff have direct knowledge of current specific needs (special products, rare blood groups, etc.) and know the current needs for production of components (platelets, cryoprecipitate, etc.). The planning of the day's blood collection should include discussion of these matters, so that recruiters are aware of any special requirements, the laboratory can plan for the expected number of units to be tested, and all departments can coordinate planning for component production. This last point is a critical one because the ability to prepare components depends upon the correct choice of collection containers before the blood is drawn.

The staff responsible for the distribution of blood products to hospitals, a department sometimes referred to as Hospital Services or Product Management, cannot carry out their function coherently if the blood supply is inadequate or unpredictable. In fact, these staff are in the delicate situation of often having to take the blame for shortages which are beyond their control. Their natural tendency to transfer this blame to the donor recruiters can be averted if the departments work closely together, with a clear understanding of the roles and problems of each.

The donor recruitment department has an important role to play in the education and training of staff, volunteers, donors and donor groups, and the general public. Therefore it is necessary that the overall training programme of the BTS include the donor recruitment staff, to ensure that recruiters are fully aware of the subject they are required to teach and play their part in the total training programme for staff.

As with all other departments, donor recruitment depends upon the support of the administration for some essential functions (budgeting, human resources management, transportation, building maintenance, purchasing, etc.). Working relationships with the corresponding officials must be maintained.

Public relations requires special mention. This function is sometimes included in the donor recruitment department and may not even be specifically assigned to one person or department. It is best, however for this important role to be self-standing in the BTS. In this case, close collaboration with donor recruitment will be essential.

It is clear, therefore, that the donor recruitment department must be effective outside the organization, must have an influential position within the internal table of organization, must be a capable operational unit and must be able to relate effectively to the other key departments of the BTS.

It has already been stressed that donor recruitment incorporates important management functions. Some of these are now discussed in more detail.

3.5.7 Management aspects of donor recruitment

Budgeting

A common mistake is to provide insufficient resources for the donor recruitment department to be able to function effectively. The size of the task should be matched by the human and material resources assigned to ensure its successful accomplishment. There should be enough people on the staff (one per 5000-10 000 donations per year); the ability to develop suitable informational and publicity materials; good communications systems (telephone, fax, mail and opportunity to travel); and suitable record-keeping systems, whether manual or electronic. Finally, in a computerized institution, staff should have appropriate equipment and suitably secured access to institutional information. All of these items must be specifically budgeted for if the capability is to be assured.

Staffing

A well balanced donor recruitment department in a major BTS will include all of the following: manager (director); representatives (consultants, officers) who work out in the community; a team, perhaps in several locations, responsible for individual recruitment of known donors, usually by telephone; someone responsible for training functions; someone responsible for records and statistical analysis; and secretarial support. The challenge is to accomplish all this with a staff that is adequate for the task but not overstaffed. Efficiency of donor recruitment is one of the most difficult challenges in BTS management.

Records

The precise records to be kept will vary from programme to programme. The key is to keep and use essential information while avoiding spending time and resources on maintaining and reporting unnecessary facts. Records should include three kinds of information: donor data, with ready access for each active donor and archives including records on all past donors; donor group information, permitting analysis of productivity and trends for each donor group; and production statistics, permitting reporting, analysis of trends and planning.

Management

The donor recruitment department has a key role to play in the overall management of the BTS. The work of the department provides the resource upon which the entire programme depends and the community outreach function can cement powerful relationships with community leaders. The manager of the donor recruitment department should therefore be an integral part of the overall management of the BTS and should be well informed about policies and programmes.

Information

Collection and dissemination of information, whether internal or external, is an important part of the continuing daily activity. Feedback from donors and donor groups, and from BTS staff of other departments, should be interpreted and put to use. All staff, donor groups and the general public should be kept informed of what is happening. The work of the donor recruitment department is greatly strengthened by accurate public information. Generally, responsibility for this function lies with the public relations department but the donor recruiters should be closely involved.

Key performance indicators

No department of the BTS has more need of accurate performance measures than donor recruitment. Key indicators of this performance are listed in Box 3.10 and some of these items require further discussion.

BOX 3.10 Key performance indicators for donor recruitment

- Meets annual goal (or adjusts goal to changed needs)
- There are no blood shortages or excesses
- Collections are steady throughout the year
- Blood group imbalances (ABO and Rh) can be corrected by specific recruitment
- Each collection operation comes close to planned production
- Daily plans fit with phlebotomist staffing levels and needs for blood and components
- There are mechanisms for recruitment of rare donors
- There is an ongoing review of the community (demographics and segments)
- There is an active leadership committee
- There is an active donor retention programme
- Records are accurate, up-to-date and used for recruitment of regular donors
- Training of staff, volunteers and donor groups is ongoing
- Evaluation of overall performance is carried out regularly
  - Individual staff members
  - donor groups
  - collection sites
- Contingency plans are in place to meet emergency needs

Meeting the annual goal seems simple at first, but needs careful analysis. Is the goal realistic? Are blood needs being satisfied by fulfilling this goal? If the goal is assumed to be realistic, and blood needs can be satisfied by achieving this goal, accurate production is needed (within 2% above or below the goal). Too much blood will be wasteful and expensive. Too little blood will lead to a shortage.

Achievement of daily production goals is usually less precise. Each operation, however, should fall within 10%, up or down, of the plan for that operation. A useful objective measure of BTS (donor recruitment) performance is the percentage of all operations which fall within 10%. Perhaps a reasonable standard would be to aim for at least 80% of all operations to fall within 10% of the target.

Detection of a blood shortage requires subtle interpretation of available information. The first indication is a falling inventory at the blood centre; at this time there is no

noticeable effect at the hospital level. The next and more serious indicator is when hospital inventories begin to fall and cannot be replenished by the blood centre. The third phase of shortage is noted when hospital inventories fall to the point where blood is not readily available for elective surgery; a critical point is reached if elective surgery has to be postponed or cancelled for lack of blood; a continuing and useful measure of performance of a BTS is data concerning postponement of elective surgery. The gravest shortage is encountered if inventories fall to the point where blood is not available for emergencies; this is very rare in fully developed programmes.

Cancellation of surgery for lack of blood reflects a serious failure of the BTS. It may be caused by poor planning (unrealistic goals), by ineffective donor recruitment, or by short-term external factors which could not be predicted (severe weather, political instability, general strike etc.). The possibility always exists of external factors, beyond the control of the BTS, disrupting planned operations. For this reason, detailed contingency plans are necessary to take care of all imaginable situations.

Blood excesses can also cause severe problems. In some situations the excess can be offered to another organization with needs for supplementary supplies. This possibility may even be planned and become a regular arrangement. But, if such inventory balancing is not possible, blood in excess of need will become out of date and have to be discarded. This is wasteful of blood and money, and squanders the gift of the donor. A certain amount of outdating is inevitable (up to 2% of total collections may be reasonable) but excessive outdating is unacceptable. Since it reflects an overabundance of blood, outdating is a concern of the donor recruitment department. It may be caused by overplanning or overcollecting. Excess collections are costly and wasteful. In this case exceeding the goal is a performance failure, not a success. The goal is accuracy, not excess. The design of performance indicators must therefore take this into account.

Year-round accuracy is also important. The short shelf-life of a unit of blood determines the need for steady and continuous production. The absence of significant seasonal difficulties with the blood supply is an important success indicator for the donor recruitment programme.

Some BTSs have difficulty maintaining an appropriate balance of major blood groups in the inventory. There is a tendency to use group A red cells for patients who are group AB, leading to abnormally high outdate rates for group AB. Others may suffer from a chronic shortage of Group O (particularly group O Rh negative); this imbalance may be caused by selective use of group O red cells for patients of other blood groups, greater rates of bleeding in group O patients or ethnic differences between the patient and donor populations in a particular community. Whatever the cause, the donor recruiters will need to adapt recruitment techniques to correct the imbalance. The maintenance of balanced inventories is a strongly positive performance indicator.

3.6 The unsuitable donor

The success and safety of a blood collection programme depends upon the suitability of the blood donors. In principle, the blood donation must be safe for the donor and the blood must be useful and safe for the recipient(s). This means that all donors must be in good health. An essential role for the BTS is to ensure that this is the case. The BTS must exclude donors with conditions which may predispose the donor to adverse effects of blood donation. Donors and their blood must be excluded if there is any factor which may harm the recipient.

Harm to blood donors is extremely rare. Experience with autologous donors of advanced age, with heart disease, advanced pregnancy and other conditions which would normally exclude homologous donors, has been universally favourable. Nevertheless, factors which may possibly harm the donor are grounds for exclusion. These include heart and cardiovascular disease, uncontrolled seizure disorders, pregnancy, anaemia, recent major injury or surgery and blood donation in the recent past. The donor may be at greater risk if too young, too old or too small. Malnourished persons should not donate; they cannot spare the blood and its quality may be inferior.

Factors likely to harm the recipient include infectious agents which may be transmitted from donor to patient, (including spirochetes of syphilis and yaws, viruses of hepatitis B (HBV), hepatitis C (HCV) and perhaps other forms of hepatitis, human immunodeficiency virus (HIV), human lymphotrophic virus type I (HTLV-I), Kreutzfeld-Jakob disease and parasites of malaria, Leishmaniasis, Chagas' disease and babesiosis). As appropriate to local conditions, donors who may transmit these dangerous infections must be excluded.

Also important is the exclusion of donors who have factors which are not fully understood but which just possibly may harm the recipient; in this category are placed persons who have had malignant tumors, have chronic systemic diseases of unknown aetiology (e.g. Crohn's disease, sarcoidosis, multiple sclerosis and rheumatoid arthritis), are taking drugs which may harm the recipient (e.g. penicillin, Tegison), or have bacterial infections which might lead to bacteraemia, thereby risking bacterial contamination of the donated blood.

The BTS can use various techniques to identify and exclude unsuitable donors. Since none of these is foolproof, they should be used to the extent reasonable in local conditions. Useful techniques are listed in Box 3.11.

BOX 3.11 Techniques for exclusion of unsuitable blood donors

Individual donors

- Health history
  - questionnaire
  - self-exclusion techniques
- Physical examination
- Blood tests
  - before donation
  - after donation
- Donor deferral register

Donor groups

- Institutionalized persons
  - prisoners
  - intellectually disabled
- Groups known to be predisposed to infections transmissible by transfusion.

Blood should not be solicited from groups known to have a high prevalence of diseases transmissible by transfusion. In part, this is the responsibility of the donor recruitment department. However, it is also a responsibility of those screening individual donors at the site of blood collection. Since hepatitis and other transmissible infections are prevalent among inmates of prisons and of institutions for the intellectually retarded, these persons must not serve as donors. Furthermore, certain segments within a particular country may have a demonstrably higher prevalence of transmissible infections (e.g. the military sector compared with the civilian sector; the urban sector compared with the rural sector); if such information is available, it may be appropriate to exclude the high prevalence segments from blood donation altogether. In view of the fact that the prevalence of transfusion transmissible diseases varies markedly from one place to another, it may be appropriate for a BTS in a low prevalence area to exclude potential donors from areas of higher prevalence. Unfortunately, application of this principle may be arbitrary and unfair in some situations because the scientific basis for decision making may be insufficient to overcome cultural or ethnic prejudices.

The emergence of the AIDS epidemic has revealed another type of donor population which must be excluded. Persons predisposed to sexually transmitted diseases are not safe blood donors and must be excluded. This is difficult because sexual practices are a sensitive and private matter and sexually unsafe persons are not segregated or easily

recognizable. It has become clear that male homosexuality is incompatible with safe blood donation, that prostitution and indiscriminate heterosexual activity facilitate the transmission of syphilis, hepatitis and AIDS, and that intravenous drug abuse is a potent source of disease spread within groups who are sharing injection equipment. Furthermore, the recipients of unsafe blood products, most notably regular transfusion recipients like people with haemophilia and thalassaemia, but also including certain recipients of sporadic transfusions, are more than usually liable to transmit dangerous infections to others. All of the above are unsuitable blood donors and must be excluded from blood donation. The same is true of their sexual partners. Box 3.12 lists those persons who are particularly liable to transmit dangerous infections through their blood and therefore must not serve as blood donors.

BOX 3.12 Individuals whose risk factors require exclusion from blood donation

- Males who have had sex with other males
- Male and female prostitutes
- Males and females whose sexual activity is indiscriminate
- Males who have used prostitutes; females who have used male prostitutes
- Intravenous drug abusers
- People with haemophilia or thalassaemia
- Sexual partners of any of the above

The challenge to the BTS is to identify and exclude those persons listed in Box 3.12 and other risk donors without giving offence to the general public. Techniques which have proved effective in certain settings are listed in Box 3.13.

BOX 3.13 Techniques for identifying and excluding risk donors

- Direct questioning, including specific questions about sexual practices
- Physical examination, including a search for stigmata of drug abuse or AIDS
- Facilitation of self-exclusion by those at risk, by
  - providing explicit written information to all donors
  - providing confidential ways for the donor to inform the BTS that the donated blood should not be used for transfusion, e.g. confidential procedure at the time of donation, opportunity to communicate with the BTS after donation
  - having contact with organizations representing persons at risk (e.g. haemophilia associations, organizations of homosexual persons) to ensure that their membership is informed not to give blood
  - informing all individuals known to be specifically at risk that they should not donate blood, i.e. persons with a history of hepatitis or AIDS, persons listed in Box 3.12, blood donors whose blood has tested positive for transmissible infections which must be excluded
- Maintaining confidential data concerning persons who have been permanently excluded from blood donation (donor deferral register)
- Discouragement of persons tempted to give blood so as to obtain results of blood tests, by
  - ensuring that the public has access to alternate systems for confidential testing
  - informing all donors that they will not be given the results of their tests and that they should not try to contact the BTS to obtain results
  - continuing public information campaign
- Criminal penalties for persons who knowingly give blood when they should be excluded

The complexity of the many techniques which may be applied requires the use of scientific and political discretion before establishing procedures. Local conditions (e.g. disease prevalence, literacy, cultural factors, prevailing sexual practices) will determine which methods should be applied in each BTS.

3.7 Donor selection criteria

3.7.1 General

The decision as to whether an individual donor is suitable for blood donation is based upon certain general criteria and upon the donor's health history, physical examination and tests done prior to donation. This decision is usually made immediately before donation, at the donation site. Some BTSs prefer to use a system of predetermination, perhaps on the day before donation. Prescreening of this kind permits more complete testing than is possible at the donation site and may prevent the collection of blood which cannot be used. However, there are two major disadvantages of this approach: a) it is inconvenient for the donor, involving the expenditure of time and travel on two different days; b) explaining a disqualification to the donor is more difficult and prone to breakdown of confidentiality. For these reasons, prescreening is generally not recommended, though there is a valid argument for using prescreening for new (first-time) donors.

The following discussion relates only to on-site (same day) screening. General information, to be obtained from all donors, should include the following:

a) Name, address, telephone, employer, etc.

The ability to identify and trace donors requires that all donors provide standard identifying information. This basic information is essential for follow-up recruitment of the donor and for the accurate maintenance of donation records. Accuracy permits comparison of laboratory results with previous donations. In situations where a donor has been permanently disqualified from blood donation, but for some reason attempts to donate again, accurate identifying information permits recognition of the unsuitability of the donor (see 3.8). Some BTSs require each donor to present his/her unique identification number (e.g., passport number, social security number). Some BTSs question donors concerning different names under which they may have donated in the past, commonly found to be the case with young women.

b) Date of last donation

Rules for frequency of donation vary from country to country; some stipulate the maximum number of donations per year while others spell out the minimum interval between donations. Some set different criteria for men and women. Whole blood donation must be restricted because the iron lost in a blood donation is not restored quickly from the diet. Frequency of whole blood donation may be from 2 to 6 times per year; intervals may be from 8 weeks to 6 months. Some may use a combination of frequency and interval (e.g., intervals of at least 8 weeks, with frequency limited to at most 4 times per year). It is simplest to use intervals alone, because interpreting frequency within a year is more difficult and is prone to error. The interval should not be less than 8 weeks; some BTSs may choose to require longer intervals but overcautious policies can restrict the availability of blood from healthy regular donors. Conservative policies, such as a minimum interval of six months, are probably never necessary.

In a well run BTS, each donor carries a card on which each blood donation is recorded. This information can be supplemented by BTS data (the manual donation record) if this can be made available quickly. This process is greatly facilitated if each donor has a specific appointment, permitting prior sorting of donation records for previously known donors. Some advanced BTSs have computerized (on-line) systems for registration of donors, allowing immediate access to previous donation records.

c) Date of birth (and age)

This information serves to ensure that donors are not too young or too old to donate. Accuracy can be confirmed by matching stated age with date of birth. This information can also serve to confirm the donor's identity in situations where there may be more than one donor with the same name.

The minimum age for donation is a decision which can be made locally. It should be the age at which young people can reasonably be expected to be sufficiently mature to serve as blood donors. This decision must be consistent with existing laws, rules and regulations. Existing rules concerning minimum age for marriage, military service, voting or driving may be relevant. A minimum age of 18 is commonly prescribed, but several countries have demonstrated the feasibility of setting the minimum age at 17 or 16. Some jurisdictions require parental consent before minors can be accepted for blood donation.

The maximum age for blood donation is commonly set at 60 to 65 years, though some countries have experience of successful donation by octogenarians [24]. This decision also can be locally determined. Flexibility is recommended, with appropriate safeguards, since a growing number of regular blood donors, still in excellent health, are in their 60s and beyond.

3.7.2. Health history

Specific health information must be elicited from every donor, at the time of each donation. The usual technique is for trained health history personnel to ask a series of questions, as set out in a questionnaire; some BTSs permit donors to complete part or all of the questionnaire themselves, prior to rechecking by professional staff. Computerized entry of this information is becoming possible in some advanced BTSs.

The questionnaire must be able to establish the state of the donor's health on the day of donation, to detect any conditions which may put the donor at risk, and to detect any factors which may render the blood unsafe or unsuitable for the recipient. Questionnaires vary from one BTS to another, though certain key elements must not be omitted. The American Red Cross Blood Services use such a questionnaire (see Box 3.14). The wording is simplified and non-technical, to facilitate comprehension by the general public. While specifically designed for conditions in the USA, and therefore not necessarily applicable to other countries, it may be used as a basis for designing questionnaires suitable for other BTSs.

In addition to completing the health history questionnaire, each donor is required to sign a statement along the lines that:

- the written information provided has been read and understood;
- blood will not be donated for transfusion if there is a risk of AIDS exposure;
- all health history information is correct.

A positive response to one or more of the specific health history questions is not necessarily disqualifying. It serves rather to alert the interviewer to the need for further questioning to establish the significance of the response. Each question must be answered by the donor. They are discussed individually below.

1.1 Jaundice, liver disease, hepatitis: a past history of viral hepatitis is disqualifying; haemolytic disease of the newborn, icterus due to biliary obstruction and jaundice due to chemical or drug toxicity are usually not disqualifying.

1.2 Intravenous drug abuse: is always disqualifying because sharing of injection equipment is common and is a potent source of cross-infection with transfusion transmissible agents.

1.3 Transfusion, transplantation: temporarily disqualifying if within the past year. Sufficient time must have elapsed for development of detectable markers of significant transmissible infections (HIV, hepatitis B or C).

1.4 Exposure to hepatitis: persons at risk of recent infection (within the past year) must be temporarily excluded. This includes intimate contact, close household contact or institutional contact where there has been an epidemic. Casual contact, such as in the workplace, is not significant.

2.1 Malaria: this question is pertinent for areas where malaria is not normally found. Those who have been in malarious areas must be further questioned concerning febrile illness and the use of antimalarial drugs. In the USA, donors are acceptable for whole blood donation after three years away from a malarious area, if free of symptoms and not taking antimalarial drugs throughout the three-year period. Temporary visitors to malarious areas are acceptable after six months if symptom-free and no antimalarial drugs were taken during the visit. Blood donation in areas which are endemic for malaria require different policies, according to local conditions.

2.2 Outside the country: this question is intended to reinforce the previous one and thus to detect any donor who is potentially a carrier of malaria. However, as the worldwide epidemiology of hepatitis B and AIDS become better known, this question is developing significance for other conditions also.

3.1 Serious illness: in general, cardiac or vascular disease require further evaluation to ensure the donor's safety. Uncontrolled seizure disorders are disqualifying for the same reason. Most forms of cancer and many blood diseases require disqualification of the blood donor.

3.2 Surgery, medical care, pregnancy: current pregnancy is disqualifying. Blood donation is inadvisable until at least six weeks after full-term delivery. Positive answers concerning surgery or recent medical care require further evaluation. In general, someone who is fully recovered following illness, surgery or pregnancy, is suitable for blood donation. Lactation and menstruation are not disqualifying.

3.3 Feeling well today: the only question requiring a 'yes' answer. A 'no' answer requires careful evaluation concerning the donor's current health and reliability as a historian. Persons not feeling well must be temporarily deferred from blood donation.

3.4 Dental work, medications: oral surgery is assumed to cause temporary bacteraemia; some BTSs require complete healing of the surgical site before blood donation; others require a wait of at least 72 hours after the procedure. The question about medication is merely a leading question concerning the donor's health status. Very few drugs (e.g., human growth hormone, Tegison, Acutane) are themselves disqualifying, but the reason that the drug is being taken may provide important information concerning pre-existing health conditions and suitability as a blood donor.

3.5 Deferral, problems donating: another leading question which requires further evaluation of any positive answer.

4.1 Vaccinations: vaccinations with killed viruses are not disqualifying. Specific deferral periods are required for persons vaccinated with live or attenuated virus vaccines and vaccination because of known disease exposure.

5.1 Respiratory infection: temporary deferral is advisable.

5.2 Other names: an important question if accurate records are to be maintained. A change of name is not a reason for disqualifying a donor.

5.3 HIV, AIDS: a positive answer is permanently disqualifying.

5.4 Male sexual practices: questions designed to identify persons at risk for transmission of HIV infection. Positive answers require permanent disqualification from blood donation.

5.5 Female sexual practices: (as for 5.4)

5.6 Syphilis, gonorrhea: these infections are temporarily disqualifying for a period of 12 months. The association of hepatitis B and AIDS with other sexually transmitted diseases requires this precaution.

BOX 3.14 **Health history questionnaire for blood donors (example used by the American Red Cross Blood Services)**

1.1 Have you ever had yellow jaundice (except as a newborn), liver disease, hepatitis or a positive test for hepatitis?

1.2 Have you:

a) ever taken street drugs by needle, even once?

b) had a sex partner who has taken street drugs by needle?

1.3 In the past year have you received blood transfusions, blood injections, tattoos, organ or tissue transplants?

1.4 In the past year have you been exposed to anyone with yellow jaundice or hepatitis?

2.1 In the past three years have you had malaria or taken anti-malarial drugs?

2.2 In the past three years have you been outside the USA (except for Canada)?

3.1 Have you ever had a serious illness such as: cancer, heart or lung disease, convulsions, chest pain, etc.?

3.2 In the past six months have you had surgery, been treated by a health professional, or been pregnant?

3.3 Are you feeling well today?

3.4 Have you:

a) had any dental work in the past three days?

b) taken any medication in the last month?

3.5 Have you ever been deferred as a donor or had problems donating?

4.1 Have you had any vaccinations (shots) or immunizations in the last year?

5.1 Do you have a cold, flu, sore throat, or trouble breathing?

5.2 Have you ever donated under another name?

5.3 Since 1977, have you:

a) to your knowledge, had a positive test for HIV (any AIDS test)?

b) been exposed to or had sex with anyone with AIDS or with a positive test for HIV (the AIDS antibody)

c) been given money or drugs for sex since 1977?

d) taken clotting factor concentrates for a bleeding disorder such as haemophilia or had sex with someone who has?

5.4 For men, have you:

a) had sex, even once, with another man since 1977?

b) had sex with a female prostitute in the last 12 months?

5.5 For women, have you:

a) had sex, even once, with a man who has had sex with another man since 1977?

b) had sex with a male prostitute in the last 12 months?

5.6 In the past year have you had, or been treated for, syphilis or gonorrhea?

3.7.3 Physical examination

The donor screening process must include a brief physical examination. Some BTSs require a full examination, X-rays, electrocardiograph, urinalysis and blood tests; a rigorous investigation of this kind is costly and generally not required unless physical examination of blood donors is part of a community health screening process. The minimum physical examination, prior to blood donation, must include weight, blood pressure, pulse (rate, rhythm), oral temperature and examination of both arms for signs of stigmata of intravenous drug abuse.

The criteria which are applicable for donor eligibility are as follows.

a) Weight

There is no upper weight limit for blood donation. Persons weighing 50 kg or more can safely donate 450 mL blood, plus up to 50 mL blood for testing purposes. Donors weighing less than 50 kg should give blood only if conditions exist for collection of proportionately smaller amounts.

b) Blood Pressure

It is usual for a BTS to set upper limits for arterial blood pressure, requiring further professional evaluation before accepting as blood donors persons whose pressure is above the limit. Typical upper limits are 100 mm of mercury for diastolic pressure and 180 mm of mercury for systolic pressure.

c) Pulse

The pulse rhythm should be regular; irregularities require professional evaluation before accepting a donor; it is important not to overlook donors who may have cardiac disorders. The pulse rate should be less than 100 beats per minute (counting for at least 30

seconds). If the rate is too high when first counted, it is reasonable to repeat the count after a rest of a few minutes; anxiety or hurrying to the blood collection centre may cause temporary tachycardia; this is of no significance and such persons are acceptable as blood donors when their pulse rate falls below 100 beats per minute.

d) Temperature

Elevation of body temperature may indicate the presence of a febrile illness and is therefore a cause for temporary deferral of a blood donor. A typical arbitrary upper limit for temperature is 37.5 °C (99.5°F). Prospective donors should not partake of hot or cold drinks just before measurement of body temperature because inaccurate readings may result.

e) Arm examination

Both arms must be clear of signs of the use of veins for injections. Prospective donors with stigmata which might indicate drug abuse are unsuitable for blood donation unless there is an acceptable explanation.

3.7.4 Blood Tests

Prior to blood donation, the haemoglobin or haematocrit of each prospective donor must be evaluated. Those whose haematocrit is too low must be deferred and, if appropriate, referred for further professional evaluation. Some BTSs set different haemoglobin standards for males and females. It is simpler, and safer, to set just one standard, equivalent to the lower end of the normal range for women during their childbearing years. Typically this may be 12.5 g/ 100 ml Hgb (Hct 38%). However, local conditions may justify a different policy; for example, normal haemoglobin levels are higher at high altitudes.

Other essential blood tests include major blood grouping (ABO and Rh, although Rh (D) grouping may be omitted in populations with a very low incidence of Rh(D) negative persons) and screening for unexpected red cell antibodies. In addition, all donors must be screened for the appropriate markers of transfusion transmissible infections. A suitable set of tests may include screening for syphilis, hepatitis B (surface antigen, core antibody), hepatitis C, HIV infection, HTLV-I infection and tests of liver enzymes.

It is usual for all such tests of donor blood to be done after the blood donation. Most BTSs require all screening tests to be done on all blood donations, although some practise the policy of doing complete screening on all first-time donors with some tests omitted for regular donors. Shortcuts of this kind are not recommended since any resulting omission of information can be life-threatening.

Predonation screening has a certain logic to it, since it makes it possible to screen out unsuitable donors before incurring the cost of collecting the blood. This system, however, requires two visits by the donor to the blood collection site and creates practical difficulties for the BTS in follow-up and counselling of those donors who must be

excluded. For example, if 100 persons from a factory are tested one week before blood collection, and 20 of these are found to be unsuitable and therefore are not called back for blood donation, work associates of these 20 will be likely to know that these people were excluded, thus negating the possibility of confidentiality. It is reasonable for each BTS to establish testing policies according to local conditions. Some BTSs have had satisfactory experience with predonation screening. Some may not need all the tests listed above. Others may seek additional test information, for malaria, Leishmaniasis or Chagas', for example.

3.8 Deferral and disqualification

3.8.1 General

The exclusion of anybody who is willing to be a blood donor is a delicate task for any BTS. Nevertheless, the safety of the donation process and of the blood supply are at stake. Systems for the exclusion of unsuitable donors must be reliable and error free. At the same time, the community's resource of healthy blood donors must be protected and encouraged. What this means, in practical terms, is:

- donors who must be permanently disqualified must be identifiable and must be effectively excluded;
- donors who are temporarily deferred must be clearly informed of the reason and actively encouraged to return after a suitable interval;
- active donors should be informed about these procedures while being reassured that, in their own case, continued regular donation is quite safe and is encouraged.

3.8.2 Permanent disqualification

In all cases, the donor must be informed of the disqualification and the reason for it. This may require a sensitive counselling process and certainly requires written communication with the donor. In situations where the reason for the disqualification pertains to significant transmissible infections, many BTSs maintain a confidential list of such excluded donors (donor deferral register). In this way, unsuitable donors may be detected should they return, for whatever reason, to donate on another occasion. Thus all blood donations must be screened against the donor deferral register before being issued for transfusion. Disqualified donors must be informed if their data is to be entered into the deferral register.

3.8.3 Temporary deferral

In all cases, the donor must be informed of the disqualification and the reason for it. A written explanation should also be given to the donor. The explanation requires sensitivity with understanding that the donor may feel upset and rejected and therefore needs

encouragement and support. It is particularly important that the donor understand clearly that the deferral is temporary and that further donation is encouraged after a suitable interval. No BTS can afford the permanent loss of donors whose deferral need only be temporary. The donor should be told when it will again be possible to donate. Some temporary deferrals require data entry into the Donor Deferral Registry; if so, the donor must be so informed.

If the donor's condition seems to warrant referral to a physician, this recommendation can appropriately be made at the time of the deferral. A written record of this referral is essential.

3.8.4 Case studies*

Case 14

A 32-year-old man, a regular blood donor, has admitted to bisexuality, with sexual contact with his wife, female prostitutes and several male acquaintances. What actions should be taken by the BTS staff?

Case 15

A 19-year-old female student, who has never previously donated blood, has revealed the following information during predonation health screening:

a) she was vaccinated four months earlier against Rubella (German measles) and Rubeola (measles);

b) she had infectious mononucleosis with jaundice two years previously, is now fully recovered and feeling well;

c) she had several severe seizures (grand mal) at age 14, but since then has been fully controlled with phenobarbital; the last seizure was at age 15;

d) she had a tooth cavity filled the previous day, without local anesthesia;

e) she has had sexual intercourse twice with different men; she has no knowledge of their prior sexual activities; she has never been pregnant; she is menstruating today;

f) she weighs 49 kg;

g) her pulse rate was 110 per minute when first counted; 10 minutes later the rate had fallen to 88 per minute.

Is this student eligible to serve as a blood donor? If so, what precautions must be taken by BTS staff?

*See Annex 5 for suggested solutions

3.9 Whole blood donation

The organization of whole blood donation has already been discussed. Whole blood collection provides the backbone for all BTSs; it is the only source of red cell products for transfusion and is, in most BTSs, the only significant source of blood components (plasma, platelets and cryoprecipitate). The specific steps required for a whole blood collection operation are outlined in Box 3.15.

BOX 3.15 **Organization of a blood collection operation**

1. Selection of location
2. Selection of sponsor(s)
3. Production planning
   a) number of donors
   b) products to be made
   c) responsibilities (BTS, sponsor)
4. Sponsor training; donor recruitment
5. Staffing
6. Supplies and equipment
7. Transportation (staff, equipment, donors)
8. Equipment set-up, cleanliness assured
9. Donor schedule
   a) reception
   b) information about blood donation
   c) registration
   d) health screening (history, physical, test(s)
   e) confidential unit exclusion (CUE) procedure
   f) assignment of collection container
   g) blood collection, blood samples
   h) management of donor reactions
   i) rest and refreshments
   j) post-donation information to the donor
   k) planning the donor's next donation
   l) thanking the donor

10. Handling the blood
    a) storage conditions
    b) record keeping
    c) transportation
11. Clearing up
    a) cleaning
    b) transportation
    c) safe disposal of hazardous waste
12. Evaluation of operation
13. Preliminary planning of next operation

The technical aspects of blood collection have been fully discussed elsewhere [17,25] and do not need consideration here. Special emphasis is required, however, upon precision in planning, ensuring a pleasant experience for the donors and quality assurance throughout the blood collection process.

3.10 Special blood donations

3.10.1 General

All previous discussion has centered upon whole blood donation by anonymous donors. This type of blood donation is known as 'homologous blood donation'. This implies that blood from one human being is donated for use by another. Donation for interspecies transfusion, 'heterologous blood donation', was briefly referred to in the early history of blood transfusion (1.1) but plays almost no role in modern blood transfusion and will not be further discussed.

Further discussion is needed of three systems of blood donation in which the donation is specifically intended for a particular patient. These are: autologous blood donation; directed (designated) donation; and rare blood donation. Each of these has a specific purpose and requires specific organizational adaptation by the BTS.

3.10.2 Autologous blood donation

In autologous blood donation, the patient serves as his/her own blood donor. The underlying principle is that one's own blood will certainly be compatible and will not contain extraneous transmissible infections. The assumption is that 'one's own blood is the safest blood'. This is true, but it should not be assumed that autologous blood is totally safe; even autologous blood should be transfused only when clearly needed. There are three basic forms of autologous blood donation:

- predeposit autologous donation
  a) prior to planned (elective) surgery
  b) long-term (frozen) storage
- presurgical haemodilution
- intraoperative blood salvage

Presurgical haemodilution is a controversial technique, designed to lower the haematocrit and blood viscosity immediately before surgery, while making a few units of the patient's blood available for reinfusion if needed during surgery. Long-term frozen storage, in case of unexpected future need, has potential value only in cases where the patient's blood group is so rare as to make it almost impossible to find homologous blood quickly. Frozen storage is expensive and frozen autologous storage is little used. Here discussion of autologous blood donation will be limited to predeposit autologous donation (prior to planned surgery).

Autologous donation prior to planned surgery

Persons who require surgery, but are otherwise in good health and able to donate blood safely, may reasonably donate blood for themselves prior to surgery. It is generally possible for a patient to donate 2 to 6 units of blood in this way, within a 2 to 4 week period. A slight fall in haemoglobin (not below 11g/100mL) is acceptable. Prescription of iron supplements is usual and generally prevents the development of significant anaemia. Some centres treat such patients with erythropoietin (EPO), a powerful hormone drug which stimulates the production of red blood cells in the bone marrow. The use of EPO in autologous donor/patients is still controversial because of the cost and the possibility of side-effects such as thrombosis.

Autologous donation has become well established in preparation for certain orthopaedic procedures which are likely to require blood transfusion (e.g. spinal fusion) and has been widely used in plastic surgery. More controversial, but also widely practised, is the collection of autologous blood prior to cardiac surgery or Caesarean section. Some centres have active autologous donation programmes for paediatric patients; others accept patients of any age (including above 90 years), regardless of cardiac status. There are concerns about the potential risk of such aggressive programmes, but to date there have been no reports of fatalities in such patients.

Autologous donation varies from a rare and special procedure in some centres to a routine and active programme in others. Up to 10% of all donations are autologous in some centres. This wide difference in emphasis upon autologous donation requires some rationalization. There is a growing feeling that some programmes are going too far and may be creating more problems than they solve [26]. Box 3.16 lists suggested criteria for recommending autologous donation to a patient prior to surgery.

BOX 3.16 Indications for autologous donation

Generally accepted

- Surgery will be required in the next 2 to 6 weeks
- Patient can safely donate blood
- Patient is likely to need blood during surgery
- Patient is willing to undergo autologous donation

Controversial

- Pregnancy
- Myocardial ischaemia, cardiac arrhythmias, cardiac insufficiency
- Children
- Donation of just one unit of blood
- Blood is not likely to be needed during surgery

Not acceptable

- Risk of bacterial contamination of donated blood
- Haemoglobin <11g/100 mL.

Autologous donation raises many interesting issues which have to be addressed before establishing an autologous programme:

- Should the blood be fully tested, as with homologous donations?
- Should autologous blood be made available to other patients if not needed by the donor?
- Should autologous blood be transfused to the donor if found to carry transmissible agents such as hepatitis B virus or HIV?
- Should components be prepared from autologous donations or should they remain as whole blood?
- Who will pay for the extra cost of autologous donation?
- Who will make the decision to accept the patient into the programme (doctor, patient, hospital or BTS)?
- Where should autologous donations be made (hospital, blood centre or mobile collection)?
- Should autologous and homologous donations be drawn at the same time and place?
- Will encouragement of autologous donation discourage homologous donors, who will feel that they are no longer needed?

Many of these questions seem simple yet create difficult dilemmas. The reader is referred to more detailed analysis of these issues [26,27,28]. In general, autologous donation is indicated for certain types of patients but adds to the cost of operating a BTS and creates many logistic difficulties. The decision to establish an autologous donor programme is important and will profoundly affect the internal operation and external relations of a BTS.

3.10.3 Directed donation

Directed, or designated, donation is similar to autologous donation in that a specific donor has been assigned to a specific patient. It differs from autologous donation in that the patient is not the donor, and that there is no known safety advantage in directed donation. Directed donors may be chosen on scientific grounds in rare cases where a specific blood group, platelet match or HLA type is required (see 3.10.3). More usually, directed donations are provided by family or friends in the mistaken belief that directed donations are safer than blood from the general community supply.

Most BTSs do not accept directed donations when no scientific basis exists for doing so. This can be a difficult issue because a patient's family may apply political pressure in their efforts to persuade the BTS to provide the service they want. Each BTS must make its own policies concerning directed donations.

3.10.4 Rare blood donation

In most situations where blood transfusion is required, the selection of a suitable donor for the patient can be accomplished by matching the ABO and Rh(D) groups (major blood groups). In rare instances, where patient circumstances require more highly specific selection of the donor(s), it may be impossible to find a suitable donor without a more advanced selection process. The commonest and best known example of this phenomenon is when the patient has antibodies to red cell antigens which render almost all donors incompatible. This may reflect sensitization by many previous transfusions, resulting in the formation of many different antibodies, a situation commonly encountered in congenital haemoglobinopathies such as thalassaemia major or sickle cell disease. It may also be found when the patient has one antibody, or a related group of antibodies, reacting with a high frequency antigen; examples are anti-cellano, anti-Tja, anti-U, Bombay, etc. In all such instances, it requires special resources to locate suitable donors for such rare needs. Typically it requires the screening of very large numbers of donors (tens of thousands). This is generally not practical in the heat of the moment. It must be done with long-range planning in mind, identifying a panel of rare donors and devising a practical method to recruit these donors. Typically, if their blood is not needed immediately it will be frozen to ensure secure storage until needed. Small blood centres cannot develop such a resource; even very large blood centres (250 000 donors annually or more) cannot be

self-sufficient in this regard so collaborative rare-donor programmes are found in several places [29,30].

Other situations in which the rare donor concept is important are indicated in Box 3.17. In all instances, the donor is hard to find without previous extensive laboratory screening. The recruitment of such donors is a specialized function requiring collaboration between the laboratory and donor recruitment staff. It is the responsibility of the laboratory to identify the need and provide the data to identify potential donor(s).

BOX 3.17 Situations where rare donors are needed

Situation	Special need
• Red cell compatibility	Problems panel of rare red cell
- multiple antibodies	donors
- Antibody (ies) to highfrequency antigen	
• Platelet compatibility problems	Panel of HLA-typed platelet-
- HLA antibodies	pheresis donors panel of
- platelet-specific antibodies	platelet-typed donors (or donation by mother in case of thrombocytopenia due to materno-fetal incompatibility)
• Neutrophil compatibility problems	Panel of neutrophil-typed donors
• IgA antibodies	Panel of IgA-deficient donors
• Unrelated bone-marrow transfusion	Huge panel of HLA-typed donors willing to serve as donors of bone marrow (may be coordinated with plateletpheresis programme)

Recruitment of rare donors falls into two categories: response to emergency need; and planned regular donation by rare donors. Dramatic emergency worldwide searches are becoming less frequent as planned donation becomes better organized. Depending upon the circumstances, blood from rare donors may be frozen (rare red cells or platelets; IgA-deficient plasma), held for a specific patient (negative for multiple red cell antigens), flagged and entered into the general inventory or collected only when needed (HLA-matched platelets, bone marrow, specifically-typed platelets or neutrophils).

A common mistake is for rare donors to become inactive, waiting for their next donation until there is an emergency need. It is better to encourage regular donation by rare donors, even if not every donation is used for rare purposes.

3.10.5 Apheresis donation

So far only whole blood donation and its use in the preparation of certain blood components has been considered. 'Apheresis'. refers to a type of donation in which the desired component is selectively withdrawn from the donor while unwanted parts of the blood are retained by the donor. Apheresis techniques are most commonly used to obtain plasma and platelets. Apheresis methods may also be used to obtain leukocyte preparations and are increasingly being applied to the separation of pluripotential stem cells to be used for bone marrow reconstitution. Apheresis takes advantage of the fact that the principal factor limiting the amount of blood that can be collected from a blood donor is the slow replacement of red cells after donation; by returning the red cells to the donor, it becomes possible to collect much larger amounts of plasma, platelets, leukocytes or stem cells. Apheresis may be applied therapeutically (therapeutic apheresis) as well as to obtain products for transfusion. Therapeutic apheresis will not be considered further here.

Plasmapheresis and plateletapheresis have become important BTS functions and are considered in more detail.

Plasmapheresis

Plasmapheresis is useful in three distinct situations:

- if the donor has some specific plasma factor which is required by the BTS (e.g., rare or valuable antibody, deficiency of a specific protein);
- to obtain plasma products for regular patients from highly selected donors;
- to obtain plasma for fractionation into specific derivatives (e.g., albumin, immune globulin, blood coagulation factors).

Plasmapheresis may be done manually [13] and by machine. In general the manual methods are both slower and less expensive. They have been preferentially used in large-scale commercial collection of plasma. Machine methods are improving and becoming less expensive. In general, they are preferred when donor convenience is a priority and in small-scale programmes where cost factors are a low priority. Many BTSs are actively developing machine plasmapheresis programmes for the collection of plasma for fractionation as part of the effort to achieve national or regional self-sufficiency for plasma products (see 2.3). This type of programme becomes a high priority when plasma obtained as a by product of whole blood donation is insufficient to meet the needs for plasma derivatives and it is the policy to avoid dependence upon the purchase of commercial plasma fractions.

Establishment of a volunteer donor plasmapheresis programme is a big decision. It is possible to develop large-scale programmes of this type, as has been demonstrated

dramatically in Belgium. Many other countries have smaller but growing programmes of this kind, for example Canada, France and England [ ]. The decision to initiate such a programme cannot be taken lightly because it requires a huge expansion in building facilities, investment in cell separators, retraining of staff and complete reorganization of the way that donors are recruited and organized.

Large-scale plasmapheresis depends upon the regular participation of dedicated donors. Each donation takes from 30 minutes (machine methods) to 90 minutes (manual method). In the United States of America, individual donors are permitted to undergo double plasmapheresis (removal of plasma from two whole blood donations) up to twice weekly [31]. In this way it is possible for one donor to contribute more than 60 litres of plasma annually. The World Health Organization acknowledges the different requirements in different countries [25]. Nevertheless, the essence of large-scale plasmapheresis is that it depends upon frequent donation by a highly selected group of regular donors. Without a high degree of donor retention, plasmapheresis will be inefficient and ineffective. The donors must be reliable and punctual so that efficient scheduling of procedures can be assured, facilities and personnel can be fully utilized and production can be predictable.

Plasmapheresis, if scaled up sufficiently to meet the demand for plasma derivatives, may become a larger operation than whole blood donation for transfusion purposes. The total donor time devoted to plasma donation in the United States of America is about three times greater than that for whole blood donation. 12 million whole blood donations, each taking 30 minutes (approximate time on the donor couch), require 6 million donor hours. 12 million plasmapheresis donations (approximately what is required to collect 7 million litres of plasma), each taking 90 minutes, require 18 million donor hours. On this basis, plasmapheresis is three times larger as an activity than whole blood donation. This point is emphasized because plasmapheresis will not succeed in its basic purpose if it is seen just as a small increment to the existing BTS activities. Plasmapheresis requires a major expansion in the BTS if it is to be useful.

Once created and effectively operational, however, plasmapheresis programmes can provide an enormous stabilizing effect upon the BTS. The extension of the donor base is such that more flexibility is possible. Group A and AB donors can be chosen for plasmapheresis, retaining a deliberate excess of group O and B donors for whole blood donation. Plasmapheresis can be stepped up during those seasons when whole blood donations tend to be in excess and reduced during seasons of anticipated blood shortage. In this way, plasmapheresis donors can help to maintain an even supply of those components dependent upon whole blood donation. Furthermore, effective volunteer donor plasmapheresis can render the purchase of commercial plasma products obsolete and thus eliminate the destabilizing and potentially dangerous impact of dependence upon the international market place.

Cytapheresis

Cytapheresis, or selective removal of specific cells from the donor while returning red cells and plasma, has become a major activity in some countries where the demand for platelets has grown massively in response to aggressive chemotherapy in the treatment of leukaemia. Plateletpheresis (or plateletapheresis) can be performed manually, by techniques similar to manual plasmapheresis, but platelet yields are limited and plateletpheresis is not really practical without machine (cell separator) technology [32,33]. Sufficient platelets can be removed from a single donor in less than two hours (typically about 4 x 1011 platelets per donation) to provide all the platelets needed for one patient.

The principles of cytapheresis can also be adapted for the harvesting of granulocytes. Furthermore, there is a growing application of cytapheresis technology to the collection of circulating pluripotential stem cells, both from bone marrow donors and, for autologous use, from patients prior to undergoing ablative therapy for cancer or leukaemia. Since granulocyte transfusion remains controversial, even after 20 years of active experience, and accounts for only a small part of cytapheresis activity, it will not be further discussed here. Stem-cell apheresis is still an area of exploratory research and is not at the point of incorporation into routine BTS activities. Plateletpheresis is another matter. The technology has been refined and proven safe, to the extent that it is possible to incorporate large-scale plateletpheresis into BTS routine operations. There is growing discussion of the possible advantages of relying entirely upon apheresis platelets for platelet transfusion. Box 3.18 lists the advantages and disadvantages of this approach.

BOX 3.18 Platelet apheresis or random-donor platelet concentrates

Advantages	Disadvantages
Plateletapheresis	
• Specific donor required for a specific patient - selection of donor by HLA-typing or platelet crossmatch - reduced antigen exposure for the patient - family members (siblings) may be suitable donors	• Higher cost • More complex technology (special training, machines, donor centres) • Sophisticated organization is required
• Patient exposed to fewer donors - less risk of virus transmission - reduced risk of bacterial contamination	
• Safe regular donors can be organized for regular plateletpheresis	
• Increased plasma yields from whole blood donation, if platelets are not prepared from whole blood	
• High quality product which can be tailored for each patient	
Random-donor platelets	
• Lower cost • Simpler technology	• Greater antigen load for patients • Greater risk of viral transmission • Greater risk of bacterial contamination

This issue of plateletpheresis or random-donor platelets thus comes down to the balancing of quality against cost. The high cost of plateletpheresis is determined not by the conspicuous cost of the equipment but by the recurring costs of the software which is

used with that equipment. The necessary calculations must be made before contemplating a plasmapheresis programme. Expensive equipment lying idle because running costs are prohibitive is a tragedy of faulty planning.

3.11 Blood donor organizations

Organizations of blood donors have been formed in many countries. There is an international federation of such organizations - Federation Internationale des Organisations des Donneurs de Sang (FIODS) - and this provides important leadership in the worldwide promotion of voluntarism. The establishment of donor organizations has generally come from donor initiative. It leads to a separate structure from the BTS itself, working supportively with common goals. Donor organizations have become a powerful ally to the BTS in some countries (e.g. France, Indonesia, Italy) and involve themselves not only in blood donor affairs but in the overall policies of blood transfusion at the national level. Such organizations are weak or non-existent in most English-speaking countries, in spite of donor-recruitment systems which are otherwise effective. This phenomenon has not been satisfactorily explained. A reasonable conclusion is that blood donor organizations can be effective and powerful supporters of the entire donor organization system but that their existence is not essential for the success of the BTS.

3.12 Converting to an all-volunteer donor programme

Much has been said about the need to achieve a voluntary, non-remunerated blood donation system (see 2.2.2 and 3.1). Furthermore, it is recognized that less satisfactory systems exist, and may even be strongly rooted, in many countries. The strongest voluntary programmes are those which were developed on a voluntary basis from the start. The dilemma lies in how to change those established programmes which are not entirely voluntary.

Conversion from one system to another is never easy. It is not sufficient to make a commitment to start a voluntary non-remunerated donor programme; many small idealistic programmes exist without successfully eliminating undesirable alternatives. It is also necessary to be committed to totally replacing the family or paid system presently in existence. Changing an existing system is always difficult because resistance to change is a normal human reaction. Furthermore, those who will be responsible for implementing the change will have to work harder than before and will have to overcome the resistance of those with vested interests in the existing system. This will need government support, best reinforced by legislation which spells out the principles of voluntarism and sets a timetable for implementation of change. The essential steps are listed in Box 3.19.

BOX 3.19 Essential steps in conversion to an all-voluntary donor programme

1. Policy decision
   a) Be committed to the idea
   b) Build consensus
   c) Seek appropriate legislation, government support and funding
2. Planning
   a) Identify key persons, and involve them
   b) Set targets and a timetable for:
      - recruitment of voluntary non-remunerated donors
      - reduction/elimination of family/paid donors
3. Implementation
   a) Create implementation team (leadership committee, staff)
   b) Inform the general public, and keep them informed
   c) Set operational schedule, with timelines and budget
   d) Implement the complete plan
4. Monitoring
   a) Evaluate progress against established targets and timetable
   b) Make corrections if targets are not being met

Successful conversions of this kind have been made in, for example Central America, Hungary, Japan, Kuwait, Nepal, Rwanda and parts of India and the United States of America. There is no reason why any country should fail in such a conversion. All that is needed is dedication to the change and the will and resources to carry it out.

4. Quality Assurance

4.1 Concept of quality assurance

Quality assurance is a global concept which has largely evolved during the last 20 years and which is still not universally understood. For this reason, the term will be discussed and clearly defined, together with two other terms with which it may be confused: good manufacturing practices and quality control. The relationship between these three terms is illustrated in Box 4.1.

Quality assurance covers the complete range of management and operational systems needed to ensure the highest quality of work. It includes the following:

- the selection, training and retention of qualified personnel;
- good manufacturing practices (GMPs) (see definition below) ;
- an awareness of the possible causes of errors and a prospective programme for error prevention and detection;
- precise documentation of all processes and procedures, with written standard operating procedures (SOPs) for every procedure and records of all the organization's work (see 4.4 and 4.5);
- assurance of the quality of buildings, equipment and vehicles, and their maintenance.

It is essential that all BTS apply the principles of quality assurance since failures in product or service quality can be dangerous for patients and for the reputation of the BTS. Quality assurance should also apply to the selection and monitoring of suppliers and service industries upon which the BTS depends. Effective management is essential for quality assurance.

Good manufacturing practices (GMPs) are that part of quality assurance aimed at ensuring that products are consistently manufactured to the required quality. GMP is concerned with every step, from the delivery of raw materials to manufacturing and packing processes, quality control and the release of finished products. The processes of GMP therefore comprise people, premises, products, procedures and associated paperwork. GMP requires technical expertise plus management skills. GMP is synonymous with good management practice.

Quality control is that part of GMP which comprises testing, inspection and measurement carried out on samples taken before, during and after manufacturing, and packaging to provide evidence that a finished product does or does not meet the required standard. Quality control comprises specifications, sampling, testing, documentation, standards and release procedures.

BOX 4.1 Quality assurance, good manufacturing practices and quality control

QUALITY ASSURANCE
- Management
- Personnel
- Error prevention
- Documentation
- Facilities
- Maintenance
- GOOD MANUFACTURING PRACTICES
- Auditing

{Process control
{Raw materials
{Finished products
{Manufacturing
{Packaging
SOPs
QUALITY CONTROL
Validation

The concept of quality assurance presupposes an understanding of the meaning of quality. Quality in a product or service implies that it has those specific features that will satisfy the customer's requirements. Quality may relate to objective physical, chemical or biological characteristics or may be purely aesthetic. It may be expressed as fitness for use (potency and safety), reliability, value for money or delivery performance (the right place at the right time). Quality does not happen by itself. It requires the deliberate creation of a quality environment, a 'quality culture'. Quality assurance requires specific attention, in four distinct stages (Box 4.2). Variables which affect quality include people, processes, materials, equipment and environment. These factors may be controlled in various ways (Box 4.3).

BOX 4.2 **Assuring quality**

1. Review all factors which affect quality
2. Write a 'quality assurance manual' describing the system(s) by which quality is assured throughout the organization
3. Appoint a manager responsible for directing and coordinating the quality assurance system
4. Audit the quality assurance system regularly, to ensure that it continues to be effective, complete and relevant

BOX 4.3 **Controlling the variables affecting quality**

- People
  - selection of qualified persons
  - training
  - performance evaluation
  - career development and growth opportunities
  - self-inspection, auditing
- Process
  - standard operating procedures
  - validating
  - testing, inspecting, measuring (quality control)
  - error prevention programme
  - documenting
- Materials
  - selection
  - quality control
- Equipment
  - selection
  - preventive maintenance
  - calibration
- Environment
  - building design and maintenance
  - housekeeping

Quality assurance does not come easily. It requires organizational commitment to excellence. This has to come from the highest levels of organizational policy making and must be harmoniously integrated by top management into the entire organization. Quality and excellence must be the foundation of the culture of the organization and must be the responsibility of every employee. This involves a chain from one end of the organization's operation to the other. Quality assurance is an attitude of mind and requires teamwork. It implies a strong organizational commitment to training and the development of people.

4.2 Potential problems and errors

4.2.1 Causes

Most of the errors which can occur in the work of a BTS arise from divided responsibilities. Errors may be clerical, technical or organizational, and may stem from lack of knowledge, inadequate skill or problems in attitude. The qualifications of staff must match the responsibilities they are given; theoretical background and experience must be sufficient to solve the expected problems; appropriate training must be provided and documented. There must be positive demonstration that the level of responsibility is matched by the level of knowledge, training and experience.

Attitude is perhaps the most important and most difficult of the essential qualities. Attitude comprises:

- morale, confidence and a sense of professional pride;
- motivation;
- consciousness of the importance of the work to be done and the seriousness of errors;
- intellectual honesty;
- understanding of each person's precise role;
- good communication throughout the staff;
- a spirit of TEAMWORK.

Underlying all of this is the organizational framework: the management and financial environment within which the BTS operates. This environment will be the ultimate determinant of quality.

When operational responsibility is fragmented, problems of quality are exacerbated. Within the setting of a BTS, such fragmentation may be horizontal (for example, there may be numerous autonomous centres operating without coordination) or vertical (for example, donor recruitment and blood collection may be the responsibility of a community organization, such as the Red Crescent, while testing and processing are in the hands of a technically-orientated blood centre driven by hospital demands). Such fragmentation can be the prime cause of quality failures.

Even in the best of organizational environments, errors may occur. Box 4.4 lists some typical causes of BTS errors.

BOX 4.4 **Typical causes of BTS errors**

- Errors in donor selection
  - health history inadequate, misinterpreted or not private
  - donor giving blood for purposes of checking on HIV status
  - significant international travel overlooked
  - date of last donation incorrect
  - below minimum age for donation
- Labelling errors during blood collection
  - confusion of donor identity
  - labels different on sample tubes and collection container(s)
  - missing or repeated unique identification numbers
- Blood collection
  - errors in haemoglobin determination
  - local anesthetic causing cross-contamination between donors
  - incorrect collection container used (e.g. double-pack when platelets needed)
  - wrong calibration of scales/balances
  - technical errors (too slow; incorrect volume; inaccurate venepuncture; contamination at venepuncture site)
  - inadequate mixing with anticoagulant
  - leaky bag; outdated containers
  - poor attitude of phlebotomist, discouraging retention of donors
- Interim storage and transportation
  - uncontrolled temperature (unsuitable containers, improper monitoring)
  - excessive delays
  - loss of sample tubes or blood containers
- Immunohaematology
  - clerical error (misreading numbers or results, transcription error)
  - test samples out of numerical order

- reagent controls not working or not tested
- reagent past expiration date

- Infectious disease testing
  - clerical error
  - failure to add reagent
  - test controls not working
  - equipment incorrectly calibrated
  - method not followed according to manufacturer's directions
  - results misinterpreted or wrongly entered
  - inappropriate working temperature invalidating result
- Labelling errors after testing
  - wrong ABO or Rh group
  - negative label after positive infectious disease test
  - labelling before testing is completed
  - inadequate checks before release for issue
- Quarantine errors
  - blood not securely segregated during required retesting
  - blood, quarantined for more than one reason, released after satisfactory retesting for just one of these
  - components quarantined at the wrong temperature
- Storage of blood
  - refrigerator, freezer and room-temperature storage improperly monitored
  - incorrect platelet agitation and storage
  - inadequate backup for power failures or fluctuations
- Component preparation
  - centrifuge programmes uncontrolled
  - centrifuge speeds not correctly calibrated
  - centrifuges not correctly balanced
  - inadequate preventive maintenance for centrifuges
  - inappropriate temperatures (before and during centrifugation, and during freezing of plasma)
  - red cell contamination of platelets, plasma

- platelet and leukocyte contamination of plasma
- broken or leaking bags
- bacterial colonization of poorly cleaned centrifuge cups
- low yields of platelets in platelet concentrates
- low yields of factor VIII in cryoprecipitate

• Distribution to and between hospitals
- incorrect delivery (wrong blood group, wrong product, wrong amount)
- inaccurate or incomplete records of shipment
- inappropriate product shipped (untested, quarantined, outdated, leaking, haemolysed)
- shipped without appropriate coolant
- poor telephone technique in handling hospital requests
- excessive delay in shipment

• Discarding biohazardous waste
- unsafe disposal of blood, blood samples and blood containers
- inaccurate or incomplete records of discards of blood and blood products

• Record-keeping
- unsystematic maintenance of records and information
- discarding essential information
- insecure storage of records (susceptible to fire, theft, misfiling, lack of confidentiality)
- records inadequate for:
- tracing individual donors
- analysing donation record of individual donors
- tracking present and past products from individual donors
- linking patient transfusion records to specific donors
- intercepting donations made by previously disqualified donors
- spotting discrepant laboratory results from different donations by one donor
- accurate identification of donors
- analysis for statistical purposes

- Hospital transfusion laboratories
  - uncontrolled or inaccurate blood grouping, antibody screening or compatibility testing
  - clerical errors (failure to identify patient, segment, blood sample or blood container; transcription errors; samples out of sequence, mislabelling of crossmatched blood)
- Clinical use of blood products
  - prescribed for inappropriate reason
  - inappropriate product prescribed
  - too much or too little prescribed
- At the bedside
  - identification of patient and blood not checked
  - inappropriate filter used
  - transfusion rate too rapid or too slow
  - transfusion reaction not recognized, appropriately investigated or treated
  - drugs or inappropriate solutions mixed with blood
  - inadequate record of the transfusion in the patient's chart

This long list of serious potential errors demonstrates the need for every BTS to develop a QUALITY (error free) environment. At the core of this is selection of staff, training, attitude-building, discipline, reliable procedures and full documentation. As already mentioned, this requires the establishment of a quality culture throughout the organization, a prime responsibility for top management.

4.2.2 Case studies*

Case 16

Two patients were admitted within minutes of each other to a busy hospital emergency room (Casualty). One was a 52-year-old man with known oesophageal varices who had had a massive haematemesis and was in shock. The other was a 21-year-old man who had been hit by a passing car while crossing the road; he was also in shock and was suspected of having internal abdominal injuries (subsequently confirmed as a ruptured spleen with 3 litres of blood in the peritoneum). Both patients were thought to need blood transfusions. Blood samples were drawn from each, labelled and sent to the transfusion service

*See Annex 5 for suggested solutions

laboratory with emergency requests for 6 units of blood for both patients. One patient was group A, the other group B. Both were transfused within 60 minutes and both had severe and almost immediate haemolytic transfusion reactions. After difficult courses, both patients survived without lasting consequence from this experience.

What went wrong in this case and what could have been done to prevent these problems?

Case 17

A 45-year-old woman was admitted to hospital for a planned hysterectomy, indicated because of severe fibroids and chronic menorrhagia. She was found to have a haemoglobin level of 6.5 g/dl, and was given 3 units of packed red blood cells prior to surgery. The subsequent course was uneventful and she was discharged from hospital. Her persistent microcytic anaemia was treated successfully with oral iron. Three years later this patient was investigated for malaise and loss of appetite. She was found to have chronic active hepatitis with significant liver damage; the cause was thought to be non-A non-B hepatitis. Her previous transfusions were thought to be a likely cause.

What error(s) were made in this case and what would have been a safer way to manage the preoperative anaemia?

Case 18

A plastic container of concentrated red cells was noticed to have an identification number on the primary container which was different from the set of numbers for labelling segments for compatibility testing.

What was the probable cause of this error and what immediate correction steps were required?

4.3 Documentation

4.3.1 Necessity for documentation

Documentation provides the historical record of all work and policy decisions. It permits key operational steps, such as the release or rejection of a product batch, to be analysed and justified. This is an essential part of quality assurance and, in extreme cases, can provide the evidence necessary to resolve conflict in the courts. The purposes of documentation are to:

- define the system of manufacture (SOPs);
- provide a durable record of the history of each production batch;
- ensure consistent and controlled manufacture;
- reduce the risk of error through oral communication;
- permit the investigation of problems and alleged defects;

- satisfy legal and regulatory requirements;
- maintain a record of all policy decisions.

People have a natural aversion to writing down what they are doing. Successful documentation must therefore be easy to carry out. When possible, it is helpful to involve the personnel who must keep the records in the design of the documents.

4. 3. 2 Specific documents

There are four main types of document: primary records, standard operating procedures (SOPs), subsidiary records and quality control records.

Primary records are those which describe the actual work of the organization. They include records of the receipt and use of raw materials, manufacturing and packaging records, product distribution and complaints (see Box 4.5).

Box 4.5 Primary records

- Receipt and use of raw materials
- Manufacturing records
  - SOPs
  - manufacturer's instructions (when the process involves a purchased system)
  - record of each product or batch (responsible persons, problems, procedure exceptions, supervisory approval for release)
- Packaging records
  - SOPs
  - record of each product or batch
  - instructions to users (package insert)
- Distribution records (including recalls, returns and discards)
- Emergency issue of incompletely processed blood (reason, requesting physician/hospital, tests not complete, special labelling, approval)
- Errors, accidents and adverse reactions (description of event, analysis of cause, corrective action taken, supervisory approval, external reporting (if any)
- Complaints and their resolution
- Records (minutes) of official meetings and policy decisions

SOPs include instructions for all common operations, including donor recruitment and selection, blood collection and testing, component production, manufacturing, packaging and labelling, equipment operation and maintenance, blood product storage, distribution (including product returns and recalls), housekeeping, dress codes and changing procedures for personnel, waste disposal, receipt and acceptance of purchased materials, stock control for purchased supplies and for blood and blood products and complaints and their resolution. SOPs may also include administrative functions such as production of statistics and reporting. Hospital transfusion services need SOPs for compatibility testing, issuing of blood for transfusion, clinical uses of specific products, administration of blood and blood products and treatment and investigation of transfusion reactions.

Subsidiary records include records of training of personnel (including documentation of competence), signatures (and/or initials) of staff authorized to sign documents, maintenance of buildings and equipment (including vehicles), validation data (new procedures, new computer software, new equipment), contracts (equipment rental lease or maintenance, building rental, consultants, etc.), monitoring of the work environment (temperature, humidity, air circulation and air quality (free from dust, bacteria, etc.), calibration of equipment and inspections of the operation (internal audits, inspections by external authorities).

Quality control records include SOPs and sampling instructions, required standards (specifications), results, reference standards used for evaluating results, and investigation and resolution of failures to meet specifications.

4.4 Management of records

A properly functioning quality assurance system requires all records to be dated and signed by authorized production and quality assurance personnel, and this documentation system Box 4.6, and its management, to be fully described in the Quality Assurance Manual.

BOX 4.6 Essentials of the documentation system

- List of required documents (4.3.2)
- What to record on each document
- Use and control of documents
  - legible and indelible
  - mistakes crossed out, leaving original visible
  - corrections added, dated and initialled
  - secure storage of master copies
  - clarity and accuracy assured by supervisory review
  - control of copies, distribution and storage
  - supervisory review of all documents prior to product release (correct process, data reconciled, required signatures present)
  - regular review and updating of all official documents
  - withdrawal and destruction of obsolete documents
  - management and control of documents and records a specific responsibility of one person
- SOP outlining every aspect of the documentation system

Since documentation is essential for the integrity of the historical record, and may be required in the future for the resolution of dispute, management of documents is an important professional function. It must be clear who is the one person responsible for this function, which includes coordination of all activities outlined in Box 4.6.

Storage of documents must take into account the need for security of permanent records (protection against fire, water, rodents, insects, tampering or theft) as well as the need for easy access to documents required for current operations. Specific procedures for storage of documents must therefore be included in the documentation system. These must include specific instructions concerning the length of time which different documents must be retained. Production documents must be retained at least as long as the shelf-life of the product, to permit investigation of complaints. However, BTSs have learned from the experience of AIDS that unexpected problems may turn up many years after the blood donation and transfusion. It is increasingly the practice to require that all production documents are retained permanently.

This raises important technical questions concerning the method of storage. Should the records be stored as paper (hardcopy), microfilm or magnetic tape or disc? The time may come when all major BTSs will record all production data electronically, without paper records, and some are already moving in this direction. Since this text cannot deal with

the complex issues of BTS computerization, it will consider only paper and microfilm. Microfilm has huge advantages in the long-term storage of bulky records. Copying is quick, production of duplicate copies is simple and inexpensive, space requirements are small, and access to information is quick and convenient. Routine microfilming of production records, in regular batches, is thus an important part of records storage. Depending on local circumstances, microfilming of production records is best accomplished 3-12 months after the original work. Verification of quality and completeness of the reproduction is important and is essential before destroying the original hardcopy records. Paper storage is essential for documents of legal importance and is most practical for production documents requiring frequent review.

SOPs present special technical problems with regard to procedures for implementing and validating changes. A change in an SOP may affect many parts of the organization. There is need, therefore, for review by many people before implementing changes in SOPs. All changes will affect documentation and quality assurance staff. Production changes will alter the product and may require new labels, packaging and instructions for users. SOP changes therefore require at least the following steps:

1. Procedure for 'request for change'
2. Review by key people of draft document
3. Agreement after discussion and, perhaps, review of further drafts
4. Sign-off by responsible staff
5. Implementation on a specific date

4.5 Quality through people

The most important resource of a BTS is its people. It is people, not technology, that provide assurance of a high quality programme. Most quality failures are caused by human failure. A strong staff team will ensure quality, even in the most difficult circumstances. Low morale and high turnover rates can defeat the best of technical plans. How can an organization make the most of its human resources? Quality can be encouraged by following some basic principles.

a) Selection Fair competition for open staff positions facilitates selection of the best person for the job; promotion of insiders (family, friends, sycophants among the existing staff) will not advance the best person, will be recognized as unfair and will damage morale. This principle applies at all levels in the organization but is of overriding importance in the most senior and visible positions.

b) Qualifications The qualifications required for each job should be clearly described; selection of the best qualified person will strengthen the staff.

c) Training Everybody starting in a new job requires formal training. This should include both instruction in how to carry out the relevant duties and also orientation to the organization, its purposes, policies, work, key people and table of organization. A

training programme should be defined in writing with each step documented as it is completed and the trainee's competence assessed at regular intervals. Once training has been successfully completed the trainee's documentation should be signed by the relevant supervisor.

d) Retention Selection of the best people and training them for effective performance is useful only if these people stay with the organization; it is extraordinarily costly in money, effort and morale to lose good, trained people. Retention of staff is perhaps the most important, and most commonly neglected aspect of BTS management. It is important that the human resources programme pay specific attention to the following:

- maintaining salaries and benefits at a level that is competitive with other employers within the community;
- ensuring that job responsibilities and quality objectives are clearly described, and that management expectations in these areas are realistic;
- ensuring that work conditions are suitable for the work that has to be done;
- carrying out performance appraisal which permits all employees to know how they are doing and what aspects of their work need further improvement;
- making promotion opportunities available for those who deserve such recognition;
- ensuring that career development opportunities are available and openly discussed;
- encouraging employees to seek growth opportunities (new responsibilities and educational advancement, with particular emphasis upon management training);
- involving employees, to the maximum possible extent, in those decisions which affect the BTS and, most important, affect the employees' work;
- ensuring that employees are treated at all times with fairness and honesty.

Underlying this discussion is the assumption, true in most instances, that employees are not working to full capacity and are not using all their talents and abilities. The people who run the BTS are its most valuable resource and development of their full potential is a most important goal. An organization that neglects its staff is storing up problems for the future, while an organization that provides the vision, resources and environment to allow staff to flourish guarantees quality.

4.6 Quality control

4.6.1 General

Quality control, as already defined in 4.1, involves tests, inspections and measurements aimed at ensuring that a finished product achieves the required standard. There are six important aspects to quality control in a BTS: serological aspects, microbiological aspects, blood collection, blood components, blood storage and equipment.

4.6.2 Serological aspects of quality control

Serological quality control requires periodic checking of technique, materials (reagents) and equipment.

Technique refers to people's work. Control of staff technique can be achieved by supervisory checking and process control, periodic testing in parallel and proficiency testing (testing of an unknown sample previously evaluated in another reference) laboratory). Some laboratories reinforce technical quality control by deliberately introducing problems or errors, in order to assess the ability of staff to recognize and correct them; this is particularly useful in laboratories where abnormal samples are rarely found in the daily routine (e.g. laboratories testing large numbers of normal blood donors).

Materials (reagents) should be checked before each new batch is introduced into the laboratory and by using controls daily with each test run. There are four types of reagent in general use in transfusion service laboratories: sera, cells, enhancing reagents (e.g. enzymes) and suspending fluids. All require quality control testing. Positive controls are designed to ensure the continuing activity of the reagent(s) and the appropriateness of the reaction time. Positive controls on antisera and enzymes are done with known weakly-reacting cells so as to detect early deterioration in reactivity. Negative controls are designed to ensure specificity and to avoid false positive reactions. All serological tests on unknown samples should include an autoagglutination control in order to detect false positive agglutination reactions. Antisera which have had undesired antibodies absorbed out (e.g. anti-A and anti-B) must be checked to ensure continuing specificity. Reagent controls must be tested at the same time and under the same conditions as the tests on unknown samples.

Equipment should be checked periodically to ensure correct operating temperature, required centrifuge speed, constant rejection rate for blood grouping machines and appropriate operation of cell-washers.

4.6.3 Microbiological aspects of quality control

Microbiological controls include prevention of transmission of infectious agents from donor to patient, and prevention of bacterial contamination during donation, component preparation and transfusion. Prevention of transmission depends upon donor selection, testing of the donor's blood, viral inactivation in certain plasma products (which is not in this text) and avoidance of unnecessary transfusions (see 4.7). Quality control is of particular importance in infectious disease testing. Each batch of tests should be accompanied by positive and negative controls, according to the manufacturers' instructions. Equipment should be suitably calibrated. Proficiency testing is an important measure of technical competence and is particularly useful when weak positive samples are included in the test. Repeat testing of positive samples is mandatory for donor evaluation and also provides quality control. Confirmatory testing of repeatedly positive samples, using an independent test system, provides important information concerning the true status of the donor and the specificity of the screening test in use.

Bacterial contamination of donated blood is rare with sterile closed systems for blood collection, but bacteria can be cultured in a significant minority of platelet products [34]. Contamination may occur in many ways (see Box 4.7). Deaths from bacterial contamination occur in less than one transfused patient per million [35] but contamination has increased somewhat with the introduction of room-temperature storage for platelet concentrates and extension of platelet shelf-life to 5 (or even 7) days [36].

BOX 4.7 **Causes of bacterial contamination of blood products**

During blood collection

- unsterile container
- defective container used for collection (leaks, pinholes)
- inadequate cleaning of the forearm
- unclean fingers of the phlebotomist
- palpation of the vein after cleaning
- core of skin gouged into the needle
- open entry to collection container
  - use of glass bottles as containers
  - reuse of container after failed phlebotomy

During handling, processing and storage

- contamination of outside of container from dirty hands, boxes, bench-tops or centrifuge cups
- inappropriate storage temperature
  - cooling too quickly after collection
  - storage above 6°C more than 12 hours beyond collection
- open system used for component preparation
  - use of glass bottles
  - open connections in plastic systems
  - storage for more than 24 hours after use of an open system
- pooling of components before storage

At the bedside

- use of same transfusion set for multiple transfusions
- injecting solutions or drugs into the blood
- prolonged storage of the blood without refrigeration

A number of recent technological advances have affected the risk of bacterial contamination:

- Sterile closed system plastic containers for blood collection have almost eliminated the risk of external contamination.
- Gas-permeable plastics and room-temperature storage of platelets have slightly increased the danger of bacterial contamination of platelet concentrates.
- The greater complexity of component production systems has introduced more possibilities for contamination.
- The invention of the sterile connecting device has greatly reduced the risk of open-system contamination.
- Cellular components are increasingly being stored with little or no contaminating plasma; the impact of this trend is ambivalent since plasma extraction will eliminate most contaminating bacteria while also removing antibodies with their potential neutralizing effect.

There are a number of factors which alleviate the dangers of bacterial contamination. Most contaminating bacteria are not pathogenic to man; fresh blood has considerable bacterial killing capacity, mainly due to phagocytic cells; and appropriate temperature maintenance for donated blood will permit phagocytosis during the period of storage at ambient temperature [37] and storage at 1-6°C will prevent growth of most residual pathogenic bacteria thereafter.

A major issue in the quality control of bacterial contamination is whether blood products should be routinely cultured. The extreme rarity of significant problems, together with the high rate of false positive cultures, has led most authorities to agree that routine culturing of blood products is unnecessary. However, it is particularly important to maintain scrupulously aseptic conditions throughout the work area, and to validate all systems for blood collection and processing by, among other things, appropriate bacterial culture studies. Effective reporting and investigation of suspected cases of contaminated transfusions is also essential.

Quality control of bacterial concentrations on workbenches, on the surface of plastic containers, in waterbaths used for thawing frozen components, in centrifuge cups and in the air is thus of critical importance. Accepted industrial standards require less than 10 microbes per 25 cm^2 on surfaces and less than 88 microbes per m^3 in air. In addition, all blood products must be inspected for signs of contamination, before distribution from the blood centre or issuing for transfusion in the hospital.

4.6.4 Quality control in blood collection

Quality control in technique is particularly important in this area so process control and supervisory review must be emphasized. Common errors are:

- inappropriate selection of donors;
- failure of sterile phlebotomy technique;
- failure to mix the anticoagulant and blood sufficiently during collection;
- permitting blood from excessively slow phlebotomies to be used for component production; and
- collection of incorrect volumes of blood into the container.

The time of the phlebotomy and the volume, or weight, of each unit of blood collected should be recorded. Balances or other weighing devices should be correctly calibrated and the results of these tests formally recorded.

Solutions and equipment used in donor evaluation should be validated and subjected to periodic quality control testing. This includes, for example, copper sulfate, solutions, scales, thermometers and sphygmomanometers.

4.6.5 Quality control for blood components

Each blood donor is unique and each blood donation is a unique batch. Most blood products used in haemotherapy are single donor products and therefore are themselves unique. It is therefore not feasible to define precise specifications for each blood product. It is necessary, however, to define minimum standards. Quality control of blood components is therefore based upon process control and the definition of minimum standards, the measurement of these parameters at regular intervals in a defined sampling of end products, and investigation of failure to meet the required quality. An example of such minimum standards is the United States Food and Drug Administration requirement for platelet concentrates; each month four units prepared from different donors shall be tested at the end of the storage period as follows: platelet count; pH not less than 6.0 measured at the storage temperature of the unit; measurement of actual plasma volume. If the results of the quality control testing indicate that the product does not meet the prescribed requirements, immediate corrective action shall be taken and a record maintained of such action.

The platelet count is required to be "not less than 5.5 x 1010 platelets per unit in at least 75% of the units tested". The plasma volume is required to be such that it has been demonstrated to assure "maintenance of a pH of not less than 6.0 during the storage period". Typically, plasma volumes for storage at 20-24°C are required to be 45-65 mL.

Quality control for other blood components will depend on the component mix in use at a particular BTS, and the purpose for which these components are prescribed. Some reasonable standards, which should be checked by quality control testing, are listed in Table 4.1.

TABLE 4.1 **Reasonable quality control for blood components**

Component	Controls	Minimum standards
Whole blood	Donor haemoglobin Volume (excluding anticoagulant) (every donation)	(every donor)12.5 g/dl 450 ml + 10 %
Red cells	Volume of red cells (4 per month) Haematocrit (4 per month)	> 170 mL < 70 % (mean) never > 80 %
Platelets	pH (4 per month) Platelet count (4 per month) Plasma volume (4 per month)	never < 6.0 5.5 x 1010 (75 % or more) 45 - 65 mL
Cryoprecipitate	Factor VIII (4 per month)	80 IU (mean)
Plasma	Volume (every unit)	235 mL (fresh frozen) 170 mL (platelet depleted) 210 ml (cryoprecipitate depleted)
	Factor VIII (4 per month)	50 iu/dl
Leukocyte depleted red cells	Red cell recovery (4 per month) Leukocyte count (4 per month)	depends upon procedures in the specific laboratory
Platelets	Platelet recovery (4 per month) Leukocyte count (4 per month)	
Plateletpheresis	pH (4 per month) Platelet count (4 per month)	not < 6.0 3 x 1011 (mean)

4.6.6 - Quality control of blood storage

Significant variances from required storage conditions may lead to increased haemolysis, bacterial growth or deterioration in effectiveness of platelets or Factor VIII. Maintenance of the correct temperature (Table 4.2) requires extensive quality control testing. Platelet agitators also require monitoring.

TABLE 4.2 **Correct temperature for storage of blood products**

Product	Storage temperature °C	Shelf-life
Wholeblood, red cells	1-6	in ACD 3 weeks in CPD 4 weeks in CPD-A1 5 weeks in SAGM 6 weeks
Platelets	20-24	3-5 days (depending on gas-permeability of container)
Plasma, cryoprecipitate	-30 or lower	12 months
Albumin	7 or lower	3 years (variable, see manufacturer's instructions)
	2-8	10 years
Antihaemophilic factor	2-8 ambient	See manufacturer's instructions

All refrigerators, freezers and platelet storage chambers require quality control testing. All blood storage equipment should be fitted with an audible alarm system, calibrated to alert personnel as temperatures approach the upper or lower limit. All storage equipment should also be fitted with monitoring devices able to generate a continuous record of storage temperatures.

Quality control of storage conditions is carried out as indicated in Table 4.3. Actual temperatures are recorded with mercury thermometers placed in a glass bottle containing a non-crystallizing fluid such as glycerol. Since the temperature within refrigeration equipment is never quite uniform throughout the storage space, it may be advisable to monitor more than one location in large pieces of equipment.

TABLE 4.3 **Quality control of storage equipment**

Test	Frequency
Manual recording of actual temperature	Twice daily
Check continuous recording against actual temperature	Daily
Supervisory review of quality	Dailycontrol data
Operation of recording devices	Weekly
Calibration of electronic thermometers	Monthly
Calibration of alarm system	Every 6 months
Calibration of recording devices	Every 6 months
Calibration of mercury thermometers	Annually

4.6.7 Quality control of equipment

Some aspects of equipment quality control have already been considered in 4.6.2 and 4.6.6. The underlying principles are the same for all items of equipment. It is not sufficient to install and operate the equipment according to instructions. It is not sufficient to carry out careful cleaning and preventive maintenance. It is necessary to check the actual performance of each piece of equipment in order to establish its reliability. Quality control requires observation and recording of the basic functioning of equipment every time it is used. Standardization and calibration need less frequent attention, but should be carried out on a regular schedule to ensure that malfunctioning of equipment is recognized quickly.

4.7 Appropriate blood transfusion

Patients who need blood products, whether for preservation of life in acute situations or for supporting health in chronic haematologic disorders, must receive what they need. On the other hand, the adequacy and effectiveness of the blood supply cannot be assured if this valuable resource is wasted at the bedside. Furthermore, the risks of blood transfusion dictate that blood should not be given to patients who do not need it. Precision in the prescription of blood products is therefore a prerequisite for quality assurance in patient care, blood safety and resource management. These comments may appear to be obvious and not worthy of mention. However, the misuse of blood products is very common and its correction needs special emphasis.

There are three general types of transfusion abuse: use of blood products when not required use of too little, or too much, in patients who do require transfusion, and use of the wrong product(s) in patients requiring transfusion.

Three factors underly this problem:

- the decision to transfuse is usually made by doctors who have not had specialist training in blood transfusion;
- transfusion practice is generally learned from colleagues in a particular area of speciality and different specialities may thus have developed different transfusion styles; and
- transfusion therapy is not effectively taught in medical schools.

Common mistakes in transfusion therapy are listed in Box 4.8. This list is not complete. It merely serves to illustrate the extent of the problem. Quality assurance requires that this issue be addressed effectively.

BOX 4.8 Common mistakes in transfusion therapy

- Preoperative transfusion of anaemic patients (See Case 17)
- Routine use of components (e.g. platelets, cryoprecipitate) during major surgery
- Overuse of blood, while overlooking volume expanders such as saline or dextran, in treatment of acute blood loss
- Inflexibility with regard to the choice between Whole Blood and Red cells
- Inadequate treatment of patients needing specific components (e.g. patients with haemophilia, leukaemia, severe burns, etc.)
- Wasteful use of albumin, when dextran or saline could be equally effective
- Use of blood in chronic anaemias, when specific treatment of the anaemia would be safer and more effective
- Use of plasma as a volume expander, when less costly (saline) and safer (dextran, albumin) effective alternatives exist
- Use of concentrates to treat mild haemophilia, when effective alternatives exist (e.g. DDAVP)
- Use of homologous blood in patients who could conveniently have made autologous donations prior to elective surgery
- Transfusion of one unit of blood during elective surgery
- Cross-matching blood for procedures where it is most unlikely to be needed (e.g. cholecystectomy, transurethral prostatectomy, Caesarean section).

Ideally, the answer lies in improved education. Correct haemotherapy should be a prominent part of the curriculum of all medical schools. Continuing education in haemotherapy should be available to all practising physicians. Certainly expanded education is a worthwhile goal but experience has shown that education alone is not sufficient. There are several reasons for this: medical curricula are already full and becoming more so; physicians are busy and have limited opportunity to seek training in areas outside their own areas of expertise; and physicians are notoriously resistant to being told what to do.

Therefore supplementary approaches are needed if blood usage is to be optimized. Innovative approaches may include the following:

- creation of a specialty in clinical haemotherapy, with certain kinds of problem referred to such specialists;
- controls on issuing of certain products;
- consultation initiated by the transfusion service when unusual requests are received;
- guidelines for blood use at each hospital;
- audit procedures whereby blood use is evaluated retrospectively;
- analysis of blood usage practices in each department and by individual physicians;
- reporting systems through which aberrant practices can be brought to the attention of the hospital and the responsible doctor(s).

The subject of blood usage is often troublesome for the physician in charge of the BTS. It is quite usual for this person to be the only transfusion expert in the area, yet it is difficult to intervene with professional colleagues without creating tension or conflict. It is a common practice, therefore, to avoid the issue by simply avoiding confrontation. Such avoidance neglects a significant part of the responsibility of the BTS medical director. If transfusion practices are neglected at this level, who else is there to pay attention? This is perhaps the most important of many reasons why the BTS medical director needs to be someone with the professional standing to command respect within the medical community and thus be able to exert influence and leadership. Quality assurance in the use of blood products requires medical leadership from the BTS.

4.8 Auditing

4.8.1 General

Auditing, or inspecting, is the process of examination of the work of an organization by independent and objective persons who are not themselves responsible for the work. Most authorities agree that auditing is a necessary part of quality assurance. For example the French GMP Guide (1985) states: "In order to assess the effectiveness of the quality assurance system, and to assure the application of good manufacturing practices, it is recommended that self-inspection and quality audits be undertaken."

Audits review all the factors associated with the manufacturing process (see Box 4.9) and may be internal or external. They are carried out for the following reasons:

- to help management gain an objective and unbiased assessment of the quality assurance system;
- to expose the organization to the concept of outside scrutiny;
- to establish whether legal and contractual obligations are being fulfilled.

Other benefits to be gained from audits include insight into training requirements, feedback and communication between various parts of the organization.

BOX 4.9 Important factors included in an audit of the manufacturing process

- Raw materials (specifications, purchasing, receipt, inventory control)
- Production process (including control and documentation)
- Quality control, documentation and release
- Packaging, labelling, storage, ordering and shipping
- Quality assurance, validation
- Premises design, operation and maintenance
- Equipment design, operation and maintenance
- Personnel selection, training and development

Internal audits are an essential part of quality assurance and may take the form of self-inspections, site audits or corporate audits. Self-inspections are carried out by supervisory personnel within their own unit, although outside personnel may be included if objectivity requires it. A site audit is an examination of the entire facility, carried out by the organization's own personnel. Larger organizations may have an audit department the sole responsibility of which is auditing. A site audit is systematic and leads to a full report to top management. Site audits can be particularly valuable if their purpose is accepted and is 'non-political'. They are useful for spotting dysfunction at the interdepartmental level. Follow-up will be needed if the audit is to be effective. A complex organization, with multiple sites of operation, may carry out a corporate audit, using a team from headquarters or selected from among the staff of the various sites.

External audits are characterized by the fact that the auditor(s) does not belong to the same organization. The reason for carrying out an external audit varies, depending upon the circumstances, and may include contractual or legal requirements or simply the promotion of customer relations. External audits may be oriented to the selection or review of suppliers or contractors or may be formal regulatory audits, carried out by national regulatory bodies or inspection agencies, in accordance with legal requirements.

4.8.2 Audit techniques

An audit is a sampling exercise, in which the auditor is responsible for assessing the operation on the basis of the sample taken. A quality assurance audit should be objective and quantitative, for purposes of comparison and assessing progress and should have a point of reference (specific standards or rules). It should be performed by qualified and trained auditors. Checklists are a prerequisite. The steps involved in a well-conducted audit are preparation; opening interview between the auditor(s) and key staff; the audit; summary session between the auditor(s) and key staff; formal report; follow-up.

The audit process can be determined by the auditor. Possible audit techniques include the following:

- trace forward (starting in the warehouse, and logically following the production process through materials distribution and production to release and shipping);
- trace back (reverse of the above);
- random (all elements, in a random order; this has the benefit of flexibility but may fail to identify interdepartmental dysfunction);
- document trail (cross-referencing all documents related to a particular production batch, a method favoured by US auditors).

It should be emphasized that much useful information can also come from general observations; the condition of locker rooms, toilets, waste-bins and rubbish disposal areas, general cleanliness of the facility and the state of the manager's office all provide insight into discipline, hygiene and organizational skills.

During the audit, the auditor should establish good rapport with the personnel. A professional image is served by smartness, punctuality and calm. The personnel undergoing the audit should cooperate fully because the purpose of the audit is essentially constructive and objective observations will be helpful to all concerned. An experienced inspector will recognize a failure to cooperate, whether it take the form of intimidation, foot-dragging or deliberate attempts to confuse. Such ploys can not only delay the completion of the audit but may lead to adverse observations in the auditor's report.

4.9 Regulatory control of blood transfusion services

The value of external audits has been discussed in 4.8. In some countries this process is formalized to the extent that government is required to regulate the operation of BTSs. Regulatory programmes of this kind require the establishment of a staff of trained inspectors and may include a national laboratory for quality control of blood products.

In the United States of America, this function is carried out by the Food and Drug Administration. In the European Community, some member states have regulatory programmes and others do not. For this reason, a unified regulatory system is being developed. Many developing countries do not have a regulatory programme, accounting

in part for difficulties in standardization of practices and quality assurance. An effective regulatory programme includes a number of distinct elements which are listed in Box 4.10.

BOX 4.10 Elements of a regulatory programme for blood transfusion services

- Basic principles (philosophy)
- Legislation (legal basis for control of blood transfusion)
- Regulations (administrative rules)
- Advisory committee
- Registration and licensing
  - facilities
  - products
- Auditing (inspection) of facilities

The basic principles will reflect the culture, traditions and priorities of the country in question. For example, in Denmark the basic principles are simply: that blood is a national resource; that the blood donation system is based upon voluntary gifts by non-remunerated donors.

Legislation can formalize the basic principles and establish responsibility and authority in blood transfusion. While legislation provides a valuable underpinning for BTSs, it is wise to keep laws of this kind as brief as possible. Laws, once enacted, are difficult to change, so legislation should not get involved in operational details. BTS legislation can usefully include matters such as basic principles; regulatory powers; membership, authority and responsibility of the advisory committee; the role of the national directorate (if any); and registration and licensing of facilities and products.

Regulations (administrative rules) provide a useful mechanism for the formal setting of standards. Such rules have a profound effect upon the daily operation of BTSs so it is essential that they are complete, technically sound and up-to-date. Mechanisms for adoption, and for changing the rules from time to time, therefore need to provide opportunities for input from those most affected by the rules. BTS rules and regulations will include those which are specific to blood, blood components and plasma fractions, as well as regulations which apply in principle to GMPs. The applicability of GMPs to BTSs will vary, depending upon the size and complexity of the operation. Some common sense can be applied in the decision as to which GMP regulations should be applied to a particular BTS. For example, GMPs should be applied completely to plasma fractionation facilities. Administrative rules and regulations provide the yardstick upon which the objectivity of audits is based.

An advisory committee, with representative membership of high professional and technical calibre, can play a valuable role in ensuring that those officials responsible for regulatory control will receive accurate and even-handed advice. Such a committee can also serve to maintain open lines of communication between regulators and BTSs.

Registration and licensing are potent tools for regulatory control. If a licence is required before a facility is permitted to collect blood, test blood, or prepare components, regulators then have the power to close down unlicensed operations. It thus becomes possible to ensure that minimum standards are met before new licences are issued or existing ones renewed. It also makes it possible to ensure that products which have not been shown to meet minimum standards of efficacy and safety, will not be licensed.

The inspection process underlies the administration of the regulatory process. To be effective, the process must be competent (4.8), with inspections sufficiently frequent to permit the recognition of deterioration.

This discussion leaves one important question unanswered: Is it necessary for every country to have a regulatory control system for BTSs? There is no simple answer to this question, but two points need stressing. First, the absence of a regulatory control system is associated with lack of standardization, inconsistency and lack of quality assurance. Second, maintaining an effective regulatory control system is administratively complex and expensive. It can be concluded, therefore, that while regulatory control is indeed desirable everywhere, it may be worthwhile for groups of countries with similar needs to combine forces and consolidate their efforts into a single regulatory system (as is the case in the European Community, for example).

Annex 1

Glossary of Terms and Abbreviations

ACD

Acid citrate dextrose: anticoagulant preservative solution for donor blood, no longer much used because better solutions exist, permitting longer storage and better preservation (e.g. CPD-A1 and various additive solutions).

additive solution

Term referring to preservative solution for red blood cells, added to the cells after centrifugation and removal of the plasma. Additive solutions can optimize the liquid storage of red blood cells and can maximize the recovery of plasma (e.g. for fractionation). Additive solutions for platelets are being investigated.

AIDS

Acquired immunodeficiency syndrome: chronic fatal disease caused by HIV infection.

albumin

Predominant plasma protein, accounting for about 60% of the protein content of human blood. Plays an important role in maintenance of fluid balance and normal blood volume. Albumin, prepared by fractionation of human plasma, is one of the important blood products for transfusion.

antibody

Protein, of the immunoglobulin class, which is produced in response to exposure to a specific antigen, and which is capable of binding specifically to that antigen.

anticoagulant

Substance which prevents blood coagulation (clotting, fibrin formation).

antigen

Substance which is capable of provoking an antibody response.

apheresis

Type of blood donation in which only one specific constituent (e.g. plasma, platelets) is retained for transfusion while the rest of the donated blood is returned to the donor (see 3.10.4, also **cytapheresis, plasmapheresis, plateletpheresis**).

Australia antigen

Term originally applied to what is now known as HBsAg.

autologous

Donation of blood by the patient who will later be transfused with this same blood (see 3.10.2).

blood bank

Facility where blood can be stored in preparation for transfusion (see also **blood centre, blood transfusion service**).

blood cells

The cellular part of blood. Each cell is a living particle, enclosed in a membrane. The principal blood cells are red cells (erythrocytes), white cells (leukocytes) and platelets.

blood centre

Building or location specifically dedicated to blood collection, component production, testing, storage, distribution, etc.

blood components

Blood products, which can be routinely prepared by a BTS from donations of whole blood, which are made by crudely separating specific parts of the blood which are useful for transfusion. Important components are red blood cells, platelets, plasma and cryoprecipitate.

blood donor

Person whose blood is collected for transfusion. This term is most commonly used for donors of whole blood but may also be used for donors of plasma, platelets, etc. (see **apheresis).**

blood fractions

See **plasma derivatives.**

blood groups

Term referring to systems of antigens on the cell surface, which vary from person to person and which determine the compatibility of blood for transfusion.

blood products

Any preparation which can be made from blood is a blood product. Blood products include whole blood, blood components, plasma derivatives and a variety of preparations which are used for non-transfusion purposes (e.g. serological or cellular reagents).

blood resource

Term commonly used to describe the available supply of blood and blood products (see also **supply**).

blood substitutes

Substances which can be used instead of blood (see discussion in 1.3).

blood transfusion

Intravenous administration of blood or blood components to a patient.

blood transfusion service (BTS)

Any organization designed to make blood and blood components available for transfusion. The typical BTS is involved in donor recruitment, blood collection, laboratory testing, component production, storage and distribution of blood products, and provides a service to multiple hospitals.

blood typing

Laboratory testing to determine a person's blood group (also referred to as 'blood grouping').

cells

See **blood cells.**

centrifugation

Technique, based upon spinning at high speed in a centrifuge, and thus exaggerating differences in specific gravity of different components, useful for separation of whole blood into its major components.

components

See **blood components.**

component therapy

System of transfusion therapy (haemotherapy) based upon the availability of blood components and their active appropriate use for transfusion purposes (see 1.2). By implication, most whole blood is used for making components and transfusion of whole blood is rare.

CPD

Citrate phosphate dextrose: anticoagulant preservative solution for donor blood, no longer much used because, like ACD, there are better solutions available.

CPD-A1

Citrate phosphate dextrose adenine formula 1 (several other formulae are in routine or experimental use). CPD-Adenine is a better preservative than ACD or CPD but has, in many countries, been largely replaced by additive solutions.

cryoprecipitate

One of the major blood components, prepared by slow thawing of frozen fresh plasma and separation of the resulting cold-insoluble precipitate from the rest of the plasma. This cryoprecipitate contains increased concentrations of factor VIII, von Willebrand factor and fibrinogen, fibronectin and cold-insoluble globulin. Cryoprecipitate has proved useful in the treatment of haemophilia A, von Willebrand's disease and fibrinogen deficiency.

cytapheresis

Apheresis procedure designed to collect specific cells from the donor's blood (see 3.10.4).

deferral

See **donor deferral.**

demand

Term referring to the blood product/service which is wanted/ordered/requested (see discussion 2.3).

designated donation

See **directed donation.**

direct transfusion

Obsolete technique whereby transfusion was accomplished by direct flow of blood from the donor into the patient.

directed donation

Blood donation where the donor's blood is reserved for a specific patient (see 3.10.2).

DNA

Deoxyribonucleic acid, the basic molecule of genetic material.

donor deferral

Term referring to the non-acceptance of a prospective blood donor (see 3.8). Deferral may be temporary (for a specific time) or indefinite (no specific time can be assigned). The term 'permanent deferral' is sometimes used for indefinite deferral but 'disqualification' is preferred.

donor motivation

Term applied to the process of public education and motivation for blood donation (see 3.2).

donor recruitment

Term applied to the whole process of ensuring that there will be a sufficient number of suitable blood donors (see 3.5).

donor retention

Term applied to the process of ensuring that known donors will become regular donors and continue to donate (see 3.5.4).

ELISA (EIA)

Enzyme-linked immunosorbent assay. A test system designed to detect specific antibodies or antigens in a test sample. An important part of BTS technology since it became necessary and possible to detect the presence of infections transmissible by blood.

EPO

See **Erythropoietin.**

Erythropoietin (EPO)

Hormone, produced in the kidney, which stimulates red cell production in the bone marrow. A recombinant DNA form of erythropoietin is available as a drug. EPO can reduce the need for transfused blood in patients with the anaemia of chronic renal disease and has been used experimentally to encourage red cell production in patients undergoing a series of autologous donations.

factor VIII

Glycoprotein macromolecule, found in normal plasma and necessary for normal blood coagulation. This factor is absent or abnormal in haemophilia A and is essential for effective treatment of this condition.

factor IX

Essential for the treatment of haemophilia B.

fibrinogen

Plasma protein which is converted to fibrin during the blood coagulation process.

fractionation

See **plasma fractionation.** The term "fractionation" is sometimes incorrectly used to refer to 'component production', but this usage is confusing and best avoided.

GMP

Good manufacturing practices (see 4.1).

HB

Hepatitis B.

HBV

Hepatitis B virus.

HBsAg

Hepatitis B surface antigen: antigenic product of infection with hepatitis B which provides the basis for blood donor screening with the ELISA test for hepatitis B.

HC

Hepatitis C.

HCV

Hepatitis C virus.

haemolytic disease of the newborn

Severe, potentially life-threatening condition caused by maternal antibodies attacking and destroying the red cells of the fetus/newborn child (see also **kernicterus, rhesus).**

haemophilia

Congenital disorder of blood coagulation. Haemophilia A (Factor VIII deficiency) and haemophilia B (Factor IX deficiency) are clinically identical but biochemically distinct; treatment depends upon specific plasma fractions for each condition.

haemotherapy

Term referring to the clinical practice of blood transfusion.

heterologous

Heterologous transfusion is transfusion of blood from one species to another. It has little application in modern haemotherapy.

hepatitis

Inflammation of the liver. In the context of blood transfusion, hepatitis refers to the various forms of viral hepatitis which can be transmitted by blood transfusion, of which hepatitis B and hepatitis C are the most important (see 1.1).

histocompatibility

Term applied to those systems of antigens which affect the success of organ or bone marrow transplantation. The HLA system is one example.

HIV

Human immunodeficiency virus: retrovirus which predisposes to AIDS.

HLA

Human lymphocyte antigen. These systems are important in organ and bone-marrow transplantation and in the transfusion of platelets (see 1.1).

homologous

Homologous transfusion refers to the transfusion of blood to a recipient of the same species. This term therefore applies to most instances of blood transfusion as currently practised, as distinct from autologous, heterologous and isologous transfusion.

HTLV I/II

Human T-cell lymphotrophic virus: retroviruses, unrelated to HIV, which can be transmitted by blood transfusion. HTLV I is found predominantly in parts of Japan and the Caribbean and leads to leukaemia or neurologic disorders. HTLV II is not known to cause disease. Routine testing for HTLV has been implemented by some BTSs but does not distinguish between types I and II.

hyperimmune

Term referring to IG with high concentration of a specific antibody.

Ig

Immune globulin.

immunoglobulin

Generic term applying to the class of plasma proteins which comprises the antibodies. Immune globulins (IG), prepared by fractionation of plasma, may be polyvalent (non-specific) or hyperimmune (with a high concentration of one specific antibody). Special production techniques are required if IG is to be administered intravenously (see IVIG).

immunoheamatology

Literally, the study of the immunological aspects of blood. In the context of a BTS, immunohaematology has traditionally referred to the study of blood groups, their corresponding antibodies, and assurance of compatibility of blood destined for transfusion.

isologous

Isologous transfusion is the transfusion of blood to a genetically identical recipient.

IVIG

Intravenous immune globulin: IG preparation suitable for IV use.

Kernicterus

Condition in which high levels of unconjugated bilirubin cause permanent brain damage in the newborn. The commonest cause of kernicterus used to be Rh

incompatibility between mother and fetus (haemolytic disease in the newborn). This problem is preventible in most cases by application of standard blood group serology.

legislation

The act of making laws. The distinction is emphasized between legslation and regulation (see 4.9).

leukocyte

white blood cell.

microbiology

The study of microbes (bacteria, viruses, etc.), increasingly important in BTSs as more has become known about transmission of infections by blood transfusion.

motivation

see **donor motivation**. see also 2.6.2.

need

The amount of blood which is needed (see 2.3).

Plasma

The straw-colored protein-rich liquid part of blood in which the blod cells are suspended.

plasma derivatives

High purity preparation of specific plasma proteins, prepared by plasma fractionation.

plasma fractions

See **plasma derivatives.**

plasma fractionation

The process by which plasma derivatives are prepared. Effective fractionation requires large quantities of good quality plasma and increasingly high technology methods, beyond the capability of most BTSs.

Plasma products

A generic term applicable to both plasma derivatives and plasma prepared at the BTS level for transfusion purposes.

Plasmapheresis

See 3.10.4.

quality assurance

See 4.1.

quality control

See 4.1.

rare blood

See 3.10.3.

recombinant DNA technology

Advanced technology enabling the mass production of specific protein molecules in cell culture. The relevance to BTSs lies in the fact that Factor VIII is now being commercially produced in this way.

region

This word is confusing in the context of a BTS. For example, it is used by international organizations, such as the World Health Organization, to refer to areas of the world which include many countries (e.g. Eastern Mediterranean Region), while it may be used for BTS purposes to refer to operational subdivisions within countries. For this reason, the word 'region' must be used with caution and only with careful explanation.

regulation

The process of creation and enforcement of administrative rules and regulation (see 4.9).

Rh

See **rhesus**.

rhesus (Rh)

Important blood group system, also as known as D, once the major cause of haemolytic of the newborn.

self-sufficiency

See discussion in 2.3.

serology

Technology, commonly used in BTS laboratories, involving the interaction between antibodies (from serum) and antigens.

sponsors

Term, commonly used in donor recruitment, referring to external organizations which collaborate with the BTS in the recruitment of blood donors. Thus universities, industries, religious groups, government offices, etc. may serve as sponsors.

supply

See **blood resource**, also 2.3.

transfusion

See **blood transfusion**.

transfusion medicine

Branch of medical science and medical education which deals specifically with blood transfusion and related scientific topics.

whole blood

Donor blood, with added anticoagulant/preservative solution, from which no components have been removed.

Annex 2

Workshop recommendations

WHO/AGFUND workshop on organization and management of blood transfusion service Amman, Jordan, 16-20 September 1989

It is recommended that National Health Authorities:

1. Recognize that blood transfusion services are an important integral part of the national health services by:-

1.1 Fostering the establishment of unified, adequately funded national services:

a) to meet current and future needs for blood and blood products;

b) to allocate the human and material resources needed to carry out systematic, professionally planned and executed voluntary donor recruitment and blood collection;

c) to undertake long-term, continuously monitored planning for the growth and development of the service, an important part of which is human resource development, ensuring recruitment and retention of key personnel by offering attractive career prospects, further training and research opportunities;

d) to ensure adoption and application of good operational training, quality and ethical standards throughout the service;

1.2 Promoting close coordination or integration of the armed forces, universities and Red Crescent Societies with the national transfusion services in order to make the best use of scarce human and national resources for the common good;

1.3 Making every effort to encourage an appropriate degree of self-sufficiency at national and regional levels.

2. Perceive that without good management, transfusion services cannot succeed, recognizing the paramount importance of adequately trained managers, supported by financial accounting personnel as an integral part of blood transfusion staff, to ensure:

2.1 That the service is capable of formulating coherent, feasible short-term and long-term plans, budgets and targets;

2.2 That the service develops management information systems which will enable managers to meet those targets in a timely, cost-effective manner, exploiting the potential of microcomputer systems;

2.3 That the service is able to establish its credibility and accountability as an effective custodian of government funds which deserves the opportunity to structure management for its growth and development with greater freedom.

3. Emphasize to national blood transfusion services that, although blood products may be life-saving, they also carry potential risks of disease transmission and represent a precious resource. Health authorities should therefore encourage transfusion services to adopt a leading role in developing consensus guidelines for the appropriate use of blood products through an active, persistent dialogue with all current and potential clinical users, starting with medical schools. These guidelines should be based upon clinical and scientific evidence, rather than dogma, with recognition that more rational utilization of blood products will promote safer, more economical and effective hospital blood transfusion practice.

WHO/AGFUND supported workshop on blood donor motivation and blood collection Amman, Jordan, 14-18 January 1990

1. The most important overall aims of national blood transfusion services are to :
   - collect sufficient blood to provide for the needs of all hospital patients;
   - apply high quality assurance standards to screening and processing of blood products in preparation for transfusion;
   - distribute these products to user hospitals in a timely manner;
   - ensure that blood products are utilized according to appropriate clinical criteria, thereby assuring all donors that their gift is put to good use.
2. In order to satisfactorily achieve the first and most fundamental of these aims, i.e. blood collection, it is recommended that national health authorities require transfusion services to:

2.1 Establish a coordinated and unified system for the whole country, with common criteria for the selection and care of blood donors.

2.2 Ensure that blood collection is based entirely upon a voluntary, non-remunerated blood donation system which avoids undue pressure (e.g. required family or replacement donation) or inducements (e.g. material rewards) in approaching potential donors.

2.3 Recognize the fundamental social dimension of blood transfusion services, rather than the technical and scientific aspects alone, by devoting the necessary material resources to the employment of a carefully trained staff dedicated to organizing effective donor recruitment and blood collection, as well as the retention of such donors to form an established panel of volunteers.

2.4 Provide for the utilization of fixed collection sites (where donors come to the blood collection centre) and mobile units (where collection teams come to the donors).

2.5 Acknowledge the importance of a spiritual dimension in the lives of people by seeking the active support of leaders of Islamic and other religious communities in motivating new recruits to the blood donor programme.

2.6 Allocate adequate funds for teaching and recruitment materials.

2.7 Work closely with all important target groups in the community.

2.8 Develop specific programmes to encourage the active participation of young people in blood donation and donor recruitment.

2.9 Take care to protect blood donors and to respond to their need to feel fully appreciated for this voluntary donation.

2.10 Maintain high technical standards in all activities of the blood collection programme.

2.11 Strive to maintain high management and accountability standards by forecasting future targets for blood products, by good forward planning and budgeting, and by regular evaluation of achievements against targets.

WHO/AGFUND Intercountry workshop on quality assurance in blood transfusion Amman, Jordan, 6-10 May 1990

The Workshop recommended that national health authorities in Member States of the Region:

1. Recognize the fundamental importance of quality assurance in blood transfusion services. Quality cannot be assessed by retrospective, end-product testing, or quality control alone. It is, therefore, essential to establish a prospective system of quality assurance. This quality system can only be attained by the creation and operation of standards, procedures and management systems which will provide complete confidence in the quality of all operations extending from donor selection to product issue. Establishment of these quality systems will also lead to achievement of value for money within the service.
2. Establish clear statements of quality policy, together with quality objectives. These can best be formulated, implemented and monitored through national blood transfusion services which should have delegated authority for progressively applying them to all blood transfusion centres and hospital blood banks in the country. Acknowledge that the task of national blood transfusion services in this context is to:
   a) review all aspects of their operations which affect quality;
   b) document an effective quality system which should include policies, quality management objectives, organization and procedures, which are presented as a quality manual;
   c) formulate and adopt guidelines and specifications for blood, blood products and services, introducing uniformity and standardization in the service which will ensure their fitness and safety;
   d) appoint quality assurance managers with relevant qualifications, technical knowledge and experience, who are independent of production and will have the authority to implement guidelines and coordinate quality initiatives;
   e) ensure the active participation of all personnel, the most important and costly element affecting quality, by fostering integrity and honesty in reporting errors and deviations from established procedures; by planning advantageous career development prospects for staff, so as to provide incentives and to retain their services and dedication; by making available training and research opportunities;
   f) introduce a system for monitoring the quality of all material and equipment purchased in order to obtain the best guarantee of cost-effectiveness, after-sales service, and maintenance;

g) as quality systems are established, progressively introduce periodic review or auditing (whether internal or external) so as to evaluate the effectiveness of these quality systems;

h) introduce a central reporting system for defects in disposables, equipment and reagents, which may ultimately be extended to an intercountry system for gathering and collecting similar data.

3. Encourage actively regional, intercountry communication and collaboration in blood transfusion practice, and establish improved methods of managing quality. Initiatives in this field should include training and research programmes.

Annex 3

World Health Assembly Resolution, WHA 28.72 "Blood and blood products"

WHA 28.72 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 the utilization and supply of human blood and blood products;

Bearing in mind resolution XVIII of the XXIIth 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 consequencies 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 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.

May 1975

WHO Official Records, No.226, 1975, p.110

Annex 4

International organizations and policies

A number of international organizations are concerned with blood transfusion. Their perspective may be organizational and humanitarian (International Federation of Red Cross and Red Crescent Societies: IFRCS), technical (World Health Organization), professional (International Society of Blood Transfusion: ISBT)) or clinical and social (World Federation of Haemophilia (WFH)). In the late 1980s, WHO, IFRCS then the League of Red Cross and Red Crescent Societies (LRCS) and ISBT joined forces with the United Nations Development Programme (UNDP) to create a new entity, the Global Blood Safety Initiative (GBSI). A synopsis of the blood transfusion roles and policies of each of these organizations follows.

World Health Organization

There are four units of the WHO Geneva Headquarters which have specific roles to play concerning blood transfusion. The Health Laboratory Technology and Blood Safety Unit has responsibilities for laboratory quality and the organization of international training programmes, and publishes Guidelines for the Organization of a Blood Transfusion Service[17]. The Global Programme on AIDS maintains a unit concerned with the transfusion aspect of HIV transmission. The Biologics Unit is concerned with technical standards, with special reference to manufacturing and plasma fractionation, and publishes Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives [25]. The Global Blood Safety Initiative (GBSI) is described in more detail below.

The fundamental policy upon which WHO blood transfusion activities are based was determined at the World Health Assembly in 1975 (see Annex 3). Voluntary non-remunerated donation of blood is emphasized [17,18]. Further information can be obtained from Health Laboratory and Blood Safety, World Health Organization, 1211 Geneva 27, Geneva, Switzerland.

International Federation of Red Cross and Red Crescent Societies

The International Federation comprises more than 160 recognized Red Cross and Red Crescent Societies, together with the Secretariat based in Geneva. This Secretariat includes the Blood Programme, which has two principal functions: the provision of information and encouragement of the development of BTSs. The philosophic underpinning for this work is the commitment to the principle of voluntary non-remunerated blood donation.

As an integral part of the Red Cross/Red Crescent movement, the Blood Programme works directly with Red Cross/Red Crescent Societies already operating BTSs at the national or local level, as well as providing a supportive and consultative role to those Societies contemplating a new or expanded BTS role. The Blood Programme maintains active links with other international organizations with common interests. The Blood Programme publishes a newsletter, *Transfusion International.* Further information can be obtained from Blood Programme, International Federation of Red Cross and Red Crescent Societies, P.O.Box 372, CH-1211 Geneva 19, Switzerland.

International Society of Blood Transfusion

ISBT is a professional organization with individual members drawn from all over the world. ISBT developed in 1980 the Code of Ethics for Blood Donation and Transfusion [38], subsequently adopted by the International Conference of the Red Cross. This document has been widely accepted and forms the basis for the operation of BTSs in many countries.

The principal ISBT activities are educational. International congresses are held every two to three years, with regional workshop interspersed. Vox Sanginis, the International Journal of Transfusion Medicine, is the official journal of the International Society of Blood Transfusion. Other publications include a variety of scientific documents and a newsletter, *Transfusion Today.* Further information can be obtained from International Society of Blood Transfusion, c/o National Directorate of NBTS, NWRHA, Gateway House, Piccadilly South, Manchester, M60 7LP, England.

Global Blood Safety Initiative

GBSI is administratively based in the Health Laboratory Technology and Blood Safety unit of WHO. GBSI has a small administrative staff, and works closely with other international units in Geneva with interests in blood transfusion, notably GPA and the Blood Programme of IFRCS. Its significance lies in its ability to coordinate and support a wide range of international initiatives concerning blood transfusion and transfusion-transmissible diseases. Further information can be obtained from GBSI Coordinator, World Health Organization, 1211 Geneva 27, Switzerland.

Annex 5

Case studies: suggested solutions

Case 1

1. The location of the three hospitals on different islands would make it very difficult to serve these hospitals from a centralized distribution point. Furthermore, the small size of the total BTS activity (hospitals averaging only 2000 blood collections per year; approximately 6 blood donations per day per hospital) can be effectively maintained by each hospital. Establishing a separate, self-standing blood centre would be an unreasonable expense. Therefore the national centralization of BTS operations is not recommended.
2. In this country the Red Cross has demonstrated its ability to recruit blood donors as needed by one of the three hospitals. Collaboration between the Red Cross and the other two hospitals may therefore be feasible and it is recommended that this possibility be seriously explored.
3. Component usage is not a high priority in this country until there is a demonstrable demand for platelets and/or cryoprecipitate. This will be determined primarily by the existence of patients with haemophilia and leukaemia and the medical expertise to treat these patients within this country's hospitals. The demand for components will come from haematologists specialized in the treatment of such patients.
4. Training of BTS personnel will require help from a larger country. This could be accomplished in three ways: a) by employing, on a temporary basis, (say for 2 years), a foreign expert to train laboratory technicians from each of the three hospitals; b) by selecting a leading laboratory technician from the existing hospital staffs and support training in a foreign country, with the goal that this person will return home and establish a training programme; c) by arranging with a foreign expert laboratory to provide training to a succession of laboratory technicians. The choice among these options will depend upon the specific circumstances. In general, training within the country is preferable because attention to the specific problems of the country is possible; moreover, there is no temptation for travelling trainees to stay and seek employment in the country where they have been trained.
5. It appears that there may be a need for both legislation and regulation. Legislation should be simple and deal only with matters of principle (e.g. voluntary nonremunerated blood donation) and the authority of the Health Ministry to regulate blood transfusion. Regulation is an administrative matter and should cover in detail the required technical standards for donor selection, blood collection and laboratory testing.

6. See the answer to question 5 above. Regulation is definitely needed. The establishment of regulations will be difficult in such a small country. Ideally it should be linked with the training programme and therefore will require collaboration with another country with greater resources. One option might be to incorporate an external audit system (see 4.8.1) with periodic audits by inspectors from another country.
7. Safety will depend upon all of the following: a) good training; b) legislation and regulation; c) maintenance of regulatory standards; d) exclusion of paid donors and donors who are unsuitable for health reasons; e) accurate performance of the appropriate donor screening tests (at least HBsAg and anti-HIV) and exclusion of all those donors who test positive; f) a programme to optimize the usage of blood, avoiding all unnecessary transfusions.

Case 2

1. National centralization may not be operationally practical in a country of this size, with obvious problems in management and transportation. However, some degree of centralization is definitely needed. It may not be necessary to have a separate BTS for each province and some consolidation may be possible. In order to maximize resource sharing, it may be practical to establish regional BTSs in some of the provincial capitals, thus providing an interlinked system covering the entire country. The retention of a completely decentralized system of hospital-based BTSs is not recommended. A strong case can be made for creating a national BTS with responsibility for establishing and enforcing regulations, coordinating training, collecting and analyzing national statistics, centralizing purchasing of equipment and essential supplies and coordinating the operations of the various regional BTSs.
2. There is definitely a need for legislation and regulation of blood transfusion in this country. As in Case 1, legislation should be kept brief and simple and the detailed operational requirements should be subject to administrative regulation.
3. Infectious disease testing should include at least HBsAg and anti-HIV for all blood donors. This should include a government commitment to support the necessary importation of test kits. It will be simplest to have all testing done at a limited number of provincial BTSs with authority to ensure that blood will not be issued until shown to be negative. This system will reduce costs and will permit the establishment of appropriate quality controls. It will, however, introduce logistic problems concerning the transportation of samples and the communication of laboratory results. ELISA test systems are suitable only for large-scale laboratories, testing about 100 or more samples per day. Thus ELISA systems are unsuitable for use in all but the largest of hospitals; if decentralized testing at the hospital is thought to be necessary, the more convenient but more expensive 'rapid test' systems will need to be introduced.
4. The only answer to this problem is a commitment by the central government to import these essential supplies. The commitment in hard currency may be facilitated by

delegation of this responsibility and authority to the national BTS and adoption of appropriate budgets.

5. In this country, where malaria is endemic everywhere, it is reasonable to assume that all blood donors may be carriers of malaria parasites. The indigenous population may be assumed to have a degree of immunity to malaria. The only donors who would be excluded for malaria would be those who are unwell at the time of proposed donation. One reasonable policy is to provide antimalarial treatment for all blood recipients. Another reasonable approach is to select patients who may be particularly at risk (expatriates who have never had malaria, newborns, immune-suppressed patients) and make a special effort to assure the freedom from malaria of blood provided to these patients, for example, by seeking malaria-free expatriate donors or undertaking immunological screening of selected donors with no history of clinical malaria. If these precautions are not feasible, antimalarial treatment of all susceptible recipients is mandatory.
6. A satisfactory career path must be provided for the country's trainees. Recognition, status, working conditions, promotional opportunities and salary are all important in this regard. Note that this problem reflects the converse of the situation covered in Case 3, question 1.

Case 3

1. This country has the size and resources to be able to develop its own human resources. Thus a national training programme for BTS personnel, including physician leadership, laboratory technologists, specialist phlebotomists, donor recruitment specialists, and BTS administrators, is essential. The initiation of this programme may require international assistance (see Case 1, question 4).
2. Operational centralization is controversial and is, to some extent, a discretionary decision (see 2.2.5). However, a strong case can be made in this country for the centralization of certain functions at the national level. Of particular importance would be overall BTS regulation, training of BTS personnel, donor recruitment, production planning, the plasma resource and plasma fractionation, specialized testing and laboratory problem-solving and control of importation of blood products. It will be very difficult to overcome the paid donor problem if donor procurement continues to be a hospital responsibility. Hence the recommendation that donor recruitment be the overall responsibility of the National BTS. Laboratory testing of donors should be restricted to the minimum number of specialized laboratories (perhaps three to four) so as to assure high standards and quality control.
3. This has already been discussed in the answer to question 2 above. The following steps are essential: a) national legislation emphasizing the requirement for voluntary nonremunerated donation; b) a national organization for donor recruitment based upon this principle; c) a specific plan, with timetable, for conversion to an all-volunteer system (see 3.12).

4. This is a complicated question. Modern fractionation technology permits the production of approximately 25 g albumin, 150 iu factor VIII and 2 g IVIG from one litre of good quality plasma. One litre of plasma comes from approximately four whole blood (WB) donations. Thus one can calculate the plasma requirement from the following table.

Sample calculation of national plasma requirements

Plasma derivative donations	Demand	Yield/litre	Plasma L	WB L
Albumin	2000 kg	25 g	40 x 2000 = 80000	320 000
Factor VIII	2 million iu	150 iu	6.666x2000 = 13 333	53 333
IVIG	70 Kg	2 g	500 x 70 = 35 000	140 000

From this calculation it is clear that this country must collect at least 320 000 units of whole blood, or the equivalent from plasmapheresis (see page 81) if its derivative demand is to be met from domestic sources. In this regard, it is noteworthy that the use of albumin seems to be excessive compared with other derivatives. An effort to rationalize albumin use may therefore be justified.

5. Building a fractionation plant will do nothing to make this country self-sufficient in plasma derivatives. The problem is not with fractionation; it lies with the absence of any organized plasma production system. As the BTSs are currently organized in this country, a plasma fractionation plant will be useless because there will be no plasma for it to fractionate. It might be more realistic to organize a progressively expanded plasma procurement programme, while using an established fractionator to prepare the derivatives. Since this may not be possible if the fractionator is reluctant to handle plasma which may be of higher infectivity than the fractionator's domestic source, the simplest short-term solution to this dilemma may be to continue buying derivatives on the international market, while examining usage patterns so as to avoid overuse.

Case 4

1. The University Hospital is short of blood components because of a combination of factors.
   - It appears that the patients who need components (patients with haemophilia or leukaemia) are concentrated at the University Hospital, creating a high need.
   - The University Hospital prepares components from only a small part of the blood collected (approximately 500 out of 12 000 donations).
   - The National Blood Transfusion Centre has the facilities to make components but does not collect sufficient blood to be able to use these facilities to increase component production.

- The army blood programme is making no components from the 18 000 units collected. Resolution of this problem will require:
- the University Hospital to prepare components from more (perhaps all) of the blood collected at the hospital;
- The National Blood Transfusion Centre to collect more blood and to make components from most (or all) of it;
- The army blood programme either to make components and give them to the University Hospital or to permit the National Blood Transfusion Centre to prepare components from blood collected by the army.

Clearly collaboration between these different organizations is highly desirable.

2. The medical director of the NBTC needs to employ a staff of donor recruitment specialists. The task of donor recruitment cannot be carried out by one person working alone (see 3.3 - 3.5). Donor recruitment is a huge task and cannot simply be given to the medical director (who has a wide range of other responsibilities).
3. This country appears to have the necessary resources (financial and human) to operate a successful BTS. The problems lie in the separation of the roles of different organizations and a lack of coordination of their resources. This is a management problem. An important first step will be to create a National Commission for Blood Transfusion, including senior representation from the University Hospital, National Blood Transfusion Centre and the army, in addition to representatives of government, and religious and community leaders, to develop a policy for a coordinated national blood transfusion programme.

Case 5

1. This country has severe problems to which there are no easy solutions. There must first be a recognition, at the national level but more important at the state level, that existing BTSs are inadequate and dangerous. BTS organizations must be created at the state level, to include the essential steps already discussed in Cases 1, 2 and 3. This will be a huge task because there is no existing climate for suitable legislation and regulation, the necessary human resources will have to be developed because they do not exist, the required network of laboratories does not exist, and the existing free market involving professional donors and street vendors of collection bags will have to be overcome. The economics of BTS operation will have to be reexamined so that decisions can be made on a financially realistic basis.
2. Case 5 involves a number of serious misconceptions. Existing BTSs (state and Red Crescent) are apparently satisfied with levels of production which are clearly inadequate. The Red Crescent discriminates between patients according to how 'deserving' they are. The system of leaving purchase of the collection container to the patient's family is dangerous and uneconomical. The notion that blood transfusion is not risky is dangerous, especially in the prevailing situation where there is no relevant

information to permit forming a rational judgement. The assumption that blood substitutes are too expensive and that blood doesn't cost anything are incorrect and based upon lack of information; at the very least, a blood transfusion in this country will cost the patient the price of the container (US$15), payment to the donor, transportation costs and whatever costs are associated with collection, handling, storage and testing at the hospital level (probably US$30/50 in total).

Case 6

1. This country has a very small and basic BTS system. It would probably be simplest for all blood for the three hospitals to be collected and tested at the one hospital with the government laboratory. This would require no more than nine blood donations per day and would not be too great a burden for one hospital. Such centralization would permit establishment of uniform standards.
2. Coordination at the country level will require the existence of a national committee, with representation from all three hospitals, and a mutually agreeable transportation system to ensure blood delivery in a timely fashion. From the information available, air transportation may need to be considered.

Case 7

1. This country has good facilities, one major population centre which is dominant, and is small enough to be organized into one BTS system. One self-standing blood centre in the capital, with sufficient resources and authority, will be able to centralize all blood collection and testing activities for the country. This is a perfect example of a country where a national blood transfusion service is not only possible but is highly desirable as the most effective way to provide safe and adequate services.
2. The NBTS should be coordinated, through the national directorate of the BTS, by a suitably constituted national committee with a balanced representation.

Case 8

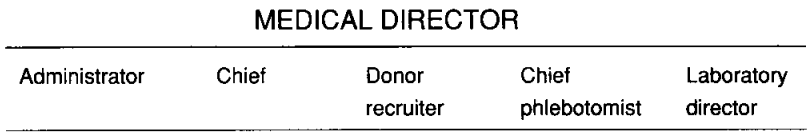
1. This country is too large, and has too many problems, to be able to operate all transfusion services from one centre in the capital. A degree of decentralization seems reasonable, perhaps with one BTS for each province. Each province could then become an organizational entity for blood transfusion, with blood collection and testing provincially centralized.
2. National (central) coordination may be needed to deal with matters such as regulation, inspection, resource sharing between provinces, statistics, problem-solving and international representation.

Case 9

There is no right or wrong table of organization. The important principles are described in Chapter 2, "Organization and management". Two possible organizational structures follow.

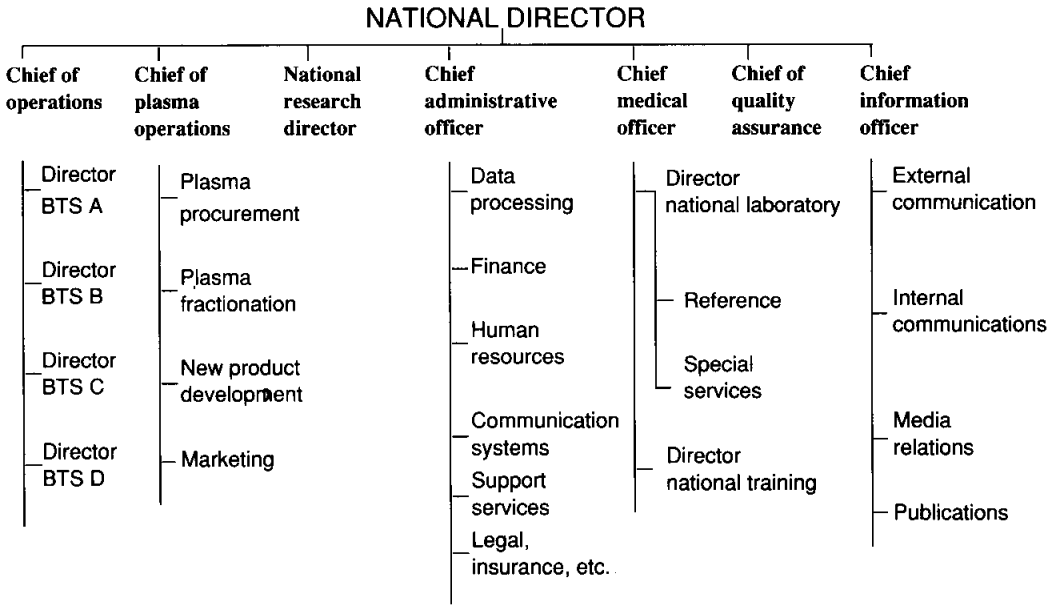
Structure 1

(Suitable for a small BTS, collecting approximately 25 000 whole blood units per year.)



Structure 2

(Suitable for a national BTS in a large country with many regional BTSs, each serving a specific section of the country.)



Case 10

The expense budget should be based upon a realistic assessment of the amount of blood that has to be collected and what products will be made from it. In this case, there is not enough information to establish exactly how much blood is needed, but clearly not enough was being collected in 1993. The target for 1994 should take this into account, together with the fact that there is an annual growth rate of 8%. Assume that 1993 collections were 10% below what was needed (i.e. the target should have been 63 800 units instead of 58 000 units) and then add a further 8% for 1994; thus a reasonable target for 1994 would be 68 904 units (say 69 000). Therefore the 1994 budget can be based on 69 000 collections. Furthermore, information from 1992 suggests that the production of red blood cells and platelets should be increased. It might be reasonable to plan to separate 70% of all blood collected (48 300 units) into red blood cells and plasma, and to plan to make 10 000 platelets and 6000 cryoprecipitate units from these. This production plan is summarized in the following table.

Production plan for Case 10

Blood collections	69 000
less technically unsuitable (4%)	2 760
less discarded for positive tests (8%)	5 520
Usable collection	60 720

Products	Production	Less for use	Losses	Available	Outdated		Used
Blood products	60 720						
whole blood (30%)	18 216	(0.5%)	91	18 125	(10%)	1 812	16313
red blood cells (70%)	42 504	(2%)	850	41 654	(5%)	2 083	39 571
plasma (70%)	42 504	(7%)	2 975	39 529	(1%)	395	39 134
platelets	10 000	(10%)	1 000	9 000	(20%)	1 800	7 200
cryoprecipitate	6 000	(15%)	900	5 100	(1%)	51	5 049
Plasma products							
fresh frozen	26 504	(7%)	1 855	24 649	(1%)	246	24 403
fresh frozen (platelets removed)	10 000	(7%)	700	9 300	(1%)	93	9 207
cryoprecipitate removed	6 000	(7%)	420	5 580	(1%)	56	5 524

Plasma products used	Transfusion (25%)	Fractionation (75%)	Total
Fresh frozen	0	24 403	24 403
Fresh frozen platelets removed	4 260	4 947	9 207
cryoprecipitate removed	5 524	0	5 524
Total	9 784	29 350	39 134

Personnel needed	Management	Support staff
Medical director	1	3
Administrator	1	16
Laboratory director	1	30
Chief, blood collection	1	24
Chief, donor recruitment	1	12
Total	5	85
Total staff 90 FTEs (full time equivalents)		

This proposed pattern of staffing is somewhat arbitrary. More detailed discussion of staffing needs has been published elsewhere [17]. A rough rule of thumb is that one full time equivalent (FTE) is required for every 500 units of blood collected per year (see 2.4.1). This figure is no more than a crude approximation, since the personnel needs will be sharply influenced by the range of services provided. The BTS described in Case 10, is a busy, medium-sized BTS with only routine services. Hence the proposed staffing pattern is modest, approximately one FTE per 770 units collected. For purposes of developing this budget, it is assumed that the salary and benefits of the medical director are US$30 000, of the other management staff an average US$15 000 per year and for the support staff an average US$5000. These figures are, of course, quite arbitrary and will be different for different countries. Personnel costs at the ABC BTS will thus be US$30 000 + 60 000 + 425 000 = US$515 000.

The cost of supplies includes collection containers, test kits for infectious disease testing, other reagents for testing, petrol for transportation and miscellaneous items. An excess of collection containers, say 5%, is necessary to allow for defective items, breakage, etc. Unavoidable wastage and unproductive control testing will require at least 15% excess test kits and other reagents. The following calculation is made for supply of collection containers:

Primary containers:	69 000 x 1.05 x US$2.50 =	US$ 181 125
Secondary containers (plasma):	42 504 x 1.05 x US$2.00 =	US$ 89 258
Tertiary containers (platelets, cryoprecipitate):	16 000 x 1.05 x US$2.00 =	US$ 33 600
	Total	US$ 303 983

The cost of test kits will depend upon the number of tests performed. Let us assume that screening will be performed for two infectious agents (HBsAg and HIV). Therefore the total cost of test kits will be 69 000 x 1.15 x 2 x US$1.50 = US$238 050.

Let us assume that the total cost of all other test reagents will be US$1.00 per unit tested (plus 15% for wastage). Then the total cost for other tests will be 69 000 x 1.15 x US$1.00 = US$79 350.

Let us assume that the cost of petrol will be US$0.05 per kilometre and that the BTS covers one million kilometres per year. Then the cost of petrol will be US$50 000 per year. Assume also that miscellaneous supplies will cost US$50 000.

Therefore the total cost of supplies will be as follows.

Collection containers	303 983
Test-kits	238 050
Other tests	79 350
Petrol	50 000
Miscellaneous	50 000
Total	US$721 380

The budget will also include an item for buildings and equipment (vehicles, laboratory equipment, blood collection equipment, computers, etc.). This type of capital budget item can be handled in a variety of different ways, all acceptable. For example, the cash cost of planned new equipment can be included in the budget, amortized over 5 years, or the corresponding cost can be calculated as depreciation of existing equipment; or a budget line-item for 'Capital fund development' can be included. This choice is a matter of financial policy, and will not be further discussed here. The essential point is that capital equipment is needed every year (new equipment or replacement of old equipment). In this budget assume an arbitrary sum of US$75 000, equivalent to approximately 5% of the total annual budget; assume also a sum of US$80 000 for the maintenance and repair of existing buildings and equipment, an essential item which must not be neglected.

Thus the final expense budget can be assembled as follows. Again, arbitrary sums are assumed for items for which information is not available, such as communications, water, electricity etc.

Personnel	515 000
Supplies	721 380
Maintenance, repairs	80 000
Capital (buildings, equipment, debt service, cash reserve)	75 000
Communications	40 000
Water, electricity, etc.	60 000
Miscellaneous	20 000
Tota	US$1 511 380

This budget of approximately US$22 per unit collected is modest and should be considered a bare minimum budget [17]. The cost of operating a BTS will be higher than this in most countries, particularly in industrialized countries where personnel costs are disproportionately high.

Case 11

1. A monthly instalment of US$125 948 will cover the planned expense budget. The existing cash reserve is an important consideration. A reserve of 60 days' operating expenses (US$251 896) is barely enough to cover expenses for the current month while leaving contingency funds for unexpected mandatory outlays. If this cash reserve did not exist, the BTS would have to find other working capital to sustain operations until receipt of the first monthly instalment of government funds. For example, it might be necessary to borrow US$125 948. Debt service (interest) on this loan would then have to be included in the expense budget, with a corresponding increase in the total budget and an equivalent increase in the government's monthly installment.
2. In this case, the principal income for the BTS comes from hospitals. There are two problems which must be overcome in preparing the income budget: a) the cash flow situation is dangerous because reserves are insufficient to cover the 45 day delay in cost recovery payments from hospitals; the generation of the necessary additional cash will add to the total expense budget; b) a fee structure will have to be calculated to ensure that the anticipated product usage will generate sufficient income to cover all expenses.

a) Quick generation of cash will almost certainly require borrowing. Assuming that two months' operating expenses will have to be borrowed at 12% interest, the cost to the annual budget will be US$251 896 x 0.12 = US$30 228. The total budget will therefore have to be increased to US$1 511 380 + 30 228 = US$1 541 608. This income need will determine the appropriate fee structure for blood products.

b) Many factors enter into consideration when determining service fees; there is no single correct way to do this. The following is suggested as a fee structure for the ABC BTS.

Service fees to be paid by hospitals

Product	Quantity used	Fee US$	Total income US$
Whole blood	16 313	20.00	326 260
Red blood cells	39 571	15.00	593 565
Platelets	7 200	12.00	86 400
Cryoprecipitate	5 049	10 000	50 490
Plasma	9 784	12.00	117 408
			1 174 123

Now, consider other possible sources of income. There are many possibilities, such as charitable donations, testing services provided by the BTS laboratory and income from plasma fractionation. In situations where the BTS is being reimbursed for plasma

submitted for fractionation, for example, it is not unreasonable to recover US$50 per litre of fresh frozen plasma. Assume that each unit of plasma fractionated contains 250 mL, thus it takes four units to generate one litre. In this case, where 29 350 units were utilized for fractionation, this is equivalent to 7337.5 litres, generating a total income of US$366 875. The final budget is as follows:

Expense budget (USD)	1 541 608
Income budget (USD)	
Hospital service fees	1 174 123
Other income	
Plasma fractionation	366 875
Total	1 540 998
Planned deficit (US$)	610

This budget is in many ways oversimplified, but it serves to illustrate the major elements of BTS budgeting. The actual numbers will vary greatly from place to place.

Case 12

It is necessary to make some assumptions in preparing the required estimates. There is no mention of blood shortages, so it is reasonable to assume that the existing blood supply is adequate. There is no information concerning trends in blood usage (e.g. annual increase due to development of health care facilities, or decrease, due to growing awareness of the risks of transfusion) so, for the purpose of this analysis, assume that there is an annual increase of 5% in blood need. Table 3.2 reveals many gaps in the data; assume, however, that the absence of information about component production reflects the fact that no components have been produced or used; therefore, the critical information is the sum of usage of whole blood and red blood cells, a total of 38 099 units. Analysis of Table 3.2. indicates that blood collections (46 480) exceed blood usage (38 099) by 22%. In other words, 22% of blood collections are not being utilized, for unspecified reasons. The reasons could be any combination of: a) technically unsuitable collections; b) units discarded because of positive infectious disease tests; and c) outdating. 22% is a high figure. In reality it would need to be investigated further. For the purposes of this exercise, assume that 22% is too high and can reasonably be reduced to 15% in the first year. Therefore 1992 blood usage is assumed to be 38 099, and 1993 blood usage will be 5% higher (40 004) and 1994 blood usage will again be 5% higher (42 004). Allowing for 15% non-utilization of blood, blood collections in 1994 should therefore be 48 305.

Case 13

This is a further analysis of the situation illustrated in Table 3.2. The question concerning need cannot be addressed, since there is no information about the clinical situations for which blood is being used. For practical purposes, in circumstances such as

this, usage and need cannot be distinguished. The recruitment goal reflects the number of donors who must be recruited to ensure that there will be sufficient blood collected. Assume that 20% of those donors that have been recruited will not actually present themselves to donate, and that 10% of those who do attend will be found unsuitable for blood donation, then calculate how many donors will have to be recruited in order to permit the collection of 48 305 units of blood. The number of donors required to attend will be 53 672 and the number of donors recruited will be 67 090. This point is emphasized because it is not generally appreciated that the recruitment goal must be so much higher than the actual need for blood collection.

Case 14

This donor is, by definition, at risk of infection with HIV and must be disqualified as a blood donor. He should be informed in writing of this disqualification, emphasizing that he should not attempt to donate again, with a full explanation. Professional counselling should be offered, to explain his 'at risk' status and potential risks from and to his sex partners, and should provide useful sensitive information concerning safe sex practices. He should be offered the opportunity for further testing for HIV. If positive, recipients of his previous donation(s) should be offered testing and, where appropriate, professional counselling. Counselling should be offered to his sex partners should they so wish.

Case 15

The following comments are offered concerning the details provided:

a) Both these vaccines comprise attenuated live viruses. There is therefore a theoretical possibility of transmitting these viruses following vaccination. The recommended deferral following rubeola vaccination is 2 weeks and following rubella vaccination 4 weeks [25]. In this case, the 4-month interval is quite sufficient and these vaccinations are not a barrier to blood donation.

b) Infectious mononucleosis is caused by infection with the Epstein - Barr virus. This virus does not lead to a chronic carrier state and is not a reason to disqualify the donor. It may be a wise precaution, however, to confirm the diagnosis with the donor's physician.

c) There is no reason to disqualify a donor with a controlled seizure disorder. However, one would not accept a person with a currently active seizure disorder in view of the undesirability of precipitating a seizure during or after donation.

d) A dental filling, without gum injury, is no cause for deferral. Some BTSs defer donors for 72 hours following dental extraction out of concern for possible bacteraemia.

e) This sex history does not reveal significant information. Menstruation is not a disqualifying factor. The information provided should not prevent donation.

e) 49 kg is just below the acceptable weight for a standard donation of 450 ml + 10% (495 ml). She would therefore not be acceptable for a standard donation, but some BTSs accept underweight donors for proportionately reduced volume donations.

g) The pulse rate of 88 per minute is acceptable. Many BTSs would not accept a donor with a pulse rate of 110 per minute. However, it is normal procedure to recheck the pulse rate after an interval of rest. The first reading is often abnormally rapid since many donors are nervous upon first arrival at the blood centre.

In conclusion, this woman is acceptable as a blood donor, with two provisos: first the diagnosis of jaundice should be confirmed; second the full volume of blood should not be collected. A reduced volume can be accomplished in one of three ways: utilizing a smaller collection bag (a paediatric pack, usually 250 ml); sterile removal of a proportionate amount of the anticoagulant from the collection pack, before collecting the calculated amount of blood; collection of a carefully measured reduced amount of blood into the standard pack, without removing anticoagulant. All three are suitable for this donor. However, for donors weighing less than 40 kg, the last option is unsuitable because the anticoagulant is present in excess.

Case 16

It is almost certain that in this case the two samples of patient blood were each wrongly labelled with information from the other patient. This can happen when there are unlabelled samples from two patients at one time, a simple error which can be prevented by insisting that all samples be labelled immediately, before other samples are drawn. In this case there would be no possible way for the hospital blood bank personnel to detect the error, but the old-fashioned practice of doing a slide cross-match at the bedside might have averted this particular problem.

Case 17

This woman's preoperative anaemia was almost certainly due to iron deficiency, safely and effectively treatable with oral iron. Transfusion was therefore not only unnecessary but, as was demonstrated in this case, dangerous. The error was to transfuse the patient instead of using the safer (but slower) specific therapy, iron.

Case 18

It is standard practice to have a series of identical unique numbers (stick-on labels) for each unit of blood. These same numbers can then be applied to the primary collection container, any satellite containers, all sample tubes collected and the donation record; additional numbers are attached to the primary container and can be used by the cross-matching laboratory for labelling samples for testing. It is the phlebotomist's responsibility to check all the numbers and make sure that they are all the same. There are many possible causes of error here: a previous number may have been made obsolete, but not discarded, permitting two sets of numbers to become involved with the processing of one donor; more than one donor may have been at the labelling station at one time; the printing of the labels may be faulty; one donor's samples may become confused with another's; the sheet to which the spare number-labels are attached may be fixed to the wrong collection container. When an error of this kind is recognized, every effort should

be made to resolve the identity of the donation record, the blood, the resulting components and the samples. It is essential when two numbers are involved (usually the case) to recover all blood, blood products, samples and records from both donors. If available information does not permit complete resolution of the identity of all items, all involved blood products must be discarded.

Annex 6

Text of Islamic roles (in Arabic)

بسم الله الرحمن الرحيم

حكم نقل الدم في الشريعة الإسلامية

إعداد

الدكتور محمود على السرطاوي

الأستاذ المشارك بكلية الشريعة

لقد حقق علم الطب تقدماً ملحوظاً في خدمة الإنسانية ، ونتيجة لهذا التقدم جدت مسائل كثيرة لم يتعرض فقهاء المسلمين الأوائل لبيان حكمها ، لأنها لم تكن في زمنهم ، ولما كانت الشريعة الإسلامية تنظم تصرفات العباد ، وجب بيان حكم الله في المسائل الطبية المستجدة مثل : زرع الأعضاء ، وأطفال الأنابيب ، والحامل المستأجرة ، والتعقيم ، ونقل الدم ، وغيرها .

وقد انبرى عدد من علماء المسلمين لبيان الحكم الشرعى في هذه المسائل وغيرها ، مستهدين بمبادىء الشريعة الإسلامية وقواعدها العامة التي توجب حفظ الأنفس ، وترفع عنها ما يلحق بها من ضرر أو حرج ومشقة ، وتحقق لها الأمن والطمأنينة .

ومن هذه المسائل الطبية ما نحن بصدد حكم الله فيه ألا وهى مسألة نقل الدم من إنسان لآخر .

إن نقل الدم إلى المريض في كثير من الحالات يعتبر ضرورياً ، لا يمكن الاستغناء عنه كما هو معروف في علم الطب ، فقد تكون حياة المريض مستحيلة بدونه .

ومعلوم أن الدم لايمكن استحضاره صناعياً لتكونه من خلايا حية لايزال العلم عاجزاً عن صنعها ، كما أنه لا يمكن الاستفادة من دماء الحيوانات في هذا المجال لاختلاف طبيعتها عن طبيعة دم الإنسان ، فتعين استعمال دم إنسان لإنقاذ حياة إنسان آخر .

والنصوص الشرعية تحض المسلم على أن يكون في عون أخيه ، لا بل توجب عليه ذلك في كثير من الأحيان . ففي الحديث الشريف (من نَفَّس عن مؤمن كربة من كرب الدنيا نَفَّس الله عنه كربة من كربات يوم القيامة)[1]. وفي الحديث أيضاً (والله في عون العبد ما دام العبدُ في عون أخيه)[2].

لقد نهى النبي صلوات الله وسلامه عليه المسلمين عن تسليمهم أفراد مجتمعهم للردى والهلاك ، قال ﷺ (المسلم أخو المسلم لا يخذله ولا يظلمه ولا يسلمه)[3]. أي لا يتركه فريسة للعدو أو المرض يفتك به .

إن العمل على إحياء النفوس المعصومة من المسلمين وغير المسلمين بإنقاذها من الهلاك ، ورفع الضرر عنها من أجَلِّ القُرُبات وأعظمها عند الله تبارك وتعالى حيث قال سبحانه ﴿ ومن أحياها فكأنما أحيا الناس جميعاً ﴾[4]. وإحياء النفس يكون بإنقاذها من أسباب الهلاك وهذا يصدق على نقل الدم للمريض من إنسان صحيح سليم .

وإذا كان إعطاء الدم للمريض ضرورياً لاستبقاء حياته أو رفع الضرر عنه كان حكمه في دين الله واجباً عملاً بالأدلة السابقة ومبادىء الشريعة التي منها حفظ الأنفس ، وعملاً بقواعد الشريعة (الضرر يزال) (والضرورات تبيح المحظورات) وبقواعد التكافل الاجتماعي المستفادة من الأدلة النصية السابقة وغيرها من الأدلة مما لا يتسع المقام لبسطه وذكره .

وإذا كان الاستطباب بالدم واجباً كان ادخاره وإعداده لوقت الحاجة واجباً كذلك لأن ما لا يتم الواجب إلا به فهو واجب ، فإن الحوادث كثيرة وتحتاج إلى معالجة فورية ، لا يمكن أن تتم إلا بتوافر وحدات من الدم ، فيقتضي أن يكون الدم متوافراً في المستشفيات هذا لغرض ، وقد وجدت بنوك حفظ الدم لهذا الغرض .

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(١) مسند الإمام أحمد ، رقم الحديث ٧٤٢١ ، تحقيق أحمد محمد شاكر .

(٢) الجامع الصحيح للترمذي ، رقم الحديث ١٤٢٥ .

(٣) الجامع الصحيح للترمذي ، رقم الحديث ١٤٢٦ .

(٤) سورة المائدة : ٣٢ .

هذا بالنسبة للمتبرع بالدم ، وبالنسبة للمريض فإنه لا يجوز له أن يمتنع عن أخذ وحدات الدم الضرورية ، لأن في امتناعه إلقاء نفسه إلى التهلكة وقد نهى الله تبارك وتعالى عن ذلك بقوله ﴿ ولا تقتلوا أنفسكم إن الله كان بكم رحيماً ﴾[٥] وبقوله سبحانه ﴿ ولا تلقوا بأيديكم إلى التهلكة ﴾[٦].

ومما تجدر الإشارة إليه في هذا المقام أنه ورد في الأحاديث الصحيحة الاستطباب بالفصد والحجامة لما فيهما من فائدة ، وهذا يبين لنا أن التبرع بالدم لا يلحق ضرراً بالمتبرع وإنما يفيد المتبرع حيث ينشط الخلايا الخاصة بإعادة كريات الدم .

قال ﷺ (الحجم أنفع ما تداوى به الناس)[٧] أي في زمانهم ، وقال ﷺ (إن كان في شيء من أدويتكم خير ففي شرطة محجم)[٨].

وأخذ الدم بطريق الحقنة كأخذ الدم بطريق الفصد إلا أن الأول يمكننا من الاستفادة من الدم المأخوذ لإنسان آخر ، وبطريقة الفصد لا يمكننا الاستفادة منه لإنسان آخر .

والخلاصة :

إن التبرع بالدم واجب على الكفاية ، إن قام به نفر من الناس وكان ما تبرعوا به يكفي الحاجة القائمة والمتوقعة ، سقط الإثم عن الباقين ، وإن لم يصل ما تبرعوا به إلى حد الكفاية أثم الجميع ، لأنهم سلموا إخوانهم المرضى وجرحى المعارك والحوادث إلى الهلاك ، فكانوا بذلك آثمين .

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(٥) سورة النساء : ٢٨ .

(٦) سورة البقرة : ١٩٤ .

(٧) البخاري بشرح القسطلاني ١٦٢/٧ .

(٨) البخاري بشرح القسطلاني ٣٣٥/٨ .

وقد يكون إعطاء الدم في بعض صوره واجباً عينياً في بعض حالاته كما لو وجد مريض فصيلة دمه تتفق مع فصيلة دم شخص آخر ولا ثالث لهما من نفس فصيلة الدم ، أو كان نقل الدم للمريض أمراً ضرورياً في فترة زمنية محددة ، إن لم يعط المريض فيها دماً جديداً هلك في الغالب ، ولم يوجد إلا شخص واحد فصيلة دمه تتفق مع فصيلة دم المريض ، ففي هذه الحالة يكون التبرع بالدم واجباً عينياً ، يأثم من تخلف عن القيام به .

وقد أفتى بجواز التبرع بالدم عدد كبير من علماء المسلمين حتى استفاض الحكم فيه واشتهر ، ولم أسمع من قال بخلافه من أهل العلم الذين يعتد بآرائهم وأقوالهم .

ولايفوتني هنا أن أبين أن الحكم الشرعي السابق الذكر مبني على وجوب توافر الشروط الطبية المعروفة عند أهل الاختصاص ومنها : أن لايُلحق أخذ الدم بالمتبرع ضرراً ، كما لو كان صغيراً أو مصاباً بمرض فقر الدم ، أو أن يؤخذ من دمه مقدار كبير يؤدي إلى إلحاق ضرر به .

ومنها : أنه لا يجوز إعطاء الدم للمريض إلا بعد التأكد من أن مصلحته متحققة في ذلك وأنه لن يلحق به ضرراً وذلك بإجراء الفحوص اللازمة للتأكد من خلو الدم من الأمراض .

ما يترتب على نقل الدم من أحكام :

١ – هل يكون الدم بعد أخذه من الجسم بواسطة الحقنة نجساً ؟ وهل يجوز التداوي به مع نجاسته ؟

لا خلاف بين العلماء في نجاسة الدم بعد انفصاله عن موضعه لقول تعالى : ﴿ أو دماً مسفوحاً ﴾[٩]. والمسفوح هو الدم المراق ، وعلى ذلك الدم المأخوذ بالحقنة ليس مسفوحاً ، فلا يأخذ حكمه من حيث النجاسة .

أمّاما ورد من الأحاديث التي توجب غسل الدم عن البدن والثوب فذلك لأنه دم مسفوح أي مراق . ولو سلمنا بنجاسته بعد خروجه بواسطة الحقنة ، فإن الفقهاء أجازوا التداوي بالنجاسات عند الحاجة .

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(٩) سورة الأنعام : ١٤٥ .

٢ – هل يؤدي نقل الدم من إنسان لإنسان آخر إلى التحريم ؟

لقد نصت الأحاديث على ثبوت التحريم بالرضاع وفق شروط مبسوطة في كتب الفقه . والعلة التي يثبت الرضاع التحريم لوجودها هى إنبات اللحم وإنشاز العظم ، وهذا يتحقق في اللبن قبل أن يعتاد الطفل أكل الطعام .

قال ﷺ : (لا رضاع إلا ما أنشز العظم وأنبت اللحم)[١٠].

ولا يتحقق هذا الأمر بنقل الدم لأن وظيفة الدم ليست تغذية الجسم وإنما حمل المواد الغذائية المنحلة فيه إلى جميع خلايا الجسم .

وعلى ذلك إذا نقل الدم من الرجل لزوجته فإن هذا لا يؤدي إلى التحريم بينهما .

٣ – هل يجوز بيع الدم ؟

الإنسان مكرم عند الله تبارك وتعالى قال سبحانه : ﴿ ولقد كرمنا بني آدم ﴾[١١]. ولذا فإنه لا يجوز بيع جسم الإنسان ولا بيع شيء من أعضائه ولا يجوز بيع دمه .. وإذا رفض القادر على التبرع بالدم أن يتبرع إلا بعوض مالي جاز إعطاؤه مالاً ، ولا يأثم من دفع العوض المالي ، ويأثم من أخذ العوض المالي ويكون كمن خلط عملاً صالحاً وآخر سيئاً .

٤ – هل أخذ الدم بواسطة الحقنة يفطر الصائم ؟

إن التبرع بالدم لا يفطر الصائم ، كما أن إعطاء المريض الدم لا يفطره أيضاً ، والله أعلم وأحكم .

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(١١) سورة الإسراء : ٧٠ .

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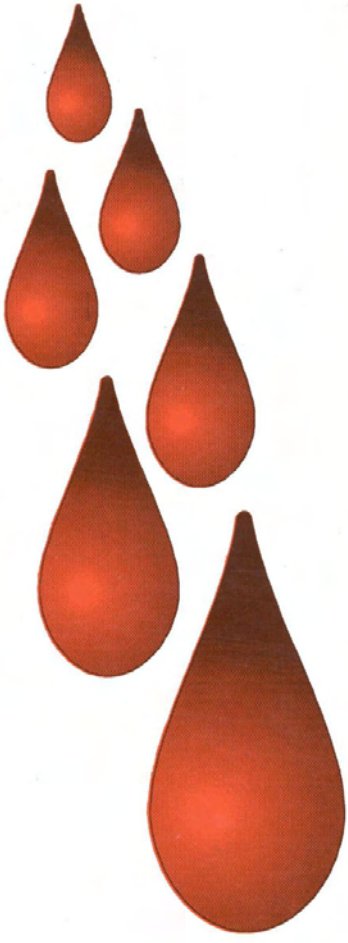
Blood Transfusion
A Basic Text



Blood Transfusion: A Basic Text

Blood Transfusion Services must keep pace with the rapid technical development of health services. This publication focuses on specific areas which are essential to any effective blood transfusion service: organization and management, blood donor motivation and blood collection, and the assurance of quality.

This publication will be of interest to hospital and health centre administrators, directors of blood transfusion services and all those who rely on blood transfusion as an essential component of their health service.

ISBN 92-9021-181-4

Price: US$ 7.50